MODULE 1
ACCREDITATION OVERVIEW

1.1 PURPOSE

The primary purpose of the AIHA Laboratory Accreditation Programs (AIHA LAP), LLC is to establish and maintain the highest possible standards of performance for laboratories analyzing samples to support the evaluation of occupational and environmental exposures to hazardous agents. AIHA LAP is committed to providing impartial accreditation service to our customers. It is the policy of AIHA LAP to manage conflict of interest, ensure objectivity of our accreditation activities and safeguard impartiality. Laboratories that comply with the elements of this program operate a quality system that meets the requirements of the International Organization for Standardization (ISO) Standard ISO/IEC 17025:2017. This standard incorporates the principles of ISO 9001 that are relevant to the scope of testing services addressed by the laboratory.

AIHA LAP, LLC is recognized by the International Laboratory Accreditation Cooperation (ILAC). AIHA LAP, LLC programs are managed and conducted in full compliance with the ISO/IEC 17011 standard.

AIHA LAP, LLC achieves and maintains the highest level of quality in its programs through the following steps:

1.1.1 Requiring the laboratory seeking accreditation to operate a laboratory in which sampling and testing procedures are performed with adequate controls by well-qualified personnel using appropriate equipment and methods. High standards of practice are encouraged and maintained through conformance with established accreditation criteria, education, proficiency testing and onsite assessments.

1.1.2 Maintaining an ongoing surveillance of laboratories participating in AIHA LAP, LLC using criteria defined by specific program requirements detailed in Modules 2A-2F, Quality System Requirements and by their participation in proficiency testing programs approved by AIHA LAP, LLC as outlined in Module 6.

1.1.3 Auditing accredited laboratories in order to ensure compliance with requirements and standards of AIHA LAP, LLC.

1.1.4 Recognizing compliance with standards by issuing certificates of accreditation for a period of two (2) years in the name of the AIHA LAP, LLC.

1.1.5 Adding, as needed, sample matrices, components, and new technologies for existing programs to serve the needs of the laboratory community.

1.1.6 Establishing, as needed, additional quality analytical programs to serve the specific needs of the laboratory community. New programs are initiated under the direction of

the AIHA LAP, LLC Analytical Accreditation Board (AAB) once it determines the suitability of the conformity assessment schemes and standards for accreditation purposes.

1.1.7 Laboratory accreditation records are maintained for five years to cover the duration of the current cycle plus the previous full accreditation cycle.

1.2 MANNER OF ACTING

The Analytical Accreditation Board (AAB) and its subordinate Technical Advisory Panel (TAP) shall conduct the technical business of the AIHA LAP, LLC according to the following directives:

1.2.1 Where a vote of the AAB is required under Module 4, a two-thirds majority of the number of AAB members eligible to vote, minus the number of abstentions, shall be required on a formal vote, written letter ballot vote, electronic vote, or meeting vote, at which a quorum is present, for matters regarding suspension, denial, or withdrawal. Program experts from the AAB will be responsible for accreditation decisions for initial applications, reaccreditation applications, FoT additions and an accredited laboratory expanding into another program.

1.2.2 An AAB member shall support any of his/her votes to suspend, deny, or withdraw accreditation by citing the specific AIHA LAP, LLC policy that is the basis of the negative vote.

1.2.3 AAB and TAP members shall comply with the AIHA LAP, LLC Conflict of Interest Policies.

1.3 AUTHORITY

AIHA LAP, LLC and the AAB shall be responsible for granting, maintaining, extending, suspending or withdrawing accreditation and shall not delegate these responsibilities. The roles and responsibilities of the AAB are documented in AIHA LAP, LLC governance documents.

1.4 SCOPE OF ACCREDITATION AND MODULES

AIHA LAP, LLC administers five (5) laboratory accreditation programs: Industrial Hygiene, Environmental Lead, Environmental Microbiology, Food and Unique Scope. The scope of accreditation for each program is defined by Field of Testing (FoT) and Method. The laboratory is responsible for selecting specific FoT(s) for which accreditation is sought. The laboratory shall also specify the method(s) used for the selected FoT(s).

Methods are subject to the approval of the AAB.

AIHA LAP, LLC shall confine its requirements, assessment and decision on accreditation to those matters specifically related to the scope of accreditation being considered.

To obtain or retain accreditation, the laboratory shall comply with the requirements of all applicable policy modules as listed below.

Module 1	Accreditation Overview
Module 2A	General Management System Requirements
Module 2B	Industrial Hygiene Laboratory Accreditation Program (IHLAP) Additional Requirements
Module 2C	Environmental Lead Laboratory Accreditation Program (ELLAP) Requirements
Module 2D	Environmental Microbiological Laboratory Accreditation Program (EMLAP) Additional Requirements
Module 2E	Unique Scopes Laboratory Accreditation Program Additional Requirements
Module 2F	Food Laboratory Accreditation Program (FoodLAP) Additional Requirements
Module 3	Accreditation, Maintenance and Reaccreditation Processes
Module 4	Suspension, Denial, or Withdrawal of Accreditation
Module 5	Appeals Process
Module 6	Proficiency Testing (PT) and Round Robin Programs
Module 7	Reference to Accreditation and Advertising
Module 8	Miscellaneous
Module 9	Terms and Acronyms
Appendix A	RESERVED
Appendix B	RESERVED
Appendix C	RESERVED
Appendix D	RESERVED
Appendix E	RESERVED
Appendix F	RESERVED
Appendix G	Evaluation of Measurement Uncertainty
Appendix H	Metrological Traceability of Measurement

MODULE 2A
GENERAL MANAGEMENT SYSTEM REQUIREMENTS

2A.1 SCOPE (See ISO/IEC 17025:2017, Section 1)

Laboratories shall meet all requirements of the ISO/IEC 17025:2017 International Standard and other AIHA LAP, LLC specific requirements, as detailed in this module and in the program-specific Modules 2B-2F, if they are to achieve and maintain AIHA LAP, LLC accreditation. Explanatory notes included in various sections of the ISO/IEC 17025:2017 International Standard shall be utilized by AIHA LAP, LLC to interpret and ensure conformity with the applicable requirements in those sections. Specific ISO/IEC 17025:2017 section references have been provided throughout this module to facilitate a better understanding of and conformity to all requirements of this International Standard. Laboratories seeking accreditation shall maintain a copy of this International Standard in its entirety.

Laboratories accredited for lead must meet all requirements for the EPA National Lead Laboratory Accreditation Program (refer to Policy Module 2C and the LQSR).

2A.2 NORMATIVE REFERENCES (See ISO/IEC 17025:2017, Section 2)

2A.3 TERMS AND DEFINITIONS (See ISO/IEC 17025:2017, Section 3)

Refer to Module 9, Terms and Acronyms, for AIHA LAP, LLC specific terms, definitions, and acronyms.

2A.4 GENERAL REQUIREMENTS (See ISO/IEC 17025:2017, Section 4)

2A.4.1 Impartiality (See ISO/IEC 17025:2017, Section 4.1)

2A.4.2 Confidentiality (See ISO/IEC 17025:2017, Section 4.2)

2A.5 STRUCTURAL REQUIREMENTS (See ISO/IEC 17025:2017, Section 5)

2A.5.1 Accreditation shall be extended to a single site only.

2A.5.2 Organizations desiring accreditation for multiple laboratory sites and types (Fixed, Mobile Operation and Field Operation Laboratories) shall submit an individual and separate application for each site or type. Refer to Module 9 for definitions of the laboratory types that can be accredited.

2A.5.3 The laboratory seeking accreditation shall perform the Field(s) of Testing (FoT) for which the accreditation is sought.

2A.6 RESOURCE REQUIREMENTS (See ISO/IEC 17025:2017, Section 6)

2A.6.1 General (See ISO/IEC 17025:2017, Section 6.1)

2A.6.2 Personnel (See ISO/IEC 17025:2017, Section 6.2)

2A.6.3 Facilities and environmental conditions (See ISO/IEC 17025:2017, Section 6.3)

2A.6.4 Equipment (See ISO/IEC 17025:2017, Section 6.4)

NOTE: These requirements also apply to reagents and standards.

2A.6.4.1 When possible, any external calibration service used shall be a calibration laboratory accredited to ISO/IEC 17025:2017 by a recognized accreditation body.

2A.6.5 Metrological traceability (See ISO/IEC17025:2017, Section 6.5)

2A.6.5.1 Laboratories shall comply with the requirements of the AIHA LAP, LLC Policy on Traceability of Measurement, Policy Appendix H. Refer to the AIHA LAP, LLC guidance document, *Guidance on Traceability of Measurement* on the AIHA LAP, LLC website for additional information.

2A.6.6 Externally provided products and services (See ISO/IEC 17025:2017, Section 6.6)

2A.6.6.1 Unless directed otherwise by a customer or regulatory agency, a laboratory accredited by AIHA LAP, LLC, or other ILAC MRA Signatory, shall be used for externally provided testing services (including subcontractors) for Fields of Testing covered by the scope of accreditation of the primary facility.

2A.7 PROCESS REQUIREMENTS (See ISO/IEC 17025:2017, Section 7)

2A.7.1 Review of requests, tenders, and contracts (See ISO/IEC 17025:2017 Section 7.1)

2A.7.2 Selection, verification and validation of methods (See ISO/IEC 17025:2017, Section 7.2)

2A.7.3 Sampling (See ISO/IEC 17025:2017 Section 7.3)

2A.7.4 Handling of test or calibration items (See ISO/IEC 17025:2017 Section 7.4)

2A.7.5 Technical records (See ISO/IEC 17025:2017 Section 7.5)

2A.7.5.1 All laboratory records shall be maintained for at least three (3) years. Records needed to support current laboratory activities shall be kept as long as necessary beyond 3 years. These records include, but are not limited to:

- Training/authorization records
- Method validation records
- Equipment maintenance records
- Equipment/reference standard calibration records
- Reference material certificates of analysis

2A.7.5.2 All entries to hard copy laboratory records shall be made using ink.

2A.7.6 Evaluation of measurement uncertainty (See ISO/IEC 17025:2017 Section 7.6)

2A.7.6.1 Test methods are classified as either qualitative or quantitative. Qualitative tests are defined as having non-numerical results. Although evaluation of measurement uncertainty is not needed for these tests, laboratories are expected to have an understanding of the contributors to variability of the results. For quantitative tests, laboratories shall determine measurement uncertainty using appropriate statistical techniques and in compliance with the AIHA LAP, LLC Policy on the Evaluation of Measurement Uncertainty, Policy Appendix G. Refer to the AIHA LAP, LLC, *Guidance on the Evaluation of Measurement Uncertainty*, on the AIHA LAP, LLC website for additional information on measurement uncertainty.

2A.7.7 Ensuring the validity of results (See ISO/IEC 17025:2017 Section 7.7)

NOTE: The definitions for Accuracy and Bias; and Precision can be found in Policy Module 9

NOTE: Accuracy and Bias: Accuracy studies are performed to determine how close a measurement comes to an actual or a theoretical value. Accuracy can be expressed as percent recovery and evaluated by analysis of matrix spikes. A matrix spike is an aliquot of a sample, or sampling media, fortified (spiked) with a known quantity of the analyte of interest and subjected to the entire analytical procedure. For gases and liquids, a known quantity of the analyte of interest is deposited as a vapor or a liquid onto the appropriate sampling device for the analysis of interest. For solids, the material may be weighed or deposited in solution. Bias is a systematic error manifested as a consistent positive or negative deviation from the known true value.

Precision: Precision is evaluated by the reproducibility of analyses. Precision is commonly expressed as standard deviation or relative percent difference and can be evaluated by the analysis of duplicate samples or duplicate sampling media spikes. Duplicate analyses are one or more additional analyses on separate aliquots of samples that can be used to assist in the evaluation of method variance.

2A.7.7.1 As part of the quality assurance program, the laboratory shall adhere to all stated QA/QC requirements in the methods used and any additional requirements defined

in Modules 2B-2F. Any deviations from these procedures shall be documented. The laboratory shall determine, where feasible, the accuracy and precision of all analyses performed. Procedures shall be in place to estimate the uncertainty of measurement of all calibrations and test methods. At a minimum, the following QC checks shall be performed per batch of samples.

2A.7.7.1.1 Blanks

Blank sampling media and analytical reagents shall be analyzed, when applicable, with each batch of samples, using the same procedure that is used for field samples. Laboratories shall advise customers to supply specimens of blank sampling media from the same source lot as was used for collecting the field samples.

2A.7.7.1.2 Acceptance Limits

Acceptance limits for each method shall be established based on statistical evaluation of the data generated by the analysis of quality control check samples, unless specific acceptance limits are established by the method. The calculation procedures for statistically derived acceptance limits shall be documented.

2A.7.7.1.3 Control Charts

Control charts or quality control databases shall be used to record quality control data and compare them with acceptance limits. Procedures shall be used to monitor trends and the validity of test results.

2A.7.7.2 Laboratories shall establish and maintain a data review process beginning at sample receipt and extending through the report process. The data review process shall be an independent review, conducted by a qualified individual other than the analyst. See definition of "Qualified Individual (for data review)" in Module 9, Terms and Acronyms.

2A.7.7.3 The data reduction and review process shall include, but not necessarily be limited to: comparison of quality control data against established acceptance limits, computation verification, transcription of data and adherence to the procedures established in the laboratory management system documents. If more than one parameter in a sample is tested, then the correlation of results shall be reviewed. The review process shall be documented before data are reported.

2A.7.8 Reporting of results (See ISO/IEC 17025:2017 Section 7.8)

2A.7.8.1 Final test reports shall also include:

a) Reporting limit
   i. EMLAP labs performing direct exam may use Analytical Sensitivity in place of a Reporting Limit.
b) Date of sample receipt

2A.7.8.2 Measurements below the method reporting limit shall be reported as "<" (less than) or not detected (ND) and reference the reportable limit. The reporting of zero concentration is not permitted.

2A.7.8.3 The final report shall state the measured quantitative result of the analysis of any blank samples submitted to the laboratory. Also, a statement shall be made that discloses whether or not the sample results have been corrected based on the field blank or other analytical blank.

2A.7.8.4 The number of significant figures reported shall reflect the precision of the analysis.

2A.7.8.5 If the laboratory chooses to include a reference to their AIHA LAP, LLC accreditation (symbol or accreditation number) on their test report, any test results not covered under AIHA LAP, LLC accreditation shall be clearly identified on the report.

2A.7.9 Complaints (See ISO/IEC 17025:2017 Section 7.9)

2A.7.10 Nonconforming work (See ISO/IEC 17025:2017 Section 7.10)

2A.7.10.1 Any outlier from a PT (external or internal), Round Robin, or Demonstration of Competency shall be addressed as a nonconforming event.

2A.7.11 Control of data and information management (See ISO/IEC 17025:2017 Section 7.11)

2A.8 MANAGEMENT SYSTEM REQUIREMENTS (See ISO/IEC 17025:2017, Section 8)

2A.8.1 Options (See ISO/IEC 17025:2017, Section 8.1)

2A.8.2 Management system documentation (Option A) (See ISO/IEC 17025:2017, Section 8.2)

2A.8.2.1 The laboratory's management system shall reflect the actual operating and quality assurance/quality control (QA/QC) programs in place in the laboratory.

2A.8.3 Control of management system documents (Option A) (See ISO/IEC 17025:2017, Section 8.3)

2A.8.4 Control of records (Option A) (See ISO/IEC 17025:2017, Section 8.4)

2A.8.5 Actions to address risks and opportunities (Option A) (See ISO/IEC 17025:2017, Section 8.5)

2A.8.6 Improvement (Option A) (See ISO/IEC 17025:2017, Section 8.6)

2A.8.7 Corrective actions (Option A) (See ISO/IEC 17025:2017, Section 8.7)

2A.8.8 Internal audits (Option A) (See ISO/IEC 17025:2017, Section 8.8)

2A.8.8.1 Internal quality assurance audits shall be conducted at least annually.

2A.8.8.2 Internal quality assurance audits shall verify compliance with AIHA LAP, LLC requirements.

2A.8.9 Management reviews (Option A) (See ISO/IEC 17025:2017, Section 8.9)

2A.8.9.1 Management reviews shall be conducted at least annually.

2A.8.10 Management system requirements (Option B) (See ISO/IEC 17025:2017, Section 8)

2A.8.10.1 A laboratory may opt to demonstrate compliance to the management system requirements through option B. The laboratory shall indicate this on the accreditation application and shall submit supporting documentation for review.

NOTE: Compliance through Option B does not exclude the applicant's management system from review by AIHA LAP, LLC during the accreditation process.

2A.9 SAFETY AND HEALTH

Laboratories are expected to follow applicable jurisdictional regulations regarding safety and health. Examples in the United States would include OSHA Standard 29 CFR 1910.1450, "Occupational Exposures to Hazardous Chemicals in Laboratories." or 29 CFR 1910.1200 "Hazard Communication", though it is recognized that laboratories outside the United States may have regulations different than these examples. As part of the application for accreditation or reaccreditation, on behalf of the organization seeking accreditation, the manager shall provide a written statement that the laboratory complies with all applicable standards. The AIHA LAP, LLC assessor shall not perform a safety inspection of the laboratory; however, he/she shall verify that a written chemical hygiene plan (and biosafety plan for EMLAP laboratories) exists for the laboratory operation.

MODULE 2B
INDUSTRIAL HYGIENE LABORATORY ACCREDITATION PROGRAM (IHLAP)
ADDITIONAL REQUIREMENTS

2B.1 SCOPE

The AIHA Laboratory Accreditation Programs (AIHA LAP), LLC's Industrial Hygiene Laboratory Accreditation Program (IHLAP) is intended for accreditation of industrial hygiene laboratories. Laboratory accreditation in this program is based upon a review of the laboratory management systems as defined in Module 2A and this program specific module, and successful participation in AIHA Proficiency Analytical Testing (AIHA PAT) Programs, LLC or an equivalent proficiency testing program approved by AIHA LAP, LLC, as defined in Module 6.

For purposes of this program, an industrial hygiene laboratory is defined as a laboratory that analyzes samples or materials for the purpose of evaluating occupational exposure or contamination resulting from occupational activities. Available Fields of Testing (FoTs) and corresponding PT requirements for the IHLAP are detailed in the *Scope/PT Table* maintained on the AIHA LAP, LLC web site (www.aihaaccreditedlabs.org).

2B.2 ANALYTICAL METHODS

A documented process for defining, establishing, verifying, and reporting of minimum reporting limits shall be established and implemented. The following specific requirements for method reporting limits and instrument calibration apply to analytical procedures for industrial hygiene testing, with the exception of gravimetric and asbestos analyses.

2B.2.1 Minimum reporting limits shall be established initially by analyzing media spiked samples, prepared at the desired minimum reporting limit concentrations, and taken through the entire analytical process. Acceptance criteria shall be documented.

2B.2.2 During the analysis of samples, instrument performance at the minimum reporting limit concentration shall be verified with each analytical batch through the analysis of an analytical standard prepared at or below the analyte's minimum reporting limit concentration. Acceptance criteria shall be documented.

2B.2.3 At least annually or when there is a change in methodology or instrumentation, minimum reporting limits shall be re-established by a process that requires analysis of a media spiked sample prepared at or below the minimum reporting limit concentration and taken through the entire analytical process. Acceptance criteria shall be documented.

2B.2.4 For industrial hygiene testing, a calibration curve shall be constructed with a minimum

of three (3) calibration standards, which bracket the expected sample concentrations. For those technologies and software packages requiring fewer calibration standards, follow the manufacturer's recommendations (e. g., the instrument operations manual). The calibration curve shall be verified by preparing an independently prepared calibration standard (from neat materials) or with a standard from an independent source. Acceptance criteria for the standard calibration curve and the independent calibration verification standard shall be documented.

2B.2.5 For inductively coupled plasma, emission spectroscopy (ICP-AES), an appropriate interference check standard shall be analyzed at the beginning and at the end of each analytical run, applying the same set of standard calibration data. Acceptance criteria shall be documented.

2B.2.6 Instrument standardization (calibration) shall be verified, at minimum, each 24-hour period of use, or at each instrument start-up by analysis of a continuing calibration verification standard. Acceptance criteria shall be documented.

2B.2.7 Calibration or working quantification ranges shall encompass the concentrations reported by the laboratory. Continuing calibration verification standards and continuing calibration blanks shall be analyzed in accordance with the specified test methods. Acceptance criteria shall be documented.

2B.2.8 Media-based laboratory control spikes (LCS) shall be prepared and analyzed concurrently with each batch of samples. The spike level shall be at a concentration to fall within the calibration curve. Acceptance criteria shall be documented for LCS recoveries.

Precision shall be monitored by the analysis of duplicate portions of client samples where subsampling is performed and where positive test results are expected. Where whole sample analysis is performed and/or where positive test results for client samples are not expected, precision shall be monitored by either the analysis of within-batch laboratory control spike duplicates (LCSD) or by using between-run LCS or reference materials. Acceptance criteria shall be documented for precision.

2B.3 ASBESTOS TESTING

Laboratories seeking accreditation for asbestos testing shall adhere to the management system requirements as defined in Module 2A and this program specific module, Sections 2B.1 through 2B.3 (as applicable), in addition to the following management system requirements:

2B.3.1 Phase Contrast Microscopy (PCM) Analysis

2B.3.1.1 U.S. laboratories performing airborne asbestos analysis shall comply with the quality assurance requirements of the Asbestos Standard Appendix A, CFR 1910.1001 and the most current revision of the NIOSH 7400 analytical method. Laboratories outside the United States or its territories have the option of using equivalent methods.

The PCM Quality Assurance program shall address and maintain records of:

a) Microscope adjustment and alignment for each day of use, including phase ring alignment
b) Frequency of verification of Walton-Beckett Graticule diameter using an ISO/IEC 17025 accredited calibration laboratory stage micrometer
c) Frequency and results of HSE/NPL test slide checks performed with either a red or green HSE/NPL Mark III test slide, or equivalent (e.g. a Mark II test slide), used in accordance with its Test Certificate's stated performance criteria (yellow HSE/NPL test slides are not acceptable for checking phase shift of microscopes used for PCM analysis).
d) Analysis and evaluation of reference slides by each analyst, each day of analysis, with acceptance criteria stated
e) Calculation of intra- and inter-analyst precision (Sr) for each fiber density range specified in NIOSH 7400, using the reference slide and/or blind recount data.
f) 10% blind recount analyses and evaluation using the intra-counter Sr for the appropriate fiber loading
g) Participation in a proficiency testing program in compliance with or equivalent to AIHA PAT, LLC's program.

2B.3.1.2 Final PCM reports shall include:

a) Both fiber density and fibers/cc (or total fibers per sample)
b) Applicable intra-laboratory Sr value(s)

2B.3.1.3 In the United States, a fiber counting microscopist is required to have completed a NIOSH 582 course or an equivalent course. AIHA LAP, LLC recognition of NIOSH 582 equivalent courses is based on course information supplied by the course provider. A certificate of completion from such a course is acceptable to AIHA LAP, LLC as evidence of 582 equivalent training. Applicants submitting a certificate of completion for a 582 equivalent training course, not on the list of AIHA LAP, LLC recognized courses, shall be required to submit a description of the course as evidence of equivalent training. The description shall include dates of training, course outline, contact hours, and record of examination.

2B.3.1.4 In addition to the requirements noted above, all laboratories providing data to be

used with OSHA requirements are required to participate in a round robin program and post the results.

2B.3.2 Polarized Light Microscopy (PLM) Analysis

2B.3.2.1 U.S. laboratories performing bulk asbestos analysis under the Asbestos Hazard Emergency Response Act (AHERA) shall utilize U.S. EPA's "Interim Method for the Determination of Asbestos in Bulk Insulation Samples" as found in 40 CFR, Part 763, Appendix E to Subpart E, the current EPA method for the analysis of asbestos in building material, or a method meeting the requirements of Module 2A, Section 2A.7.2.

2B.3.2.2 A bulk asbestos microscopist is required to have completed a course on the theory and use of polarized light microscopy pertinent to asbestos fiber identification and quantification.

2B.3.2.3 The laboratory shall have a stereo microscope (~ 7-40x mag.) and HEPA-filtered hood with appropriate flow documented for sample preparation.

2B.3.2.4 The laboratory shall have sample preparation tools, including a mortar and pestle or other grinding equipment.

2B.3.2.5 The laboratory shall have the appropriate refractive index liquids in the range of 1.490 to 1.570 and 1.590 to 1.720. The refractive indices of the liquids shall be calibrated.

2B.3.2.6 The laboratory shall have a PLM microscope with the following:

a) Crosshair reticule or equivalent, capable of being aligned with the polarizer and analyzer
b) Range of objectives giving a total magnification of ~ 50 to 400X, with each objective capable of being centered with respect to stage rotation
c) Light source
d) 360 degree rotating stage
e) Substage condenser with iris diaphragm
f) Polarizer and analyzer at 90 degrees
g) 45 degree accessory slot with 530-550 nm (Red 1) compensator

2B.3.2.7 The laboratory shall have standards – NIST 1866 and 1867 (six regulated asbestos types and fibrous glass) or equivalent.

2B.3.2.8 The laboratory shall document, for each asbestos fiber type, morphology, color, pleochroism, indices of refraction, birefringence, extinction and sign of elongation.

The laboratory shall document, for each non asbestos type, at least one of the above which distinguishes it from asbestos.

2B.3.2.9 The Quality Assurance program shall address:

a) Reanalysis by same and different analyst, including frequency and acceptance criteria
b) Verification of the refractive indices of the refractive index liquids
c) Recording temperature during analysis and refractive index liquid calibration
d) Microscope alignment for each day of use
e) Analysis of reference samples of known asbestos content to calibrate/evaluate analysts' fiber identification and quantitation ability
f) Proficiency testing

2B.3.3 Transmission Electron Microscopy (TEM) Analysis

2B.3.3.1 Analysts performing TEM shall be trained in use, calibration, alignment, EDXA use, collection and interpretation of spectra. Interpretation of spectra training should include, but is not limited to, recognition of artifacts, electron diffraction interpretation, determination of d-spacings, Miller indices and zone axes, asbestos counting methods, asbestos identification, and recognition of acceptable sample preparation.

2B.3.3.2 The laboratory shall have a clean bench or clean room (Class 100).

2B.3.3.3 The laboratory shall have appropriate equipment for sample preparation which may include:

a) Exhaust hood for solvent use
b) Low-temperature oxygen plasma asher with controlled venting
c) Carbon evaporator, which can obtain better than 10^{-4} torr

2B.3.3.4 The electron microscope (80-120 keV) used for analysis shall be capable of:

a) producing a diffraction pattern from a single fibril of chrysotile;
b) resolving the hollow tube in chrysotile;
c) fiber measurement at the length(s) of interest for the method used;
d) producing a diffraction pattern in a form that is capable of being indexed;
e) producing a spot at crossover less than or equal to 250 nm; and
f) recording images.

2B.3.3.5 The EDXA system shall be capable of producing resolution equal to or less than 175 eV at Mn K-alpha, statistically significant Na peak in crocidolite, statistically significant Mg and Si peaks from a single fibril of chrysotile and have software for calculating background corrected net intensities.

2B.3.3.6 The laboratory shall have 6 asbestos types (NIST SRM 1866 & 1867), NIST SRM 2063 or equivalent for calculating k-factors, optical grating for magnification calibration, and Au diffraction standard or equivalent.

2B.3.3.7 The Quality Assurance program shall address:

a) 10% QA analysis
b) TEM alignment for each day of use
c) Grid opening size calibration (each lot) and measuring system calibration
d) EDXA energy calibration for each day of use
e) EDXA k-factor measurement for Mg, Si, Ca, Fe using SRM 2063 or equivalent; Mg:Fe sensitivity shall be $\leq$1.5
f) EDXA resolution
g) TEM magnification
h) TEM minimum beam size
i) Plasma asher calibration
j) Recounts
k) Verification of training
l) External proficiency samples
m) Internal proficiency samples using reference unknowns

2B.4 COMPRESSED/BREATHING AIR TESTING

Accreditation for compressed/breathing air testing in the IHLAP is intended for all laboratories, company, government, trade and independent, performing air tests on samples of compressed and/or breathing air. Typically, these samples come from compressed air sources, but may be from ambient air as well. Fire departments, divers, hospitals and commercial industry use breathing air from compressed gas sources. OSHA, National Fire Protection Association (NFPA), Compressed Gas Association (CGA), Professional Association of Diving Instructors (PADI) plus many others have specifications for the requirements of compressed/breathing air.

Laboratories seeking accreditation for compressed/breathing air testing shall adhere to the management system and quality system requirements as defined in Module 2A, this program specific Module 2B, Sections 2B.1 through 2B.4 (as applicable), and Module 6, with the following exceptions:

2B.4.1 The laboratory shall use methods that are recognized nationally and internationally, including, but not limited to, the following sources: CGA, NFPA, and U.S. Pharmacopoeia (USP). Proprietary methods may also be used when appropriate.

2B.4.2 A calibration curve shall be constructed with a minimum of three (3) calibration standards which bracket the expected sample concentrations. If a full calibration curve

is not run each 24- hour period, then a single point calibration in the range of the three (3) point calibration curve can be used. Validity of this one (1) point calibration shall be checked at least once for each 24-hour period with an additional calibration standard that falls within the three (3) point range. Acceptance criteria for the standard calibration curve shall be documented. These requirements supersede the requirements of this module, Section 2B.2.4.

2B.5 BERYLLIUM TESTING

Accreditation for beryllium testing is intended for all laboratories that perform beryllium analysis related to industrial hygiene monitoring. Laboratories seeking accreditation for beryllium testing shall adhere to the management system requirements as defined in Module 2A and this program specific module, Sections 2B.1 through 2B.2 (as applicable).

2B.6 PHARMACEUTICAL TESTING

Accreditation for pharmaceutical testing is intended for industrial hygiene laboratories that develop methods and analyze samples for the purpose of evaluating potential occupational exposure to pharmaceutical compounds in the workplace. Laboratories seeking accreditation for pharmaceutical testing shall adhere to the management system and quality system requirements as defined in Module 2A, this program specific module, Sections 2B.1 through 2B.6 (as applicable) maintained on the AIHA LAP, LLC web site.

Successful participation in the Pharmaceutical Round Robin Proficiency Testing Program, or other equivalent program approved by AIHA LAP, is required in accordance with the requirements defined in Module 6. The Pharmaceutical Round Robin Proficiency Testing Program is designed to share samples among participating laboratories to document that accurate analytical results can be generated by independent analysts following documented procedures. As a round robin program, each laboratory takes turns being the lead laboratory and coordinating the testing round.

2B.6.1 Sample Handling and Preparation

Due to the increasing potency of pharmaceutical industrial hygiene samples and the unique hazards this poses, the following procedures shall apply to both proficiency samples and customer samples.

a) Sample handling procedures shall ensure the safety of all employees handling pharmaceutical industrial hygiene samples.
b) Sample handling procedures shall minimize cross contamination.
c) Samples shall be extracted using in-situ extraction procedures.

d) Effective decontamination and cleanup procedures shall be followed.

MODULE 2C
ENVIRONMENTAL LEAD LABORATORY ACCREDITATION PROGRAM (ELLAP) REQUIREMENTS

2C.1 SCOPE

The AIHA Laboratory Accreditation Programs (AIHA LAP), LLC's Environmental Lead Laboratory Accreditation Program (ELLAP) is intended for accreditation of laboratories performing lead analysis in the following Fields of Testing (FoTs): airborne particulates, composited wipes, dust wipes, paint chips and soil. A FoT may also be referred to as a "matrix" in this module. Laboratory accreditation in this program is based upon a review of the laboratory management systems as defined in Module 2A and this program specific module, and successful participation in the appropriate proficiency testing program, as defined in Module 6.

2C.2 LEAD IN PAINT/SOIL/DUST WIPE ACCREDITATION REQUIREMENTS

AIHA LAP, LLC has a Memorandum of Agreement (MOA) with the United States EPA (U.S. EPA) to implement the Laboratory Quality System Requirements (LQSR) of the National Lead Laboratory Accreditation Program (NLLAP). Laboratories that are ELLAP accredited for lead analysis of dust wipes, paint chips and soil are also recognized by EPA as capable of performing analysis of paint, soil and/or settled dust wipe samples collected from or during lead-based paint activities as defined in 40 CFR Part 745. ELLAP accreditation requires participation in the AIHA PAT Program, LLC proficiency testing program for lead for each FoT where proficiency samples exist. The laboratory shall maintain proficiency in the FoT(s) for which it is accredited. Unless otherwise noted, where there are discrepancies between the requirements in Module 2A and the LQSR, the requirements in the LQSR shall take precedent.

The specific criteria for determining lead (Pb) contamination are maintained in the Laboratory Quality System Requirements (LQSR) revision 3.0 published by the EPA National Lead Laboratory Accreditation Program (NLLAP).

This document is available from: U.S. Environmental Protection Agency Ariel Rios Building (7404T) Office of Pollution Prevention and Toxics 1200 Pennsylvania Ave., N.W. Washington D.C. 20460 Phone: (202) 566-0500

http://www.epa.gov/lead/national-lead-laboratory-accreditation-program-laboratory-quality-system-requirements-revision

2C.3 LEAD IN AIR ACCREDITATION REQUIREMENTS

Laboratories analyzing lead in air shall adhere to and satisfy the requirements of Module 2B and participate successfully in the ELPAT lead in air program.

2C.4 LEAD IN COMPOSITED WIPES ACCREDITATION REQUIREMENTS

For composited wipes, all requirements for wipes listed in the LQSR apply. In addition, the laboratory shall meet the PT requirements as outlined in Policy Module 6 and the Scope/PT Table.

MODULE 2D
ENVIRONMENTAL MICROBIOLOGICAL LABORATORY ACCREDITATION PROGRAM (EMLAP) ADDITIONAL REQUIREMENTS

2D.1 SCOPE

The AIHA Laboratory Accreditation Programs (AIHA LAP), LLC's Environmental Microbiological Laboratory Accreditation Program (EMLAP) is intended for accreditation of microbiological laboratories specializing in the analysis of microorganisms commonly detected in air (e.g., spore trapping), surface (e.g., tape lifts, swabs, wipes), and bulk (e.g., dust, liquids, building materials) samples collected from schools, hospitals, offices, industrial, agricultural, and other work environments. Laboratory accreditation in this program is based upon a review of the laboratory management systems as defined in Module 2A, this program specific module, and successful participation in AIHA PAT, LLC Programs EMPAT program (www.aihapat.org) or an equivalent proficiency testing program approved by AIHA LAP, LLC, as defined in Module 6.

Available FoTs and corresponding PT for the EMLAP shall meet the requirements detailed in the EMLAP section of the *Scope/PT Table* maintained on the AIHA LAP, LLC web site (www.aihaaccreditedlabs.org).

2D.2 FACILITIES

2D.2.1 The laboratory shall have a documented routine monitoring program to verify adequate contamination control. The laboratory shall have proper facilities for biological and chemical storage and disposal of waste.

NOTE: The most current biosafety level guidelines are defined by the Centers for Disease Control (CDC), the World Health Organization (WHO), and the AIHA LAP, LLC.

2D.3 EQUIPMENT

2D.3.1 General

2D.3.1.1 The laboratory shall utilize a microscope/magnification system suitable for performing the methods in use at the laboratory (e.g., capable of the magnifications required).

2D.3.1.1.1 The microscope/magnification system for non-fluorescence microscopy shall consist of one of the following:

a) A compound optical microscope having a high magnification (e.g.,

100x) liquid immersion objective having a numerical aperture (n.a.) of at least 1.25; or,

b) An optical microscope having a theoretical or calculated point to point resolution at 0.34 µm or better. The resolution is calculated as follows: 1.22 x 0.55 µm/ [condenser n.a. + objective n.a.]; or,

c) A magnification system having a measured optical resolution of 0.34µm or better. For example, the optical resolution may be measured with resolution target testing slides.

2D.3.1.1.2 Each non-fluorescence microscope shall have an ocular micrometer which is checked annually with a stage micrometer.

2D.3.1.1.3 A microscope used for fluorescence microscopy shall have a non-immersion objective of at least 40X magnification and shall be used in conjunction with oculars of at least 10X magnification.

2D.3.1.1.4 The alignment of each microscope/magnification system shall be documented for each day of use.

2D.3.1.2 The laboratory shall have a reference library appropriate to the FoT(s) to be accredited.

2D.3.1.3 The laboratory shall utilize a molecular detection system suitable for performing the methods in use at the laboratory (e.g., qPCR machine for performing real-time qPCR tests, plate reader for ELISA, etc.)

2D.3.2 Additional Requirements for All Culturable FoTs

2D.3.2.1 The laboratory shall have a Class II biological safety cabinet (BSC) whose performance has been certified by an NSF accredited field certifier according to NSF Standard 49 field requirements (or national equivalent outside the U.S.) Annual certification is required.

2D.3.2.2 The laboratory shall have a steam sterilizer (autoclave) with functioning temperature and pressure gauges or a contract with a biohazard waste disposal company for the disposal of potentially viable waste.

2D.3.2.2.1 Laboratories with steam sterilizers shall use indicators to document successful sterilization with each use.

2D.3.2.2.2 Laboratories with steam sterilizers shall use biological indicators (e.g., spore strips or ampoules) with each use or at least once a week,

whichever is less to document the sterilization process.

2D.3.2.3 The laboratory shall have incubators, refrigerators, and freezers with temperature settings appropriate for the scope of work performed at the laboratory.

2D.4 ANALYTICAL METHODS

2D.4.1 General

The laboratory shall have written Standard Operating Procedures (SOPs), in accordance with the requirements of Module 2A, for the following: processing and analysis of samples; determining analytical sensitivities for each quantitative or semi-quantitative method; appropriate retention, waste treatment and disposal of environmental microbial samples; the identification of fungi and/or bacteria; identification of fungal spores and structures; and biosafety and decontamination for the applicable FoT(s).

2D.4.2 Additional Requirements for Air Fungal Direct Examination FoT

Analytical methods shall include a description of sample trace analysis, scope magnification, counting rules, percentage of trace analyzed and calculations.

2D.4.3 Additional Requirements for Molecular FoT

2D.4.3.1 Analytical methods shall include a description of the primer/probe combinations, the master mix formulation, the thermal cycling program including temperatures and number of cycles, and/or antibody antigen combinations.

2D.4.3.2 To each run of samples the following QC shall be included:

2D.4.3.2.1 One Laboratory Control Sample (LCS) or one per every 20 samples, whichever is greater.

2D.4.3.2.2 One duplicate analysis per every 20 samples, whichever is greater.

2D.4.3.2.3 One reagent blank sample analysis or one reagent blank sample analysis per every 20 samples, whichever is greater.

2D.5 QUALITY ASSURANCE/QUALITY CONTROL

Routine QA/QC procedures shall be an integral part of laboratory procedures and functions. The laboratory Quality Assurance program shall address the elements in Module 2A, Section

2A.8.2.1 and shall also include the following additional elements.

2D.5.1 General

2D.5.1.1 Compliance with acceptable quality assurance and quality control guidelines for microbiology laboratories, such as APHA-AWWA-WPCF guidelines in *Standard Methods for the Examination of Water and Wastewater*, *The Manual of Environmental Microbiology*, or equivalent national guidelines for foreign laboratories.

2D.5.1.2 To assess precision, intra-analyst analyses shall be completed at a minimum of five (5) percent, or at least one (1) each month samples are received, whichever is greater, for each Field of Testing for which the laboratory is accredited, except for Molecular FoTs (see 2D.4.3.2 for requirements specific to Molecular FoTs).

2D.5.1.3 To assess accuracy**,** inter-analyst analyses shall be completed at a minimum frequency of five (5) percent or at least one (1) each month samples are received, whichever is greater, for each Field of Testing for which the laboratory is accredited except for Molecular FoTs (see 2D.4.3. for requirements specific to Molecular FoTs).

2D.5.1.4 The laboratory shall use control charts or quality control databases to compare intra- and inter-analyst analysis performance to established control limits.

2D.5.1.5 The laboratory shall ensure quality control of culture media and analytical reagents per lot number for appropriate sterility, microbial growth and/or analytical reactions. Records shall be maintained. Acceptance criteria shall be documented.

2D.5.1.6 Acceptance criteria on 5%intra-analyst and inter-analyst analyses, daily reference slide analysis (spore traps) and monthly reference culture analysis (all culturable FoTs) shall be documented. Acceptance criteria shall include:

a) Taxon identification acceptability
b) Taxon abundance ranking acceptability
c) Count or concentration acceptability determined statistically (quantitative QC analysis only)

2D.5.2 Additional Laboratory Requirements for All Culturable FoTs

2D.5.2.1 The laboratory shall keep routine temperature documentation of refrigerators,

freezers, and incubators. Acceptance criteria shall be documented.

2D.5.2.2 The laboratory shall maintain a microbial culture collection of common organisms relevant to the applicable FoT(s). Cultures shall be from recognized sources when possible. Source and date of acquisition for each culture shall be documented. Procedures for maintaining the cultures and using them for training and QC purposes shall be available.

2D.5.2.3 The culture collection shall be used at least monthly to provide blind cultures for each active analyst as part of the routine QC program to monitor accuracy in culture identification.

2D.5.3 Additional Requirements for Fungal Direct Examination FoTs

2D.5.3.1 A slide collection shall consist of field samples with various count levels and genera/groups of spores shall be maintained and used as part of total spore analysis quality control. Each day of analysis, at least one slide from this collection shall be reviewed by each analyst. Analysis shall be consistent with the method for field samples. Slides shall be reviewed on a rotational schedule such that a different slide is reviewed each day until the entire slide collection has been examined. The analysis of these slides shall be incorporated into the daily QC plan. Acceptance criteria for spore concentration(s) for each reference slide shall be stated. The upper and lower control limits shall be statistically calculated based on three (3) standard deviations from the reference slide means.

2D.5.3.2 For the Fungal Direct Examination Air FoT, the laboratory shall participate in and have documentation of a round robin slide exchange consistent with the requirements of AIHA LAP, LLC Policy Module 6. The following are additional requirements:

2D.5.3.2.1 Analytical data shall include raw counts and final concentrations for each fungal structure observed.

2D.5.3.2.2 Acceptance criteria shall be determined and take into account organism identification, ranking and quantification.

2D.5.3.3 The traverse width or field of view to be used in calculations for each microscope shall be documented at least annually, if applicable.

2D.5.4 Additional Requirements for Molecular FoT's

2D.5.4.1 The laboratory shall maintain a collection of positive controls (either cultures or DNA extracts), antigen/antibody combinations for the molecular tests it provides. Source and date of acquisition for each shall be documented. Procedures for maintaining the cultures and/or reagents and using them for training and QC purposes shall be available.

2D.6 REPORTING THE RESULTS

The laboratory's results shall address the elements in Module 2A, Section 2A.7.8 and shall also include the following additional elements:

2D.6.1 Reports shall include raw counts. See definition of "Raw Count" in Module 9 – Terms and Acronyms.

2D.6.2 For quantitative results, the analytical sensitivity shall be stated in the final reporting units. See definition of "Analytical Sensitivity" in Module 9 – Terms and Acronyms.

2D.6.2.1 For analyses utilizing multiple dilutions and/or varying percentages of sample and/or trace analyzed, the applicable analytical sensitivities shall be reported.

2D.7 SAFETY, HEALTH, ENVIRONMENTAL AND TRANSPORTATION REGULATIONS

Laboratories accredited under EMLAP are expected to follow jurisdictional regulations regarding safety, health, environment, or transportation. Potentially viable microbial waste shall be collected in properly designated biohazard containers and disposed of properly, either by autoclaving, sterilizing, or incinerating, or by contracting with a biohazard waste disposal company. Failure to comply with applicable jurisdictional regulations regarding safety, health, environment, or transportation may result in suspension, denial, or withdrawal of EMLAP accreditation.

MODULE 2E
UNIQUE SCOPES LABORATORY ACCREDITATION PROGRAM ADDITIONAL REQUIREMENTS

2E.1 SCOPE

The AIHA Laboratory Accreditation Programs (AIHA LAP), LLC offers a Unique Scope accreditation for those laboratories wishing accreditation under AIHA LAP, LLC and ISO/IEC 17025:2017. A unique scope accreditation can only be applied to an area of testing that is not addressed under an existing AIHA LAP, LLC program. Laboratories seeking this accreditation shall be in compliance with the requirements found in appropriate AIHA LAP, LLC Policy Modules including Modules 2A and 6. All applications of this Unique Scopes accreditation are subject to approval by the AAB.

2E.2 FACILITIES

Laboratory facilities supporting unique scope testing shall be equipped and designed to meet the needs of the specific testing.

2E.3 ANALYTICAL METHODS

In addition to the requirements in Module 2A, the following requirements apply to unique scope testing procedures.

2E.3.1 For quantitative testing procedures, the laboratory shall establish and verify the minimum reporting limit(s) and linear ranges annually. This shall be completed and documented for each test and matrix.

2E.3.2 Laboratories shall only report levels below the minimum reporting limit as “<” (less than) or with a “ND” (not detected) and reference the reporting limit. The reporting of zero concentration is not permitted.

2E.3.3 All analytical reagents shall be of ACS grade or better.

2E.3.4 A calibration curve shall be constructed with a minimum of three (3) calibration standards, which bracket the expected sample concentrations. For those technologies and software packages requiring fewer calibration standards, follow the manufacturer’s recommendations (e. g., the instrument operations manual). The calibration curve shall be verified by preparing an independently prepared calibration standard (from neat materials) or with a standard from an independent source. Acceptance criteria for the standard calibration curve and the independent calibration

verification shall be documented.

2E.4 INTERNAL QUALITY CONTROL PROCEDURES

As part of the quality assurance program for each unique scope procedure, the laboratory shall adhere to all stated QA/QC requirements as published in the method(s) used. At a minimum, the laboratory shall analyze laboratory control spike samples, duplicate samples, matrix spiked samples, and blanks with each batch of samples, as appropriate. These QC samples shall be completed with each set of samples having less than 20 samples, and within each batch of 20 samples. The laboratory shall define the acceptance criteria for the evaluation of each of these quality control samples. Acceptance criteria shall be statistically determined if the method does not define such criteria.

MODULE 2F
FOOD LABORATORY ACCREDITATION PROGRAM (FOODLAP)
ADDITIONAL REQUIREMENTS

2F.1 SCOPE

The AIHA Laboratory Accreditation Programs (AIHA LAP), LLC's Food Laboratory Accreditation Program (FoodLAP) is intended for all laboratory, company, government, trade, and independent organizations that perform tests on food products and associated ingredients, including but not limited to, raw agricultural commodities, finished food product, ingredients, in-process samples and associated environmental samples. Food testing laboratories may become accredited for any or all of the Fields of Testing (FoT) in the following testing areas: Chemistry, Microbiology and Residue Chemistry (for a list of AIHA LAP, LLC-approved proficiency testing providers see the web site, www.aihaaccreditedlabs.org).

The scope of testing applicable to this accreditation program may include the following areas:

Food Chemistry: Food laboratories performing chemical analyses may perform tests such as fat, protein, salt, vitamin and mineral content, associated with nutritional labeling. Residue chemistry testing laboratories may focus on analysis of halogenated hydrocarbons, pesticides, sulfonamides, nitrosamines, and toxic elements.

Food Microbiology: Food laboratories performing microbiological testing may perform qualitative and/or quantitative analyses for bacteria, yeasts, fungi, protozoa, and viruses. The microbiological procedures may include testing of pathogens such as *Salmonella species, Staphylococcus aureus, Listeria monocytogenes* and *Bacillus cereus, E. coli O157:H7* and other sanitation-related tests (e.g., fecal coliform).

Food Rheology and other Physical Tests: Food laboratories performing testing in this area may perform testing on the characteristics of the material, such as viscosity, elasticity, color or color appearance.

Food Toxicology: Food laboratories performing testing in this area may perform testing to determine the contaminants, chemical attributes or residues of the material.

Functional Testing: Food laboratories perform testing in this area may perform testing to determine the vitamin and mineral content of the material.

Molecular Biology: (including testing for genetically modified organisms): Food laboratories performing testing in this area may perform testing to detect pathogens in the material.

Sensory Testing: Food laboratories performing testing in this area may perform testing of a material to determine the flavor, odor or texture.

The requirements listed here, and in Modules 2A and 6, are not intended to replace or supersede any laboratory requirements specified in other Food Laboratory recognition programs, such as Federal or State programs, that AIHA LAP, LLC laboratories may participate in. Such requirements shall remain in effect, in addition to the AIHA LAP, LLC program requirements, for those laboratories participating in the AIHA LAP, LLC Food Laboratory Accreditation Program and an approved food proficiency testing program, as defined in Module 6.

2F.2 FACILITIES AND EQUIPMENT

The laboratory shall have space, facilities, and equipment adequate for the scope of services to be accredited, and the facility and equipment shall meet all the appropriate requirements.

2F.2.1 Microbiology Laboratories

The most current biosafety level guidelines are defined by the Centers for Disease Control (CDC), the World Health Organization (WHO), and the AIHA LAP, LLC. Microbiology laboratories seeking/maintaining accreditation shall have the following, as a minimum:

2F.2.1.1 Procedures addressing laboratory access, ventilation, prohibited practices, and decontamination.

2F.2.1.2 Compound microscopes with low and high power. Microscopes shall be serviced at least annually, and documentation maintained.

2F.2.1.3 Class II biological safety cabinet whose performance has been certified according to NSF Standard 49 (or national equivalent outside the United States). Cabinets shall be certified annually, and documentation maintained.

2F.2.1.4 Proper ventilation of laboratory hoods and instruments, according to current acceptable standards (e.g., ASHRAE).

2F.2.1.5 A steam sterilizer or autoclave with functioning temperature and pressure gauges.

2F.2.1.6 Adequate services, such as electricity, water, vacuum source, hand washing facilities, and appropriate infectious and chemical waste storage, treatment, and disposal procedures.

2F.2.1.7 Proper facilities and equipment for chemical storage and disposal of used containers, chemicals, and refuse.

2F.2.1.8 Incubator(s) with temperature settings appropriate for scope of work performed at the laboratory.

2F.2.2 Chemistry Laboratories, Equipment (See ISO/IEC 17025:2017, Section 6.4)

2F.3 ANALYTICAL METHODS

In addition to the requirements in AIHA LAP, LLC Policy Module 2A, the following requirements apply to laboratories seeking FoodLAP accreditation.

2F.3.1 Laboratories shall use methods that are recognized nationally and internationally including, but not limited to, the following sources: EPA, AOAC International Official Methods of Analysis, Compendium of Methods for the Microbiological Examination of Foods (CMMEF), American Public Health Association (APHA), FDA Bacteriological Analytical Manual, U.S. Department of Agriculture (USDA), U.S. Pharmacopeia (USP), and Standard Methods for the Examination of Dairy Products. The laboratory shall obtain customer agreement before using any of these methods for customer samples.

2F.3.2 When a laboratory must use a method that is not recognized nationally or internationally (see Section 2F.3.1), the laboratory shall validate the procedure according to ISO/IEC 17025:2017. The laboratory shall obtain customer agreement before using the method for customer samples.

2F.3.3 Prior to analysis, sample integrity shall be maintained through proper storage and handling conditions. Such conditions shall be documented.

2F.3.4 The laboratory shall have Standard Operating Procedures (SOPs) to address all areas of laboratory responsibility with respect to sample handling and analysis. These responsibilities may include: sampling, transportation, storage, and preparation of test items, QA/QC procedures, and equipment calibrations.

2F.4 QUALITY ASSURANCE / QUALITY CONTROL

Routine QA/QC procedures shall be an integral part of laboratory procedures and functions. These shall include the following in addition to those defined in Module 2A. For qualitative microbiological

determinations, some of the statistical requirements in Module 2A may not fully apply.

2F.4.1 The laboratory shall have documented procedures and appropriate facilities to avoid deterioration, damage, or cross contamination of any test item or sample during storage and handling. All necessary environmental conditions, including special security arrangements for sample integrity as needed for some samples, shall be established, maintained, monitored and recorded.

2F.4.2 All method specific quality control requirements shall be met. All statistical approaches required by the published method shall be used to verify data acceptability.

2F.4.3 The laboratory shall include reference cultures (RC) and/or certified reference cultures (CRC), when available, with all test batches for all microbiological tests. The data obtained from the RC and/or CRC (when available) shall be used to verify the acceptability of the sample media, evaluate laboratory performance, and support the validity of the test procedure(s).

2F.4.4 Chemistry laboratories shall include certified reference materials (CRMs), when available, with all test batches. If a CRM is not available, then an internally developed reference material may be used. The data obtained from the CRM or other reference material shall be used to verify the acceptability of the reagents and other supplies, evaluate laboratory performance, and support the validity of the test procedure(s).

2F.4.5 The laboratory shall comply with any specific food safety program that requires the use of blind samples to monitor analyst proficiency. Such compliance shall be supported within the SOP for the given procedure and the data shall be documented, including the review and approval process, within the laboratory record keeping system.

2F.4.6 Molecular laboratories shall maintain a collection of positive controls (e.g., cultures, DNA extracts, antigen/antibody combinations, etc.) for the molecular tests it provides.

2F.4.6.1 Source and date of acquisition for each shall be documented.

2F.4.6.2 Procedures for maintaining the cultures and/or reagents and using them for training and QC purposes shall be available.

2F.5 SAFETY AND HEALTH

Laboratories participating in the FoodLAP are expected to follow all applicable jurisdictional regulations regarding safety, health, environment, or transportation. Failure to comply with applicable jurisdictional regulations may result in denial, suspension, or withdrawal of FoodLAP accreditation. The assessor shall not perform a safety inspection of the laboratory. However, the

assessor will verify that the laboratory has a safety manual that is reviewed annually, and includes handling and disposal procedures for biological wastes, chemical wastes, toxic materials, and biohazards and addresses spill response procedures.

2F.6 AOAC ADDITIONAL REQUIREMENTS

When applying for FoodLAP accreditation, a laboratory has the option to include the AOAC International requirements (Guidelines for Laboratories Performing Microbiological and Chemical Analysis of Food and Pharmaceuticals, August 2018). These documents have been identified by the regulators as the type of model that they would utilize in conjunction with the application of the Food Safety Modernization Act (FSMA).

To obtain accreditation, the laboratory shall comply with the General Accreditation requirements defined in ISO/IEC 17025:2017 and relevant AIHA LAP Policy Modules as noted in Section 2F.1.

Laboratories seeking accreditation in this area shall maintain a copy of the AOAC International Requirements in its entirety.

MODULE 3
ACCREDITATION, MAINTENANCE AND REACCREDITATION PROCESSES

3.1 INITIAL ACCREDITATION

Laboratories wishing to obtain accreditation under any of the AIHA Laboratory Accreditation Programs, LLC (AIHA LAP, LLC) must successfully complete the accreditation process outlined in Figure 3-1. The accreditation process is summarized in the following steps:

3.1.1 A complete laboratory application shall be submitted to AIHA LAP, LLC with the associated, non-refundable fees. The AIHA LAP, LLC staff shall review and approve the application for completeness before it is forwarded to a site assessor.

3.1.2 The completed application shall be forwarded to an AIHA LAP, LLC site assessor for review prior to the completion of a site assessment.

3.1.3 The laboratory shall address all of the nonconformities identified by the site assessor with appropriate corrective actions.

3.1.4 The laboratory may be selected (see Section 3.6) to receive an accreditation process and technical review by the Technical Advisory Panel (TAP).

3.1.5 The Analytical Accreditation Board (AAB) shall vote to grant or deny laboratory accreditation, taking into account all of the requirements for accreditation.

3.1.6 The laboratory shall be rated proficient in accordance with the requirements of Policy Module 6 in each Field of Testing (FoT) for which accreditation is sought at the time of the AAB ballot vote for accreditation.

Laboratories that fail to complete all of the requirements for accreditation for any or all selected FoT(s) within twelve (12) months from the date of receipt of the application by AIHA LAP, LLC will have their application for the FoT(s) not meeting accreditation requirements removed from consideration.

3.2 PROFICIENCY TESTING

Successful participation in applicable proficiency testing programs is required to qualify for accreditation. Consistent with their scope of accreditation, laboratories are required to analyze all proficiency testing samples as defined in AIHA LAP, LLC Policy Module 6 and outlined on the Scope/PT Table. The laboratory shall have a documented policy regarding participation in proficiency testing programs. Proficiency testing samples shall be analyzed on-site in a manner

similar to customer samples. Results or analysis of proficiency samples shall not be discussed with other laboratories until the results have been publicly made available.

3.3 APPLICATION FOR ACCREDITATION

To apply for AIHA LAP, LLC accreditation under a single or multiple programs, a laboratory shall complete an Accreditation Application. Additional relevant information shall be provided to applicant laboratories upon request.

3.3.1 The completed Accreditation Application and supporting documentation shall be submitted to the AIHA LAP, LLC office, in accordance with the accreditation application instructions, with the required fees as set forth in the Fee Schedule. All application materials must be submitted in English.

3.3.2 AIHA LAP, LLC staff shall have twenty (20) business days to complete the application review. The review includes a completeness check of the application, a preliminary evaluation of critical components to verify conformance, and verification of proficiency testing participation and proficiency status based on the scope of accreditation selected by the laboratory.

3.3.3 If the application is incomplete, AIHA LAP, LLC staff works with the laboratory to obtain the necessary information to continue with the application process. The laboratory shall provide all required information within thirty (30) business days of the request. Failure to do so shall result in the loss of the application fee and the laboratory shall be required to resubmit a completed application for consideration.

3.3.4 The application materials, used to prepare for the site assessment, are the property of AIHA LAP, LLC and shall be treated with appropriate confidentiality. The application materials shall remain in AIHA LAP, LLC files as an official record.

3.4 SITE ASSESSOR REVIEW

The AIHA LAP, LLC staff shall assign the completed application and supporting documentation to the site assessor for review. The laboratory shall be notified in advance of the site assessor's identity. If a laboratory believes that a particular assessor may represent a conflict of interest, the laboratory is allowed one rejection of an assessor with a reason provided. The site assessor shall complete the application package review and the site evaluation within a period of 12 weeks from the time of receipt of the application from AIHA LAP, LLC provided the site assessor is given access to the laboratory within a reasonable amount of time. Where the assessment cannot be conducted in a timely manner, this shall be communicated to the laboratory. If the laboratory delays the process by failing to cooperate with the site assessor's scheduling

requirements, then they shall have no basis for complaint to AIHA LAP, LLC.

3.4.1 The site assessor shall complete a comprehensive technical review of the application. If the site assessor finds all components of the application to be in order, then a site assessment will be scheduled with the laboratory for the earliest possible date.

3.4.2 If any critical nonconformities (e.g., lack of key personnel, no established management system, inadequate facilities, improper equipment, etc.) are identified, the site assessor shall notify the AIHA LAP, LLC staff. The site assessor and, if necessary, staff, will then contact the laboratory to potentially resolve the issue(s) prior to the site assessment. If the laboratory agrees to correct the critical nonconformities, documentation shall be submitted to substantiate the corrective action(s) taken to address the nonconformity before the site assessor proceeds with scheduling the assessment. A pre-assessment may be suggested by the assessor or requested by the laboratory. See Section 3.13 for details on converting an initial accreditation application to a pre-assessment.

If the laboratory chooses to stop the accreditation process by not addressing the critical nonconformities, then the site assessor shall delete all laboratory application materials. The application fee shall be forfeited and the laboratory will be responsible for any costs incurred by the site assessor (travel, lodging, etc.). The laboratory shall be required to resubmit a completed application, in accordance with all AIHA LAP, LLC requirements, for future consideration.

3.5 SITE ASSESSMENT

A laboratory site assessment is required for accreditation. Multiple program assessments for a single laboratory shall be combined when the application is submitted with combined program information. Combined accreditations may require participation by more than one site assessor. AIHA LAP, LLC shall not delegate fully or partially the responsibility of an ELLAP laboratory assessment to another organization which is not recognized under NLLAP. The duration of the site assessment shall not exceed a maximum period of five (5) business days unless otherwise approved by the AIHA LAP, LLC and the laboratory. The laboratory shall bear all costs associated with the site assessment based upon the Fee Schedule. For international assessments, it is the responsibility of the laboratory to ensure that there is someone onsite who can communicate with the assessor in English and translate, if necessary. At the completion of the site assessment, the laboratory will be be given the opportunity to provide feedback on both the assessment and AIHA LAP, LLC staff. This feedback will be used to facilitate continuous improvement efforts at AIHA LAP, LLC and to evaluate the site assessor's performance.

3.5.1 The site assessor shall utilize a checklist, based on the ISO/IEC 17025:2017 Standard and AIHA LAP, LLC policy requirements, to evaluate the laboratory during the site

assessment portion of the accreditation process. Conformity with all checklist items is required for a laboratory to be considered for accreditation.

3.5.2 Once the site assessment is complete, the site assessor shall submit a summary report, with nonconformities and/or comments, to the laboratory at the conclusion of the site assessment. If there are a high number of nonconformities, or some aspects of the laboratory were not able to be assessed due to no fault of the assessor, then the assessor may recommend a follow-up or surveillance assessment at the close of the assessment.

3.5.2.1 Nonconformities are problems or deficits (identified by the AIHA LAP, LLC policy number and/or the ISO clause) that must be corrected and proof of conformity provided. The laboratory shall provide an analysis of the extent and cause (e.g., root cause analysis) of any nonconformity noted. Nonconformities shall be addressed by mutually agreeable goal dates before the accreditation process can proceed.

3.5.2.2 Comments are areas of potential improvement noted during the assessment. There is no requirement to respond to comments. However, comments can be considered for inclusion into the laboratory's preventive action program.

3.5.3 The site assessor may recommend, via the site assessment report and/or request for additional information form, an immediate suspension, withdrawal, or denial of the laboratory's accreditation due to nonconformities that show a lack of comprehension or serious disregard for AIHA LAP, LLC policies, fraudulent or erroneous data, or a large number of repeat nonconformities.

3.5.3.1 In such events, the site assessor shall notify the AIHA LAP, LLC management, of the request for immediate suspension, withdrawl or denial.

The policies defined in AIHA LLP, LLC Policy Module 4 shall be followed. Initial assessments with egregious nonconformities may be converted to pre-assessments at the laboratory's request. (See Section 3.13 for details on converting an initial accreditation site assessment to a pre-assessment.)

3.5.4 The site assessor shall submit a final report (Site Assessment Report) and the completed checklist to AIHA LAP, LLC within ten (10) business days after completion of the site assessment. In addition, the Site Assessor shall submit the completed checklist to the laboratory at this time.

3.5.5 The laboratory shall respond in writing to all of the nonconformities to the site

assessor and AIHA LAP, LLC within twenty (20) business days of completion of the site assessment. All nonconformity responses must be submitted in English. If the site assessor considers all of the laboratory corrective actions appropriate and complete, then the site assessor shall provide an affirmative recommendation for laboratory accreditation to AIHA LAP, LLC.

3.5.6 If the laboratory fails to respond to the site assessor and AIHA LAP, LLC regarding nonconformities within twenty (20) business days of completion of the site assessment, then AIHA LAP, LLC will inform the laboratory that they have ten (10) business days from the date of the notification to respond to the nonconformities. Failure to respond by the deadline will terminate the accreditation process. The laboratory shall be responsible for the site assessor fees, and the application fees shall be forfeited.

3.5.7 If the laboratory responses to the nonconformities are unacceptable to the site assessor, he/she shall notify the laboratory within ten (10) business days of receiving the responses. The assessor shall specify what additional information and/or actions are required to adequately address the nonconformities. The laboratory shall be given twenty (20) business days to respond to this request for additional information. Failure to submit the required supplemental information to the site assessor within the specified time period shall result in the termination of the accreditation process. The laboratory shall be responsible for the site assessor fees, and the application fees shall be forfeited.

3.5.8 If the laboratory's supplemental responses to the nonconformities continue to be unacceptable to the site assessor, the laboratory shall be given ten (10) business days to provide a second supplemental response to any remaining issues. If the laboratory's second supplemental response to the nonconformities continues to be unacceptable to the site assessor, the laboratory may be recommended for a follow-up assessment, or may be assessed additional fees by AIHA LAP, LLC for extended site assessor review. Such recommendations for follow-up assessment or additional fees shall be referred to the Technical Advisory Panel (TAP) for concurrence. A follow-up assessment must be approved by the Managing Director, or designee, of AIHA LAP, LLC and, if approved, must be completed prior to granting accreditation or reaccreditation. If the laboratory's response schedule does not allow sufficient time to complete the accreditation process within the twelve (12) month time frame; or if there are irresolvable differences of opinion between the laboratory and the site assessor, then the site assessor shall recommend that the laboratory be denied accreditation. (see Policy Module 4)

3.5.9 A *Follow-Up Site Assessment* is an on-site check of the implementation of the laboratory's corrective actions to the routine site assessment. The follow-up site assessment occurs prior to the granting of accreditation.

The site assessor may recommend a follow-up assessment at the close of the routine assessment or after receiving the laboratory responses. A follow-up assessment must be approved by the Managing Director, or designee, of AIHA LAP, LLC and, if approved, must be completed prior to granting accreditation or reaccreditation.

A follow-up assessment may be required if:
a) the site assessment has revealed a large number of nonconformities;
b) there are a large number of repeat nonconformities; or
c) the laboratory's responses to the nonconformities indicate an unwillingness or inability to implement compliance.

The laboratory shall bear all costs associated with the site assessment based upon a predetermined fee schedule. A follow-up site assessment will focus on implementation of corrective actions to nonconformities, but any other nonconformities identified during a follow-up site assessment must also be corrected prior to granting accreditation or reaccreditation. The laboratory is typically limited to one nonconformity response, but may be allowed an additional opportunity to respond at the site assessor's discretion. A laboratory must respond to all nonconformities found during a follow-up assessment in order for the site assessor to recommend accreditation or reaccreditation.

3.5.10 A *Surveillance Site Assessment* is a site assessment performed between routinely scheduled assessments and after the granting of accreditation or reaccreditation. All initially accredited laboratories shall be contacted for site assessment assignment and scheduling within six to nine months of their approval by the AAB, and undergo an on-site surveillance assessment within twelve (12) months of their approval.

A surveillance site assessment may be required
a) due to a credible complaint;
b) high personnel turnover;
c) a large number of nonconformities during the most recent routine assessment;
d) repeat nonconformities;
e) poor proficiency testing performance; or
f) any other reason(s) that call into question the laboratory's compliance with accreditation requirements.

The Analytical Accreditation Board (AAB) may request a surveillance assessment as a condition of the granting of accreditation.

Surveillance assessments may be announced or unannounced. For announced surveillance assessments, the laboratory shall be contacted for site assessment assignment and scheduling within six (6) to nine (9) months of their approval by the AAB. The laboratory will bear all costs associated with the site assessment based upon

a predetermined fee schedule. Surveillance assessments follow the same processes outlined in 3.5.1 to 3.5.8, but are typically limited to one day and may be extended at AIHA LAP, LLC discretion.

The surveillance assessment focuses on those issues outstanding from the scenarios listed above, but the laboratory may have new nonconformities cited; the laboratory may also choose to extend their scope of accreditation within an accredited program during surveillance. The laboratory is typically limited to one nonconformity response, but may be allowed an additional opportunity to respond at the site assessor's discretion. A laboratory must respond to all nonconformities found during a surveillance assessment in order for the site assessor to recommend that they maintain their accreditation status.

3.6 TECHNICAL ADVISORY PANEL REVIEW

All laboratories may be subjected to a process and technical review by the Technical Advisory Panel (TAP).

The Site Assessor may recommend a TAP review at the close of the assessment or upon final recommendation. Upon the site assessor's discretion, those laboratories with a large number of methods shall have a TAP review assigned to ensure a thorough review of the laboratory's scope has been conducted. Upon review of the assessment report, AIHA LAP, LLC may also request that the application record be forwarded for TAP Reivew. All initial accreditation and surveillance laboratories are subject to a TAP review. Any reaccreditation may be selected for TAP review.

The scope of the TAP review shall include a thorough assessment of all accreditation process steps to ensure conformity to process and technical requirements. The TAP recommendation shall be submitted to AIHA LAP, LLC within ten (10) business days. Issues arising from the TAP recommendations shall be resolved prior to the AAB ballot and may include additional contact with the laboratory.

3.7 GRANTING OF ACCREDITATION

3.7.1 AAB Ballot

The AIHA LAP, LLC Analytical Accreditation Board (AAB) has the authority to approve laboratories for accreditation. If a laboratory meets all accreditation program requirements, successfully completing each review step of the accreditation process (AIHA LAP, LLC staff review, site assessment, TAP review), then the laboratory shall be placed on an AAB ballot. The AAB shall vote, in accordance with Policy Module 1, Section 1.2.1, to grant or deny laboratory accreditation.

Laboratory accreditation shall be granted for a period of two (2) years. All AAB decisions may be appealed to an appeals committee. The appeals process is discussed in Policy Module 5.

3.7.2 Proficiency at Time of AAB Ballot

If at the time of AAB ballot vote, a laboratory is non-proficient for any FoT(s) for which it is seeking accreditation or reaccreditation (as per Policy Module 6), but has met all other accreditation requirements, then the following shall apply.

3.7.2.1 Laboratories for Initial Accreditation

If a laboratory for initial accreditation has any non-proficient PT status (as applicable), the AAB may vote to accredit with suspension. This means that the laboratory shall be accredited, but also immediately suspended, for the non-proficient FoT(s). Proficient FoTs are not affected by an accredit with suspension vote. When the laboratory attains a proficient status in an FoT suspended through accredit with suspension, then AIHA LAP, LLC shall remove the suspension.

3.7.2.2 Laboratories for Reaccreditation

If a laboratory is non-proficient and its accreditation is suspended for the FoT(s), then the AAB shall grant accreditation and continue the suspended accreditation status for the FoT(s). When the laboratory attains a proficient status for the FoT(s), then AIHA LAP, LLC shall reissue an updated scope of accreditation to that laboratory reflecting a full accreditation status for the FoT(s). A formal AAB ballot vote is not required to reinstate full accreditation status.

In all cases, proficiency must be attained within twelve (12) months from the date of receipt of the application by the AIHA LAP, LLC or the laboratory's application for the FoT(s) not meeting accreditation requirements, inclusive of proficiency, will be removed from consideration (see Section 3.1).

3.8 MAINTENANCE OF ACCREDITATION

Laboratory accreditation shall be maintained by continued conformity with AIHA LAP, LLC requirements, continued successful participation in the appropriate proficiency testing programs, and payment of appropriate fees.

3.8.1 Reporting of Significant Changes

Any changes in laboratory ownership, location (except for mobile and field operations laboratories), management, laboratory key personnel, or any other change that significantly affects the laboratory's capability, scope of accreditation, or ability to meet the policy requirements, shall be reported in writing to AIHA LAP, LLC within twenty (20) business days of the change. Any absence of personnel for a period in excess of twenty (20) consecutive working days, that impacts the laboratory's ability to perform its scope of testing, shall be reported to AIHA LAP, LLC within twenty (20) business days. This notification requirement shall be in effect if any laboratory key personnel are absent for reasons of extended family leave, illness, temporary disability, etc.

AIHA LAP, LLC shall notify the laboratory of the results of the evaluation and shall amend the record within twenty (20) business days. During the period between laboratory change notification submittal and formal acceptance of the changes, AIHA LAP, LLC may elect to suspend the laboratory's accreditation status until the changes are assessed and determined to be in conformance with the policy requirements. An additional laboratory assessment may be required for facility or procedural modifications. Ownership changes shall be evaluated in consideration of proposed management and location changes. Significant changes in ownership or laboratory location shall require the laboratory to reapply under a new accreditation number.

3.8.2 Maintenance of Proficiency

Accredited laboratories shall maintain proficiency for all applicable FoTs as defined in Policy Module 6. If a laboratory becomes non-proficient in a specific FoT(s), based on proficiency testing sample performance, and there is no retest sample available, then its accredited status for the FoT(s) in question shall be suspended.

If the laboratory becomes non-proficient in a specific FoT(s), based on proficiency testing sample performance, and there is a retest sample available, then the laboratory may choose to purchase the retest proficiency testing sample to attempt to regain a proficient status immediately, thereby maintaining a fully accredited status for the applicable FoT(s). If the laboratory does not opt to purchase a FoT-specific, round-specific proficiency testing retest sample within the required time frame, then its accredited status for the FoT(s) in question shall be suspended immediately.

3.8.3 Maintenance of Fees

If the laboratory fails to pay the fees assessed by AIHA LAP, LLC in an invoice, then AIHA LAP, LLC reserves the right to suspend the laboratory's accreditation(s) for any or all FoTs until all fees are paid in full. AIHA LAP, LLC shall notify the participant of this action in writing, specifying a payment deadline. If payment is not received by AIHA LAP, LLC within the

specified time frame and a written request from the laboratory to extend the payment deadline has not been received and approved by the AIHA LAP Manager of Operations, then the AIHA LAP, LLC shall administratively remove the laboratory from the program(s).

3.8.4 Notice of Intended Change

AIHA LAP, LLC shall notify the laboratory of intended changes relating to the requirements of this document and other referenced documents. Date of implementation of the changes will be stated. Compliance may be verified using the site assessment process or required submissions as requested by AIHA LAP, LLC.

3.8.5 Complaints

If requested, the laboratory shall assist AIHA LAP, LLC in the investigation and resolution of any acceditation related complaints regarding the laboratory.

3.9 ADDITION OF A FIELD OF TESTING (FoT)

An accredited laboratory that wishes to add a new Field of Testing (FoT) shall determine how competency for that FoT will be demonstrated. Refer to Policy Module 6 and the Scope/PT Table to make this determination. Competency shall be demonstrated prior to applying for the new FoT. The laboratory shall submit an updated application to AIHA LAP, LLC staff that includes equipment verification information (reporting limit verification, standard curve, QC analyses), a test method, appropriate traceability, estimation of uncertainty of measurement, evidence of analyst competency, and required demonstrations of competency associated with the addition of the new FoT.

A laboratory may add a FoT to an existing Core Scope category between assessments. If a laboratory chooses to add a FoT outside a Core Scope category, the FoT addition application will be referred to the previous site assessor for determination on a case-by-case basis. The laboratory may be required to undergo an additional site assessment before expansion of the accreditation is finalized. If no site assessment is required, the application shall be reviewed by the member of the TAP who shall make a recommendation to the AAB regarding accreditation for the new FoT within ten (10) business days of receiving the application.

For FoT additions at the time of assessment, the laboratory must first give sufficient notice to the site assessor (a minimum of ten (10) business days) notice, subject to agreement by the assessor.

The AAB shall vote on the TAP and/or Site Assessor recommendation on the next scheduled ballot, see Section 3.7, Granting of Accreditation.

3.10 ADDITION OF A METHOD

An accredited laboratory that wishes to add a method within a field of testing (FoT) for which the laboratory is currently accredited shall submit a method addition application through the Data Management System and the standard operating procedure(s) for each method being added. The information submitted shall be reviewed by a member of TAP who shall approve or deny the method addition within ten (10) business days of receiving the method addition documentation.

For accredited laboratories seeking to add a method(s) within an ELLAP matrix which requires new instrumentation, please see Section 3.9, Addition of a Field of Testing (FoT).

For accredited laboratories seeking to add a method(s) within a FoT/Core Scope category for which the laboratory is not currently accredited, please see Section 3.9, Addition of a Field of Testing (FoT).

3.11 TRANSFER OF ACCREDITATION

A laboratory that is currently accredited by another ILAC recognized Accreditation Body may transfer their accreditation. The applicant must indicate on the application that it is a request for a transfer of accreditation. These requests will be handled on a case-by-case basis, but generally applicants must meet the criteria below.

To be eligible for a transfer of accreditation, the applicant laboratory shall:

a) Be accredited in good standing by an ILAC-recognized AB;
    i. Good standing means that the laboratory is not currently suspended with their current accreditation body.
b) Have been accredited by the AB for at least four years;
c) Provide AIHA LAP, LLC with the last assessment report of the AB and any associated corrective actions;
d) Undergo an initial assessment with acceptable results; i.e., evidence that the management system has been and continues to be fully implemented with findings of reasonable technical and management system nonconformities; and,
e) Provide recent proficiency testing results that show a pattern of successful participation.

3.12 REQUIREMENTS FOR REACCREDITATION

Laboratory accreditation shall be granted for a period of two (2) years. Laboratories must reaccredit every two (2) years by completing an application that conforms to all AIHA LAP, LLC

requirements, and successfully completing a site assessment (see Accreditation Process, Figure 3-1). The laboratory shall also demonstrate continued, successful participation in the appropriate proficiency testing program(s). If a laboratory chooses not to seek reaccreditation, then the laboratory accreditation(s) shall expire on the accreditation expiration date, provided the laboratory remains proficient in the applicable FoT(s). Additionally, the laboratory shall notify AIHA LAP, LLC in writing of its intentions not to seek reaccreditation, in lieu of submitting an application for consideration of reaccreditation.

3.12.1 Reapplication

The reaccreditation process shall begin with the laboratory completing the Accreditation Application. Nine (9) months prior to the expiration of the existing accreditation(s), AIHA LAP, LLC shall notify the laboratory, in writing, requesting that the laboratory complete and submit an application for reaccreditation. The laboratory must complete and submit this application, or notify AIHA LAP, LLC in writing of their intention to allow their accreditation to expire, within thirty (30) business days from the date of notification. The reaccreditation application process is similar to the process defined in Sections 3.1 – 3.4.

Laboratories shall undergo reaccreditation for all FoTs (all accreditation programs), at the same time, regardless of the date of initial accreditation for each program FoT. For instance, if the laboratory sought and received accreditation of an additional FoT since the last full (re)accreditation cycle, the additional FoT shall be evaluated as part of the current application.

The laboratory may request from AIHA LAP, LLC, in writing, an extension of time for submitting the reaccreditation application or for providing notification to AIHA LAP, LLC regarding reaccreditation intentions. AIHA LAP will notify the laboratory if this extension will result in a truncation of the next accreditation period. If an application is not received and the laboratory accreditation expires, the laboratory will need to apply as an initial applicant.

3.12.2 Site Assessment

The reaccreditation process shall require a site assessment that shall follow the same process as that described in Sections 3.4 and 3.5.

In addition to the site assessment that is completed every two (2) years, unannounced assessments may be authorized by the AAB to investigate potential problems with an accredited laboratory. In the event of an unannounced assessment, the laboratory may be charged for the site assessment. Refusal to allow an unannounced laboratory assessment may be grounds for immediate suspension and eventual withdrawal of accreditation.

In rare cases, the AAB, with input from the site assessor, may require a surveillance

assessment to verify resolution of major nonconformities as identified in the site assessment performed as part of the (re)accreditation process. When possible, laboratories shall be notified at the time of the site assessment of the requirement for a subsequent announced or unannounced surveillance assessment. Laboratories shall bear the cost of a required surveillance assessment.

3.12.3 Technical Advisory Panel Review

This review follows the same system defined in Section 3.6.

3.12.4 Granting of Reaccreditation

Reaccreditation shall be voted upon by the AAB as defined in Section 3.7.

3.13 PRE-ASSESSMENT

Pre-Assessments:

- are only conducted for laboratories seeking initial accreditation
- include all applicable fees for the application, review, and site assessment
- are assigned and conducted as detailed in 3.5
- end with the site assessment report
- do not include the submission of nonconformity responses

The two types of pre-assessments are listed below.

3.13.1 Pre-Assessment prior to Accreditation Application

A laboratory may request a pre-assessment as a gap analysis of their program to ISO/IEC 17025 and the AIHA LAP Policies with the submittal of a pre-assessment application. The pre-assessment option allows the laboratory to better prepare for a full accreditation assessment at a later date.

NOTE: The AIHA LAP site assessment checklist, based on the ISO/IEC 17025 standard and AIHA LAP policy requirements, is available upon request. Utilizing the site assessment checklist may help avoid the need for a pre-assessment.

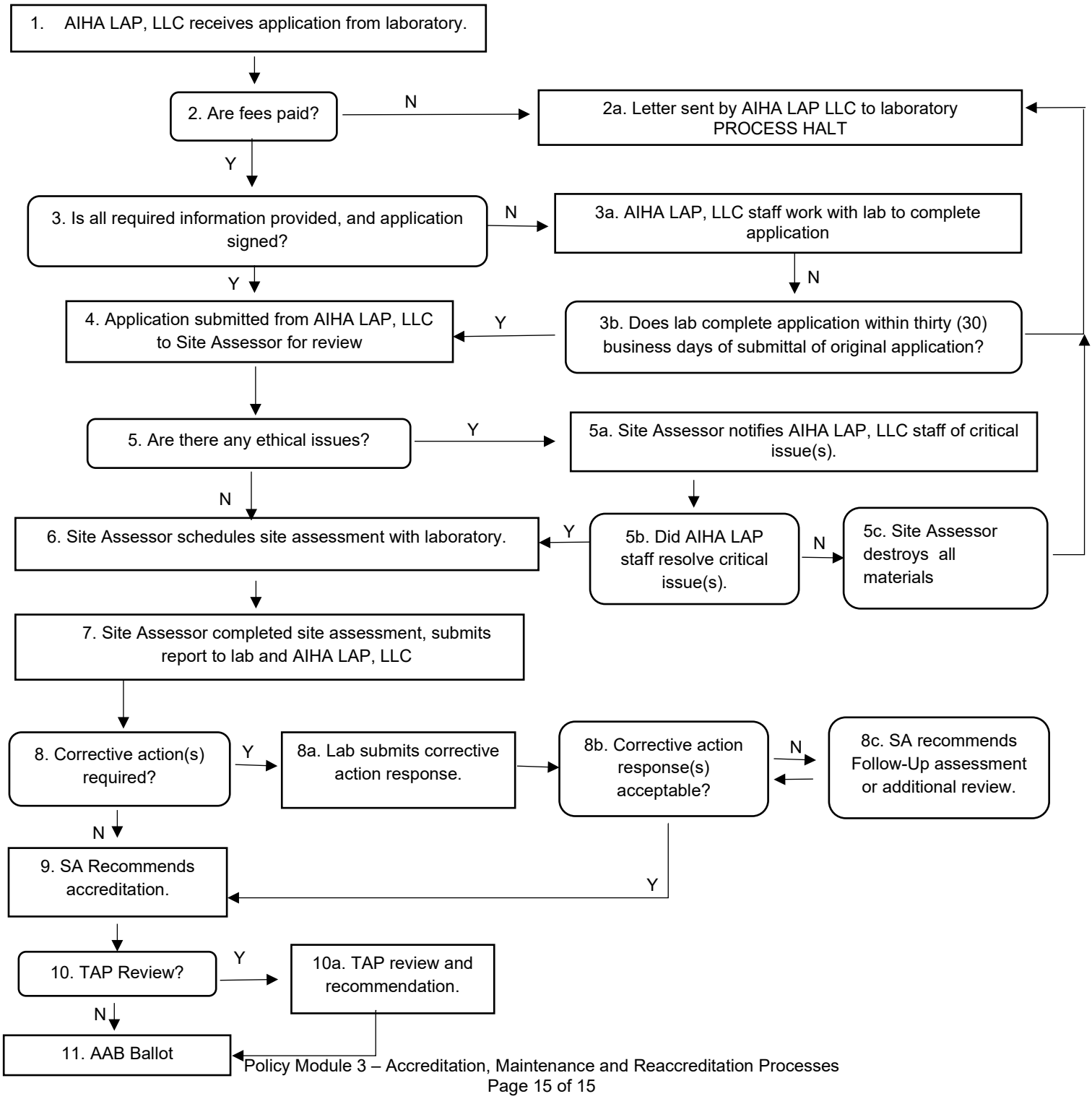
3.13.2 Conversion of an Initial Accreditation Application to a Pre-Assessment

A laboratory seeking initial AIHA LAP accreditation may request their accreditation application be converted to a pre-assessment any time after application submittal and before the closing meeting of the site assessment. It may be practical to do so if the assessor finds critical

nonconformities during application review (See Section 3.4.2) or site assessment (See Section 3.5.3).

After a pre-assessment, when a laboratory is ready to proceed with accreditation, a new initial accreditation application shall be required.

FIGURE 3-1 Accreditation Process



MODULE 4
SUSPENSION, DENIAL, OR WITHDRAWAL OF ACCREDITATION

4.1 INTRODUCTION

AIHA LAP, LLC staff shall continuously monitor the accreditation/reaccreditation application process, performance in the proficiency programs, and other pertinent information obtained from AIHA LAP, LLC site assessors and stakeholders, to identify situations of nonconformity. If a laboratory fails to maintain conformity to accreditation requirements, then AIHA LAP, LLC may initiate the following processes to suspend, deny, or withdraw accreditation.

4.2 DEFINITIONS

4.2.1 Suspension - A temporary removal of the laboratory's accreditation status for any or all FoTs.

4.2.2 Denial - The decision not to grant a laboratory initial accreditation.

4.2.3 Withdrawal - The removal of a laboratory's existing accreditation.

4.3 GROUNDS

AIHA LAP, LLC may suspend, deny, or withdraw accreditation if any of the following circumstances apply.

Suspension of accreditation for 4.3.1 through 4.3.4 requires a vote of the AAB in accordance with the process set forth in Section 4.5;

4.3.1 The laboratory fails to comply with any of the requirements of AIHA LAP, LLC, as detailed in Modules 1 through 8, and Appendices G and H.

4.3.2 The laboratory submits, as its own, results for proficiency testing that were analyzed by another laboratory.

4.3.3 The laboratory misrepresents material information in an application (initial or reaccreditation) or in any written correspondence with AIHA LAP, LLC.

4.3.4 The owner of the laboratory, laboratory key personnel or the laboratory itself has been convicted of a violation of federal/state statutes or regulations related to the accreditation program in question.

The following are grounds for immediate suspension upon decision of AIHA LAP, LLC staff or suspension may be imposed by AAB vote.

4.3.5 The laboratory knowingly reports fraudulent or erroneous data or knowingly creates fraudulent laboratory records.

4.3.6 The laboratory misrepresents its accreditation through false or misleading advertising as defined in Module 7, communication (written or verbal), or in any other form.

4.3.7 The laboratory uses its accreditation in any manner that brings disrepute to AIHA LAP, LLC.

4.3.8 The laboratory is no longer in the business of conducting analyses associated with its specific scope of accreditation(s).

4.3.9 The laboratory fails to respond to a written request for information within the specified time frame (e.g., reaccreditation application, corrective action(s) response, etc.).

4.3.10 The laboratory fails to conform to the requirements as specified in the laboratory assessment report by the assessor, within the required time frame.

4.3.11 The laboratory fails to maintain FoT proficiency (as applicable) based on proficiency testing sample performance, as defined in these policies.

4.3.12 The laboratory fails to notify AIHA LAP, LLC of changes in ownership, laboratory location for fixed site facilities, or laboratory key personnel within the specified time frame.

4.3.13 The laboratory alters the AIHA LAP, LLC Laboratory Accreditation Certificate in any way.

4.3.14 The laboratory refuses to allow an unannounced site assessment.

4.3.15 The laboratory does not submit the required AIHA LAP, LLC fees by the required due date.

4.3.16 An application may be denied at any point in the application or initial assessment process in the event that the laboratory engages in fraudulent behavior, knowingly reports or conceals fraudulent or erroneous data.

4.4 ADDITIONAL SUSPENSION INFORMATION

Suspension is a temporary removal of the laboratory's accreditation status for any or all FoTs when it is found to not be in conformity with specific program requirements. Suspension may occur at any time for cause.

4.4.1 Suspension may be initiated upon the recommendation of the AAB Chairperson, the Chief Site Assessor, or AIHA LAP, LLC management.

4.4.2 A laboratory may elect to voluntarily suspend its accreditation status for any or all FoTs for a predetermined period of time. The laboratory shall submit, in writing, its request providing the reason and timeframe for the suspension.

4.4.3 AIHA LAP, LLC shall notify a laboratory of the reasons for and conditions of the suspension, the action(s) required for reinstatement, and the deadline for satisfactory completion of the action(s). In the case of a voluntary suspension, AIHA LAP, LLC shall formally respond to the request and provide the reasons for and conditions of the suspension, the actions(s) required for reinstatement and the deadline for satisfactory completion of the actions(s).

4.4.4 During the suspension, the laboratory may not advertise that it is accredited for the suspended FoT(s). The laboratory may advertise that it is accredited in other FoT(s), but must advise their customers, without undo delay, that analyses within the suspended FoT(s) are not covered under AIHA LAP, LLC accreditation. This notification shall be given to the customer upon receipt of the sample(s) and noted on the report. Additionally, upon the change of the laboratory's accreditation status for the accreditation/FoT(s) in question, these accreditation/FoT(s) will be removed from the listing of accredited laboratories on the AIHA LAP, LLC web site and additional notifications and information may appear on the AIHA LAP, LLC website.

4.4.5 Suspension shall be lifted upon resolution of the initial cause to the satisfaction of AIHA LAP, LLC.

4.4.6 Suspension may proceed to withdrawal if the action(s) required for reinstatement are not met by the deadline, as determined by AIHA LAP, LLC.

4.4.7 AIHA LAP, LLC shall notify the laboratory, in writing, of any action at the conclusion of the suspension period.

4.5 PROCESS FOR SUSPENSION, DENIAL, OR WITHDRAWAL OF ACCREDITATION

The AIHA LAP, LLC staff shall continuously monitor the accreditation/reaccreditation application process, performance in the proficiency programs, and other pertinent information obtained from AIHA LAP, LLC stakeholders, to identify situations of nonconformity. If a laboratory fails to maintain conformity to accreditation requirements, then AIHA LAP, LLC may initiate the following process to suspend, deny, or withdraw accreditation, as outlined in Figure 4-1. This process could also but need not apply in cases of voluntary suspension and immediate suspension imposed by AIHA LAP, LLC staff for reasons set forth in 4.3.5 through 4.3.16.

4.5.1 AIHA LAP, LLC shall immediately promptly notify the AAB Chairperson of the nonconformity indicating the laboratory identity; grounds for suspension, denial, or withdrawal; and all pertinent supporting or background information.

4.5.2 Within five (5) business days of AAB Chairperson notification, a subcommittee consisting of the most recent site assessor (if applicable), Chief Site Assessor, AIHA LAP, LLC staff and two TAP members, will be formed.

4.5.3 The laboratory shall be notified of the initiation of the process for suspension, denial, or withdrawal and given five (5) business days to submit additional information, or a statement of its position as to why the action is not warranted.

4.5.4 Within ten (10) business days of receipt of additional information, or upon the expiration of the five (5) business day response window, the subcommittee shall be given all pertinent information needed to make a recommendation.

4.5.5 The subcommittee shall provide a recommendation within ten (10) business days. The findings of the subcommittee shall be forwarded to the AAB Chairperson.

4.5.6 AIHA LAP, LLC shall submit all necessary information to the AAB via ballot and a vote of the full AAB voting membership (see Module 1, Section 1.2.1) on the suspension, denial, or withdrawal action shall be taken within ten (10) business days.

4.5.7 Within ten (10) business days from completion of the AAB vote, the AIHA LAP, LLC shall notify the laboratory, in writing, of the AAB decision to:

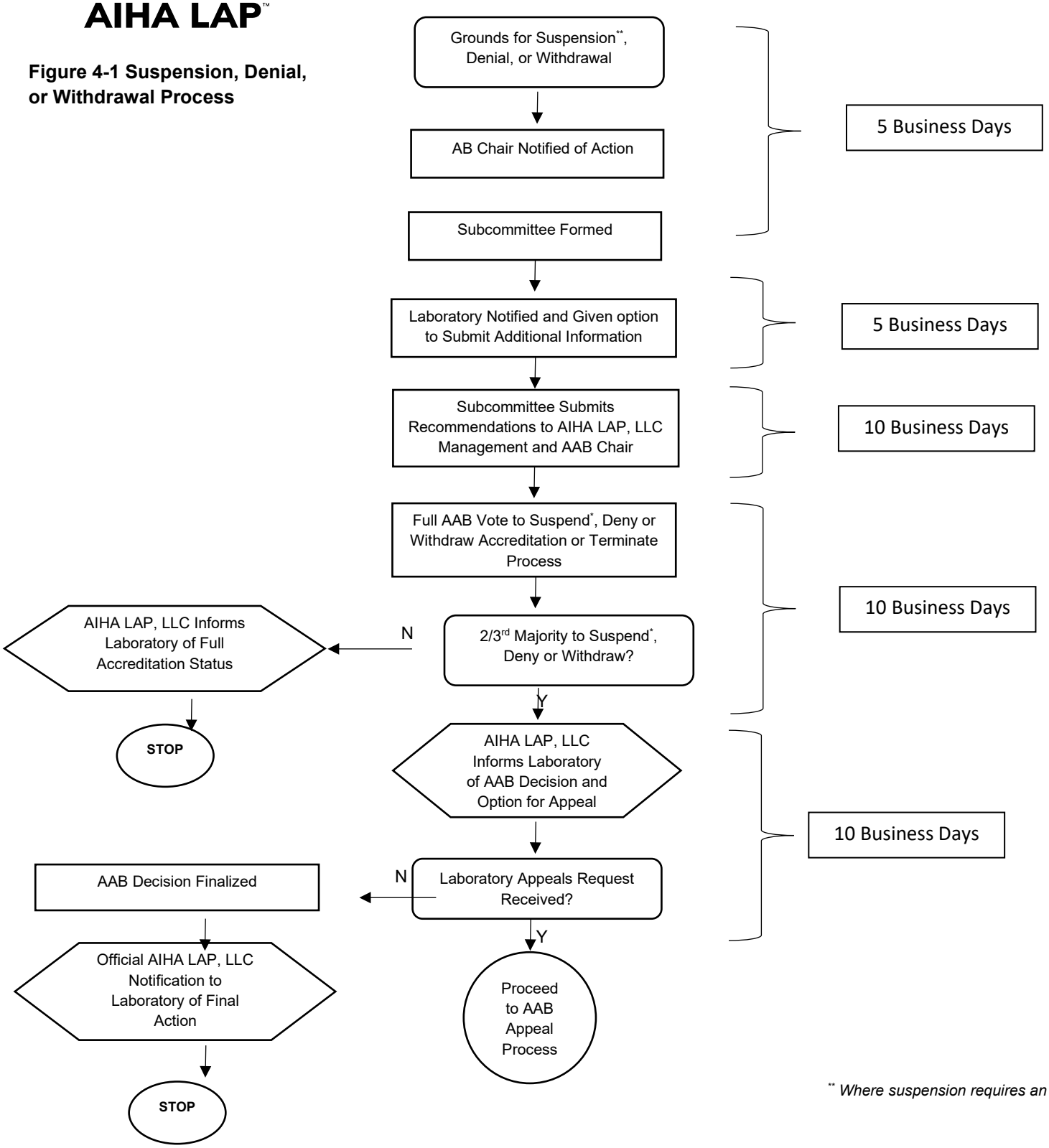
4.5.7.1 Continue or grant accreditation; or

4.5.7.2 Affirm the recommendation to suspend, deny, or withdraw accreditation and offer the laboratory the right to appeal the AAB Decision (see Policy Module 5). The laboratory shall have ten (10) business days from the date of receipt of this notification to provide the AIHA LAP, LLC management with a written request to appeal.

4.5.8 Absent an appeals request, the AAB suspension, denial, or withdrawal decision is final. The laboratory shall take measures to inform its affected clients of the withdrawal of its accreditation and the associated consequences without undue delay. AIHA LAP, LLC shall take the necessary steps to officially suspend (Section 4.2) or withdraw the accreditation status of accredited laboratories for the specified FoT(s), consistent with the AAB decision, and shall provide official notification to the laboratory of such actions. Appeals are covered in Policy Module 5.

4.5.9 If accreditation is denied or withdrawn, a laboratory may reapply for initial accreditation at any time upon satisfaction of conditions established by the AAB and/or AIHA LAP, LLC staff.

Figure 4-1 Suspension, Denial, or Withdrawal Process



** *Where suspension requires an AAB vote.*

MODULE 5
APPEALS PROCESS

5.1 RIGHT TO APPEAL

A laboratory has the right to appeal the decision of the Analytical Accreditation Board (AAB) to deny, suspend or withdraw accreditation and the decision of AIHA LAP, LLC staff to suspend accreditation. If the laboratory chooses to appeal, it shall be responsible for fifty percent (50%) of the costs associated with the appeals process. The expenses of any witnesses for either party shall be paid by the party producing such witnesses. All other expenses shall be borne by the party incurring those expenses. The appeals process is outlined in Figure 5-1.

5.2 NOTICE OF APPEAL

If the laboratory wishes to appeal the AAB decision, it must notify the Managing Director of AIHA LAP, LLC in writing within ten (10) business days of the date of receipt of the letter from the AIHA LAP, LLC outlining the AAB decision to deny, suspend or withdraw the laboratory's accreditation. If the laboratory wishes to appeal the AIHA LAP, LLC staff decision to suspend, it must notify the Managing Director of AIHA LAP, LLC in writing within five (5) business days of the date of receipt of the letter from the AIHA LAP, LLC outlining the decision to suspend the laboratory's accreditation. This notification shall include the reason for the appeal and a statement accepting responsibility for monetary expenses as described in Section 5.1. The denial, suspension or withdrawal decision is final if the laboratory fails to submit an appeal request within the specified time frame.

If the laboratory notifies the AIHA LAP, LLC within ten (10) business days of its desire to appeal the AAB or AIHA LAP, LLC staff decision, then the AIHA LAP, LLC management shall contact the AAB Chairperson within five (5) business days.

AIHA LAP, LLC shall acknowledge receipt of the appeal and provide the appellant with progress reports and the outcome as outlined is section 5.6.

5.3 APPEALS COMMITTEE

Within ten (10) business days of notification, the AAB Chairperson shall have the responsibility to formally appoint an appeals committee and designate a chairperson to hear the appeal.

The committee shall consist of at least three (3) persons not involved in the accreditation decision. At least two (2) of these individuals must have experience in laboratory accreditation. A signed Conflict of Interest (COI)/Confidentiality form is required for all appeals committee members.

5.4 DETERMINATION OF VALIDITY

5.4.1 After the appeals committee has been selected, the committee shall meet, either in person or via conference call, to review the written notification of appeal and determine the validity of the appeal. If the appeal is determined to be invalid, AIHA LAP, LLC shall respond to the laboratory in writing (including email), to explain the basis of the decision. If the appeal is valid, then AIHA LAP, LLC shall contact the laboratory to schedule the appeals hearing.

If the appeal is determined to be valid by the committee and the laboratory is in conformance, the AAB may reconsider voting on the laboratory's status.

5.4.2 An appeal is valid if it is filed within the time allotted for appeal by Section 5.2 above, and the laboratory is able to provide conclusive evidence that they are in conformance with the policy cited for denial or suspension of accreditation.

5.4.3 If an appeal is determined to be invalid by the committee, the laboratory shall be granted
five (5) business days from receipt of the letter notifying them of the decision to modify the appeal to make it valid and resubmit the appeal. Only one opportunity for modification shall be granted.

5.5 APPEALS HEARING

5.5.1 Site of Hearing

The chairperson of the appeals committee shall designate a time and place for the hearing that does not represent an undue burden for the laboratory or required participants, including conference calls or virtual meetings. Attempts shall be made to reduce costs to all parties. The time shall be no later than thirty (30) business days after the formation of the appeals committee. The hearing shall commence at that time unless the chairperson grants a continuance for good cause shown by the party requesting the continuance. The AIHA LAP, LLC shall give at least twenty (20) business days written notice to the laboratory of the reasons for the denial, suspension or withdrawal action against it, the time and place of the hearing, the opportunity to examine evidence submitted against it, and present evidence on its behalf. In addition, notice shall be provided to the AAB Chairperson.

5.5.2 Representation by Counsel

Counsel at the hearing may represent each party, at its own cost.

5.5.3 Record

A record of the hearing shall be made.

5.5.4 Attendance at Hearing

In the event the laboratory fails to attend the hearing without good cause, the laboratory shall be deemed to have waived its rights to appeal and the appeals committee shall find that the adverse action be affirmed.

5.5.5 Parties

The parties of the hearing shall be the laboratory and the AAB. The AAB may be assisted in the presentation of its case by AIHA LAP, LLC staff members. Either party may choose to have witnesses; however, the chairperson may require the exclusion of witnesses during presentation of evidence.

5.5.6 Order of Proceedings

The appeals hearing shall proceed in the following order:

5.5.6.1 The hearing shall be opened by the chairperson of the appeals committee, who shall note the time, place and date, the presence and identity of the members of the appeals committee, the laboratory, AAB representative, and witnesses to the hearing.

5.5.6.2 At the commencement of the hearing, the chairperson shall offer each party an opportunity to make an opening statement to clarify the issues involved.

5.5.6.3 The appellant laboratory and the AAB Chairperson or representative shall each present its case. Any documentation or presentations by witnesses may be subject to review and questions by the other party to the appeal.

5.5.6.4 The chairperson shall have the discretion to vary this procedure but shall provide full and equal opportunity to each party for the presentation of all materials or relevant facts.

5.5.6.5 Information offered by any party may be received as evidence by the chairperson.

5.5.6.6 The names and addresses of all witnesses and the identification of each exhibit in the order received shall be made a part of the record, which shall be maintained by the chairperson.

5.5.6.7 On conclusion of the presentation of evidence, the chairperson shall permit each party an opportunity to make a brief closing statement.

5.5.7 Evidence

The parties to the hearing may offer any evidence that is material, relevant and bears on the issues before the appeals committee. The chairperson and the appeals committee will give weight to the evidence presented as they see appropriate. In addition to the evidence taken in the presence of the hearing tribunal, a party may, subject to the approval of the chairperson, submit evidence of witnesses by affidavit. The appeals committee shall give such weight to affidavits, as it deems appropriate, after considering any objections made to the admission of such affidavits. The proponent of an issue or proposition has the burden of proof on the matter.

5.5.8 Adjournment

The chairperson, for good cause, may adjourn the hearing upon request or upon his/her own initiative, subject to reconvening at a specific future date.

5.5.9 Closing the Appeals Hearing

The chairperson shall declare the hearing closed at the conclusion of closing statements or at a later date if he/she decides to permit the parties to file briefs or other documents subsequent to the hearing.

5.5.10 Reopening the Appeals Hearing

The chairperson may reopen the hearing, for good cause, upon application by any party thereto or upon his/her own initiative.

5.5.11 Report of the Appeals Committee

The appeals committee chairperson shall render a final written report, approved by a majority of the members of the appeals committee, no later than twenty (20) business days after the close of the hearing. The chairperson shall submit a copy of the report to the AAB Chairperson, the AIHA LAP, LLC management, and to all participants of the appeals hearing. The report shall include the appeals committee findings, conclusions and final decision concerning the action that had been the subject of the appeal. The appeals committee shall recommend that the adverse action be affirmed unless it determines such adverse action was arbitrary, capricious, an abuse of discretion, not in accordance with the required procedures, or

not based upon substantial evidence. If follow-up actions are recommended, a description of such actions shall be included in the report.

5.6 FINAL DECISION

The appeals committee shall possess exclusive authority to render a final decision in any matter appealed in accordance with this appeal procedure. Investigation and decision on appeals shall not result in any discriminatory actions. Within thirty (30) business days of issuance of the report of the appeals committee, the AIHA LAP, LLC (on behalf of the AAB) shall give written notice of its final accreditation decision to all parties to the appeal hearing.

5.6.1 If the appeals committee renders a decision to uphold the withdrawal, suspension or denial of accreditation, the AIHA LAP, LLC staff shall:

5.6.1.1 Inform the laboratory, in writing, of the decision and request the return of the accreditation certificate, as appropriate; and

5.6.1.2 Delete the laboratory name from all official AIHA LAP, LLC listings in accordance with the decision.

5.6.2 If the appeals committee renders a decision to grant or reinstate accreditation, the AIHA LAP, LLC staff shall:

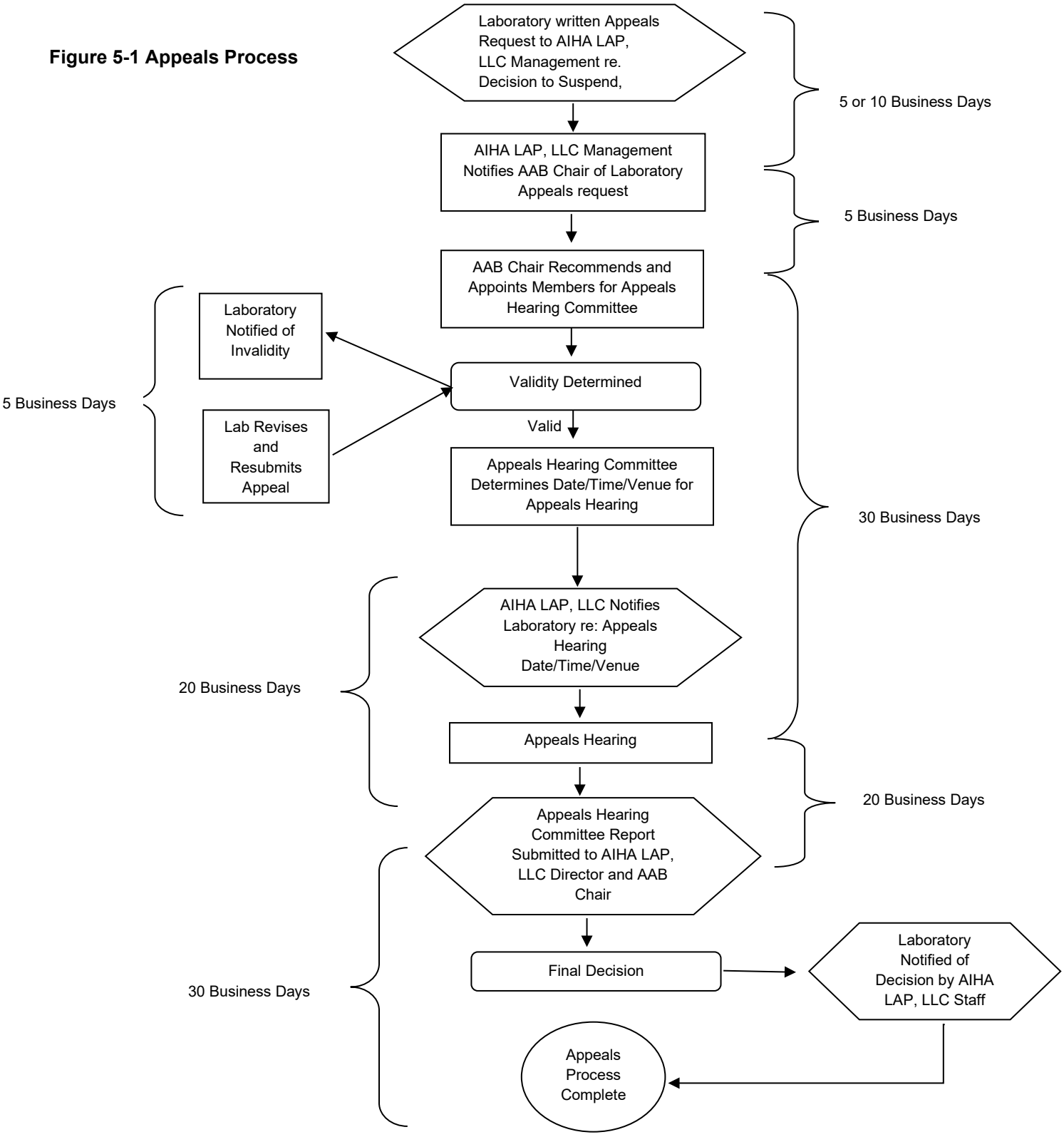
5.6.2.1 Inform the laboratory of the decision and issue the accreditation certificate, if applicable; and

5.6.2.2 Reinstate accreditation status or add the laboratory name to any of the lists of AIHA LAP, LLC accredited laboratories (including the National Lead Laboratory Accreditation Program [NLLAP]), in accordance with the decision.

5.7 APPEALS RECORDS

AIHA LAP, LLC shall keep all records of appeals, both valid and invalid, records of final decisions relating to those appeals and records of any follow-up actions.

Figure 5-1 Appeals Process



MODULE 6
PROFICIENCY TESTING (PT) AND ROUND ROBIN PROGRAMS

6.1 INTRODUCTION

For all Fields of Testing (FoT) in a laboratory's scope of accreditation, the laboratory shall demonstrate proficiency in one of the following categories, in priority order:

1. Category 1: External PT through an AIHA LAP, LLC approved external PT program as outlined in 6.2.

2. Category 2: Demonstration of Proficiency via Round Robin and/or Demonstration of Proficiency via an Internal Proficiency Testing Program as outlined in 6.3

3. Category 3: Demonstration of Proficiency via Internal Quality Control as outlined in 6.4.
   Note: This option will be allowed only in very rare cases and through the AIHA LAP, LLC approval process.

For a list of approved External PT providers and exceptions, refer to the Scope/PT Table on the AIHA LAP, LLC's website.

Samples from approved proficiency testing and round robin programs, shall be analyzed as specified by the program administrator, using the same preparation, analytical procedure and instrumentation combination used to test customer samples as far as practicable.

The results from all PT program**s** and Round Robins shall be shared with analysts.

6.2 CATEGORY 1 – EXTERNAL PROFICIENCY TESTING

6.2.1 The laboratory shall have participated and passed at least one (1) most recent reporting round of testing per FoT to be considered for initial accreditation.

6.2.2 When a single proficiency testing analyte category can be used to demonstrate proficiency for multiple FoTs, and the lab seeks accreditation for these FoTs, the laboratory may elect to use the analyte category for this scheme to demonstrate proficiency for only one FoT and elect to demonstrate proficiency for the other(s) by choosing an option from Section 6.3.

6.2.3 When a single proficiency testing scheme analyte category can be used to demonstrate proficiency for two FoTs/technologies/matrices, and the lab seeks

accreditation for these FoTs, the laboratory may elect to tie all methods in each FoT to the Proficiency Testing (e.g., Organics under AIHA IHPAT for GC and GC/MS). Under ELLAP, the laboratory may use a single set of ELPAT samples to demonstrate proficiency for multiple technologies within a FoT/matrix (e.g., Paint under ELPAT for FAA and ICP).

6.2.4 The laboratory may not elect to tie more than two (2) FoTs/technologies to any single proficiency testing analyte category. For example, although IHPAT Silica may be used to demonstrate competency for XRD, UV/VIS, and IR, no laboratory could choose to link all three FoTs to the IHPAT Silica proficiency testing category.

6.2.5 When two (2) FoTs are tied to a single proficiency testing analyte category, the laboratory must alternate analysis between the two technology types.

6.2.6 If an accredited laboratory fails to maintain proficiency in a given proficiency testing category to which they have elected to tie to two (2) FoTs/Technologies, the accreditation shall be suspended for both FoTs and/or technologies, regardless of which FoT or technology led to the non-proficiency status.

6.2.7 AIHA LAP, LLC APPROVED EXTERNAL PROFICIENCY TESTING PROGRAM

AIHA LAP, LLC reviews and formally approves proficiency testing programs for its accreditation programs and accepts data from these approved programs. Laboratories shall analyze all samples provided for a given scheme by the proficiency testing programs in which they are enrolled and participate.

6.2.7.1 Requirements for Approval of Proficiency Testing Programs

When approving proficiency testing programs, AIHA LAP, LLC will look for the following features:

a) Proficiency samples and background matrices shall resemble real-world samples to the degree possible.

b) Target concentrations of the proficiency testing samples shall be appropriate for the program in which they are being applied. For example, if the samples submitted to the laboratory are for occupational hygiene purposes, the target concentrations shall be relevant to evaluation of an occupational exposure guideline.

c) The units of results for reported data shall be appropriate for the type of testing performed. Reported results shall be in units appropriate to the end use of the

data, such as for comparison to target standards.

d) All proficiency testing programs shall conclude with a performance rating, preferably a proficient or non-proficient rating based on a common statistic or other procedure acceptable to the AIHA LAP, LLC.

e) Samples taken from reference atmospheres (laboratory or field) are preferable to samples spiked using solutions or slurries.

f) Samples shall be in or on collection media, similar to media used in the field, to the degree possible.

g) All proficiency testing programs shall have at least two (2) rounds per year or as specified by the appropriate accreditation module.

h) For those programs not meeting the 2-round annual minimum, the laboratory shall augment their participation with a Demonstration of Proficiency Testing program as specified in Section 6.3 below.

6.3 CATEGORY 2 – DEMONSTRATION OF PROFICIENCY – ROUND ROBIN AND INTERNAL PROFICIENCY TESTING

6.3.1 Round Robin

For FoTs where external PT is not available, the laboratory shall participate in a round robin program designed to allow for the accreditation of laboratories that share the same key analyte(s) of interest (e.g., formaldehyde and isocyanates) and meeting the requirements of Policies 6.3.1.1- 6.3.1.9. An independent vendor or one (1) of the participating laboratories shall generate and distribute the round robin samples to other participating laboratories. A laboratory with multiple facilities may participate as individual entities with the stipulation that samples are analyzed and reported by each facility as a separate entity. Acceptable criteria shall be determined.

Actions to be taken in the event of an unacceptable result shall be described in the laboratory's management system documentation, per Policy Module 2A.

The following are requirements for round-robin programs:

6.3.1.1 Round robin samples shall consist of or resemble real-world samples to the degree possible.

6.3.1.2 Round robins shall include participation of at least three (3) laboratories.

6.3.1.3 All round robin programs shall have at least two (2) rounds per year, with each round completed within a six-month time frame.

6.3.1.4 Each round shall include a minimum of four samples at varying concentrations. Target concentrations of the round robin samples shall be appropriate for the program in which they are being applied.

6.3.1.5 When analysis includes subjective analyst evaluation (e.g., microscopic identification and/or quantitation) each laboratory shall have all analysts assess each round robin sample independently and shall report all individual analyst's results separately.

6.3.1.6 The units of results for reported data shall be appropriate for the type of testing performed. Reported results shall be in units appropriate to the end use of the data, such as for comparison to target standards.

6.3.1.7 A designated laboratory shall be responsible for data collection and distribution.

6.3.1.8 Resulting data shall be evaluated using appropriate statistical methods.

6.3.1.9 The laboratories shall attempt to resolve any significant differences in results among laboratories.

6.3.2 Internal Proficiency Testing

For FoTs where external PT is not available, and where a round robin is prohibited, proprietary, or impractical, the laboratory shall implement a comprehensive internal PT program for at least one method in the FoT.

6.3.2.1 A minimum of twenty (20) QC data points shall be obtained initially to determine upper and lower control limits at three (3) standard deviations.

6.3.2.2 The laboratory shall have at least two rounds per year, each round separated by approximately six months. For initial accreditation or addition of a FoT, the time between rounds of internal PT can be performed at a minimum of 15 days apart.

6.3.2.3 Each round shall consist of a minimum of four independently prepared blind spikes at varying levels with the resulting data treated as it would be in a round robin program. The spiking procedures, to include frequency, responsibility for implementation, statistical treatment of resultant data, acceptance criteria, and actions to be taken in the event of an unacceptable result, shall be fully described in the laboratory's management system documentation. The spiking must be performed on an appropriate matrix.

6.4 CATEGORY 3- DEMONSTRATION OF PROFICIENCY – INTERNAL QUALITY CONTROL

In very rare cases, the laboratory may be permitted to demonstrate proficiency for a minimum of one (1) method per FoT through the implementation of internal quality control (internal QC).

Internal QC is defined as routine activities and checks, such as periodic calibration, duplicate analyses and matrix spikes that are included in routine internal procedures to control the accuracy and precision of measurements.

6.5 GENERAL PROFICIENCY TESTING INFORMATION

6.5.1 Documentation of Program Participation

All documentation between the participating laboratory and the proficiency testing program or round robin administrator shall be retained by the laboratory for three (3) years (five (5) years for ELLAP) and shall be made available to AIHA LAP, LLC or its agents (e.g., AAB, TAP, Site Assessors) upon request.

6.5.2 Reporting of Proficiency Testing Results and PT Data Reports

6.5.2.1 The laboratory shall provide a scored report of proficiency sample results in accordance with the AIHA LAP, LLC accreditation requirements through the Data Management System (DMS_WI_Proficiency_Testing is available in the LAP Document Library). The proficiency testing report provided shall contain adequate information to make a determination on FoT proficiency in accordance with stated criteria.

6.5.3 Proficiency Status

AIHA LAP, LLC considers laboratories to be proficient when the laboratory has a passing score for the applicable PT analyte class in two (2) of the last three (3) consecutive PT

rounds.

6.5.3.1 Laboratories must be proficient in the selected proficiency testing program or round robin to obtain and maintain accreditation for the applicable FoT/Method(s). Accredited laboratories shall maintain proficiency for all applicable FoT/Method(s).

6.5.3.2 Laboratories that become non-proficient for any FoT/Method shall adhere to the procedures outlined in Module 3, Section 3.8.2. Laboratories shall evaluate their results and take appropriate actions. See Policies 2A.7.10, on nonconforming work and 2A.8.7 on corrective actions for proficiency testing failures, including outliers.

6.6 INDUSTRIAL HYGIENE ACCREDITED LABORATORIES

Laboratories in the IHLAP are required to analyze samples for those Fields of Testing (FoT)/Method(s) for which accreditation is sought, according to the approved IHLAP Scope/PT Table maintained on the AIHA LAP, LLC's website

6.6.1 Compressed/Breathing Air Analysis Accredited Laboratories: IH Laboratories seeking or maintaining accreditation for Compressed/Breathing Air analysis shall participate and maintain proficiency in the Compressed/Breathing Air Round Robin (CAPT) in accordance with the Protocol for Compressed Air Proficiency Testing (CAPT) Program.

6.6.2 Pharmaceutical Accredited Laboratories: IH Laboratories seeking or maintaining accreditation for Pharmaceutical Analyses shall participate and maintain proficiency in the Pharmaceutical Round Robin Program in accordance with the Protocol for Pharmaceutical Round Robin Proficiency Testing Program.

6.7 ENVIRONMENTAL LEAD ACCREDITED LABORATORIES

Participation in AIHA Proficiency Analytical Testing Programs (AIHA PAT Programs), LLC Environmental Lead Proficiency Analytical Testing (ELPAT) is a prerequisite to qualification under the AIHA LAP, LLC Environmental Lead Laboratory Accreditation Program (ELLAP). This program has adopted the National Institute for Occupational Safety and Health (NIOSH) Proficiency Analytical Testing Statistical Protocol as the ELLAP Standard. Laboratories in the ELLAP are required to analyze samples for those Fields of Testing (FoT)/Method(s) for which accreditation is sought, according to the approved ELLAP Scope/PT Table maintained on the AIHA LAP, LLC's website.

Laboratories participating in an AIHA LAP approved proficiency testing program to seek

accreditation for the ELLAP shall conform to all proficiency testing requirements as outlined in this module.

6.7.1 NLLAP Recognition

Analyses conducted by a laboratory in a non-proficient FoT/Method are not recognized under the NLLAP until a proficient rating is achieved. Those laboratories that are NP following a main ELPAT round while waiting on the retest shall be removed from the AIHA LAP, LLC accredited ELLAP labs listing and the NLLAP until such time as a proficient rating is achieved. A laboratory shall not be recognized under the NLLAP for a FoT/Method for which accreditation has been suspended. When a laboratory is suspended or rated non-proficient in a FoT/Method, AIHA LAP, LLC shall notify the laboratory that analysis conducted by that laboratory for the non-proficient or suspended FoT/Method are not recognized by NLLAP.

6.8 ENVIRONMENTAL MICROBIOLOGY ACCREDITED LABORATORIES

Participation in proficiency testing program approved by AIHA LAP, LLC is a prerequisite to qualification under the AIHA LAP, LLC Environmental Microbiology Laboratory Accreditation Program (EMLAP). Laboratories in the EMLAP are required to analyze samples for those Fields of Testing (FoT)/Method(s) for which accreditation is sought, according to the approved EMLAP Scope/PT Table maintained on the AIHA LAP, LLC's website.

Laboratories participating in an AIHA LAP approved proficiency testing program to seek accreditation for the EMLAP shall conform to all proficiency testing requirements as outlined in this module.

6.9 FOOD ACCREDITED LABORATORIES

All laboratories pursuing/maintaining accreditation in the Food Laboratory Accreditation Program (FoodLAP) shall participate in an AIHA LAP, LLC approved proficiency testing program as maintained on the AIHA LAP, LLC web site. Laboratory accreditation for each Field of Testing (FoT) shall be defined by the extent of participation in an AIHA LAP, LLC approved proficiency testing program.

6.9.1 Prior to becoming accredited, a laboratory shall have successfully analyzed a set of proficiency testing samples for each matrix/test/method and/or techniques for which the laboratory seeks accreditation.

6.9.2 In order to maintain accreditation, the laboratory shall participate in an external, approved proficiency testing program at least one time per year, per matrix. At a minimum, the proficiency testing activities should cover one activity per method/test

type and/or technology per year. The laboratory's entire scope should be covered over a four-year period.

6.9.3 If no external proficiency testing program is available for a matrix, the laboratory will participate in a round robin, perform an inter laboratory comparison, or conduct internal proficiency testing specific to that matrix at least one time per year per matrix.

6.10 UNIQUE SCOPE ACCREDITED LABORATORIES

6.10.1 All laboratories pursuing/maintaining accreditation in the Unique Scope program are required to participate in proficiency testing programs approved by AIHA LAP, LLC as outlined in Section 6.1above. Approval is determined at time of application.

6.10.2 The AIHA LAP, LLC may seek input from the AAB and the TAP during this approval process and have further review during the on-site assessment prior to accreditation. The purpose of the proficiency testing requirements is to ensure that accredited laboratories, and those seeking accreditation, meet established performance criteria.

MODULE 7
REFERENCE TO ACCREDITATION AND ADVERTISING

7.1 INTRODUCTION

All AIHA Laboratory Accreditation Programs, LLC (AIHA LAP, LLC) Accredited laboratories are encouraged to advertise their accreditation by using prescribed language defined in this module and the approved AIHA LAP, LLC accreditation symbol. ISO/IEC Standard 17011 requires that accreditation bodies, such as the AIHA LAP, LLC, "have a policy governing the use of the accreditation symbol and claims of accreditation status" of reference to its accreditation and symbol. The following policies govern a lab's reference to its accreditation in all communication media, such as the Internet, documents, reports, business cards, brochures, or advertising. AIHA LAP, LLC routinely monitors accredited organizations for compliance regarding the use of the symbols, statements about and reference to accreditation.

Failure to conform to these policies or the advertising/symbol license agreement shall result in any or all of the following: request for corrective action, suspension or withdrawal of accreditation, publication of the transgression or possible initiation of legal actions.

Only accredited AIHA LAP, LLC laboratories may use the AIHA LAP, LLC accreditation symbol for purposes of advertising their laboratory accreditation. The laboratory shall contact the AIHA LAP, LLC office if they would like to reproduce the symbol in a size or color palette different from the original artwork provided.

7.2 DEFINITIONS

7.2.1 Symbol – AIHA LAP, LLC maintains and issues an accreditation symbol, shown below, for laboratories to advertise their accreditation.

7.2.2 Logo – AIHA LAP, LLC also maintains an accreditation logo, shown below, that is for use by the organization (AIHA LAP, LLC) only.

7.2.3 Mark – AIHA LAP, LLC also maintains a combined mark, shown below, in which its logo and the ILAC mark are used in combination. This mark is for use by the organization (AIHA LAP, LLC) only. For more information on how an AIHA LAP accredited laboratory can obtain use of the ILAC combined mark, see section 7.9

7.3 REFERENCE TO AIHA LAP, LLC ACCREDITED FIELDS OF TESTING (FoTs)

AIHA LAP, LLC accreditation may be advertised by:

a) use of a statement of AIHA LAP, LLC accreditation with Laboratory ID number, (see Section 7.5); or
b) AIHA LAP, LLC accreditation symbol with Laboratory ID number; or
c) Laboratory ID number (See Section 7.6).

Any of these references may not be used or implied for a FoT(s) for which the laboratory is not accredited by AIHA LAP, LLC.

A laboratory shall not advertise that it is accredited by AIHA LAP, LLC until the laboratory has received its accreditation certificate and scope of accreditation with laboratory ID number from AIHA LAP, LLC indicating that it has been accredited. Also, an AIHA LAP, LLC accredited laboratory that adds an additional laboratory accreditation program and/or FoT to its existing scope of accreditation (see Policy Module 3) shall not advertise that it is accredited for that scope of testing until it receives its accreditation certificate and/or updated scope of accreditation with Laboratory ID number from AIHA LAP, LLC.

7.4 REFERENCE TO AIHA LAP, LLC ACCREDITATION FOR SUSPENDED-STATUS FoTs

An accredited laboratory whose accreditation has been suspended or withdrawn shall not reference AIHA LAP, LLC accreditation for the FoT/Method(s) for which it is suspended or withdrawn for the duration of the suspension period. Upon suspension or withdrawal, the laboratory shall discontinue the use of all communication media that contains any reference to the suspended or withdrawn accreditation.

7.5 STATEMENT OF AIHA LAP, LLC ACCREDITATION

7.5.1 An AIHA LAP, LLC accredited laboratory may use the following statements, or equivalent, in communication media, subject to the limitations listed in 7.8, below.

"_____Laboratory (ID ____) is accredited by the AIHA Laboratory Accreditation Programs, LLC (AIHA LAP, LLC) in the _____accreditation program(s) for _____Fields of Testing as documented by the Scope of Accreditation Certificate and associated Scope"

(Blanks are to be filled with the applicable terms, as listed on the accreditation certificate.)

7.5.2 AIHA LAP, LLC accredited laboratories may also use the following statement in their communication media discussing the laboratory only, in conjunction with 7.5.1.

"AIHA LAP, LLC accreditation complies with the ISO/IEC Standard 17025:2017 requirements, but this does not imply ISO certification or registration."

7.5.3 Laboratories with multiple locations must clearly identify the location of the accredited laboratory(s) and their applicable accreditation programs in their communication media.

7.6 LABORATORY ID NUMBER

An AIHA LAP, LLC accredited laboratory may use its AIHA LAP, LLC assigned Laboratory ID Number in its media communications subject to the limitations listed in Section 7.8.

7.7 AIHA LAP, LLC ACCREDITATION SYMBOL

The AIHA LAP, LLC accreditation symbol may be used by accredited laboratories, subject to the limitations listed in Section 7.8.

An AIHA LAP, LLC accredited laboratory shall only use the AIHA LAP, LLC accreditation symbol after signing the appropriate licensing agreement, detailing the permissible usage. The AIHA LAP, LLC accreditation licensing agreement is provided by the AIHA LAP, LLC at the time the accreditation certificate is issued. The laboratory shall sign and return the licensing agreement to AIHA LAP, LLC before the AIHA LAP, LLC will release the copy ready artwork of the symbol to the laboratory.

All uses of the AIHA LAP, LLC accreditation symbol must be accompanied by the laboratory identification number, as shown above in section 7.2.1.

7.8 LIMITATIONS TO REFERENCING AIHA LAP, LLC ACCREDITATION

7.8.1 A statement of AIHA LAP, LLC accreditation or the AIHA LAP, LLC accreditation symbol shall only be displayed by laboratories that hold AIHA LAP, LLC accreditation, using the organization name as stated on the accreditation certificate.

7.8.2 A statement of AIHA LAP, LLC accreditation or the AIHA LAP, LLC accreditation symbol shall only be used by the laboratory on its Internet web site, letterhead documents, reports, business cards, brochures or advertising referring to the laboratory only ("communication media"). The laboratory shall not use a statement of AIHA LAP, LLC accreditation or AIHA LAP, LLC accreditation symbol on communication media when such testing is outside the scope of accreditation, unless the laboratory provides a clear disclaimer and/or identifies the testing that is outside the scope of AIHA LAP, LLC accreditation.

7.8.3 A statement of AIHA LAP, LLC accreditation and/or the AIHA LAP, LLC accreditation symbol signifies that a laboratory meets certain standards. The laboratory shall not display a statement of AIHA LAP, LLC accreditation or the AIHA LAP, LLC accreditation symbol on products, product catalogs, product packaging or inserts or otherwise on any item not specifically outlined as communication media, above; However, accredited laboratories may make statements in connection with certain products, if accurate, that those products will be analyzed by laboratories accredited by AIHA LAP, LLC in the appropriate field of testing. Any reference to accredited analysis must be on the packaging insert only and not displayed on the outside of the packaging. Furthermore, a statement of AIHA LAP, LLC accreditation or the AIHA LAP, LLC accreditation symbol may not be displayed on communication media or any other laboratory materials that are outside the scope of accreditation for which the laboratory is accredited by the AIHA LAP, LLC.

Laboratories accredited under NLLAP shall use proper statements 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 Testing Lab" or "EPA-Recognized NLLAP Lab" to denote its status to the public.

7.8.4 The laboratory shall only display a statement of AIHA LAP, LLC accreditation or the AIHA LAP, LLC accreditation symbol on the internet or on other segmented materials on

those web pages or those areas of materials that are relevant to the scope of accreditation for which the laboratory is accredited by AIHA LAP, LLC.

7.8.5 The laboratory shall not make any statement regarding its AIHA LAP, LLC accreditation which AIHA LAP, LLC may consider to be misleading or unauthorized.

7.8.6 The laboratory shall take care that no report or certificate nor any part thereof referencing AIHA LAP, LLC accreditation is used in a misleading manner.

7.8.7 Accreditation by AIHA LAP, LLC does not imply that a product, process, system, or person is approved by AIHA LAP, LLC. Accordingly, a statement of accreditation or an AIHA LAP, LLC symbol shall not be used in manner suggesting or implying that a product, process, system or person is approved or certified by AIHA LAP, LLC or that AIHA LAP, LLC is otherwise certifying something other than the laboratory itself.

7.8.8 The customers of an AIHA LAP accredited laboratory may need, in reports or certificates endorsed with the accreditation symbol or otherwise make reference to accreditation status, additional comments regarding the serviceability or suitability for specific purposes of the items, samples, batches or consignments, or an amplification or interpretation of the results obtained. The laboratory shall follow 7.8.7 of ISO/IEC 17025, that allows for the inclusion of expressions of opinions, interpretations or other statements on endorsed reports or certificates.

7.9 USE OF THE ILAC MARK

Accredited AIHA LAP, LLC laboratories interested in using the Laboratory Combined Mark that includes the ILAC mark and the AIHA LAP accredited laboratory symbol with the AIHA LAP laboratory ID number should contact the AIHA LAP, LLC Quality Systems Manager for additional information on the requirements.

MODULE 8
MISCELLANEOUS

8.1 INDEMNITY

AIHA Laboratory Accreditation Programs (AIHA LAP), LLC shall indemnify and hold harmless its directors, officers, employees, agents, volunteers (members of the Analytical Accreditation Board (AAB), Technical Advisory Panel (TAP)), and site assessors, their heirs and legal representatives from any and all claims of loss, liability or damage, including costs, fees and expenses that arise out of or in connection with acts of omissions of such person committed in the performance of the accreditation program activities provided that such person acted in good faith and in a manner he/she reasonably believed to be in or not opposed to the best interests of AIHA LAP, LLC.

8.2 CERTIFICATE AND SCOPE OF ACCREDITATION

The AIHA LAP, LLC shall issue a certificate of accreditation to each accredited laboratory. The certificate shall indicate the name, address and unique identification number for the accredited laboratory, the expiration date and authorized signatures.

AIHA LAP, LLC shall issue a scope of accreditation, which includes the Fields of Testing and Methods, the date of initial accreditation and the date issued. In the event of withdrawal from the designated program(s), the laboratory shall destroy the accreditation Certificate and Scope of Accreditation documents, which are the property of AIHA LAP, LLC.

8.3 DURATION OF ACCREDITATION

The duration of accreditation is two (2) years, provided the laboratory maintains all requirements for continued accreditation as defined in Policy Module 3.

8.4 LIST OF ACCREDITED LABORATORIES

AIHA LAP, LLC maintains a list of accredited laboratories by accreditation program with corresponding scope of accreditation on the AIHA LAP, LLC web site: www.aihaaccreditedlabs.org. If a laboratory is suspended for any Field of Testing, this status is noted on the web site. If a laboratory's accreditation is withdrawn, the laboratory name is immediately removed from the accredited laboratory directory and the laboratory's current status is reflected on the website.

8.5 CONFIDENTIALITY OF RECORDS

All files and records associated with the AIHA LAP, LLC shall be confidential, and their use restricted to personnel engaged in the administration of the programs.

8.6 CONFLICTS OF INTEREST

AIHA LAP, LLC requires that all members of the Analytical Accreditation Board (AAB), Technical Advisory Panel (TAP), site assessors, or other agents involved in AIHA LAP, LLC sign a Confidentiality/Conflict of Interest statement that prohibits these individuals from participating in any activities and/or proceedings to accredit, reaccredit, suspend, deny, or withdraw the accreditation of any laboratory where such person has a vested interest in the granting or denial of accreditation or reaccreditation.

8.7 FEES

The fees associated with the accreditation programs and the proficiency testing programs shall be determined by the AIHA LAP, LLC. The AIHA LAP, LLC Fee Schedule shall include all appropriate fees for the laboratory accreditation programs. The current AIHA LAP, LLC Fee Schedule may be requested by contacting a staff member noted on the AIHA LAP, LLC website.

8.8 FEEDBACK FROM PARTICIPATING LABORATORIES

Participating laboratories desiring changes in the AIHA LAP, LLC or its policies shall detail their suggestion(s) in writing to the AIHA LAP, LLC. AIHA LAP, LLC shall consider and respond to the laboratory suggestion(s), as appropriate.

8.9 COMPLAINTS

Laboratory users and others desiring to file a complaint against a laboratory as a result of performance or misrepresentation, or a complaint concerning other AIHA LAP, LLC issues, may do so in writing to the AIHA LAP, LLC. AIHA LAP, LLC management shall take actions, as appropriate, and respond to the complainant in a reasonable amount of time. AIHA LAP, LLC management may inform the AAB Chair and the AIHA LAP, LLC Board Liaison of the complaint, as necessary.

If requested, the laboratory shall assist AIHA LAP, LLC in the investigation and resolution of any accreditation related complaints regarding the laboratory.

MODULE 9
TERMS AND ACRONYMS

TERM AND/OR ACRONYM	DEFINITION
AAB	Analytical Accreditation Board
ACS	American Chemical Society
AHERA	Asbestos Hazard Emergency Response Act
AIHA	American Industrial Hygiene Association
AIHA LAP, LLC	AIHA Laboratory Accreditation Programs, LLC
AIHA PAT Program, LLC	AIHA Proficiency Analytical Testing Programs, LLC
APHA	American Public Health Association
APAC	Asia-Pacific Accreditation Cooperation
ASHRAE	American Society of Heating, Refrigerating, and Air- Conditioning Engineers
ASM	American Society for Microbiology
ASV	Anodic Stripping Voltammetry
AWWA	American Water Works Association
Acceptance Limits	Established mathematical data quality limits for analytical method performance.
Accreditation	A third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.
Accredited Laboratory	A testing laboratory that has been evaluated and granted accreditation covering a specified type of measurement or task, usually for a specific property or analyte, and for a specified period of time.
Accuracy	Closeness of agreement between a measured quantity value and a true quantity value of a measurand.
Aliquot	See "*Subsample*".
Analysis	The qualitative or quantitative determination of a property or analyte in a substance or material.
Analytical Run	For chemical analyses, an analytical run consists of all samples processed continuously using an item of instrumentation or equipment. Samples in one analytical run are analyzed using the same set of standard calibration data.
Analytical Sensitivity	Quotient of the change in an indication of a measuring system and the corresponding change in

TERM AND/OR ACRONYM	DEFINITION
	a value of a quantity being measured (e.g., for methods involving a count, the analytical sensitivity equals 1 raw count per amount or portion of sample analyzed, calculated, and expressed in the final reporting units).
Approved Signatory	Person who is recognized by a laboratory as competent and authorized by laboratory management to sign test reports.
Assessor	An individual assigned by an accreditation body to perform, alone or as part of an assessment team, an assessment of a CAB.
Bulk Asbestos Proficiency Analytical Testing (BAPAT)	AIHA PAT Program, LLC proficiency testing program for laboratories involved in bulk asbestos analysis.
Beryllium Proficiency Analytical Testing (BePAT)	AIHA PAT Program, LLC proficiency testing program for laboratories analyzing beryllium on filter media.
BSC	Biological Safety Cabinet
BSL	Biological Safety Level
Batch	A group of samples that are processed in one operation: considered to be a uniform, discrete unit.
Bias	An estimate of a systematic measurement error
Blind Sample	A sample submitted for analysis with a composition and identity known to the submitter, but unknown to the analyst, and used to evaluate proficiency in the execution of the measurement process.
CAB	Conformity Assessment Body; A body that performs conformity assessment services and that can be the object of accreditation. (i.e. a testing laboratory, calibration laboratory, inspection body)
CCB	Continuing Calibration Blank, see "Calibration Verification Blanks"
CCV	See "*Continuing Calibration Verification (CCV)*"
CDC	Centers for Disease Control
CFR	Code of Federal Regulations
CIPM	International Committee for Weights and Measures *(Comité International des Poids et Mesures)*
CMMEF	Compendium of Methods for the Microbiological Examination of Foods
CRC	Certified Reference Culture

TERM AND/OR ACRONYM	DEFINITION
Calibration	1) Process used to establish a relationship, with determined uncertainty, between analyte concentration and instrument response. 2) An operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication. (VIM 2.39 JCGM 200:2012).
Calibration Blank	A matrix matched material lacking analyte used in the construction of a calibration curve.
Calibration Curve	Expression of the relation between indication and corresponding measured quantity value. A calibration curve expresses a one-to-one relation that does not supply a measurement result as it bears no information about the measurement uncertainty.
Calibration Verification Blanks	Calibration Verification Blanks (ICB and CCB) demonstrate that the instrument is able to return to baseline after the analyte is detected. They also provide a means to monitor instrument baseline drift.
Calibration Standard	A matrix matched material prepared at a known amount of analyte from a reference material and used to construct a calibration curve.
Certification	Third-party attestation related to products, processes, systems or persons. Certification is applicable to all objects of conformity assessment except for conformity assessment bodies themselves, to which accreditation is applicable.
Certified Reference Material (CRM)	A reference material, accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities, using valid procedures (VIM 5.14 JCGM 200:2012)
Chain of Custody	Definitive evidence (a record) of the persons who had possession or custody of the sample(s) for all periods of time, as it moved from the point of

TERM AND/OR ACRONYM	DEFINITION
	collection to the final analytical result.
Check Sample	An uncontaminated sample matrix spiked with a known amount of analyte, usually from the same source as the calibration standard. It is generally used to establish the stability of the analytical system, but also may be used to assess the performance of all or a portion of the measurement system. See also "*Quality Control.*"
Communications	Transmission of information by any means including verbal, mail, and electronic.
Competent Reference Material Supplier	An NMI or an accredited reference material producer (RMP) that conforms to ISO Guide 34 in combination with ISO/IEC 17025.
Continuing Calibration Verification (CCV)	A standard solution (or set of solutions) analyzed periodically to verify freedom of excessive instrumental drift.
Control Chart or database	A graph or database showing measurement responses over time or sequence of sampling, together with acceptance and warning limit(s). Control Charts are used to monitor the validity of test results and trends of successive test results.
Corrective Action (CA)	All activities taken, whether successful or not, to eliminate the cause(s) of an existing nonconformity in order to prevent recurrence. See "*Nonconformity" and "Technical Systems Audit.*"
Customer	Any person or organization that engages the services of a laboratory.
Define	See: Document [verb].
Demonstration of Competency (DOC)	Documented proof that an analyst can perform a given method and, using it, obtain results having the accuracy and precision appropriate for that method. For AIHA LAP, LLC purposes, a DOC can consist of PT, round robin, internal proficiency testing, or internal quality control results.
Demonstration of Proficiency (DOP)	Documented proof that a laboratory can perform a given Field of Testing and, using it, obtain results having the accuracy and precision appropriate for that FOT. For AIHA LAP, LLC purposes, a DOP can take the form of a round robin, an internal or external proficiency testing program, or internal

TERM AND/OR ACRONYM	DEFINITION
	quality control, as described in AIHA LAP policies 6.1 through 6.4.
Denial	The decision not to grant a laboratory initial accreditation.
Deviation (Procedural)	A departure from written procedures, test methods, contracts or any other standard operating procedure that is part of the laboratory quality assurance system. May or may not be considered a nonconformity.
Document [verb]	Record, substantiate or annotate for retrieval later. Source (ISO 30300:2011(en) Information and documentation — Management systems for records — Fundamentals and vocabulary; 3.3.6)
Document	Information and its supporting medium. Source (ISO 14005:2010(en)Environmental management systems — Guidelines for the phased implementation of an environmental management system, including the use of environmental performance evaluation; 2.6)
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.
Dust Wipe	A sample collected by wiping a representative surface of known area with an acceptable wipe material.
EPA	Environmental Protection Agency
Environmental Lead Laboratory Accreditation Program (ELLAP)	The AIHA LAP, LLC accreditation program, complying with the requirements of the EPA National Lead Laboratory Accreditation Program (NLLAP) Laboratory Quality System Requirements (LQSR), AIHA LAP, LLC requirements and the ISO/IEC 17025

TERM AND/OR ACRONYM	DEFINITION
	Standard and ISO/IEC 17011 requirements.
Environmental Lead Proficiency Analytical Testing (ELPAT)	AIHA PAT Program, LLC proficiency testing program for environmental lead laboratories.
Environmental Microbiology	The area of microbiology that focuses on the biology, physiology, ecology and sampling and analysis of microorganisms inhabiting or affecting air, water, soil and other natural or man-made substances and/or systems in a variety of work environments, and that may contribute to adverse health effects.
Environmental Microbiology Laboratory Accreditation Program (EMLAP)	This AIHA LAP, LLC accreditation program intended for the accreditation of environmental microbiology laboratories. This program complies with AIHA LAP, LLC requirements and the ISO/IEC 17025 Standard and ISO/IEC 17011 requirements.
Environmental Microbiology Proficiency Analytical Testing (EMPAT)	AIHA PAT Program, LLC proficiency testing program for environmental microbiology laboratories.
Ensure	Guarantee a strong causal relationship between an action and its consequences. Source (ISO/IEC 15408-1:2009(en) Information technology — Security techniques — Evaluation criteria for IT security — Part 1: Introduction and general model; 3.1.25)
Equipment	All physical items (including software and instruments) in the facility used in the performance of analytical testing.
Equipment Log	A chronological record of preventive and emergency maintenance performed on any equipment. The logs include a record of calls, service technician summaries, records of calibration by the manufacturer, routine user maintenance, and other information as required by these policies.
FAAS	Flame Atomic Absorption Spectroscopy
FoT	Field of Testing
Facility	A fixed site, mobile or field operation established for the purpose of performing laboratory testing and/or sampling.
Field Blank	An analyte-free matrix carried to the sampling site, exposed to the sampling conditions (e.g., media unsealed and re-sealed), returned to the laboratory,

TERM AND/OR ACRONYM	DEFINITION
	treated as a sample, and carried through all steps of the analysis. For example, a clean culture media plate, sorbent tube, or a clean filter could be used as a field blank. The field blank, which should be treated just like the sample, evaluates possible effects attributable to shipping and field handling procedures.
Field Operations Laboratory	A field operations laboratory is one that uses portable testing technologies and performs analytical testing on-site, near the sampling location under evaluation.
Fixed Site Laboratory	A fixed site laboratory is one that performs analytical testing from a fixed site location associated with improved real estate.
Food Laboratory Accreditation Program (FoodLAP)	This AIHA LAP, LLC program is intended for the accreditation of food testing laboratories. This program complies with AIHA LAP, LLC requirements, the ISO/IEC 17025 Standard, AOAC requirements (when applicable) and ISO/IEC 17011 requirements.
GC	Gas Chromatography
GC/MS	Gas Chromatography/Mass Spectroscopy
GFAA	Graphite Furnace Atomic Absorption Spectroscopy
HPLC	High Performance Liquid Chromatography
HUD	Housing and Urban Development
IC	Ion Chromatography
ICB	Initial Calibration Blank
ICP-AES	Inductively Coupled Plasma – Atomic Emission Spectroscopy
ICP-MS	Inductively Coupled Plasma – Mass Spectroscopy
ICS	Interference Check Standard
ICV	See "*Initial Calibration Verification (ICV)*"
ILAC	International Laboratory Accreditation Cooperation
ILAC MRA	International Laboratory Accreditation Cooperation Mutual Recognition Arrangement
IR	Infra-Red Spectroscopy
ISE	Ion Selective Electrode
ISO/IEC	International Organization for Standardization/International Electrotechnical Commission – nonprofit organizations that develop

TERM AND/OR ACRONYM	DEFINITION
	and publish international standards.
Identify	To reference something without ambiguity. Source (ISO/IEC 9075-1:2016 Information technology — Database languages — SQL — Part 1: Framework (SQL/Framework); 3.1.1.9)
Independently Prepared Calibration Standard	A standard prepared from a reference material other than that used for calibration. When using neat materials this may be a standard prepared from the same starting material but using a different dilution technique.
Industrial Hygiene Laboratory Accreditation Program (IHLAP)	This AIHA LAP, LLC program is intended for accreditation of industrial hygiene laboratories. This program complies with AIHA LAP, LLC requirements and the ISO/IEC 17025 Standard and ISO/IEC 17011 requirements.
Industrial Hygiene Proficiency Analytical Testing (IHPAT)	AIHA PAT Program, LLC proficiency testing program for industrial hygiene laboratories.
Initial Calibration Verification (ICV)	A standard solution (or set of solutions) used to verify calibration standard levels. The ICV shall be prepared independently from the calibration standards (from a stock solution having a different manufacturer or different manufacturer's lot identification or as an independent preparation from a neat material).
Instrument	A device used for observation or measurement or chemical analysis that yields test results.
Instrumental Drift	The continuous or incremental change over time in indication, due to changes in metrological properties of a measuring instrument.
Internal Proficiency Testing Program	A program based on multiple analyses of SRMs, CRMs, or stand-ins for such when none are commercially available, in adherence to Module 6.
Internal Quality System Audit	An audit of the laboratory's Quality Management System, conducted by quality management personnel or persons contracted by the laboratory, to ensure compliance with external organization (AIHA LAP, LLC and ISO/IEC 17025) and internal quality requirements (See ISO/IEC 17025, Section 8.8).
Internal Quality Control	Routine activities and checks, such as periodic

TERM AND/OR ACRONYM	DEFINITION
	calibrations, duplicate analyses and matrix spikes that are included in routine internal procedures to control the accuracy and precision of measurements.
In-House Quality Control Samples	Laboratory prepared samples containing analyte and media which are taken through the analytical procedure
International Vocabulary of Metrology	Basic and general concepts and associated terms (VIM), JCGM 200:2012
LC	Liquid Chromatography
LIMS	Laboratory Information Management System
LQSR	Laboratory Quality System Requirements of US EPA for recognition by NLLAP
Laboratory	An entity that tests, either at a fixed site, mobile facility or field operations facility. Also referred to as a CAB.
Laboratory Blank	Same as Method Blank
Laboratory Control Sample (LCS)	A matrix-based reference material with an established concentration obtained from a source traceable to NIST or other similar reference materials. The LCS is carried through the entire procedure from sample preparation through analysis as if it were a field sample. The purpose of the LCS is to evaluate bias of the method.
Laboratory Control Sample Duplicate (LCSD)	A duplicate of the LCS.
Lot	A batch of chemicals or sampling media manufactured at the same time.
Management Review	A wholesale review of the laboratory's management system and testing activities to determine whether or not the laboratory's quality management system meets the organization's ongoing management goals and requirements. (see ISO/IEC 17025 Section 8.9).
Management System	The quality, administrative and technical systems that govern the operations of a laboratory.
Matrix	The component or substrate (e.g., soil, air or charcoal tube) that contains the analyte of interest.
Matrix Spike (MS)	An aliquot of sample, or sample media, spiked with a known concentration of target analyte(s). The spiking occurs prior to sample preparation and

TERM AND/OR ACRONYM	DEFINITION
	analysis.
Matrix Spike Duplicate (MSD)	A duplicate of the MS.
Method	An orderly arrangement of steps to describe a process for accomplishing something, whether sample analysis or an administrative operation.
Method Blank	An unexposed sampling media or reagent(s), not taken to the field or shipped, but carried through the complete sample preparation and analytical procedure. The blank is used to assess possible background contamination from the analytical process. This blank may also be referred to as a laboratory blank.
Method Detection Limit (MDL)	The minimum concentration of an analyte that, in a given matrix and with a specific method, has a 99 percent probability of being identified, qualitatively or quantitatively measured, and reported to be greater than zero.
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 and uncertainty of measurement. See "*Acceptance Limits*."
Mobile Laboratory	A mobile laboratory is a transportable, self-contained laboratory that can perform analytical testing under controlled environmental conditions at any location.
ND	Not Detected
NIH	National Institute for Health
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute of Standards and Technology
NLLAP	National Lead Laboratory Accreditation Program – program recognizing laboratories complying with the USEPA LQSR.
NMI	National Metrology Institute
NSF	National Sanitation Foundation
NVLAP	National Voluntary Laboratory Accreditation Program organization within NIST that provides laboratory accreditations complying with ISO/IEC 17025 requirements.

TERM AND/OR ACRONYM	DEFINITION
National Lead Laboratory Accreditation Program (NLLAP) Requirements	Requirements of the EPA National Lead Laboratory Accreditation Program for accreditation of lead analysis in paint, soil and dust matrices by an EPA-recognized laboratory accreditation organization.
Nonconformity	A failure to comply with a requirement of the AIHA LAP, LLC accreditation program(s) requirements, ISO/IEC 17025 or a laboratory's own stated management system requirements.
Non-Standard Method	Method not meeting the definition of "*Standard Method*" contained in this module.
Objective	Result to be achieved. Source (ISO 9000:2015(en) Quality management systems — Fundamentals and vocabulary; 3.7.1)
OSHA	Occupational Safety and Health Administration
PT	See "*Proficiency Testing*"
Policy	Intentions and direction of an organization as formally expressed by its top management. Source (ISO 9000:2015(en) Quality management systems — Fundamentals and vocabulary; 3.5.8)
Precision	Closeness of agreement between indications or measured quality values obtained by replicate measurement on the same or similar objects under specified conditions. Measurement precision is usually expressed numerically by measures of imprecision, such as standard deviation, variance or coefficient of variation under the specified condition of measurement.
Preventive Action	A proactive planned activity to identify, recognize and control potential sources of nonconformities and to introduce needed improvements.
Procedure	Specified way to carry out an activity or a process. Source (ISO 9000:2015(en) Quality management systems — Fundamentals and vocabulary; 3.4.5)
Process	Set of interrelated or interacting activities that use inputs to deliver an intended result. Source (result-ISO 9000:2015(en) Quality management systems — Fundamentals and vocabulary; 3.4.1)

TERM AND/OR ACRONYM	DEFINITION
Proficiency Testing (PT)	A program for determining the ongoing acceptable performance of a laboratory in performing specified tests or analyses. PT samples may be obtained from an approved PT Provider or prepared internally as described in AIHA LAP, LLC policies.
Program	A structured plan consisting of requirements and actions that may be taken to achieve a stated goal (e.g., accreditation).
QSP(s)	Quality System Procedure(s)
Qualified Individual (for data review)	A qualified individual shall be defined as an individual that, minimally, has the education, experience and technical understanding of the work being reviewed.
Quality	The suitability of a product or service for use, as perceived by the user.
Quality Assurance (QA)	An integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure a product or service meets defined standards of quality within a stated level of confidence.
Quality Assurance Program	See "*Quality Assurance*."
Quality Control (QC)	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 (QM)	An employee of an accredited laboratory, having quality assurance responsibilities.
Quality System Audit	An evaluation of the laboratory's Quality Management System from a quality perspective (See also Internal Quality System Audit).
Raw Count	Actual count without extrapolation or calculation.
Reference Culture (RC)	A microbial culture from a recognized source. Reference Cultures are used for training and quality control purposes.
Reference Material (RM)	A material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal

TERM AND/OR ACRONYM	DEFINITION
	properties. When possible, the material must be a SRM or a material obtained from an accredited Reference Material Producer (RMP) or other Competent Reference Material Supplier.
Reference Standard	1) An object that has a measured physical property or attribute related to a physical attribute (e.g., mass, length, temperature) determined to a stated uncertainty. Reference standards shall be NIST traceable or equivalent. 2) Measurement standard designated for the calibration of other measurement standards for quantities of a given kind in a given organization or at a given location. 3) supported by a certificate showing analysis in accordance with ISO/IEC 17025.
Relative Percent Difference (RPD)	A term defined as RPD = $((R_1 - R_2)/R) \times 100$ where $R_1 - R_2$ represents the absolute difference of two (2) values and R represents the average of the two (2) values.
Replicate	A sample analyzed multiple times in order to evaluate the precision of an instrument or procedure.
Reporting Limit	The lowest concentration of analyte in a sample that can be reported with a defined, reproducible level of certainty. This value is based on the low standard used for instrument calibration. For environmental lead analyses, the reporting limit must be at least twice the MDL.
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.
Requirement	An essential criterion necessary for accreditation.
Risk	Effect of uncertainty. Source (ISO 9000:2015(en) Quality management systems — Fundamentals and vocabulary; 3.7.9)

TERM AND/OR ACRONYM	DEFINITION
Run	A set of consecutive measurements performed on different samples (See also Analytical Run).
SA	Site Assessor
SI	International System of Units of Measurement (meter, kilogram, second, ampere, Kelvin, mole and candela)
Sample Tracking	A documentation system of following a sample from receipt at the laboratory, through sample processing and analysis, to final reporting. The system includes unique numbering, or bar-coding labels for samples.
Site Assessment	An evaluation of a laboratory for the purpose of conducting an on-site Technical Systems Audit. The audit assesses compliance with AIHA LAP, LLC accreditation requirements and technical competence to perform the testing for which the lab is seeking accreditation.
Specify	Stipulate in detail within an approved document. Source (ISO 11737-1:2018(en) Sterilization of health care products — Microbiological methods — Part 1: 3.20)
Standard	A substance or material with properties believed to be known with sufficient accuracy to permit its use to evaluate the same property of another substance or material. In chemical measurements, it often describes a solution or substance commonly prepared by the analyst to establish a calibration curve or the analytical response function of an instrument.
Standard Method	Procedures recommended by national or international agencies, such as the Environmental Protection Agency (EPA), the National Institute for Occupational Safety and Health (NIOSH), ASTM International, AOAC International, the American Public Health Association (APHA), or the Occupational Safety and Health Administration (OSHA).
Standard Operating Procedure (SOP)	A written document that details the procedures of an operation; an analysis or action whose techniques and procedures are thoroughly prescribed, and which are accepted as the procedure for performing certain routine or repetitive tasks.
Standard Reference Material®	A certified reference material produced by the U.S.

TERM AND/OR ACRONYM	DEFINITION
(SRM®)	National Institute of Standards and Technology (NIST), or other national metrology organization, and characterized for absolute content, independent of analytical method. It is accompanied by a certificate that reports the results of the characterization and the intended use of the material.
Standardization	The process of establishing the quantitative relationship between a known mass of target material and the measurement system (example, instrument response). See "*Calibration*" and "*Calibration Curve*." The term may also refer to activities that establish provisions for common and repeated use of accreditation policies to achieve an optimum level of conformity.
Stock Solution	A concentrated solution of analyte(s) or reagent(s) prepared and verified by prescribed procedure(s) and used for preparing calibration standards.
Subsample	A representative portion of a sample; in analytical chemistry, an "aliquot." Not the same as a *duplicate* sample.
Suggestion	Suggested activity, observation or advice for improving laboratory performance, often made during a site assessment. A suggestion is not a requirement.
Suspension	A temporary removal of the laboratory's accreditation status for any or all FoTs.
TAP	Technical Advisory Panel - panelists are appointed to provide technical expertise for each of AIHA Laboratory Accreditation Programs (IHLAP, ELLAP, EMLAP, FoodLAP, and Unique Scopes) as well as to provide expertise in related areas.
TSCA	Toxic Substances Control Act
Technical Manager	The individual designated as the primary technical management for AIHA LAP, LLC accreditation purposes.
Technical Systems Audit	A thorough, systematic, onsite, qualitative evaluation of facilities, equipment, personnel, training, procedures, record keeping, data validation, data management and reporting aspects of a management system (See also Site Assessment).

TERM AND/OR ACRONYM	DEFINITION
Test	A technical operation that consists of determining one or more properties or constituents in a sample according to a specified procedure.
Test Method	Specified technical procedure for performing a test. See "*Standard Operating Procedure".*
Traceability	The process of documenting the value of a reference material or standard as related to SI or NIST standards or equivalent through an unbroken chain of comparisons with stated uncertainties.
Unique Scopes Laboratory Accreditation Program	The AIHA LAP, LLC accreditation program for areas of testing not addressed under other AIHA LAP, LLC programs. This program complies with AIHA LAP, LLC requirements and the ISO/IEC 17025 Standard and ISO/IEC 17011 requirements.
USDA	United States Department of Agriculture
US EPA	United States Environmental Protection Agency
USP	United States Pharmacopeia
UV-VIS	Ultra Violet-Visible Spectroscopy
Uncertainty of Measurement	Result of the evaluation aimed at characterizing the range within which the true value of a test result is estimated to lie, generally within a given likelihood. Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.
Verification	Provision of objective evidence that a given item fulfils specified requirements. For example – Confirmation that a given reference material as claimed is homogeneous for the quantity value and measurement procedure concerned
VIM	Same as International vocabulary of metrology – Basic and general internationally-accepted concepts and associated terms
WASP	Workplace Analysis Scheme for Proficiency (Great Britain PT Provider)
WHO	World Health Organization
Withdrawal	The removal of a laboratory's existing accreditation.
WPCF	Water Pollution Control Federation
XRD	X-Ray Diffraction

TERM AND/OR ACRONYM	DEFINITION
XRF	X-Ray Fluorescence Spectroscopy

APPENDIX G
EVALUATION OF MEASUREMENT UNCERTAINTY

Table of Contents

1. SCOPE

This AIHA LAP, LLC Policy documents the requirements for accredited laboratories to maintain accreditation to ISO/IEC 17025:2017 regarding the evaluation of measurement uncertainty. This policy applies to all laboratories accredited by the AIHA LAP, LLC. AIHA LAP, LLC wishes to thank and acknowledge the Canadian Association for Laboratory Accreditation (CALA) for its permission to incorporate elements of CALA P19 – *CALA Policy on the Estimation of Uncertainty of Measurement in Environmental Testing* in preparing the initial version of this policy document.

2. REFERENCES

The following documents provide the basis and assist with application of the principles stated in this policy.

- **CALA P19** – *CALA Policy on the Estimation of Uncertainty of Measurement in Environmental Testing*, Canadian Association for Laboratory Accreditation
- **JCGM 100:2008 (GUM 1995 with minor corrections) Evaluation of measurement data — Guide to the expression of uncertainty in measurement,** https://www.bipm.org/en/publications/guides/gum.html
- **ILAC Guide 17:** Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025., https://ilac.org/publications-and-resources/ilac-guidance-series/
- ILAC P14:09/2020 ILAC Policy for Measurement Uncertainty in Calibration
- JCGM 200:2012, **International vocabulary of metrology — Basic and general concepts and associated terms (VIM)** published by (BIPM, IEC, IFCC, ILAC, ISO, IUPAC, IUPAP and OIML), https://www.bipm.org/en/publications/guides/
- **ISO/IEC 17025:2017** - General Requirements for the Competence of Testing and Calibration Laboratories
- **Quantifying Uncertainty in Analytical Measurement**, 3rd Edition, 2012, Eurachem/CITAC,

3. TERMS AND DEFINITIONS

Bias (measurement bias) (VIM 2.18 JCGM 200:2012): estimate of a **systematic measurement error**
NOTE: Bias is the total systematic error as contrasted to random error. There may be one or more systematic error components contributing to the bias. A larger systematic difference from the accepted reference value is reflected by a larger bias value.

Combined standard uncertainty (combined standard measurement uncertainty) (VIM

2.31 JCGM 200:2012): **standard measurement uncertainty** that is obtained using the individual **standard measurement uncertainties** associated with the **input quantities in a measurement model**

Coverage factor (VIM 2.38 JCGM 200:2012): number larger than one by which a **combined standard measurement uncertainty** is multiplied to obtain an **expanded measurement uncertainty**
NOTE: A coverage factor, *k*, is typically in the range of 2 to 3.

Coverage probability (VIM 2.37 JCGM 200:2012): probability that the set of **true quantity values** of a **measurand** is contained within a specified **coverage interval**
NOTE 1 This definition pertains to the Uncertainty Approach as presented in the GUM.
NOTE 2 The coverage probability is also termed "level of confidence" in the GUM.

Expanded uncertainty (expanded measurement uncertainty) (VIM 2.35 JCGM 200:2012): product of a **combined standard measurement uncertainty** and a factor larger than the number one
NOTE 1 The factor depends upon the type of probability distribution of the **output quantity in a measurement model** and on the selected **coverage probability.**
NOTE 2 The term "factor" in this definition refers to a **coverage factor.**
NOTE 3 Expanded measurement uncertainty is termed "overall uncertainty" in paragraph 5 of Recommendation INC-1 (1980) (see the GUM) and simply "uncertainty" in IEC documents.

Level of confidence GUM term used for **Coverage Probability**
NOTE The value is often expressed as a percentage.

Measurand (VIM 2.3 JCGM 200:2012): **quantity** intended to be measured
NOTE 1 The specification of a measurand requires knowledge of the **kind of quantity,** description of the state of the phenomenon, body, or substance carrying the quantity, including any relevant component, and the chemical entities involved.
NOTE 4 In chemistry, "analyte", or the name of a substance or compound, are terms sometimes used for 'measurand'. This usage is erroneous because these terms do not refer to quantities.

Measurement (VIM 2.1 JCGM 200:2012): process of experimentally obtaining one or more quantity **values** that can reasonably be attributed to a **quantity**
NOTE 1 Measurement does not apply to **nominal properties.**
NOTE 2 Measurement implies comparison of quantities or counting of entities.
NOTE 3 Measurement presupposes a description of the quantity commensurate with the intended use of a **measurement result,** a **measurement procedure,** and a calibrated **measuring system** operating according to the specified measurement procedure, including the conditions **standard uncertainty** (VIM 2.30 JCGM 200:2012) **measurement uncertainty**

as a standard deviation.

Type A evaluation of measurement uncertainty (VIM 2.28 JCGM 200:2012): evaluation of a component of **measurement uncertainty** by a statistical analysis of **measured quantity values** obtained under defined measurement conditions.
NOTE For various types of measurement conditions, see **repeatability condition of measurement, intermediate precision condition of measurement,** and **reproducibility condition of measurement.**

Type B evaluation of measurement uncertainty (VIM 2.29 JCGM 200:2012): evaluation of a component of **measurement uncertainty** determined by means other than a **Type A evaluation of measurement uncertainty**

EXAMPLES Evaluation based on information
— associated with authoritative published **quantity values,**
— associated with the quantity value of a **certified reference material,**
— obtained from a **calibration** certificate,
— about drift,
— obtained from the **accuracy class** of a verified **measuring instrument,**
— obtained from a limits deduced through personal experience.

Uncertainty of measurement (measurement uncertainty) (VIM 2.26 JCGM 200:2012): non-negative parameter characterizing the dispersion of the **quantity values** being attributed to a **measurand,** based on the information used.
NOTE 1 Measurement uncertainty includes components arising from systematic effects, such as components associated with **corrections** and the assigned quantity values of **measurement standards,** as well as the **definitional uncertainty.** Sometimes estimated systematic effects are not corrected for but, instead, associated measurement uncertainty components are incorporated.
NOTE 2 The parameter may be, for example, a standard deviation called **standard measurement uncertainty** (or a specified multiple of it), or the half-width of an interval having a stated **coverage probability.**
NOTE 3 Measurement uncertainty comprises, in general, many components. Some of these may be evaluated by **Type A evaluation of measurement uncertainty** from the statistical distribution of the quantity values from series of **measurements** and can be characterized by standard deviations. The other components, which may be evaluated by **Type B evaluation of measurement uncertainty,** can also be characterized by standard deviations, evaluated from probability density functions based on experience or other information.
NOTE 4 In general, for a given set of information, it is understood that the measurement uncertainty is associated with a stated quantity value attributed to the measurand. A modification of this value results in a modification of the associated uncertainty.

4. BACKGROUND

Knowledge of the measurement uncertainty of test results is important for laboratories, their customers and regulators. Laboratories must understand the performance of their test methods and the uncertainty associated with test results to ensure their test results meet their customers' needs. Therefore, the measurement uncertainty process must be incorporated into method validation or verification exercises. Customers use test results to make rational, cost effective decisions and need to understand the reliability of the test results especially as they approach regulatory limits. Regulatory agencies need to understand the impact and risk of the test results reported to them.

The degree of rigor needed in an evaluation of measurement uncertainty will depend on such factors as the requirements of the test method, the requirements of the customer and the existence of narrow limits on which decisions on conformance to a specification are based. It is recognized that customers and regulatory agencies are not consistent in their knowledge or use of measurement uncertainty evaluations, however this is expected to change over time.

This AIHA LAP, LLC policy complies with the requirements of ISO/IEC 17025:2017 and the policies and guidance provided by APLAC and ILAC. The AIHA LAP, LLC provides examples for common approaches used in different disciplines in a separate guidance document. However, the examples are not exhaustive, nor can they include every valid or reasonable approach. Several organizations and groups have published guidance and worked examples on the evaluation of measurement uncertainty. Laboratories are encouraged to review many sources for examples of other statistically valid approaches that pertain to their activities. Refer to the AIHA LAP, LLC Guidance on the Evaluation of Measurement Uncertainty document for a list of sources.

5. EVALUATION OF MEASUREMENT UNCERTAINTY POLICY

The requirements which underlies this policy is given in ISO/IEC 17025:2017, Clauses 7.6 and 7.8.3.1 c).

Laboratories accredited under the AIHA LAP, LLC Accreditation Program shall fulfil the following requirements with respect to the evaluation of measurement uncertainty for tests associated with their scope of accreditation:

5.1 Laboratories shall be able to demonstrate their ability to evaluate measurement uncertainty for all accredited quantitative test methods. In those cases where a rigorous evaluation is not possible, the laboratory must make a reasonable attempt to estimate the uncertainty of test results. All approaches that provide a reasonable and valid evaluation of uncertainty are equally acceptable.

5.2 Laboratories shall make independent evaluations of uncertainty for tests performed on samples with significantly different matrices. For example, evaluations made for filter samples cannot be applied to bulk samples.

5.3 Evaluations of measurement uncertainty are not needed where the reported test results are qualitative. Laboratories are, however, expected to have an understanding of the contributors to variability of test results. Examples of such tests are those that report only organism identifications or presence/absence.

5.4 Laboratories shall have a written procedure describing the process used to evaluate measurement uncertainty, including at a minimum:

5.4.1 Definition of the measurand.
5.4.2 Identification of the contributors to uncertainly of measurement.
5.4.3 Details of the approaches used for evaluating measurement uncertainty, such as Type A and/or Type B.

When using the Type A approach, laboratories shall utilize one or more of the following options. These options are generally considered from 1) most suitable, to 4) least suitable:

1) Uncertainty specified within a standard method. In those cases where a well-recognized test method (such as a peer-reviewed AOAC, NIOSH, OSHA, ASTM, etc. method), specifies limits to the values of the major sources of measurement uncertainty and specifies the form of presentation of calculated results, laboratories need not do
anything more than follow the reporting instructions as long as they can demonstrate they follow the reference method without modification and can meet the specified reliability.

2) Laboratory Control Samples (LCS) and Matrix Spikes. In cases where matrix specific LCS (CRM or media spikes) and/or matrix spike data are available, include uncertainty evaluated from the standard deviation of long term data collected from routine sample runs for existing test methods or from the standard deviation of the LCS or matrix spike data for method validation/verification studies for new test methods.

3) Duplicate Data. In cases where sub-sampling occurs and there are data over the reporting limit, include uncertainty evaluated from long term duplicate data collected from routine sample runs for existing test methods or method validation/verification studies for new test methods.

4) Proficiency Testing (PT) Sample Data. In cases where the previous options are not available and where PT samples are analyzed with sufficient data above the reporting limit, pooled PT sample data can be used to evaluate uncertainty.

5.4.4 Identification of the contributors of variability for qualitative test methods.

5.4.5 All calculations used to evaluate measurement uncertainty and bias.

5.4.6 The reporting procedure.

5.5 Laboratories are required to re-evaluate measurement uncertainty when changes to their operations are made that may affect sources of uncertainty.

5.6 Laboratories shall report the expanded measurement uncertainty, along with the reported analyte concentration, in the same units as analyte concentration, when:

- it is relevant to the validity or application of the test results, or
- a customer's instructions so requires, or
- the uncertainty affects compliance to a specification limit.

5.7 When reporting measurement uncertainty, the test report shall include the coverage factor and confidence level used in the evaluations (typically k = approximately 2 at the 95% confidence level).

5.8 When the test method has a known and uncorrected systematic bias, it shall be reported separately from the test result and measurement uncertainty, as a probable bias value.

6. ASSESSMENT FOR ACCREDITATION

During assessment and surveillance of a laboratory, the assessor will evaluate the capability of the laboratory to evaluate the measurement uncertainty for test methods included in the laboratory's scope of accreditation. The assessor will verify that the methods of evaluation applied are valid, all significant contributors to uncertainty have been considered, and all the criteria of the AIHA LAP, LLC policy are met.

7. GUIDANCE AND EXAMPLES

Refer to the AIHA LAP, LLC Guidance on the Evaluation of Measurement Uncertainty document for suggestions and examples for implementing the policies listed in this document and a list of helpful references.

APPENDIX H
METROLOGICAL TRACEABILITY OF MEASUREMENT RESULTS

Table of Contents

1. SCOPE

This AIHA LAP, LLC Policy documents the requirements for laboratories to maintain accreditation to ISO/IEC 17025:2017 regarding metrological traceability of measurement results. This policy applies to all laboratories accredited under the AIHA LAP, LLC Laboratory Accreditation Program. AIHA LAP, LLC wishes to thank and acknowledge the Canadian Association for Laboratory Accreditation (CALA) for its permission to incorporate elements of CALA A61 – *CALA Traceability Policy* in preparing the initial version of this policy document.

2. REFERENCES

The following documents provide the basis and assist with application of the principles stated in this policy.

- **AIHA LAP, LLC Policy Appendix G on the Evaluation of Measurement Uncertainty**
- **CALA A61 - *CALA Traceability Policy*,** Canadian Association for Laboratory Accreditation
- ISO/IEC 17025:2017, **General requirements for the competence of testing and calibration laboratories,**
- ILAC P10:07/2020, **ILAC Policy on Metrological Traceability of Measurement Results,** https://ilac.org/publications-and-resources/ilac-policy-series/
- VIM JCGM 200:2012, **International vocabulary of metrology — Basic and general concepts and associated terms (VIM)** published by (BIPM, IEC, IFCC, ILAC, ISO, IUPAC, IUPAP and OIML**) https://www.bipm.org/en/publications/guides/**
- **Metrological Traceability Of Measurement Results In Chemistry: Concepts And Implementation (IUPAC Recommendations 2009),** International Union of Pure and Applied Chemistry (IUPAC), Paul De Bièvre1, René Dybkaer, Aleš Fajgelj And D. Brynn Hibbert,
- *EURACHEM/CITAC Guide: Traceability in Chemical Measurement – A guide to achieving comparable results in chemical measurement* (2003)
- Meeting the traceability requirements of ISO 17025: An Analyst's Guide, 3rd edition
- ISO 17034:2016, **General requirements for the competence of reference material producers**

3. TERMS AND DEFINITIONS

BIPM
Bureau International des Poids et Mesures

BIPM is the intergovernmental organization through which Member States act together on matters related to measurement science and measurement standards. (ILAC P10:07/2020)

Calibration: operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, use this information to establish a relation for obtaining a measurement result from an indication. (VIM 2.39 JCGM 200:2012)

Certified Reference Material (CRM): reference material, accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities, using valid procedures. (VIM 5.14 JCGM 200:2012)

Certified Reference Material (CRM): Reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a reference material certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability. (ISO 17034:2016)

CIPM MRA

International Committee for Weight and Measures Mutual Recognition Arrangement
The CIPM MRA – is an arrangement between National Metrology Institutes which provides the technical framework to assure the mutual recognition of national measurement standards and for recognition of the validity of calibration and measurement certificates issued by National Metrology Institutes. (ILAC P10:07/2020)

Critical equipment: "Critical" equipment used by testing and calibration laboratories is considered by ILAC to be those items of equipment necessary to perform a test or calibration from the scope of accreditation and which have a significant effect on the uncertainty of measurement of test or calibration results. For the purposes of this policy, AIHA LAP LLC considers any contribution that is ≥ 1/3 of the largest measurement uncertainty contributor for a test method to be a significant contributor to measurement uncertainty.

JCTLM

Joint Committee for Traceability in Laboratory Medicine
JCTLM formed by the BIPM, the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and ILAC, provides a worldwide platform to promote and give guidance on internationally recognized and accepted equivalence of measurements in Laboratory Medicine and traceability to appropriate measurement standards. (ILAC P10:07/2020)

KCDB
Key Comparison Database
The KCDB is a publicly available, free web resource related to the CIPM MRA. It contains information on participants of the CIPM MRA, results of key and supplementary comparisons and peer reviewed Calibration and Measurement Capabilities (CMCs) (https://www.bipm.org/kcdb). (ILAC P10:07/2020)

Measurement Result: (result of measurement): set of quantity values being attributed to a measurand together with any other available relevant information. (VIM 2.9 JCGM 200:2012)

Measurement Standard: realization of the definition of a given quantity, with stated quantity value and associated measurement uncertainty, used as a reference (VIM 5.1JCGM 200:2012). All laboratories are encouraged to review the VIM in its entirety; however, the following are examples and notes presented in the VIM (as numbered) that may be relevant to the measurements performed by AIHA LAP, LLC laboratories:

> EXAMPLE 1: 1 kg mass measurement standard with an associated standard measurement uncertainty of 3 µg.
>
> EXAMPLE 4: Standard buffer solution with a pH of 7.072 with an associated standard measurement uncertainty of 0.006.
>
> EXAMPLE 6: Reference material providing quantity values with measurement uncertainties for the mass concentration of each of ten different proteins.
>
> NOTE 2 A measurement standard is frequently used as a reference in establishing measured quantity values and associated measurement uncertainties for other quantities of the same kind, thereby establishing metrological traceability through calibration of other measurement standards, measuring instruments, or measuring systems.
>
> NOTE 5 Quantity value and measurement uncertainty must be determined at the time when the measurement standard is used.

Measuring System: set of one or more measuring instruments and often other devices, including any reagent and supply, assembled, and adapted to give information used to generate measured quantity values within specified intervals for quantities of specified kinds. (VIM 3.2 JCGM 200:2012)

> NOTE: A measuring system may consist of only one measuring instrument.

Measurement Uncertainty (uncertainty of measurement) (uncertainty): non-negative

parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used (VIM 2.26 JCGM 200:2012)

NOTE 1 Measurement uncertainty includes components arising from systematic effects, such as components associated with corrections and the assigned quantity values of measurement standards, as well as the definitional uncertainty. Sometimes estimated systematic effects are not corrected for but, instead, associated measurement uncertainty components are incorporated.

NOTE 2 The parameter may be, for example, a standard deviation called standard measurement uncertainty (or a specified multiple of it), or the half-width of an interval, having a stated coverage probability.

NOTE 3 Measurement uncertainty comprises, in general, many components. Some of these may be evaluated by Type A evaluation of measurement uncertainty from the statistical distribution of the quality values from series of measurements and can be characterized by standard deviation, evaluated from probability density function based on experience or other information.

NOTE 4 In general, for a given set of information, it is understood that the measurement uncertainty is associated with a stated quantity value attributed to the measurand. A modification of this value results in a modification of the associated uncertainty.

Metrological Traceability (traceability): property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty. (VIM 2.41 JCGM 200:2012)

NOTE 1 For this definition, a 'reference' can be a definition of a **measurement unit** through its practical realization, or a **measurement procedure** including the measurement unit for a non-**ordinal quantity,** or a **measurement standard.**

NOTE 2 Metrological traceability requires an established **calibration hierarchy.**

NOTE 3 Specification of the reference must include the time at which this reference was used in establishing the calibration hierarchy, along with any other relevant metrological information about the reference, such as when the first calibration in the calibration hierarchy was performed.

NOTE 4 For **measurements** with more than one **input quantity in the measurement model,** each of the input **quantity values** should itself be metrologically traceable and the calibration hierarchy involved may form a branched structure or a network. The effort involved in establishing metrological traceability for each input quantity value should be

commensurate with its relative contribution to the measurement result.

NOTE 5 Metrological traceability of a measurement result does not ensure that the measurement uncertainty is adequate for a given purpose or that there is an absence of mistakes.

NOTE 6 A comparison between two measurement standards may be viewed as a calibration if the comparison is used to check and, if necessary, correct the quantity value and measurement uncertainty attributed to one of the measurement standards.

NOTE 7 The ILAC considers the elements for confirming metrological traceability to be an unbroken **metrological traceability chain** to an **international measurement standard** or a **national measurement standard,** a documented measurement uncertainty, a documented measurement procedure, accredited technical competence, metrological traceability to the **SI**, and calibration intervals. (see ILAC P10:2002)

NOTE 8 The abbreviated term "traceability" is sometimes used to mean 'metrological traceability' as well as other concepts, such as 'sample traceability' or 'document traceability' or 'instrument traceability' or 'material traceability', where the history ("trace") of an item is meant. Therefore, the full term of "metrological traceability" is preferred if there is any risk of confusion.

Metrological Traceability to a measurement unit: metrological traceability where the reference is the definition of a measurement unit through its practical realization. (VIM 2.43 JCGM 200:2012)

NOTE: The expression "traceability to the SI" means 'metrological traceability to a measurement unit of the International System of Units'.

National Metrology Institute
National Metrology Institute (NMI) and Designated Institutes (DI) maintain measurement standards in countries (or regions) all over the world. Throughout this document, the term "NMI" is used to cover both a National Metrology Institute as well as a Designated Institute. (ILAC-P10:07/2020)

Note that ILAC considers an "appropriate" national metrology institute to be one that participates regularly and successfully in relevant international interlaboratory comparisons performed by BIPM and/or by regional metrology bodies.

ILAC encourages BIPM and regional bodies to conduct and publish details of as broad a range of international comparisons as possible to provide transparency on the equivalence

and linkages of national measurement standards, which underpin accreditation activities. ILAC has taken note that the results of international comparisons carried out in the scope of the Metre Convention are published in Appendix B of the CIPM MRA (www.bipm.org).

NIST Standard Reference Material® (SRM): A CRM issued by NIST that also meets additional NIST-specific certification criteria and is issued with a certificate or certificate of analysis that reports the results of its characterizations and provides information regarding the appropriate use(s) of the material. (NIST SP 260-136).

NOTE An SRM is prepared and used for three main purposes: (1) to help develop accurate methods of analysis; (2) to calibrate measurement systems used to facilitate exchange of goods, institute quality control, determine performance characteristics, or measure a property at the state-of-the-art limit; and (3) to ensure the long-term adequacy and integrity of measurement quality assurance programs. The terms "Standard Reference Material" and the diamond-shaped logo which contains the term "SRM," are registered with the United States Patent and Trademark Office. (NIST Definitions)

Primary measurement standard (primary standard): measurement standard established using a primary reference measurement procedure, or created as an artifact, chosen by convention. (VIM 5.4 JCGM 200:2012)

EXAMPLE 1 Primary measurement standard of amount- of-substance concentration prepared by dissolving a known amount of substance of a chemical component to a known volume of solution.

EXAMPLE 3 Primary measurement standard for isotope amount-of-substance ratio measurements, prepared by mixing known amount-of-substances of specified isotopes.

EXAMPLE 4 Triple-point-of-water cell as a primary measurement standard of thermodynamic temperature.

EXAMPLE 5 The international prototype of the kilogram as an artifact, chosen by convention [for mass].

Reference Material (RM): material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties. (VIM 5.13 JCGM 200:2012)

Reference Material (RM): Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process. (ISO 17034:2016).

To provide clarity for testing laboratories, AIHA LAP, LLC uses the term reference material to be those related to chemical and microbiological references. Reference materials include neat materials, chemical solutions, and microbiologic cultures.

Reference Material Producer (RMP): Body (organization or company, public or private) that is fully responsible for project planning and management; assignment of, and decision on property values and relevant uncertainties; authorization of property values; and issuance of a reference material certificate or other statements for the reference materials it produces. (ISO 17034:2016).

Reference Measurement Standard (reference standard): measurement standard designated for the calibration of other measurement standards for quantities of a given kind in a given organization or at a given location. (VIM 5.6 JCGM 200:2012)

To provide clarity for testing laboratories, AIHA LAP, LLC uses the term reference standard to be those related to physical attributes such as mass, length, and temperature that are defined by convention as traceable to the SI through an NMI such as NIST.

Secondary Measurement Standard (secondary standard): measurement standard established through calibration with respect to a primary measurement standard for a quantity of the same kind. (VIM 5.5 JCGM 200:2012)

> NOTE 1 Calibration may be obtained directly between a primary measurement standard and a secondary measurement standard, or involve an intermediate measuring system calibrated by the primary measurement standard and assigning a measurement result to the secondary measurement standard.
>
> NOTE 2 A measurement standard having its quantity value assigned by a ratio primary reference measurement procedure is a secondary measurement standard.

SI (International System of Units): System of units. The name adopted by the 11th General Conference on Weights and Measures (1960) for the recommended practical system of units of measurement. The base units are a choice of seven well-defined units: the metre, the kilogram, the second, the ampere, the Kelvin, the mole, and the candela.

Verification: provision of objective evidence that a given item fulfils specified requirements. (VIM 2.44 JCGM 200:2012)

(CALA/AIHA LAP, LLC) A procedure normally associated with the acquisition of data regarding an instrument to provide some indication as to whether it is operating within expected tolerances. For example, weights may be placed on a balance and the reading can

provide some indication as to whether the balance is operating within expected tolerances. This operation should not be confused with **calibration**. Verification does not establish traceability. Verification seeks only to determine whether or not the instrument is operating within its expected tolerances. It is not a method of establishing the expanded uncertainty, which is the core issue in a *calibration*.
Note that manufacturer's tolerances, as provided in data sheets and instrument manuals, will use the same method of expression as an uncertainty, such as +/- 3% or +/- 4 grams. These are still only *tolerances* and should not be confused with the expanded *uncertainties* associated with the measurement result.

Working measurement standard (working standard): measurement standard that is used routinely to calibrate or verify measuring instruments or measuring systems. (VIM 5.7 JCGM 200:2012)

4. BACKGROUND

ISO/IEC 17025:2017, section 6.5 requires laboratories to demonstrate that the results produced by their measuring systems are traceable in accordance with the international definition of that term. See the definition for metrological traceability above and the ***International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*** (VIM JCGM 200:2012).

This allows

- Laboratories to support the validity of test results.
- Laboratories and users to make objective comparison of different test results.
- Laboratories and users to make sound interpretation of individual test results.

Traceability is characterized (in ILAC documents and the VIM) by:
(a) **an unbroken chain of comparisons** going back to stated references acceptable to the parties, usually a national or international standard;
(b) **uncertainty of measurement;** the uncertainty of measurement for each step in the traceability chain must be calculated or estimated according to agreed methods and must be stated so that an overall uncertainty for the whole chain may be calculated or estimated
(c) **documentation;** each step in the traceability chain must be performed according to documented and generally acknowledged procedures; the results must be recorded;
(d) **competence;** the laboratories or bodies performing one or more steps in the traceability chain must supply evidence for their technical competence (e.g. by demonstrating that they are accredited for that activity);
(e) **reference to SI units;** the chain of comparisons must, where possible, end at primary standards for the realization of the SI units;

(f) **calibration intervals;** calibrations must be repeated at appropriate intervals; the length of these intervals will depend on a number of variables (e.g. uncertainty required, frequency of use, way of use, stability of the equipment).

In the area of chemistry, traceability of all measurements is problematic due to recent changes in terminology, difficulties in melding of chemical concepts with metrological traceability as required by ISO/IEC 17025:2017, and lack of reference materials from metrological organizations. The IUPAC Committee has been working towards a recommendation document addressing traceability in chemical measurements since 2001. The 2009 version was reviewed to help establish the concepts presented in this document along with the other references (Section 2). The concepts used in chemistry may also be applied to microbiological measurements. As the international community in the fields of chemistry and biology continues to develop consensus statements, AIHA LAP, LLC will adopt those that are appropriate to its scope of accreditation activities.

AIHA LAP, LLC provides this policy and associated general guidance on acceptable and appropriate methods for accredited laboratories to:

- Ensure the continuing conformance to the requirements of the standard.
- Demonstrate metrological traceability of all accredited results.
- Include metrological traceability requirements in the performance of equipment calibration.
- Make sound decisions on the purchasing of services and supplies in support of accredited testing.

5. METROLOGICALTRACEABILITY OF MEASUREMENT RESULTS POLICY

The requirement which underlies this policy is given in ISO/IEC 17025:2017, Clause 6.5

5.1 Laboratories accredited by AIHA LAP, LLC shall demonstrate, when possible, that calibrations of critical equipment and hence the measurement results generated by that equipment, relevant to their scope of accreditation, are traceable to the SI through an unbroken chain of calibrations.

5.2 External calibration services shall, wherever possible, be obtained from an ISO/IEC 17025 accredited calibration laboratory whose service is suitable for the intended use (i.e., the scope of accreditation specifically covers the appropriate calibration) and the Accreditation Body is covered by the ILAC Arrangement or by Regional Arrangements recognised by ILAC, a National Metrology Institute (NMI) whose service is suitable for the intended use and is covered by the International Committee for Weight and Measures Mutual Recognition Arrangement (CIPM MRA), or a State Weights and Measures Facility that is part of the NIST Laboratory

Metrology Program. Calibration certificates shall be endorsed by a recognized accreditation body symbol or otherwise make reference to accredited status by a specific, recognized accreditation body, or contain endorsement by the NMI. Certificates shall indicate metrological traceability to the SI or reference standard and include the measurement result with the associated uncertainty of measurement.

5.3 Where traceability to the SI is not technically possible or reasonable, the laboratory shall use certified reference materials provided by a competent supplier or use specified methods and/or consensus standards that are clearly described and agreed to by all parties concerned. Certified values assigned to CRMs are considered to have established valid metrological traceability when:

1) CRMs are produced by NMIs using a service that is included in the BIPM KCDB, or
2) CRMs are produced by an ISO 17034 accredited RMP under its scope of accreditation and the Accreditation Body is covered by the ILAC Arrangement or by Regional Arrangements recognised by ILAC, or
3) The certified values assigned to CRMs are covered by entries in the Joint Committee for Traceability in Laboratory Medicine (JCTLM) database.

NOTE There are many gaps in the measurement traceability of the calibration infrastructure in the world and there are a relatively small, but increasing, number of accredited reference material producers. In recognition of this situation, AIHA LAP, LLC requires the use of accredited reference material producers for newly purchased reference materials with known accredited RMPs (e.g., many metals, inorganic anions, some organic mixtures, some microbial organisms). Existing reference materials may be used until expired or exhausted. This requirement is not enforced for reference materials not readily available from an accredited RMP.

5.4 Reference materials shall have a certificate of analysis that documents metrological traceability to a primary standard or certified reference material and associated uncertainty, when possible. When applicable, the certificate must document the specific NIST SRM® or NMI certified reference material used for traceability.

5.5 Calibrations performed in-house shall be documented in a manner that demonstrates metrological traceability via an unbroken chain of calibrations regarding the reference standard/material used, allowing for an overall uncertainty to be evaluated for the in-house calibration.

5.6 Calibrations shall be repeated at appropriate intervals, the length of which can be dependent on the uncertainty required, the frequency of use and verification, the manner of use, stability of the equipment, and risk of failure considerations. Table 5-1 includes a list of reference standards and support equipment, commonly

found in AIHA LAP, LLC accredited laboratories that require calibration and/or verification.

5.7 Periodic verifications shall be performed to demonstrate the continued validity of the calibration at specified intervals between calibrations. The frequency of verifications can be dependent on the uncertainty required, the frequency of use, the manner of use, stability of the equipment, and risk of failure considerations.

5.8 The laboratory shall have procedures describing their external and internal calibration and verification activities and frequencies, and the actions to follow if the equipment is found to be out of acceptable specification. Although the frequency of recalibration can be extended, it cannot be eliminated. The procedures shall describe the action(s) that will be taken when recalibrations or verifications fail to meet the established criteria, including the use of the nonconformance and corrective action system to identify the root cause, prevent recurrence, and evaluate the impact to data reported since the last passing calibration or verification, including data recall where appropriate.

5.9 Laboratory staff performing in-house calibrations and verifications shall have received documented training.

Table 5-1
Common Reference Standards and Support Equipment Requiring Calibration and/or Verification

Reference Standard / Equipment	Calibration Frequency	Verification Frequency
Reference Thermometer	Initial and as determined by the laboratory	Not applicable
Working Thermometer	Not Applicable	As defined by the laboratory
Reference Masses	Initial and as determined by the laboratory	Not applicable
Working Masses	Not Applicable	As defined by the laboratory
Stage Micrometer	Initial and as determined by the laboratory	As defined by the laboratory

Balance	Initial and as determined by the laboratory	As defined by the laboratory
Mechanical Pipettes	Initial and as determined by the laboratory	As defined by the laboratory
Volumetric Containers for critical functions	Initial and as determined by the laboratory	As defined by the laboratory

NOTE 1: For some laboratories, this list may not be complete. It is the responsibility of each laboratory to identify all reference standards and support equipment whose calibration has a significant impact on analytical uncertainty.

NOTE 2: It is the laboratory's responsibility to establish a calibration and verification schedule suitable to the use of equipment. (See Section 5.6 and 5.7 above)

NOTE 3: Laboratories should be mindful of ISO/IEC 17025, clause 6.4.7 when developing the schedule, "The laboratory shall establish a calibration programme, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration."

NOTE 4: Laboratories should be prepared to show supporting data and rationale for the schedule chosen.

6. AOAC ADDITIONAL FOOD LABORATORY REQUIREMENTS

Laboratories that are seeking compliance to the AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analysis of Food and Pharmaceuticals are expected to meet the criteria defined in Appendix A of the aforementioned document.

The criteria outlined in the AOAC International document supersede the requirements noted in Table 5-1 above for equipment used under this scope of accreditation, only.

7. GUIDANCE ON IMPLEMENTING THIS POLICY

Refer to the AIHA LAP, LLC Guidance on the Metrological Traceability of Measurement Results document for additional background information and guidance regarding reference standard and equipment calibrations and locating accredited calibration laboratories and reference material producers.