MODULE 1
ACCREDITATION OVERVIEW

1.1 PURPOSE

The primary purpose of the AIHA Laboratory Accreditation Programs, LLC (AIHA LAP)~~, LLC~~ is to establish and maintain the highest possible standards of performance for laboratories analyzing samples to support the evaluation of quality data for their clients and the communities we all serve ~~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-2G~~F~~, 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 and Confidentiality 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~~six (6~~5~~) laboratory accreditation programs: Industrial Hygiene, Environmental Lead, Environmental Microbiology, Food, ~~and~~ Unique Scopes, and Be Field/Mobile. 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 2G	Beryllium Field/Mobile Accreditation Program (Be Field/Mobile) 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 Laboratory Accreditation Programs, LLC (AIHA LAP)~~AIHA LAP, LLC~~ specific requirements, as detailed in this module and in the program-specific Modules 2B-2G~~F~~, 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/Mobile Analytical Facility~~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 Metrological Traceability of Measurement Results~~Traceability of Measurement~~, Policy Appendix H. Refer to the AIHA LAP~~, LLC~~ guidance document, Guidance on Metrological Traceability of Measurement Results ~~*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-2~~F~~G. 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~~ Final calculated target analyte concentrations below the method reporting limit shall be reported as "<" (less than), ~~or~~ not detected (ND), or equivalent 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 2D
ENVIRONMENTAL MICROBIOLOGICAL LABORATORY ACCREDITATION PROGRAM (EMLAP) ADDITIONAL REQUIREMENTS

2D.1 SCOPE

The AIHA Laboratory Accreditation Programs, LLC's (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 appropriate Proficiency Testing as defined in Module 6. Available Fields of Testing (FoTs) and corresponding PT requirements for EMLAP are detailed in the Scope/PT Table maintained on the AIHA LAP website, www.aihaaccreditedlabs.org.~~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 If potential for sample contamination during processing and analyses of samples exists then the work shall be done in a Class II biological safety cabinet (BSC)~~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. Samples for which the media is not exposed to the ambient air do not need to meet this requirement.

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,~~ consisting of a minimum of 5 ~~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 by each analyst ~~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. See 2D.5.1.6. ~~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 2F
FOOD LABORATORY ACCREDITATION PROGRAM (FOODLAP)
ADDITIONAL REQUIREMENTS

2F.1 SCOPE

The AIHA Laboratory Accreditation Programs, LLC's (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. 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 appropriate Proficiency Testing as defined in Module 6. ~~(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.

2F.7 FDA LABORATORY ACCREDITATION FOR ANALYSES OF FOODS (LAAF) ADDITIONAL REQUIREMENTS

AIHA LAP is a FDA recognized accreditation body with the ability to accredit laboratories to the standards established in the final rule, Subpart R. LAAF-accredited laboratories are authorized to conduct certain food testing as described in this rule. A LAAF-accredited laboratory will be listed on a publicly available registry on the FDA website, §1.1109. A LAAF-accredited laboratory will have requirements for submitting information to FDA, §1.1110.

To obtain LAAF-accreditation, the laboratory shall comply with the requirements defined in ISO/IEC 17025:2017, relevant AIHA LAP Policy Modules as noted in Section 2F.1, and FDA's LAAF-accreditation requirements. Laboratories seeking accreditation in this area shall maintain a copy of the Final Rule – Subpart R.

General Requirements from Subpart R - Title 21, Chapter I, Subchapter A, Part 1, Subpart R

§1.1107 When must food testing be conducted under this subpart?

(a) Food testing must be conducted under this subpart whenever such testing is conducted by or on behalf of an owner or consignee:

(1) In response to explicit testing requirements that address an identified or suspected food safety problem, which are contained in the following provisions:
(i) *Sprouts.* Section 112.146(a), (c), and (d) of this chapter;
(ii) *Shell eggs.* Sections 118.4(a)(2)(iii), 118.5(a)(2)(ii) and (b)(2)(ii), and 118.6(a)(2) and (e) of this chapter; and
(iii) *Bottled drinking water.* Section 129.35(a)(3)(i) of this chapter (for the requirement to test five samples from the same sampling site that originally tested positive for *Escherichia coli);*
(2) As required by FDA in a directed food laboratory order issued under §1.1108;
(3) To address an identified or suspected food safety problem and presented to FDA as part of evidence for a hearing under section 423(c) of the Federal Food, Drug, and Cosmetic Act prior to the issuance of a mandatory food recall order, as part of a corrective action plan under section 415(b)(3)(A) of the Federal Food, Drug, and Cosmetic Act submitted after an order suspending the registration of a food facility, or as part of evidence submitted for an appeal of an administrative detention order under section 304(h)(4)(A) of the Federal Food, Drug, and Cosmetic Act.
(4) In support of admission of an article of food under section 801(a) of the Federal Food, Drug, and Cosmetic Act; and
(5) To support removal from an import alert through successful consecutive testing.

MODULE 2G
BERYLLIUM FIELD/MOBILE ACCREDITATION PROGRAM (Be FIELD/MOBILE) ADDITIONAL REQUIREMENTS

2G.1 SCOPE

The AIHA Laboratory Accreditation Programs, LLC's (AIHA LAP), ~~LLC's~~ Beryllium Field/Mobile Accreditation Program (Be Field/Mobile) is intended for accreditation of field/mobile analytical facilities. 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 appropriate Proficiency Testing as defined in Module 6.~~a proficiency testing program approved by AIHA LAP, LLC, as defined in Module 6.~~

2G.2 DATA INTEGRITY REQUIREMENTS

2G.2.1 Procedures shall be in place to maintain the integrity of the data. At a minimum these procedures shall include:

a. signed record for each employee that demonstrates that they understand their responsibilities for the integrity of the data they generate.
b. data integrity training for all employees with annual refresher training.
c. all data integrity measures must have prior approval from senior laboratory management.
d. annual auditing of data integrity.

2G.3 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 field/mobile testing of Be.

2G.3.1 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.

2G.3.2 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.

2G.3.3 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.

2G.3.4 For field/mobile testing of Be, 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.

2G.3.5 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.

2G.3.6 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.

2G.3.7 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.

2G.3.8. The Be field/mobile analytical facility shall have documented procedures that address calibration or standardization measures when field/mobile equipment is left unattended. The procedures shall state the amount of time the equipment can be left unattended without identifying and characterizing drift from the last standardization performed.

2G.3.9 Drift from the instrument standardization shall not be used to adjust data.

2G.3.10 The location of the Be field/mobile analytical facility at the time of the analysis shall be documented.

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. AIHA LAP ensures the site assessor selected has sufficient understanding and appropriate knowledge of the specific scope to make a reliable assessment of the competency of the laboratory to operate.

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. Available FoT(s) and corresponding PT requirements are detailed on the Scope/PT Table maintained on the AIHA LAP website, www.aihaaccreditedlabs.org. 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 tentative 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 twelve (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, withdrawal, or denial.

The policies defined in AIHA LAP~~LP, 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~~charged 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 (6) to nine (9) 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~~Review. All initial accreditation and surveillance laboratories are subject to a TAP review. Any reaccreditation may be selected for TAP review. The laboratory shall be notified in advance of the tentative TAP reviewer's identity. If a laboratory believes that a particular TAP member may represent a conflict of interest, the laboratory is allowed one rejection of a TAP reviewer with a reason provided.

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. The laboratory shall be notified in advance of the AAB members' identities. If a laboratory believes that a particular AAB member may represent a conflict of interest, the laboratory is allowed to reject the AAB member with a reason provided.

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 accreditation with suspension vote. When the laboratory attains a proficient status in an FoT suspended through accreditation 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 field/mobile analytical facilities~~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. Laboratories that are merging can be considered for a facility change.

3.8.2 Maintenance of Proficiency

Accredited laboratories shall maintain proficiency for all applicable FoTs as defined in Policy Module 6 and as detailed on the Scope/PT Table maintained on the AIHA LAP website. 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). A laboratory's ownership and/or corporation will be held accountable for any outstanding payments and reinstatement fees.

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 accreditation 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~~ Field of ~~testing~~ 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 a FoT or~~n~~ 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; and,

~~e)~~f) Review from the TAP and gain approval from the AAB.

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.

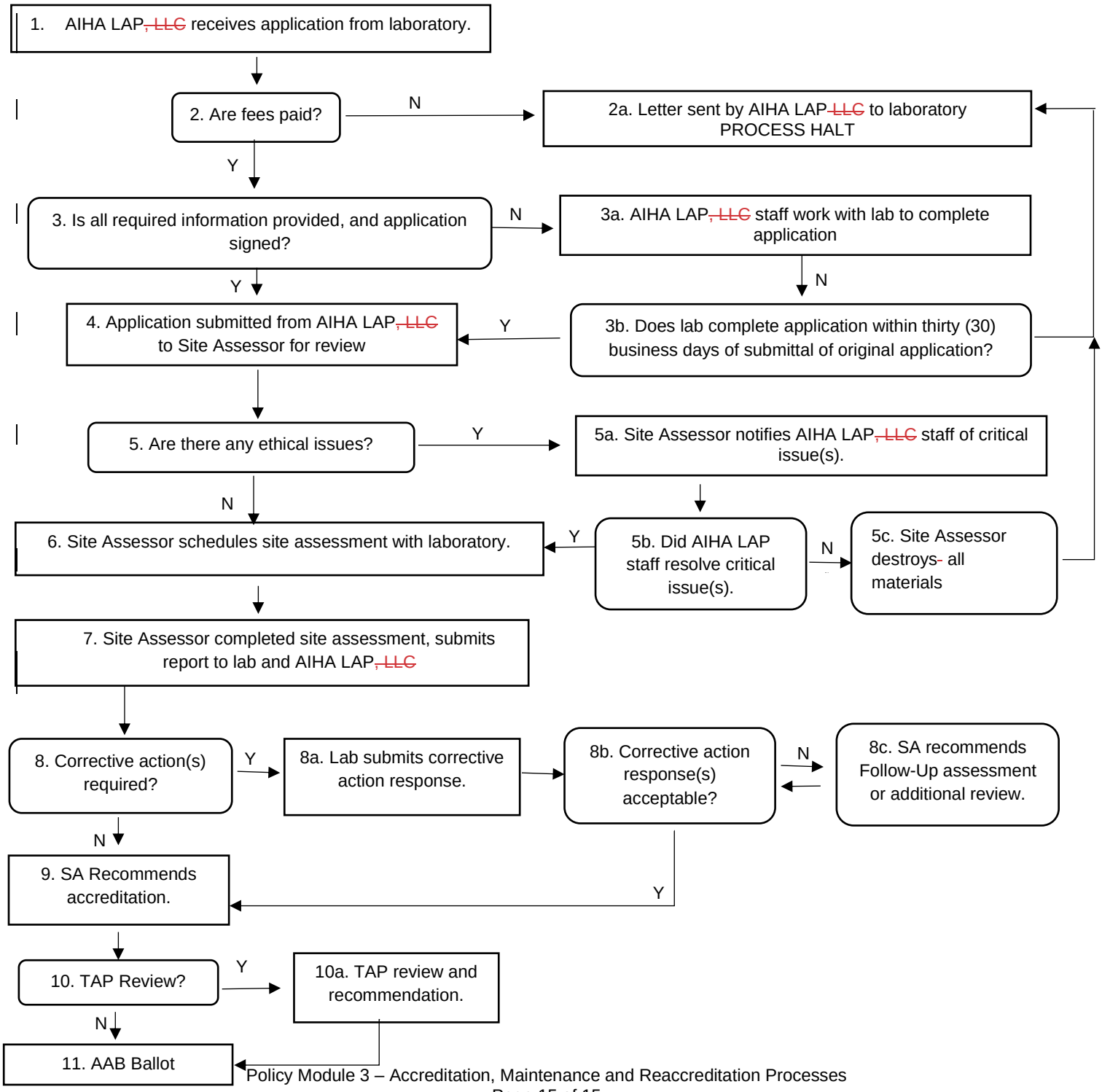
NOTE: The AIHA LAP site assessment checklist, based on the ISO/IEC 17025 standard and AIHA LAP policy requirements, is available upon request. Utilizing the site assessment checklist may help avoid the need for a pre-assessment.

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 Laboratory Accreditation Programs, LLC (AIHA LAP)~~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 and Scope of ~~Accreditation~~Accreditation 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~~ shall 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:

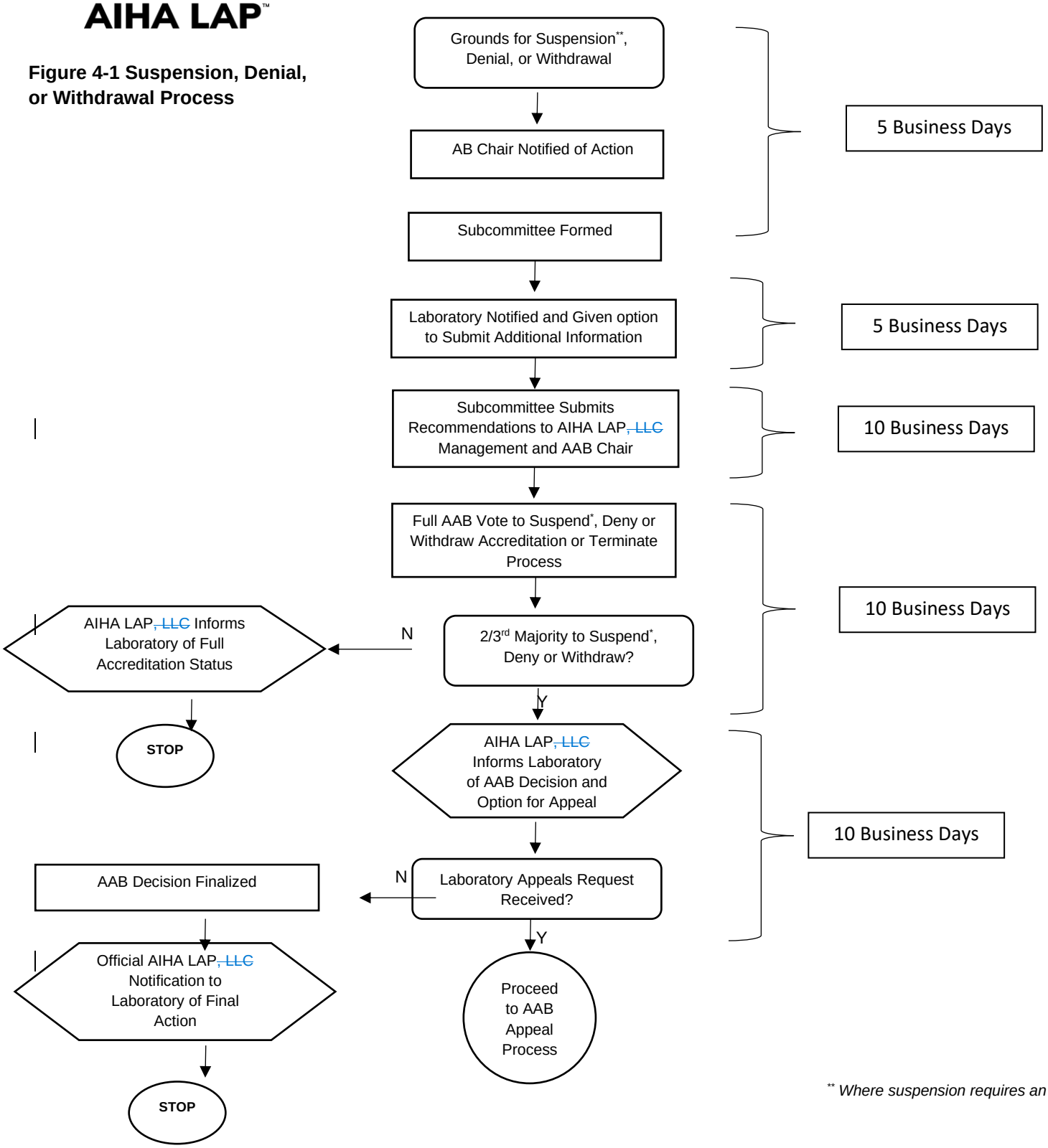
4.5.7.1 Continue or grant accreditation; or

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 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~~ based on the Scope/PT Table maintained on the AIHA Laboratory Accreditation Programs, LLC (AIHA LAP) website, www.aihaaccreditedlabs.org.
~~I,~~ in priority order:

1. Category 1: External PT through an AIHA LAP~~, LLC~~ approved external PT program as outlined in 6.2. A list of approved PT programs for each FoT and exceptions (e.g., Diffusive Sampler see 6.6.2) can be found on the AIHA LAP website.

2. Category 2: Demonstration of Proficiency – Round Robin and Internal Proficiency Testing as outlined in 6.3~~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 – Internal Quality Control ~~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~~PT programs 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

To find which PT program a laboratory should use based on FoT, review the Scope/PT Table on the AIHA LAP website. The PT plan shall be declared in the Accreditation Application for each FoT.

Formatted: Indent: Left: 0.13", Hanging: 1.06"
Formatted: Indent: Left: 0.13", Hanging: 1.06"
Formatted: Indent: Left: 1.19"
Formatted: Indent: Left: 0"
Formatted: Indent: Left: 0.13"
Formatted: Indent: Hanging: 0.68"
Formatted: Font: Bold
Formatted: Font: Bold
Formatted: Font: Bold

Review the following sections in this policy for additional requirements based on program:

- 6.6 INDUSTRIAL HYGIENE ACCREDITED LABORATORIES
- 6.7 ENVIRONMENTAL LEAD ACCREDITED LABORATORIES
- 6.8 ENVIRONMENTAL MICROBIOLOGY ACCREDITED LABORATORIES
- 6.9 FOOD ACCREDITED LABORATORIES
- 6.10 UNIQUE SCOPE ACCREDITED LABORATORIES
- 6.11 BERYLLIUM FIELD/MOBILE ACCREDITED LABORATORIES

6.2.1 For initial accreditation or initial FoT addition, ~~T~~the laboratory shall have participated in and passed the~~at least one (1)~~ most recent reporting round from the PT provider for accreditation application consideration.~~ of testing per FoT to be considered for initial accreditation.~~

~~6.2.2 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).~~ ~~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~~6.2.2 AIHA LAP, ~~LLC~~ APPROVED EXTERNAL PROFICIENCY TESTING PROGRAM

Formatted: Font: Not Bold
Formatted: Font: Not Bold
Formatted: Font: Not Bold
Formatted: Font color: Auto
Formatted: Tab stops: 1.38", Left + Not at 1.31"
Formatted: Font: (Default) Muli
Formatted: List Paragraph, Bulleted + Level: 1 + Aligned at: 0.75" + Indent at: 1", Tab stops: 1.31", Left + 1.38",
Formatted: Strikethrough
Formatted: Indent: Left: -0.44"
Formatted: Strikethrough
Formatted: Normal
Formatted: No bullets or numbering
Formatted: Indent: Left: 0"
Formatted: No bullets or numbering
Formatted: Font: (Default) Muli, Strikethrough
Formatted: Indent: Left: -0.44"
Formatted: Strikethrough
Formatted: Normal
Formatted: No bullets or numbering
Formatted: Normal, Right: 0.04", No widow/orphan control, Don't adjust space between Latin and Asian text, Don't adjust space between Asian text and numbers, Tab stops: 0.81", Left

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.

6.2.2~~7~~.1 Requirements for Approval of Proficiency Testing Programs

When approving proficiency testing programs, AIHA LAP~~, LLC~~ will request and review~~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 an appropriate~~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.

Formatted: Indent: Left: 0.88", Hanging: 0.25"

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.

Formatted: Right: 0.43"

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 (2) 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 (4) 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 LAAF) 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). (W~~(~~ork instruction, DMS_WI_Proficiency_Testing, is~~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.

~~6.5.2.1~~6.5.2.2 A laboratory shall submit all scored reports of proficiency tests and comparison program results, including excused rounds, approximately 45 business days after results are received regardless of the outcome. LAAF-accredited labs, see 6.9.5.

Formatted: Indent: Left: 1.25", No bullets or numbering

Formatted: No underline, Font color: Auto

Formatted: No underline, Font color: Auto

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. An excused round will not be counted in the three (3) consecutive PT rounds, but the proficiency testing report showing an excused round shall be turned into the DMS portal.

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~~he~~ 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 ~~the~~ AIHA LAP~~, LLC's~~ website.

When two (2) FoTs are tied to a single proficiency testing analyte category, the laboratory must alternate analysis between the two (2) FoTs. The laboratory may elect to tie all methods in each FoT to the proficiency testing analyte category (e.g., silica under IHPAT for IR and XRD)~~. two technology types~~

6.6.1

6.6.1.1 If an accredited laboratory fails to maintain proficiency in a given PT program to which they have elected to tie to two (2) FoTs, the accreditation shall be suspended for both FoTs, regardless of which FoT led to the non-proficiency status.

6.6.1.2 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.

6.6.1.3 The laboratory may not elect to tie more than two (2) FoTs to any single proficiency testing analyte category.

6.6.2 Diffusive Sampler Analysis Accredited Laboratories: IH Laboratories seeking or maintaining accreditation for Diffusive Sampler analysis shall participate and maintain proficiency in the AIHA PAT, LLC IHPAT – Diffusive Sampler Proficiency Testing.

~~6.6.1~~6.6.3 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.

6.6.4 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.

Formatted: Highlight

Formatted: Not Expanded by / Condensed by
Formatted: No bullets or numbering
Formatted: Highlight
Formatted: English (United States), Highlight
Formatted: Highlight
Formatted: Not Expanded by / Condensed by , Highlight
Formatted: Not Expanded by / Condensed by
Formatted: Indent: Left: 0.81", No bullets or numbering

~~6.6.2~~

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 accreditation 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 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). The laboratory must alternate analysis between the technologies.

~~**6.7.1**~~ NLLAP Recognition

6.7.2

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 pursuing/maintaining accreditation 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

Formatted: Indent: Left: -0.44"

Formatted: Indent: Left: 0.81", No bullets or numbering

Formatted: Indent: Left: 0.38", Hanging: 0.44", Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.83" + Indent at:

Formatted: Indent: Left: 0.81"

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

6.9 FOOD ACCREDITED LABORATORIES

~~All l~~Laboratories pursuing/maintaining accreditation in the Food Laboratory Accreditation Program (FoodLAP) shall participate in an AIHA LAP~~, LLC~~ approved proficiency testing program as listed on the Scope/PT Table 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.

6.9.4 For LAAF-accredited labs and AOAC accredited labs, they shall demonstrate successful proficiency testing for every applicable test on their scope in a 12-month period.

~~6.9.3~~6.9.5 For LAAF-accredited labs, a laboratory must submit all proficiency testing results approximately 30 calendar days after results are received regardless of the outcome.

6.10 UNIQUE SCOPES ACCREDITED LABORATORIES

~~All l~~Laboratories pursuing/maintaining accreditation in the Unique Scopes program shall participate in an ~~are required to participate in proficiency testing programs approved by~~ AIHA LAP~~, LLC~~ approved proficiency testing program as ~~outlined~~listed on the Scope/PT Table maintained on the AIHA LAP website. Laboratory accreditation for each Field of Testing (FoT) shall be defined by the extent of participation in an AIHA LAP approved proficiency testing program.~~in Section 6.1above~~. ~~Approval is determined at time of application.~~

Formatted: List Paragraph, Right: 0", No bullets or numbering, Widow/Orphan control, Adjust space between Latin and Asian text, Adjust space between Asian text and numbers

Formatted: List Paragraph, Right: 0", No bullets or numbering, Widow/Orphan control, Adjust space between Latin and Asian text, Adjust space between Asian text and numbers

Formatted: Indent: Left: 0.06", No bullets or numbering

~~6.10.1~~ AIHA LAP 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.

6.10.1

~~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.~~

6.11 BERYLLIUM FIELD/MOBILE ACCREDITED LABORATORIES

Laboratories pursuing/maintaining accreditation in Be Field/Mobile are required to analyze samples for those FoT for which accreditation is sought, according to the approved Be Field/Mobile Scope/PT Table on the AIHA LAP website.

Formatted: Indent: Left: 0.94", No bullets or numbering

Formatted: Tab stops: 0.81", Left

Formatted: Indent: First line: 0", Tab stops: 0.81", Left

Formatted: Font: Not Bold

Formatted: Indent: Left: 0.06", First line: 0", Right: 0.05"

Formatted: Indent: Left: 0.06"

MODULE 7
REFERENCE TO ACCREDITATION AND ADVERTISING

7.1 INTRODUCTION

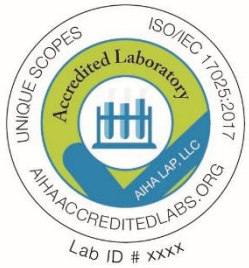
All AIHA Laboratory Accreditation Programs, LLC (AIHA LAP~~, LLC~~) a~~A~~ccredited laboratories are encouraged to advertise their accreditation by using prescribed language defined in this module and the approved AIHA LAP~~, LLC~~ accreditation symbol. ISO/IEC Standard 17011 requires that accreditation 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~~.

An AIHA LAP accredited laboratory that displays its accreditation certificate shall also display the relevant scope of accreditation.

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, LLC (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 C~~c~~ertificate 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 S~~s~~cope of A~~a~~ccreditation, 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~~.

The Certificate is not valid without the attached Scope of Accreditation.

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 Certificate and S~~s~~cope of A~~a~~ccreditation 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 - Required for Environmental Lead Proficiency Analytical Testing (ELPAT) accreditation~~, 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.

TERM AND/OR ACRONYM	DEFINITION
Analytical Sensitivity	Quotient of the change in an indication of a measuring system and the corresponding change in 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).
AOAC International Requirements	Guidelines for Laboratories Performing Microbiological and Chemical Analysis of Food and Pharmaceuticals, August 2018. Accreditation is held under AIHA LAP FoodLAP.
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.
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.
Beryllium Field/Mobile Accreditation Program (Be Field/Mobile)	This AIHA LAP program is intended for accreditation of Beryllium Field/Mobile analytical facilities. This program complies with AIHA LAP requirements and the ISO/IEC 17025 Standard and ISO/IEC 17011 requirements.
~~***Beryllium Proficiency Analytical Testing (BePAT)***~~	~~AIHA PAT Program, LLC proficiency testing program for laboratories analyzing beryllium on filter media.~~
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.
~~***Bulk Asbestos Proficiency Analytical Testing (BAPAT)BSC***~~	~~AIHA PAT Program proficiency testing program for laboratories involved in bulk asbestos analysis. Biological Safety Cabinet~~
CAB	Conformity Assessment Body; A body that performs conformity assessment services and that can be the object of accreditation. (i.e. a testing laboratory,

TERM AND/OR ACRONYM	DEFINITION
	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
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 Standard	A matrix matched material prepared at a known amount of analyte from a reference material and used to construct a calibration curve.
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.
Certification	Third-party attestation related to products, processes, systems or persons. Certification is

TERM AND/OR ACRONYM	DEFINITION
	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 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	Documented proof that an analyst can perform a

TERM AND/OR ACRONYM	DEFINITION
(DOC)	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 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

TERM AND/OR ACRONYM	DEFINITION
	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 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,

TERM AND/OR ACRONYM	DEFINITION
	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, 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/Mobile Analytical Facility ~~Operations Laboratory~~	A field~~-~~/mobile analytical facility~~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

TERM AND/OR ACRONYM	DEFINITION
	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 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

TERM AND/OR ACRONYM	DEFINITION
	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 Control	Routine activities and checks, such as periodic calibrations, duplicate analyses and matrix spikes that are included in routine internal procedures to control the accuracy and precision of measurements.
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).
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 Accreditation for Analyses of Foods (LAAF)	Laboratory accreditation program for the testing of food in certain circumstances. Accreditation is held under AIHA LAP FoodLAP.
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	A duplicate of the LCS.

TERM AND/OR ACRONYM	DEFINITION
Duplicate (LCSD)	
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 17025:2017 Section 9.8~~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 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 defined space that is not fixed at one location, operating under the control of a defined management

TERM AND/OR ACRONYM	DEFINITION
	system (e.g., ISO/IEC 17025:2017 or current version).~~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.
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.
OSHA	Occupational Safety and Health Administration
Objective	Result to be achieved. Source (ISO 9000:2015(en) Quality management systems — Fundamentals and vocabulary; 3.7.1)
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

TERM AND/OR ACRONYM	DEFINITION
	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)
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

TERM AND/OR ACRONYM	DEFINITION
	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 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

TERM AND/OR ACRONYM	DEFINITION
	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)
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

TERM AND/OR ACRONYM	DEFINITION
	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), Food and Drug Administration (FDA), 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® (SRM®)	A certified reference material produced by the U.S. 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

TERM AND/OR ACRONYM	DEFINITION
	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, and Be Field/Mobile) 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).
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~~Ultraviolet-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

TERM AND/OR ACRONYM	DEFINITION
	likelihood. Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.
***VIM*~~*Verification*~~**	Same as International vocabulary of metrology – Basic and general internationally-accepted concepts and associated terms~~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~~
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
WASP	Workplace Analysis Scheme for Proficiency (Great Britain PT Provider)
WHO	World Health Organization
WPCF	Water Pollution Control Federation
Withdrawal	The removal of a laboratory's existing accreditation.
XRD	X-Ray Diffraction
XRF	X-Ray Fluorescence Spectroscopy