MODULE 2A
GENERAL MANAGEMENT SYSTEM REQUIREMENTS

2A.1 SCOPE (See ISO/IEC 17025:~~2005~~2017, Section 1)

Laboratories shall meet all requirements of the ISO/IEC 17025:~~2005~~2017 International Standard and other AIHA-LAP, LLC-specific requirements, as detailed in this module and in the program-specific Modules 2B-2F, if they are to achieve and maintain AIHA-LAP, LLC accreditation. Explanatory notes included in various sections of the ISO/IEC 17025:~~2005~~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:~~2005~~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:~~2005~~2017, Section 2)

2A.3 TERMS AND DEFINITIONS (See ISO/IEC 17025:~~2005~~2017, Section 3)

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

2A.4 ~~MANAGEMENT~~ GENERAL REQUIREMENTS (See ISO/IEC 17025:~~2005~~2017, Section 4)

2A.4.1 Impartiality ~~Organization~~ (See ISO/IEC 17025:~~2005~~2017, Section 4.1)

~~**2A.4.1.1** Accreditation shall be extended to a single site only.~~

~~**2A.4.1.2** Organizations desiring accreditation for multiple laboratory sites and types (Fixed, Mobile Operation and Field Operation Laboratories) shall submit an individual and separate application for each site or type. Refer to Module 9 for definitions of the laboratory types that can be accredited.~~

~~**2A.4.1.3** The laboratory seeking accreditation shall perform the Field(s) of Testing (FoT) for which the accreditation is sought.~~

2A.4.2 ~~Management System~~Confidentiality (See ISO/IEC 17025:~~2005~~2017, Section 4.2)

~~**2A.4.2.1** The laboratory's management system shall reflect the actual operating and quality assurance/quality control (QA/QC) programs in place in the laboratory. The management system shall be documented in the laboratory's Quality Manual (however named) and other referenced quality documents.~~

~~**2A.4.2.2** The Quality Manual shall be updated whenever necessary and shall be~~

~~reviewed and approved by management at least annually.~~

2A.~~4.3~~5 ~~Document Control~~STRUCTURAL REQUIREMENTS~~tructural Requirements~~ (See ISO/IEC 17025:~~2005~~2017, Section ~~4.3~~5)

2A.~~4.1~~5.1 Accreditation shall be extended to a single site only.

2A.~~4.1~~5.2 Organizations desiring accreditation for multiple laboratory sites and types (Fixed, Mobile Operation and Field Operation Laboratories) shall submit an individual and separate application for each site or type. Refer to Module 9 for definitions of the laboratory types that can be accredited.

2A.~~4.1~~5.3 The laboratory seeking accreditation shall perform the Field(s) of Testing (FoT) for which the accreditation is sought.

2A.~~4.4~~6 RESOURCE REQUIREMENTS~~esource Requirements~~~~Review of Requests, Tenders and Contracts~~ (See ISO/IEC 17025:~~2005~~2017, Section ~~4.4~~6)

2A.~~4.5~~6.1 General ~~Subcontracting of Tests and Calibrations~~ (See ISO/IEC 17025:~~2005~~2017, Section ~~4.5~~6.1)

~~**2A.4.5.1** 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 subcontracted work for Fields of Testing covered by the scope of accreditation of the primary facility.~~

~~**2A.4.5.2** The laboratory shall advise the customer of the subcontract arrangement in writing, including the subcontractors' accreditation credentials (scope and accrediting body).~~

2A.~~4.6~~6.2 Personnel ~~urchasing Services and Supplies~~ (See ISO/IEC 17025:~~2005~~2017, Section ~~4.6~~6.2)

~~**2A.5~~6.2.1 Technical Manager (TM) These requirements do not apply for those laboratories applying for accreditation under the ELLAP~~

~~The laboratory shall provide day to day supervision of its technical operations by designating at least one Technical Manager (TM) per program. The TM in a program shall:~~
~~have appropriate education, training, and experience, or combination thereof for the measurement technologies used by the laboratory, to 1) be able to design and implement the management system, and 2) enable that individual to identify the occurrence of departures from the implemented quality management system or test procedures and to initiate actions to prevent or minimize such departures.~~
~~be an employee of the laboratory;~~
~~be present on site at least 20 hours per week or 50 percent of the laboratory operating hours (whichever is less) to address technical issues for laboratory staff and customers;~~
~~ensure that adequate supervision is provided for all laboratory technical personnel.~~

~~2A.56.2. 2 Quality Manager (QM) – These requirements do not apply for those laboratories applying for accreditation under the ELLAP.~~

~~The individual who functions as the quality manager (or however named) of the laboratory shall have the education, training, and experience, or combination thereof, to enable that individual to identify the occurrence of departures from the implemented quality management system and to initiate actions to prevent or minimize such departures. The quality manager shall be knowledgeable of the quality management system and the technical and management system procedures used.~~

~~The Quality Manager may be a part-time employee or a consultant.~~

~~2A.56.2.3 Analyst~~

~~Successful training (in-house courses are acceptable) in specific methodologies used in the laboratory shall be documented. Analysts shall have demonstrated ability to produce reliable results through accurate analysis of certified reference materials (CRMs), proficiency testing samples, or in-house quality control samples. Their performance shall be documented.~~

~~2A.56.2.3.1 All analysts shall have a minimum of twenty (20) business days of hands-on experience conducting applicable analyses in a laboratory before initiation of independent work on customer samples.~~

~~2A.56.2.3.2 Analysts shall complete an external or internal training program for all applicable analyses or analytical techniques prior to performing unsupervised analyses on samples submitted by customers.~~

~~2A.56.2.3.3 Training shall be documented in laboratory records and include a description of the content and duration of the program.~~

~~2A.56.2.3.4 At a minimum of every six (6) months, each analyst shall complete a Demonstration of Competency (DOC) for each accredited Field of Testing in which they participate. This may be accomplished through the accurate analysis of certified reference materials (CRMs), proficiency testing samples, or in-house quality control samples. Demonstrations of Competency shall be documented.~~

2A.46.7 3 Facilities and Environmental Conditions~~Service to the Customer~~ (See ISO/IEC 17025:~~2005~~2017, Section ~~4.7~~6.3)

~~2A.56.3.1 Ventilation hood face velocities shall be appropriate and shall be measured and recorded at least semiannually (annually, if alarmed).~~

2A.~~4.8~~6.4 ~~Complaints~~ Equipment (See ISO/IEC 17025:~~2005~~2017, Section ~~4.8~~6.4)

~~**2A.5.5**~~**6.4.1** ~~The~~ date and the ~~name or initials of the person performing the maintenance or repair shall be recorded.~~

~~**2A.5.5**~~**6.4.2** ~~Calibration procedures shall specify frequency of calibration checks.~~

2A.~~5.5~~6.4.~~2~~3 When possible, any external calibration service used shall be a calibration laboratory accredited to ISO/IEC 17025:~~2005~~2017 by a recognized accreditation body.

NOTE: These requirements also apply to reagents and standards.

2A.~~4~~6.~~9~~ 5 Metrological Traceability ~~Control of Nonconforming Testing and/or Calibration Work~~ (See ISO/IEC 17025:~~2005~~2017, Section ~~4.9~~6.5)

~~**2A.5.6**~~**6.5.1** ~~Requirements for reagents and standards shall be specified by the laboratory to ensure the quality of testing.~~

~~**2A.5.6**~~**6.5.2** ~~Reagents and standards shall be inspected, dated and initialed upon receipt. Calibration standards and analytical reagents shall have an expiration or reevaluation date assigned.~~

~~**2A.5.6**~~**6.5.3** ~~Reagents and standards shall not be used beyond assigned expiration dates. Materials designated for reevaluation, which are determined to have adequate purity upon reevaluation, shall be assigned a new expiration date.~~

~~**2A.5.6**~~**6.5.4** ~~Strict control and documentation of reagent solutions and calibration standards shall be maintained.~~

~~**2A.5.6**~~**6.5.5** ~~Documentation of standard~~ reference materials, reagents ~~and solution preparations shall include a description of the content, the date of preparation, concentration and/or purity of parent material, manufacturer and lot number of parent material, assigned expiration date and the preparer's initials. Solutions shall be adequately identified to trace back to preparation documentation.~~

2A.~~5.6~~6.5.~~5~~6 Laboratories shall comply with the requirements of the AIHA-LAP, LLC Policy on Traceability of Measurement, Policy Appendix H. Refer to the AIHA-LAP, LLC guidance document, *Guidance on Traceability of Measurement* on the AIHA-LAP, LLC website for additional information.

~~**2A.4.9.1** The laboratory shall document and keep records of all non-conforming events.~~

~~**2A.4.9.2** Any outlier from a PT, Round Robin, or Demonstration of Competency shall be addressed as a nonconforming event.~~

2A.~~4.10~~6.6 ~~Improvement~~ Externally Pprovided Pproducts and Sservices (See ISO/IEC 17025:~~2005~~2017, Section ~~4.10~~6.6)

2A.~~4.5~~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) ~~subcontracted work~~ for Fields of Testing covered by the scope of accreditation of the primary facility.

~~**2A.4.56.6.2** The laboratory shall advise the customer of the subcontract arrangement in writing, including the subcontractors' accreditation credentials (scope and accrediting body).~~

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.5.47.2.1** Laboratory-developed methods and non-standard methods may be used if the laboratory 1) has developed and documented procedures considering the topics a-k f contained in the note in ISO/IEC 17025:2017(E), Section 5.4.47.2.2.1; and 2) has validated the method, considering the following topics as appropriate: minimum acceptance criteria, analyte specificity, linearity, range, accuracy, precision, detection limit, quantification limit, stability of samples and reagents, interlaboratory precision, and analysis robustness.~~

~~**2A.5.47.2.2** The laboratory shall define the process utilized in the adoption and revision of analytical procedures employed by the laboratory including when and how these procedures are reviewed and/or revised.~~

~~**2A.5.47.2.3** Method performance criteria (estimates of bias and precision) and acceptance limits shall be stated.~~

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.5.87.4.1** The laboratory shall have a written description of the chain-of-custody and sample receiving procedures followed in the laboratory. Procedures shall include criteria for rejection of samples.~~

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

2A.~~4.13~~7.5.1 All laboratory records shall be maintained for at least three (3) years. ~~For ELLAP laboratories recognized by the NLLAP, records shall be maintained for five (5) years.~~

Records needed to support current laboratory activities shall be kept as long as necessary beyond 3 years. These records ~~may~~ 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.4.137.5.2** Corrections to laboratory records shall be dated.~~

2A.~~4.13~~7.5.~~3~~2 All entries to hard copy laboratory records shall be made using ~~indelible~~ ink. ~~No correction fluid may be used on original laboratory data records.~~

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

2A.~~5.4~~7.6.~~4~~ 1 Test methods are classified as either qualitative or quantitative. Qualitative tests are defined as having non-numerical results. Although estimation 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 Estimation of Uncertainty of Measurement, Policy Appendix G. Refer to the AIHA-LAP, LLC, *Guidance on the Estimation of Uncertainty of Measurement*, on the AIHA-LAP, LLC website for additional information on measurement uncertainty.

2A.7.7 Ensuring the Validity o~~O~~f 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.~~5.9~~7.7.1 As part of the quality assurance program, the laboratory shall adhere to all stated QA/QC requirements in the methods used and any additional

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

2A.~~5.9~~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.~~5.9~~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.~~5.9~~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.~~5.4.5~~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.~~5.4.6~~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~~(E)~~ Section 7.8)

2A.~~5.10~~7.8.1 Final test reports shall also include:

a) ~~a)~~ Reporting limit

i. EMLAP labs performing direct exam may use Analytical Sensitivity in place of a Reporting Limit

b) Date of sample receipt

~~c) Page numbers on each page, and either "x of y" page numbering or a clear indication of the end of the report.~~

2A.~~5.10~~7.8.2 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.

~~For ELLAP laboratories recognized by the NLLAP, the final report shall include the identification of the NLLAP recognized accreditation body.~~

2A.~~5.10~~7.8.3 Measurements below the method reporting limit shall be reported as "<" (less than) or not detected (ND) and reference the reportable limit. The reporting of zero concentration is not permitted.

2A.~~5.10~~7.8.4 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 ~~for contamination~~ based on the field blank or other analytical blank.

~~For ELLAP laboratories recognized by the NLLAP, method blanks (or other QC results) shall not be used to correct sample results.~~

2A.~~5.10~~7.8.5 The number of significant figures reported shall reflect the precision of the analysis.

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

2A.7.10 Nonconforming ~~w~~Work (See ISO/IEC 17025:2017 Section 7.10)

~~**2A.4.9~~7.10.1** ~~The laboratory shall document and keep records of all non-conforming events.~~

2A.~~4.9~~7.10.~~2~~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 o~~O~~f Data a~~A~~nd 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.~~4~~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.

~~The management system shall be documented in the laboratory's Quality Manual (however named) and other referenced quality documents.~~

~~**2A.48.2.2** The Quality Manual shall be updated whenever necessary and shall be reviewed and approved by management at least annually.~~

2A.8.3 Control of management system documentation (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 ~~Improvement~~ (Option A) (See ISO/IEC 17025:2017, Section 8.7)
~~2A.4.11 Corrective Action (See ISO/IEC 17025:2005, Section 4.11)~~

~~**2A.4.118.7.1** Any PT round that leads to the NP status of a laboratory shall be addressed by the corrective action process.~~

~~**2A.4.12 Preventive Action (See ISO/IEC 17025:2005, Section 4.12)**~~

~~**2A.4.13 Control of Records (See ISO/IEC 17025:2005, Section 4.13)**~~

~~**2A.4.13.1** All laboratory records shall be maintained for at least three (3) years. For ELLAP laboratories recognized by the NLLAP, records shall be maintained for five (5) years.~~

~~Records needed to support current laboratory activities shall be kept as long as necessary beyond 3 years. These records may 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.4.13.2** Corrections to laboratory records shall be dated.~~

~~**2A.4.13.3** All entries to hard copy laboratory records shall be made using indelible ink. No correction fluid may be used on original laboratory data records.~~

2A.~~4.14~~8.8 Internal Audits (Option A & Option B) (See ISO/IEC 17025:~~2005~~2017, Section ~~4.14~~8.8)

2A.~~4.14~~8.8.1 Internal quality assurance audits shall be conducted at least annually.

2A.~~4.14~~8.8.2 Internal ~~quality~~ assurance~~-~~ audits ~~shall~~ verify compliance ~~with~~ AIHA-LAP, LLC requirements.

2A.~~4.15~~8.9 Management Reviews (Options A & Option B) (See ISO/IEC 17025:~~2005~~2017, Section ~~4.15~~8.9)

2A.~~4.15~~8.9.1 ~~-~~Management reviews shall be conducted at least annually.

2A.8.10 Management system requirement (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.4.15~~8.9.2** ~~At least quarterly, the quality manager shall provide reports to laboratory management regarding quality assurance matters. These reports shall include information on internal audits, proficiency program performance, nonconformities and corrective/preventive actions taken.~~

~~**2A.5 TECHNICAL REQUIREMENTS (See ISO/IEC 17025:2005, Section 5)**~~

~~**2A.5.1 General (See ISO/IEC 17025:2005, Section 5.1)**~~

~~**2A.5.2 Personnel (See ISO/IEC 17025:2005, Section 5.2)**~~

~~**2A.5.2.1** Technical Manager (TM) – These requirements do not apply for those laboratories applying for accreditation under the ELLAP.~~

~~The laboratory shall provide day to day supervision of its technical operations by designating at least one Technical Manager (TM) per program. The TM in a program shall:~~

- ~~have appropriate education, training, and experience, or combination thereof for the measurement technologies used by the laboratory, to 1) be able to design and implement the management system, and 2) enable that individual to identify the occurrence of departures from the implemented quality management system or test procedures and to initiate actions to prevent or minimize such departures.~~
- ~~be an employee of the laboratory;~~
- ~~be present on site at least 20 hours per week or 50 percent of the laboratory operating hours (whichever is less) to address technical issues for laboratory staff and customers;~~
- ~~ensure that adequate supervision is provided for all laboratory technical personnel.~~

~~**2A.5.2. 2** Quality Manager (QM) – These requirements do not apply for those laboratories applying for accreditation under the ELLAP.~~

The individual who functions as the quality manager (or however named) of the laboratory shall have the education, training, and experience, or combination thereof, to enable that individual to identify the occurrence of departures from the implemented quality management system and to initiate actions to prevent or minimize such departures. The quality manager shall be knowledgeable of the quality management system and the technical and management system procedures used.

The Quality Manager may be a part-time employee or a consultant.

2A.5.2.3 Analyst

Successful training (in-house courses are acceptable) in specific methodologies used in the laboratory shall be documented. Analysts shall have demonstrated ability to produce reliable results through accurate analysis of certified reference materials (CRMs), proficiency testing samples, or in-house quality control samples. Their performance shall be documented.

2A.5.2.3.1 All analysts shall have a minimum of twenty (20) business days of hands-on experience conducting applicable analyses in a laboratory before initiation of independent work on customer samples.

2A.5.2.3.2 Analysts shall complete an external or internal training program for all applicable analyses or analytical techniques prior to performing unsupervised analyses on samples submitted by customers.

2A.5.2.3.3 Training shall be documented in laboratory records and include a description of the content and duration of the program.

2A.5.2.3.4 At a minimum of every six (6) months, each analyst shall complete a Demonstration of Competency (DOC) for each accredited Field of Testing in which they participate. This may be accomplished through the accurate analysis of certified reference materials (CRMs), proficiency testing samples, or in-house quality control samples. Demonstrations of Competency shall be documented.

2A.5.3 Accommodation and Environmental Conditions (See ISO/IEC 17025:2005, Section 5.3)

2A.5.3.1 Ventilation hood face velocities shall be appropriate and shall be measured and recorded at least semiannually (annually, if alarmed).

2A.5.4 Test Methods and Method Validation (See ISO/IEC 17025:2005, Section 5.4)

2A.5.4.1 Laboratory-developed methods and non-standard methods may be used if the laboratory 1) has developed and documented procedures considering the topics a-k contained in the note in ISO/IEC 17025:2005, Section 5.4.4; and 2) has validated the method, considering the following topics as appropriate: minimum acceptance criteria, analyte specificity, linearity, range, accuracy, precision,

detection limit, quantification limit, stability of samples and reagents, interlaboratory precision, and analysis robustness.

2A.5.4.2 The laboratory shall define the process utilized in the adoption and revision of analytical procedures employed by the laboratory including when and how these procedures are reviewed and/or revised.

2A.5.4.3 Method performance criteria (estimates of bias and precision) and acceptance limits shall be stated.

2A.5.4.4 Test methods are classified as either qualitative or quantitative. Qualitative tests are defined as having non-numerical results. Although estimation 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 Estimation of Uncertainty of Measurement, Policy Appendix G. Refer to the AIHA-LAP, LLC, *Guidance on the Estimation of Uncertainty of Measurement*, on the AIHA-LAP, LLC website for additional information on measurement uncertainty.

2A.5.4.5 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.5.4.6 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.5.5 Equipment (See ISO/IEC 17025:2005, Section 5.5)

2A.5.5.1 The name or initials of the person performing the maintenance or repair shall be recorded.

2A.5.5.2 Calibration procedures shall specify frequency of calibration checks.

2A.5.5.3 When possible, any external calibration service used shall be a calibration laboratory accredited to ISO/IEC 17025:2005 by a recognized accreditation body.

2A.5.6 Measurement Traceability (See ISO/IEC 17025:2005, Section 5.6)

2A.5.6.1 Requirements for reagents and standards shall be specified by the laboratory to ensure the quality of testing.

2A.5.6.2 Reagents and standards shall be inspected, dated and initialed upon receipt. Calibration standards and analytical reagents shall have an expiration or reevaluation date assigned.

2A.5.6.3 Reagents and standards shall not be used beyond assigned expiration dates. Materials designated for reevaluation, which are determined to have adequate purity upon reevaluation, shall be assigned a new expiration date.

2A.5.6.4 Strict control and documentation of reagent solutions and calibration standards shall be maintained.

2A.5.6.5 Documentation of standard and solution preparations shall include a description of the content, the date of preparation, concentration and/or purity of parent material, manufacturer and lot number of parent material, assigned expiration date and the preparer's initials. Solutions shall be adequately identified to trace back to preparation documentation.

2A.5.6.6 Laboratories shall comply with the requirements of the AIHA-LAP, LLC Policy on Traceability of Measurement, Policy Appendix H. Refer to the AIHA-LAP, LLC guidance document, *Guidance on Traceability of Measurement* on the AIHA-LAP, LLC website for additional information.

2A.5.7 Sampling (See ISO/IEC 17025:2005, Section 5.7)

2A.5.8 Handling of Test Items (See ISO/IEC 17025:2005, Section 5.8)

2A.5.8.1 The laboratory shall have a written description of the chain-of-custody and sample receiving procedures followed in the laboratory. Procedures shall include criteria for rejection of samples.

2A.5.9 Assuring the Quality of Test Results (See ISO/IEC 17025:2005, Section 5.9)

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.5.9.1 As part of the quality assurance program, the laboratory shall adhere to all stated QA/QC requirements in the methods used and any additional requirements defined in Modules 2B-2F. Any deviations from these procedures shall be documented. The laboratory shall determine, where feasible, the accuracy and precision of all analyses performed. Procedures shall be in place to estimate the uncertainty of measurement of all calibrations and test methods. At a minimum, the following QC checks shall be performed per batch of samples.

2A.5.9.1.1 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.5.9.1.2 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.5.9.1.3 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.5.10 Reporting the Results (See ISO/IEC 17025:2005, Section 5.10)

2A.5.10.1 Final test reports shall also include:

a) Reporting limit
b) Date of sample receipt
c) Page numbers on each page, and either "*x of y*" page numbering or a clear indication of the end of the report.

2A.5.10.2 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.
For ELLAP laboratories recognized by the NLLAP, the final report shall include the identification of the NLLAP recognized accreditation body.

2A.5.10.3 Measurements below the method reporting limit shall be reported as "<" (less than) or not detected (ND) and reference the reportable limit. The reporting of zero concentration is not permitted.

~~**2A.5.10.4** 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 for contamination based on the field blank or other analytical blank.~~

~~For ELLAP laboratories recognized by the NLLAP, method blanks (or other QC results) shall not be used to correct sample results.~~

~~**2A.5.10.5** The number of significant figures reported shall reflect the precision of the analysis.~~

2A.~~6~~ 9 SAFETY AND HEALTH

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

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

2B.1 SCOPE

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

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

2B.2 ANALYTICAL METHODS

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

2B.2.1 Minimum reporting limits shall be established initially for each instrument used in the analysis of reported analytes by analyzing media spiked samples, prepared at the desired minimum reporting limit concentrations, and taken through the entire analytical process. Acceptance criteria shall be documented.

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

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

2B.2.4 For industrial hygiene testing, a calibration curve shall be constructed with a minimum of three (3) calibration standards, which bracket the expected sample concentrations and a calibration blank. ~~For inductively coupled plasma - atomic emission spectroscopy (ICP-AES) analyses, where possible, a minimum of a two-point calibration plus a blank shall be performed.~~ For those technologies and software packages requiring fewer calibration standards, follow the manufacturer's recommendations (e. g., the instrument operations manual). The calibration curve shall be verified by preparing an independently prepared

calibration standard (from neat materials) or with a standard from an independent source. Acceptance criteria for the standard calibration curve and the independent calibration verification standard shall be documented.

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

2B.2.6 Instrument calibration/standardization shall be verified each 24-hour period of use or at each instrument start-up if the instrument is restarted during the 24-hour period, by analysis of a continuing calibration verification standard. Acceptance criteria shall be documented.

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

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

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

2B.3 ASBESTOS TESTING

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

2B.3.1 Phase Contrast Microscopy (PCM) Analysis

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

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

a) Microscope adjustment and alignment for each day of use, including phase ring alignment

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

2B.3.1.2 Final PCM reports shall include:
a) Both fiber density and fibers/cc (or total fibers per sample)
b) Applicable intra-laboratory Sr value(s)

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

2B.3.1.4 In addition to the requirements noted above, all laboratories providing data to be used with OSHA requirements are required to participate in round robin program and post the results.

2B.3.2 Polarized Light Microscopy (PLM) Analysis

2B.3.2.1 U.S. laboratories performing bulk asbestos analysis under the Asbestos Hazard Emergency Response Act (AHERA) shall utilize U.S. EPA's "Interim Method for the Determination of Asbestos in Bulk Insulation Samples" as found in 40 CFR, Part 763, Appendix E to Subpart E, the current EPA method for the analysis of asbestos in building material, or a method meeting the requirements of Module 2A, Section 2A.5.4.

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

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

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

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

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

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

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

2B.3.2.8 The laboratory shall document, for each asbestos fiber type, morphology, color, pleochroism, indices of refraction, birefringence, extinction and sign of elongation. The laboratory shall document, for each non asbestos type, at least one of the above which distinguishes it from asbestos.

2B.3.2.9 The Quality Assurance program shall address:

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

2B.3.3 Transmission Electron Microscopy (TEM) Analysis

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

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

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

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

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

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

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

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

2B.3.3.7 The Quality Assurance program shall address:

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

2B.4 COMPRESSED/BREATHING AIR TESTING

Accreditation for compressed/breathing air testing in the IHLAP is intended for all laboratories, company, government, trade and independent, performing air tests on samples of compressed and/or breathing air. Typically, these samples come from compressed air sources, but may be from ambient air as well. Fire

departments, divers, hospitals and commercial industry use breathing air from compressed gas sources. OSHA, National Fire Protection Association (NFPA), Compressed Gas Association (CGA), Professional Association of Diving Instructors (PADI) plus many others have specifications for the requirements of compressed/breathing air.

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

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

2B.4.2 A calibration curve shall be constructed with a minimum of three (3) calibration standards which bracket the expected sample concentrations. If a full calibration curve is not run each 24- hour period, then a single point calibration in the range of the three (3) point calibration curve can be used. Validity of this one (1) point calibration shall be checked at least once for each 24-hour period with an additional calibration standard that falls within the three (3) point range. Acceptance criteria for the standard calibration curve shall be documented. These requirements supersede the requirements of this module, Section 2B.3.4.

2B.5 BERYLLIUM TESTING

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

2B.6 PHARMACEUTICAL TESTING

Accreditation for pharmaceutical testing is intended for industrial hygiene laboratories that develop methods and analyze samples for the purpose of evaluating potential occupational exposure to pharmaceutical compounds in the workplace. Laboratories seeking accreditation for pharmaceutical testing shall adhere to the management system and quality system requirements as defined in Module 2A, this program specific module, Sections 2B.1 through 2B.4 (as applicable) maintained on the AIHA-LAP, LLC web site.

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

2B.6.1 Sample Handling and Preparation

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

customer samples.

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

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

2D.1 SCOPE

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

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

2D.2 FACILITIES

2D.2.1 The laboratory shall have adequate facilities for the scope of services to be accredited. The facility shall meet the requirements of the appropriate and most current biosafety level guidelines, as defined by CDC/NIH, WHO and AIHA. 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.

2D.3 EQUIPMENT

2D.3.1 General

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

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

a) A compound optical microscope having a high magnification (e.g., 100x) liquid immersion objective having a numerical aperture (n.a.) of at least 1.25; or,
b) An optical microscope having a theoretical or calculated point to point resolution at 0.34 µm or better. The resolution is calculated as follows: 1.22 x 0.55 µm/ [condenser n.a. + objective n.a.]; or,
c) A magnification system having a measured optical resolution of 0.34µm or better. For example, the optical resolution may be measured with resolution target testing slides.

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

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

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

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

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

2D.3.2 Additional Requirements for All Culturable FoTs

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

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

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

2D.3.2.2.2 Laboratories with steam sterilizers shall use biological indicators (e.g. spore strips or ampoules) with each use or at least once a week, whichever is less to document the sterilization process.

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

~~**2D.3.3** Additional Requirements for All Molecular FoT's~~

~~**2D.3.3.1** The laboratory shall have centrifuges and pipettes appropriate for the scope of work performed at the laboratory.~~

~~**2D.3.3.2** The laboratory shall keep routine temperature documentation of refrigerators, freezers, and incubators. Acceptance criteria shall be documented.~~

~~**2D.3.3.3** Conventional PCR / Sequencing~~

~~**2D.3.3.3.1** The laboratory shall have the appropriate equipment to run and~~

~~document gel electrophoresis applicable to the methods used by the laboratory.~~

~~**2D.3.3.3.2** The laboratory shall have the appropriate software to perform sequence editing, alignment, and database searches for the methods used by the laboratory.~~

~~**2D.3.3.4** qPCR~~

~~**2D.3.3.4.1** The laboratory shall have a qPCR machine with, at minimum, the required number of channels for running the assay used by the laboratory.~~

~~**2D.3.3.5** Plate Readers~~

~~**2D.3.3.5.1** The laboratory shall have a plate reader with the appropriate absorbance, luminescence, or fluorescence for the running the assay used by the laboratory~~

2D.4 PERSONNEL

The laboratory shall conform to the personnel requirements ~~as specified in Module 2A, Section 2A.5.2 (and all sub-sections), and to the requirements~~ as detailed in the following sections. In all cases, training records for degreed laboratory staff shall include a copy of the transcript or diploma from an accredited college/university. The laboratory must have key personnel within the organization with the expertise outlined below.

2D.4.1 ~~Technical Manager~~

~~Qualifications of the Technical Manager in addition to those in 2A are:~~

~~**2D.4.1.1**~~ The ~~Technical Manager~~laboratory key personnel shall be experienced, where applicable, in the selection and use of bioaerosol, surface, fluid and raw material sampling methods and in sample processing for the quantification and identification appropriate to the FoTs of mesophilic and thermophilic bacteria, and mesophilic, xerophilic, thermotolerant fungi (molds and yeasts), fungi identified by spore trap collection methods and DNA extraction, PCR, gel electrophoresis, sequencing, phylogenetic analysis and ELISA.

2D.4.~~1.~~2 Training records for the ~~Technical Manager~~laboratory key personnel shall include documentation of ability to identify genus/group of fungi from spore trap analysis and genus/species of fungi that are reported. Bacterial identification training records shall document training of relevant diagnostic procedures (e.g., gram stain, oxidase, biochemical reactions) as appropriate to the FoT(s). Legionella training records shall include documentation of relevant diagnostic procedure (ability to recognize presumptive colonies, confirmation using DFA, latex agglutination, or molecular methods). PCR training records shall document training of relevant diagnostic procedures (DNA extraction, PCR, gel electrophesis, sequencing, phylogenetic analysis and ELISA).

2D.4.3~~2~~ Laboratory Analytical Staff

The environmental microbiological program distinguishes two titles for those conducting analytical procedures within the laboratory.

2D.4.3~~2~~.1 Laboratory Technicians

These staff members shall have a high school diploma or General Education Development (GED). During this required training period, the trainee shall perform work (and have work reviewed prior to release) under the direct supervision of a qualified technician, analyst and/or the Technical Manager.

Technicians may function in the same manner as analysts for Air – Direct Examination (spore trap) analysis after completion of six (6) months documented on the job training and demonstrated proficiency. For all other analyses, technicians may function in the same manner as analysts after one (1) year documented on the job training and demonstrated proficiency.

2D.4.3~~2~~.2 Laboratory Analysts

These staff members shall have a bachelor's degree in a physical or biological science. Analysts shall have three (3) months of documented training for Air - Direct Examination (spore trap) and six (6) months of documented on-the-job training functioning for all other analyses as an analyst trainee. During the required analyst training period, the trainee shall be under the direct supervision of another qualified analyst and/or the Technical Manager. During this period, the trainee shall have all work reviewed prior to release by another qualified analyst and/or the Technical Manager.

2D.4.3~~2~~.3 Training Records

Training records for technicians and analysts shall include documentation of ability to identify genus/species of fungi and genus/group of fungi that are reported. Bacterial identification training records shall document training of relevant diagnostic procedures (e.g., gram stain, oxidase, biochemical reactions). Legionella training records shall include documentation of relevant diagnostic procedure (ability to recognize presumptive colonies, confirmation using DFA, latex agglutination, or molecular methods). Molecular training records must include document of relevant diagnostic procedure (DNA extraction, PCR, gel electrophoresis, sequencing, phylogenetic analysis and/or ELISA. All analysts and technicians shall have demonstrated ability to produce reliable results through accurate analysis of certified reference materials (CRMs), proficiency testing samples or in-house quality control samples.

2D.5 ANALYTICAL METHODS

2D.5.1 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.5.2 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.5.3 Additional Requirements for Molecular FoT

2D.5.3.1 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.5.3.2 To each run of samples the following QC shall be included:

2D.5.3.2.1 One Laboratory Control Sample (LCS) or one per every 20 samples, whichever is greater.

2D.5.3.2.2 One duplicate analysis per every 20 samples, whichever is greater.

2D.5.3.2.3 One reagent blank sample analysis or one reagent blank sample analysis per every 20 samples, whichever is greater.

2D.6 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.4.2.1 and shall also include the following additional elements.

2D.6.1 General

2D.6.1.1 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.6.1.2 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.5.3.2 for requirements specific to Molecular FoTs).~~.~~

2D.6.1.3 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.5.3.2 for requirements specific to Molecular FoTs~~.~~).

2D.6.1.4 The laboratory shall use control charts or quality control databases to compare intra- and inter-analyst analysis performance to established control limits.

2D.6.1.5 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.6.1.6 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.6.2 Additional Laboratory Requirements for All Culturable FoTs

2D.6.2.1 The laboratory shall keep routine temperature documentation of refrigerators, freezers and incubators. Acceptance criteria shall be documented.

2D.6.2.2 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.6.2.3 The culture collection shall be used at least monthly to prepare blind cultures to be used as part of the routine QC program to monitor accuracy in culture identification.

2D.6.3 Additional Requirements for Fungal Direct Examination ~~Air~~ FoTs

2D.6.3.1 A slide collection shall consist of field samples with various count levels and genera/groups of spores shall be maintained and used as part of total spore analysis quality control. Each day of analysis, at least one slide from this collection shall be reviewed by each analyst. Analysis shall be consistent with the method for field samples. Slides shall be reviewed on a rotational schedule such that a different slide is reviewed each day until the entire slide collection has been examined. The analysis of these slides shall be incorporated into the daily QC plan. Acceptance criteria for spore concentration(s) for each reference slide shall be stated. The upper and lower control limits shall be statistically calculated based on three (3) standard deviations from the reference slide means.

2D.6.3.2 For the Fungal Direct Examination Air FoT, the laboratory shall participate in and have documentation of a round robin slide exchange ~~of real samples~~ consistent with the requirements of AIHA-LAP, LLC Policy Module 6. The following are additional requirements:

2D.6.3.2.1 Analytical data shall include raw counts and final concentrations for each fungal structure observed.

2D.6.3.2.2 Acceptance criteria shall be determined and take into account organism identification, ranking and quantification.

2D.6.3.3 The traverse width or field of view to be used in calculations for each microscope shall be documented at least annually, if applicable.

2D.6.4 Additional Requirements for Molecular FoT's

2D.6.4.1 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.7 REPORTING THE RESULTS

The laboratory's results shall address the elements in Module 2A, Section 2A.~~5.10~~7.8 and shall also include the following additional elements:

2D.7.1 Reports shall include raw counts. See definition of "Raw Count" in Module 9 – Terms and Acronyms.

2D.7.2 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.7.2.1 For analyses utilizing multiple dilutions and/or varying percentages of sample and/or trace analyzed, the applicable analytical sensitivities shall be reported.

2D.8 SAFETY, HEALTH, ENVIRONMENTAL AND TRANSPORTATION REGULATIONS

Laboratories accredited under EMLAP are expected to follow ~~all applicable federal, state, and local~~ 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 ~~federal, state and/or local~~jurisdictional regulations regarding safety, health, environment or transportation may result in suspension, denial, or withdrawal of EMLAP accreditation.

MODULE 2E
UNIQUE SCOPES LABORATORY ACCREDITATION PROGRAM
ADDITIONAL REQUIREMENTS

2E.1 SCOPE

The AIHA-Laboratory Accreditation Programs (AIHA-LAP), LLC offers a Unique Scope accreditation for those laboratories wishing accreditation under AIHA-LAP, LLC and ISO/IEC 17025:~~2005~~2017. A unique scope accreditation can only be applied to an area of testing that is not addressed under an existing AIHA-LAP, LLC program. Laboratories seeking this accreditation shall be in compliance with the requirements found in appropriate AIHA-LAP, LLC Policy Modules including Modules 2A and 6. All applications of this Unique Scopes accreditation are subject to approval by the AAB.

2E.2 FACILITIES

Laboratory facilities supporting unique scope testing shall be equipped and designed to meet the needs of the specific testing. If the unique scope testing is performed in a mobile and/or field operation, the laboratory shall maintain records of the locations where analyses are performed.

~~2E.3 PERSONNEL~~

~~Laboratory personnel shall consist, at a minimum, of a Technical Manager (TM) and a qualified individual not directly involved with the analysis of the samples set. They are to review and concur on the data for use in the final report. See Policy Module 9 for definition of "*Qualified Individual (for data review).*"~~

2E.~~3~~4 ANALYTICAL METHODS

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

2E.~~3~~4.1 For quantitative testing procedures, the laboratory shall establish and verify the minimum reporting limit(s) and linear ranges annually. This shall be completed and documented for each test and matrix.

2E.~~3~~4.2 Laboratories shall only report levels below the minimum reporting limit as "<" (less than) or with a "ND" (not detected) and reference the reporting limit. The reporting of zero concentration is not permitted.

2E.~~3~~4.3 All analytical reagents shall be of ACS grade or better.

2E.~~3~~4.4 Daily working calibration curves, as specifically described in the applicable SOP, shall fall within the established linear calibration range. A minimum of three (3) calibration standards and a calibration blank shall be used to construct the calibration curve. ~~For inductively coupled plasma - atomic emission spectroscopy (ICP-AES) analyses, where~~

~~possible, a minimum of a two-point calibration plus a blank shall be performed.~~ For those technologies and software packages requiring fewer calibration standards, follow the manufacturer's recommendations (e. g., the instrument operations manual). All calibration curves shall be dated and labeled with applicable method, instrument identification, analysis date, analyte concentrations, and instrument response. Acceptance criteria in terms of relative percent difference (RPD) of response factors or correlation coefficient shall be stated. New calibration curves shall be prepared whenever an out of control condition is indicated and/or after new calibration standards and/or reagents are prepared.

2E.~~4~~5 INTERNAL QUALITY CONTROL PROCEDURES

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

2E.~~5~~6 TRANSFER OF ACCREDITATION

2E.~~5~~6.1 Laboratories wishing to add an accreditation under Module 2E to their existing accreditation certificate shall be required to coordinate their new application and site assessment with those from the other programs. Laboratories may choose to seek early reaccreditation for their existing programs to enable submission of a combined application package.

2E.~~5~~6.2 Laboratories wishing to substitute their current AIHA-LAP, LLC accreditation with accreditation under Module 2E may do so at the end of their current accreditation cycle when their next review and site assessment shall be based on a new application package. Laboratories may choose to submit their reaccreditation early to quicken this process.

~~2E.7 LEVY OF FEES~~

~~The AIHA-LAP, LLC reserves the right to levy fees for additional activities associated with accreditation under Module 2E including, but not limited to, auditing proficiency test sample providers, assessing proficiency test programs, and handling data.~~

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

2F.1 SCOPE

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

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

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

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

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

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

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

Molecular Biology: (including testing for genetically modified organisms): Food laboratories performing testing in this area may perform testing to detect pathogens in the material. ~~The testing procedures may include testing of pathogens such as *Salmonella, E.coli, Campylobacter* Infections, *Listeria monocytogenes, Shigella* spp., *etc.*~~

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.2.1.9** If the laboratory is utilizing molecular techniques, 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.)~~

~~2F.2.1.9.1 If the laboratory is performing qPCR analyses, it shall have a qPCR instrument with, at a minimum, the required number of channels for running the assay used by the laboratory.~~

~~2F.2.1.9.2 If the laboratory is performing qPCR analyses, it shall have a plate reader with the appropriate absorbance, luminescence, or fluorescence for the running the assay used by the laboratory.~~

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

~~All facility and equipment requirements for the chemistry and residue chemistry laboratories can be found in Module 2A.~~

~~2F.3 PERSONNEL~~

~~**2F.3.1** For non-routine testing procedures, the analysts shall have the required knowledge, skills and abilities to adequately perform their assigned tasks. Proof of such testing capabilities shall be documented.~~

2F.34 ANALYTICAL METHODS

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

2F.43.1 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. Pharmocopeia (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.43.~~.~~2 When a laboratory must use a method that is not recognized nationally or internationally (see Section 2F.34.1), the laboratory shall validate the procedure according to ~~AIHA-LAP, LLC Policy Module 2A, Section 2A.5.4, document the validation process, and maintain the appropriate records~~ISO/IEC 17025:2017. The laboratory shall obtain customer agreement before using the method for customer samples.

2F.34.3 Prior to analysis, sample integrity shall be maintained through proper storage and handling conditions. Such conditions shall be documented.

2F.34.4 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.45 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~~5.1 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~~5.2 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~~5.3 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~~5.4 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~~5.5 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~~5.6 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.5.6.1 Source and date of acquisition for each shall be documented.

2F.5.6.2 Procedures for maintaining the cultures and/or reagents and using them for training and QC purposes shall be available.

2F.~~5~~6 SAFETY AND HEALTH

Laboratories participating in the FoodLAP are expected to follow all applicable ~~federal, state, and local~~jurisdictional regulations regarding safety, health, environment or transportation. As part of the application for accreditation or reaccreditation and on behalf of the organization seeking accreditation, the ~~Technical Manager~~laboratory's key personnel shall provide a written statement that the laboratory complies with all applicable standards. Failure to comply with applicable ~~federal, state, and local~~ 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~~7~~ 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). 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~~8~~ REFERENCES

2F.7~~8~~.1 APLAC TC 007, Guidelines for Food Testing Laboratories, Issue Date 2014/01

2F.~~8~~7.2 AOAC International Gudelines got Laboratories Performing Microbiological and Chemical Analysis of Food and Pharmaceuticals, March 2010

2F.7~~8~~.3 Evaluation of Milk Laboratories, U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, 1995.

2F.7~~8~~.4 Accredited Laboratory Program, U.S. Department of Agriculture, Food Safety and Inspection Service, 1997.

2F.7~~8~~.5 Trichina Certification Program, Procedures and Checklists, Agricultural Marketing Service, 1995.

2F.7~~8~~.6 Pasteurized Egg Products Recognized Laboratory Program, U.S. Department of Agriculture, Food Safety and Inspection Service.

2F.7~~8~~.7 National Laboratory Accreditation Program, U.S. Department of Agriculture.

MODULE 3
ACCREDITATION, MAINTENANCE AND REACCREDITATION PROCESSES

3.1 INITIAL ACCREDITATION

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

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

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

3.1.3 The laboratory shall address all of the ~~findings and~~ deficiencies identified by the site assessor with appropriate corrective actions.

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

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

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

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

3.2 PROFICIENCY TESTING

Successful participation in applicable proficiency testing programs is required to qualify for accreditation. Consistent with their scope of accreditation, laboratories are required to analyze all proficiency testing samples as defined in AIHA-LAP, LLC Policy Module 6 and outlined on the Scope/PT Table. The laboratory shall have a documented policy regarding participation in proficiency testing programs. Proficiency testing samples shall be analyzed on-site in a manner similar to customer samples. Results or analysis of proficiency samples shall not be discussed with other laboratories until the results have been publicly made available.

3.3 APPLICATION FOR ACCREDITATION

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

3.3.1 The completed Accreditation Application and supporting documentation ~~laboratory Quality Manual~~ 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 ~~current year's~~ 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 ~~appropriate~~ 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 forward one copy of the completed application and supporting documentation ~~Quality Manual~~ to the assigned site assessor for review. The laboratory shall be notified in advance of the site assessor's identity. If a laboratory believes that a particular assessor may represent a conflict of interest, the laboratory is allowed one rejection of an assessor with a reason provided. The site assessor shall complete the application package review and the site evaluation within a period of 12 weeks from the time of receipt of the application from AIHA-LAP, LLC provided the site assessor is given access to the laboratory within a reasonable amount of time. 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 deficiencies (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 deficiencies, documentation shall be submitted to substantiate the corrective action(s) taken to address the deficiency(s) 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 deficiencies, 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 ~~current year's~~ 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~~2005~~ 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 the completed assessment checklist, with deficiencies and/or comments, to the laboratory at the conclusion of the site assessment. If there are a high number of deficiencies, 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 Deficiencies 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. Deficiencies 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 an excessive number of deficiencies that show a lack of comprehension or serious disregard for AIHA-LAP, LLC policies, fraudulent or erroneous data, or a large number of repeat deficiencies.

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

The policies defined in AIHA-LLP, LLC Policy Module 4 shall be followed. Initial assessments with egregious deficiencies 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.

3.5.5 The laboratory shall respond in writing to all of the deficiencies to the site assessor and AIHA-LAP, LLC within twenty (20) business days of completion of the site assessment. All deficiency 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 deficiencies 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 deficiencies. 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 deficiencies 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 deficiencies. 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 deficiencies 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 deficiencies continues to be unacceptable to the site assessor, the laboratory may be recommended for a follow-up assessment, or may be assessed additional fees by AIHA-LAP, LLC for extended site assessor review. Such recommendations for follow-up assessment or additional fees shall be referred to the Technical Advisory Panel (TAP) for concurrence. A follow-up assessment must be approved by the Managing Director, or designee, of AIHA - LAP, LLC and, if approved, must be completed prior to granting accreditation or reaccreditation. If the laboratory's response schedule does not allow sufficient time to complete the accreditation process within the twelve (12) month time frame; or if there are irresolvable differences of opinion between the laboratory and the site assessor, then the site assessor shall recommend that the laboratory be denied accreditation. (see Policy Module 4)

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

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

be completed prior to granting accreditation or reaccreditation.

A follow-up assessment may be required if :
a) the site assessment has revealed a large number of deficiencies;
b) there are a large number of repeat deficiencies; or
c) the laboratory's responses to the deficiencies 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 deficiencies, but any other deficiencies identified during a follow-up site assessment must also be corrected prior to granting accreditation or reaccreditation. ~~.~~ The laboratory is typically limited to one deficiency response, but may be allowed an additional opportunity to respond at the site assessor's discretion. A laboratory must respond to all deficiencies found during a follow-up assessment in order for the site assessor to recommend that they maintain their accreditation status.

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

A surveillance site assessment may be required
a) due to a credible complaint;
b) high personnel turnover;
c) a large number of deficiencies during the most recent routine assessment;
d) repeat deficiencies;
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 visit as a condition of the granting of accreditation.

Surveillance visits 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 visits 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 deficiencies 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 deficiency response, but may be allowed an additional opportunity to respond at the site assessor's discretion. A laboratory must respond to all deficiencies 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

Some laboratories shall be subjected to a process and quality 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 package be forwarded for TAP Reivew. All initial accreditation laboratories are subject to a TAP review. Any reaccreditation may be selected for TAP review.

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

3.7 GRANTING OF ACCREDITATION

3.7.1 AAB Ballot

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

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

3.7.2 Proficiency at Time of AAB Ballot

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

3.7.2.1 Laboratories for Initial Accreditation

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

3.7.2.2 Laboratories for Reaccreditation

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

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

3.8 MAINTENANCE OF ACCREDITATION

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

3.8.1 Reporting of Significant Changes

Any changes in laboratory ownership, location (except for mobile and field operations laboratories), management, ~~quality control~~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 ~~the Technical Manager, the Quality Manager, or an analyst who is the only staff member that performs a given test,~~any laboratory key personnel are absent for reasons of extended family leave, illness, temporary disability, etc.

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

3.8.2 Maintenance of Proficiency

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

If the laboratory becomes non-proficient in a specific FoT(s), based on proficiency testing sample

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

3.8.3 Maintenance of Fees

If the laboratory fails to pay the fees assessed by AIHA-LAP, LLC in an invoice, then AIHA-LAP, LLC reserves the right to suspend the laboratory's accreditation(s) for any or all FoTs until all fees are paid in full. AIHA-LAP, LLC shall notify the participant of this action in writing, specifying a payment deadline. If payment is not received by AIHA-LAP, LLC within the specified time frame and a written request from the laboratory to extend the payment deadline has not been received and approved by the Manager of Operations, AIHA Affiliate Laboratory Programs, then the AIHA-LAP, LLC shall administratively remove the laboratory from the program(s).

3.8.4 Notice of Intended Change

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

3.9 ADDITION OF A FIELD OF TESTING (FoT)

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

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

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

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

3.10 ADDITION OF A METHOD

An accredited laboratory that wishes to add a method within a field of testing (FoT) for which the laboratory is currently accredited shall submit the "Request for Method Addition Form," located on the AIHA-LAP, LLC web site, and the standard operating procedure(s) for each method being added. The information submitted shall be reviewed by a member of TAP who shall approve or deny the method addition within ten (10) business days of receiving the method addition documentation.

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

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

3.11 TRANSFER OF ACCREDITATION

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

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

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

3.12 REQUIREMENTS FOR REACCREDITATION

Laboratory accreditation shall be granted for a period of two (2) years. Laboratories must reaccredit every two (2) years by completing an application that conforms to all AIHA-LAP, LLC requirements, and successfully completing a site assessment (see Accreditation Process, Figure 3-1). The laboratory shall also demonstrate continued, successful participation in the appropriate proficiency testing program(s). If a laboratory chooses not to seek reaccreditation, then the laboratory accreditation(s) shall expire on the accreditation expiration date, provided the laboratory remains proficient in the applicable FoT. 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 obtain, complete and submit an

application for reaccreditation. The laboratory must complete and return 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 shall not 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 deficiencies 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 deficiency 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.

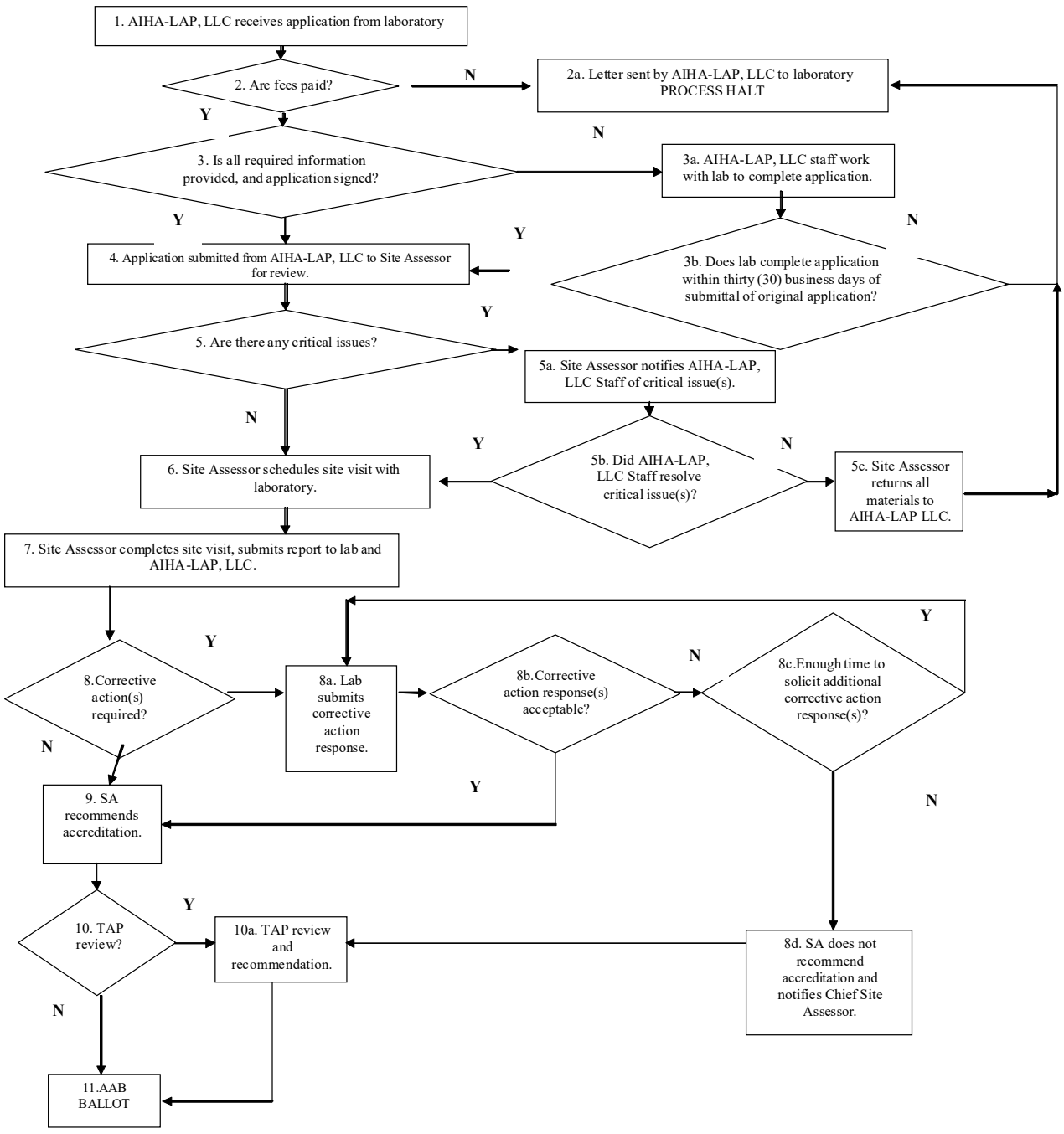
NOTE: The AIHA-LAP site assessment checklist, based on the ISO/IEC 17025 standard and AIHA-LAP policy requirements, is available upon request. Utilizing the site assessment checklist may help avoid the need for a pre-assessment.

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 deficiencies 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 9
TERMS AND ACRONYMS

TERM AND/OR ACRONYM	DEFINITION
AAB	Analytical Accreditation Board
ACS	American Chemical Society
AHERA	Asbestos Hazard Emergency Response Act
AIHA	American Industrial Hygiene Association
AIHA-LAP, LLC	AIHA Laboratory Accreditation Programs, LLC
AIHA-PAT Program, LLC	AIHA Proficiency Analytical Testing Programs, LLC
APHA	American Public Health Association
APLAC	Asia-Pacific Laboratory Accreditation Cooperation
ASHRAE	American Society of Heating, Refrigerating, and Air- Conditioning Engineers
ASM	American Society for Microbiology
ASV	Anodic Stripping Voltammetry
AWWA	American Water Works Association
Acceptance Limits	Established mathematical data quality limits for analytical method performance.
Accreditation	A third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.
Accredited Laboratory	A testing laboratory that has been evaluated and granted accreditation covering a specified type of measurement or task, usually for a specific property or analyte, and for a specified period of time.
Accuracy	Closeness of agreement between a measured quantity value and a true quantity value of a measurand.
Aliquot	See "*Subsample*".
Analysis	The qualitative or quantitative determination of a property or analyte in a substance or material.
Analytical Run	For chemical analyses, an analytical run consists of all samples processed continuously using an item of instrumentation or equipment. Samples in one analytical run are analyzed using the same set of standard calibration data.
Analytical Sensitivity	Quotient of the change in an indication of a measuring system and the corresponding change in a value of a quantity being measured (e.g., for methods involving a count, the analytical sensitivity equals 1 raw count per amount or portion of sample analyzed, calculated and expressed in the final reporting units).
Approved Signatory	Person who is recognized by a laboratory as competent and authorized by laboratory management to sign test reports.
Assessor	An individual assigned by an accreditation body to perform, alone or as part of an assessment team, an assessment of a CAB.

TERM AND/OR ACRONYM	DEFINITION
Bulk Asbestos Proficiency Analytical Testing (BAPAT)	AIHA-PAT Program, LLC proficiency testing program for laboratories involved in bulk asbestos analysis.
Beryllium Proficiency Analytical Testing (BePAT)	AIHA-PAT Program, LLC proficiency testing program for laboratories analyzing beryllium on filter media.
BSC	Biological Safety Cabinet
BSL	Biological Safety Level
Batch	A group of samples that are processed in one operation: considered to be a uniform, discrete unit.
Bias	An estimate of a systematic measurement error
Blind Sample	A sample submitted for analysis with a composition and identity known to the submitter, but unknown to the analyst, and used to evaluate proficiency in the execution of the measurement process.
CAB	Conformity Assessment Body; A body that performs conformity assessment services and that can be the object of accreditation. (i.e a testing laboratory, calibration laboratory, inspection body)
CCB	Continuing Calibration Blank, see "Calibration Verification Blanks"
CCV	See "*Continuing Calibration Verification (CCV)*"
CDC	Centers for Disease Control
CFR	Code of Federal Regulations
CIPM	International Committee for Weights and Measures *(Comité International des Poids et Mesures)*
CMMEF	Compendium of Methods for the Microbiological Examination of Foods
CRC	Certified Reference Culture
Calibration	1) Process used to establish a relationship, with determined uncertainty, between analyte concentration and instrument response. 2) An operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication. (VIM 2.39 JCGM 200:2012).
Calibration Blank	A matrix matched material lacking analyte used in the construction of a calibration curve.
Calibration Curve	Expression of the relation between indication and corresponding measured quantity value. A calibration curve expresses a one-to-one relation that does not supply a measurement result as it bears no information about the measurement uncertainty.
Calibration Verification Blanks	Calibration Verification Blanks (ICB and CCB) demonstrate

TERM AND/OR ACRONYM	DEFINITION
	that the instrument is able to return to baseline after the analyte is detected. They also provide a means to monitor instrument baseline drift.
Calibration Standard	A matrix matched material prepared at a known amount of analyte from a reference material and used to construct a calibration curve.
Certification	Third-party attestation related to products, processes, systems or persons. Certification is applicable to all objects of conformity assessment except for conformity assessment bodies themselves, to which accreditation is applicable.
Certified Reference Material (CRM)	A reference material, accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities, using valid procedures (VIM 5.14 JCGM 200:2012)
Chain of Custody	Definitive evidence (a record) of the persons who had possession or custody of the sample(s) for all periods of time, as it moved from the point of 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 or deficiency in order to prevent recurrence. See "*Deficiency" and* "*Technical Systems Audit.*"
Customer	Any person or organization that engages the services of a laboratory.
Deficiency	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

TERM AND/OR ACRONYM	DEFINITION
	requirements. See also Nonconformity.
Define	See: Document [verb].
Demonstration of Competency (DOC)	Documented proof that an analyst can perform a given method and, using it, obtain results having the accuracy and precision appropriate for that method. For AIHA-LAP, LLC purposes, a DOC can consist of PT, round robin, internal proficiency testing, or internal quality control results.
Demonstration of Proficiency (DOP)	Documented proof that a laboratory can perform a given Field of Testing and, using it, obtain results having the accuracy and precision appropriate for that FOT. For AIHA-LAP, LLC purposes, a DOP can take the form of a round robin, an internal or external proficiency testing program, or internal quality control, as described in AIHA-LAP policies 6.1 through 6.4.
Denial	The decision not to grant a laboratory initial accreditation.
Deviation (Procedural)	A departure from written procedures, test methods, contracts or any other standard operating procedure that is part of the laboratory quality assurance system. May or may not be considered a nonconformity.
Document [verb]	Record, substantiate or annotate for retrieval later. Source (ISO 30300:2011(en) Information and documentation — Management systems for records — Fundamentals and vocabulary; 3.3.6)
Document	Information and its supporting medium. Source (ISO 14005:2010(en)Environmental management systems — Guidelines for the phased implementation of an environmental management system, including the use of environmental performance evaluation; 2.6)
Duplicate Analyses or Measurements	The analyses or measurements of the variable of interest performed identically on two subsamples of the same sample. The results from duplicate analyses are used to evaluate analytical or measurement precision but not the precision of sampling, preservation or storage internal to the laboratory.
Duplicate Samples	Two samples taken from and representative of the same population and carried through all steps of the sampling and analytical procedures in an identical manner. Duplicate samples are used to assess variance of the total method including sampling and analysis.
Dust Wipe	A sample collected by wiping a representative surface of known area with an acceptable wipe material.
EPA	Environmental Protection Agency
Environmental Lead Laboratory Accreditation Program (ELLAP)	The AIHA-LAP, LLC accreditation program, complying with the requirements of the EPA National Lead Laboratory Accreditation Program (NLLAP) Laboratory Quality System Requirements (LQSR), AIHA-LAP, LLC requirements and the ISO/IEC 17025 Standard and ISO/IEC 17011 requirements.

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

TERM AND/OR ACRONYM	DEFINITION
	from a fixed site location associated with improved real estate.
Food Laboratory Accreditation Program (FoodLAP)	This AIHA-LAP, LLC program is intended for the accreditation of food testing laboratories. This program complies with AIHA-LAP, LLC requirements, the ISO/IEC 17025 Standard, AOAC requirements (when applicable) and ISO/IEC 17011 requirements.
GC	Gas Chromatography
GC/MS	Gas Chromatography/Mass Spectroscopy
GFAA	Graphite Furnace Atomic Absorption Spectroscopy
HPLC	High Performance Liquid Chromatography
HUD	Housing and Urban Development
IC	Ion Chromatography
ICB	Initial Calibration Blank
ICP-AES	Inductively Coupled Plasma – Atomic Emission Spectroscopy
ICP-MS	Inductively Coupled Plasma – Mass Spectroscopy
ICS	Interference Check Standard
ICV	See "*Initial Calibration Verification (ICV)*"
ILAC	International Laboratory Accreditation Cooperation
ILAC MRA	International Laboratory Accreditation Cooperation Mutual Recognition Arrangement
IR	Infra-Red Spectroscopy
ISE	Ion Selective Electrode
ISO/IEC	International Organization for Standardization/International Electrotechnical Commission – nonprofit organizations that develop 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

TERM AND/OR ACRONYM	DEFINITION
	manufacturer's lot identification or as an independent preparation from a neat material).
Instrument	A device used for observation or measurement or chemical analysis that yields test results.
Instrumental Drift	The continuous or incremental change over time in indication, due to changes in metrological properties of a measuring instrument.
Internal Proficiency Testing Program	A program based on multiple analyses of SRMs, CRMs, or stand-ins for such when none are commercially available, in adherence to Module 6.
Internal Quality System Audit	An audit of the laboratory's Quality Management System, conducted by quality management personnel or persons contracted by the laboratory, to ensure compliance with external organization (AIHA-LAP, LLC and ISO/IEC 17025) and internal quality requirements (See ISO/IEC 17025, Section 4.14).
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.
In-House Quality Control Samples	Laboratory prepared samples containing analyte and media which are taken through the analytical procedure
International Vocabulary of Metrology	Basic and general concepts and associated terms (VIM), JCGM 200:2012
LC	Liquid Chromatography
LIMS	Laboratory Information Management System
LQSR	Laboratory Quality System Requirements of US EPA for recognition by NLLAP
Laboratory	An entity that tests, either at a fixed site, mobile facility or field operations facility. Also referred to as a CAB.
Laboratory Blank	Same as Method Blank
Laboratory Control Sample (LCS)	A matrix-based reference material with an established concentration obtained from a source traceable to NIST or other similar reference materials. The LCS is carried through the entire procedure from sample preparation through analysis as if it were a field sample. The purpose of the LCS is to evaluate bias of the method.
Laboratory Control Sample Duplicate (LCSD)	A duplicate of the LCS.
Lot	A batch of chemicals or sampling media manufactured at the same time.
Management Review	A wholesale review of the laboratory's management system and testing activities to determine whether or not the laboratory's quality management system meets the organization's ongoing management goals and requirements. (see ISO/IEC 17025 Section 4.15).

TERM AND/OR ACRONYM	DEFINITION
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 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.
	A failure to comply with a requirement of the AIHA-LAP, LLC

TERM AND/OR ACRONYM	DEFINITION
Nonconformity	accreditation program(s) requirements, ISO/IEC 17025 or a laboratory's own stated management system requirements.
Non-Standard Method	Method not meeting the definition of "*Standard Method*" contained in this module.
Objective	Objective-result to be achieved. Source (ISO 9000:2015(en) Quality management systems — Fundamentals and vocabulary; 3.7.1)
OSHA	Occupational Safety and Health Administration
PT	See "*Proficiency Testing*"
Policy	~~An organization's written statement of commitment to implement a management program element.~~Intentions and direction of an organization as formally expressed by its top management. Source (ISO 9000:2015(en) Quality management systems — Fundamentals and vocabulary; 3.5.8)
Precision	Closeness of agreement between indications or measured quality values obtained by replicate measurement on the same or similar objects under specified conditions. Measurement precision is usually expressed numerically by measures of imprecision, such as standard deviation, variance or coefficient of variation under the specified condition of measurement.
Preventive Action	A proactive planned activity to identify, recognize and control potential sources of nonconformities and to introduce needed improvements.
Procedure	~~A written set of instructions that describe how to implement a policy requirement, or how to carry out a specific task.~~ 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.
	The suitability of a product or service for use, as perceived

TERM AND/OR ACRONYM	DEFINITION
Quality	by the user.
Quality Assurance (QA)	An integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure a product or service meets defined standards of quality within a stated level of confidence.
Quality Assurance Program	See "*Quality Assurance*."
Quality Control (QC)	Technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users. The aim is to provide quality that is satisfactory, adequate, dependable and economical.
Quality Manager (QM)	An employee of an accredited laboratory, having quality assurance responsibilities. ~~Responsibilities required for accreditation by AIHA-LAP, LLC are given in AIHA-LAP, LLC policies 2A.5.2.1.2).~~
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 the two (2) values.
Replicate	A sample analyzed multiple times in order to evaluate the precision of an instrument or procedure.

TERM AND/OR ACRONYM	DEFINITION
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 describes a solution or substance commonly prepared by the analyst to establish a calibration curve or the analytical response function of an instrument.
Standard Method	Procedures recommended by national or international agencies, such as the Environmental Protection Agency (EPA), the National Institute for Occupational Safety and Health (NIOSH), ASTM International, AOAC International, the American Public Health Association (APHA), or the Occupational Safety and Health Administration (OSHA).
Standard Operating Procedure (SOP)	A written document that details the procedures of an operation; an analysis or action whose techniques and procedures are thoroughly prescribed, and which are accepted as the procedure for performing certain routine or repetitive tasks.

TERM AND/OR ACRONYM	DEFINITION
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 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's Laboratory Accreditation Programs (IHLAP, ELLAP, EMLAP and FoodLAP) 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.

TERM AND/OR ACRONYM	DEFINITION
Unique Scopes Laboratory Accreditation Program	The AIHA-LAP, LLC accreditation program for areas of testing not addressed under other AIHA-LAP, LLC programs. This program complies with AIHA-LAP, LLC requirements and the ISO/IEC 17025 Standard and ISO/IEC 17011 requirements.
USDA	United States Department of Agriculture
US EPA	United States Environmental Protection Agency
USP	United States Pharmacopeia
UV-VIS	Ultra Violet-Visible Spectroscopy
Uncertainty of Measurement	Result of the evaluation aimed at characterizing the range within which the true value of a test result is estimated to lie, generally within a given likelihood. Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.
Verification	Provision of objective evidence that a given item fulfils specified requirements. For example – Confirmation that a given reference material as claimed is homogeneous for the quantity value and measurement procedure concerned
VIM	Same as International vocabulary of metrology – Basic and general internationally-accepted concepts and associated terms
WASP	Workplace Analysis Scheme for Proficiency (Great Britain PT Provider)
WHO	World Health Organization
Withdrawal	The removal of a laboratory's existing accreditation.
WPCF	Water Pollution Control Federation
XRD	X-Ray Diffraction
XRF	X-Ray Fluorescence Spectroscopy

APPENDIX H

TRACEABILITY OF MEASUREMENT

Table of Contents

1. SCOPE

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

2. REFERENCES

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

- **AIHA-LAP, LLC Policy Appendix G on the Estimation of Uncertainty of Measurement**
- **CALA A61, CALATraceability Policy, Canadian Association for Laboratory Accreditation** ~~CALA A61 http://www.cala.ca/A61-CALA_Trac.pdf~~
- ISO/IEC 17025:~~2005~~2017, **General requirements for the competence of testing and calibration laboratories,**
- ILAC P10:01/2013, **ILAC Policy on the Traceability of Measurement Results,** ~~http://ilac.org/publications-and-resources/ilac-documents/procedural-series/~~International Laboratory Accreditation Cooperation
- VIM JCGM 200:2012, **International vocabulary of metrology — Basic and general concepts and associated terms (VIM)** published by (BIPM, IEC, IFCC, ILAC, ISO, IUPAC, IUPAP and OIML**,** ~~VIM JCGM 200:2012~~
- **Metrological Traceability Of Measurement Results In Chemistry: Concepts And Implementation (IUPAC Recommendations 2009),** International Union of Pure and Applied Chemistry (IUPAC), Paul De Bièvre1, René Dybkaer, Aleš Fajgelj And D. Brynn Hibbert,
- *EURACHEM/CITAC Guide: Traceability in Chemical Measurement – A guide to achieving comparable results in chemical measurement* (2003)
- Meeting the traceability requirements of ISO 17025: An Analyst's Guide, 3rd edition

3. TERMS AND DEFINITIONS

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

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

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

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

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

EXAMPLE 1: 1 kg mass measurement standard with an associated standard measurement uncertainty of 3 µg.

EXAMPLE 4: Standard buffer solution with a pH of 7.072 with an associated standard measurement uncertainty of 0.006

EXAMPLE 6: Reference material providing quantity values with measurement uncertainties for the mass concentration of each of ten different proteins.

NOTE 2 A measurement standard is frequently used as a reference in establishing measured quantity values and associated measurement uncertainties for other quantities of the same kind, thereby establishing metrological traceability through calibration of other measurement standards, measuring instruments, or measuring systems.

NOTE 5 Quantity value and measurement uncertainty must be determined at the time when the measurement standard is used.

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

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

Measurement Uncertainty (uncertainty of measurement) (uncertainty): non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used (VIM 2.26 JCGM 200:2012)

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

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

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

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

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

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

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

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

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

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

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

NOTE 7 The ILAC considers the elements for confirming metrological traceability to be an unbroken **metrological traceability chain** to an **international measurement standard** or a **national measurement standard,** a documented measurement uncertainty, a documented measurement procedure, accredited technical competence, metrological traceability to the **SI**, and calibration intervals (see ILAC P-10:2002).

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

Metrological Traceability to a measurement unit: metrological traceability where the reference is the

definition of a measurement unit through its practical realization. (VIM 2.43 JCGM 200:2012)

NOTE: The expression “traceability to the SI” means ‘metrological traceability to a measurement unit of the International System of Units’.

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

ILAC encourages BIPM and regional bodies to conduct and publish details of as broad a range of international comparisons as possible to provide transparency on the equivalence and linkages of national measurement standards, which underpin accreditation activities. ILAC has taken note that the results of international comparisons carried out in the scope of the Metre Convention are published in Appendix B of the CIPM MRA (www.bipm.org).

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

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

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

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

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

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

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

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

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

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

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

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

NOTE 1 Calibration may be obtained directly between a primary measurement standard and a secondary measurement standard, or involve an intermediate measuring system calibrated by the primary measurement standard and assigning a measurement result to the secondary measurement standard.

NOTE 2 A measurement standard having its quantity value assigned by a ratio primary reference measurement procedure is a secondary measurement standard.

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

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

(CALA/AIHA-LAP, LLC) A procedure normally associated with the acquisition of data regarding an instrument to provide some indication as to whether it is operating within expected tolerances. For example, weights may be placed on a balance and the reading can provide some indication as to whether the balance is operating within expected tolerances. This operation should not be confused with **calibration**. Verification does not establish traceability. Verification seeks only to determine whether or not the instrument is operating within its expected tolerances. It is not a method of establishing the expanded uncertainty, which is the core issue in a *calibration*.
Note that manufacturer's tolerances, as provided in data sheets and instrument manuals, will use the same method of expression as an uncertainty, such as +/- 3% or +/- 4 grams.
These are still only *tolerances* and should not be confused with the expanded *uncertainties* associated with the measurement result.

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

4. BACKGROUND

ISO/IEC 17025:2017, section ~~5.6~~6.5 requires ~~conformant~~ laboratories to demonstrate that the results

produced by their measuring systems are traceable in accordance with the international definition of that term. See the definition for metrological traceability above and the ***International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*** (VIM JCGM 200:2012).

This allows

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

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

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

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

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

5. TRACEABILITY OF MEASUREMENT POLICY

The requirement which underlies this policy is given in ISO/IEC 17025:2017, Clause ~~5.6.~~6.5

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

5.2 External calibration services shall, wherever possible, be obtained from providers accredited to ISO/IEC 17025 by an ILAC recognized signatory, a CIPM recognized National Metrology Institute (NMI), or a State Weights and Measures Facility that is part of the NIST Laboratory Metrology Program. Calibration certificates shall be endorsed by a recognized accreditation body symbol or otherwise make reference to accredited status by a specific, recognized accreditation body, or contain endorsement by the NMI. Certificates shall indicate traceability to the SI or reference standard and include the measurement result with the associated uncertainty of measurement.

5.3 Where traceability to the SI is not technically possible or reasonable, the laboratory shall use certified reference material provided by a competent supplier, or use specified methods and/or consensus standards that are clearly described and agreed to by all parties concerned. A competent supplier is an NMI or an accredited reference material producer (RMP) that conform with ISO Guide 34 in combination with ISO/IEC 17025. ~~, or ILAC Guidelines for the Competence of Reference Material Producers, ILAC G12.~~ Conformance is demonstrated through accreditation by an ILAC recognized signatory.

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

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

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

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

5.7 Periodic verifications shall be performed to demonstrate the continued validity of the calibration at specified intervals between calibrations. The frequency of verifications can be

dependent on the uncertainty required, the frequency of use, the manner of use, stability of the equipment, and risk of failure considerations.

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

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

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

Reference Standard / Equipment	Calibration Frequency	Verification Frequency
Reference Thermometer	Initial and as determined by the laboratory	Not applicable
Working Thermometer	Not Applicable	As defined by the laboratory
Reference Masses	Initial and as determined by the laboratory	Not applicable
Working Masses	NA	As defined by the laboratory
Stage Micrometer	Initial and as determined by the laboratory	As defined by the laboratory
Balance	Initial and as determined by the laboratory	As defined by the laboratory
Mechanical Pipettes	Initial and as determined by the laboratory	As defined by the laboratory
Volumetric Containers for critical functions ~~(non-Class A or B)~~	Initial and as determined by the laboratory~~Not applicable~~	As defined by the laboratory

NOTE 1: For some laboratories, this list may not be complete. It is the responsibility of each laboratory to

identify all reference standards and support equipment whose calibration has a significant impact on analytical uncertainty.

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

NOTE 3: Laboratories should be mindful of ISO/IEC 17025, clause ~~5.6.1~~6.4.7 when developing the schedule, "The laboratory shall establish a calibration programme, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.~~All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the results of the rest, calibration or sampling shall be calibrated before being put into service. The laboratory shall have an established programme and procedure for the calibration of its equipment.~~"

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

6. AOAC ADDITIONAL FOOD LABORATORY REQUIREMENTS

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

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

7. GUIDANCE ON IMPLEMENTING THIS POLICY

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