



MODULE 2A GENERAL MANAGEMENT SYSTEM REQUIREMENTS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

NOTE: These requirements also apply to reagents and standards.

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

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

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

2A.6.6 Externally Provided Products and Services (See ISO/IEC 17025:2017, Section 6.6)

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

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

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

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

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

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

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

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

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

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

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

2A.7.6.1 Test methods are classified as either qualitative or quantitative. Qualitative tests are defined as having non-numerical results. Although 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 Evaluation of Measurement Uncertainty, Policy Appendix G. Refer to the AIHA-LAP, LLC, *Guidance on the Evaluation of Measurement Uncertainty*, on the AIHA-LAP, LLC website for additional information on measurement uncertainty.

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

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

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

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

2A.7.7.1 As part of the quality assurance program, the laboratory shall adhere to all stated QA/QC requirements in the methods used and any additional requirements defined in Modules 2B-2F. Any deviations from these procedures shall be documented. The laboratory shall determine, where feasible, the accuracy and precision of all analyses performed. Procedures shall be in place to estimate the uncertainty of measurement of all calibrations and test methods. At a minimum, the following QC checks shall be performed per batch of samples.

2A.7.7.1.1 Blanks

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

2A.7.7.1.2 Acceptance Limits

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



2A.7.7.1.3 Control Charts

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

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

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

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

2A.7.8.1 Final test reports shall also include:

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

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

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

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

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

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

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

2A.7.10.1 Any outlier from a PT (external or internal), Round Robin, or Demonstration of Policy Module 2A – General Management System Requirements



Competency shall be addressed as a nonconforming event.

2A.7.11 Control of Data and Information Management (See ISO/IEC 17025:2017 Section 7.11)

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

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

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

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

2A.8.3 Control of management system 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 (Option A) (See ISO/IEC 17025:2017, Section 8.7)

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

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

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

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

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

2A.8.10 Management system 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.9 SAFETY AND HEALTH

Laboratories are expected to follow applicable jurisdictional regulations regarding safety and health. Examples in the United States would include OSHA Standard 29 CFR 1910.1450, "Occupational Exposures to Hazardous Chemicals in Laboratories." or 29 CFR 1910.1200 "Hazard Communication",



though it is recognized that laboratories outside the United States may have regulations different than these examples. As part of the application for accreditation or reaccreditation, on behalf of the organization seeking accreditation, the manager shall provide a written statement that the laboratory complies with all applicable standards. The AIHA-LAP, LLC assessor shall not perform a safety inspection of the laboratory; however, he/she shall verify that a written chemical hygiene plan (and biosafety plan for EMLAP laboratories) exists for the laboratory operation.