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## MODULE 2A GENERAL MANAGEMENT SYSTEM REQUIREMENTS

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

Laboratories shall meet all requirements of the ISO/IEC 17025:2005 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 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 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.

### 2A.2 NORMATIVE REFERENCES (See ISO/IEC 17025:2005, Section 2)

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

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

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

#### 2A.4.1 Organization (See ISO/IEC 17025:2005, 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 must perform the Field(s) of Testing (FoT) for which the accreditation is sought.

#### 2A.4.2 Management System (See ISO/IEC 17025:2005, 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 and shall be consistent with the requirements of ISO/IEC 17025:2005, QA/QC requirements of the approved methods used, and other AIHA-LAP, LLC-specific requirements detailed in this module. The QA Manual shall address, but not be limited to, the following elements:

- a) Title Page
- b) Table of Contents
- c) Quality Manual Maintenance and Update Procedures

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- d) Customers' confidential information and proprietary rights
- e) Impartiality and Operational Integrity
- f) Organization and Responsibility
- g) Quality Assurance Objectives and Policies
- h) Document Control
- i) Review of Requests, Tenders, and Contracts
- j) Purchasing of Services and Supplies
- k) Service to the Customer
- l) Complaints
- m) Control of Nonconforming Testing Work
- n) Corrective Action
- o) Preventive Action
- p) Control of Records
- q) Internal Audits
- r) Personnel Qualifications and Training
- s) Analytical Methods
- t) Equipment Calibration and Maintenance Procedures
- u) Reagents and Standards
- v) Sampling Materials and Procedures
- w) Handling of Test Items
- x) Sample Retention and Disposal
- y) Internal Quality Control Procedures
- z) Data Reduction, Validation and Reporting
- aa) Quality Assurance Reports
- bb) Reference to other Management System Documentation

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 Document Control (See ISO/IEC 17025:2005, Section 4.3)**

**2A.4.4 Review of Requests, Tenders and Contracts (See ISO/IEC 17025:2005, Section 4.4)**

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

2A.4.5.1 Unless directed otherwise by a client or regulatory agency, an AIHA LAP, LLC accredited laboratory shall be used for subcontracted work for Fields of Testing covered by the scope of accreditation of the primary facility.

**2A.4.6 Purchasing Services and Supplies (See ISO/IEC 17025:2005, Section 4.6)**

**2A.4.7 Service to the Customer (See ISO/IEC 17025:2005, Section 4.7)**

**2A.4.8 Complaints (See ISO/IEC 17025:2005, Section 4.8)**

**2A.4.9 Control of Nonconforming Testing and/or Calibration Work (See ISO/IEC 17025:2005, Section 4.9)**

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**2A.4.10 Improvement (See ISO/IEC 17025:2005, Section 4.10)**

**2A.4.11 Corrective Action (See ISO/IEC 17025:2005, Section 4.11)**

**2A.4.11.1** The laboratory shall document and keep records of all nonconforming events, the determined cause(s), and corrective actions taken. See ISO/IEC 17025:2005 4.9.2 and 17025:2005 4.13.1.1.

**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** The procedures shall include the manner and duration of record retention.

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**2A.4.13.2** All laboratory records shall be maintained for at least three (3) years.

**2A.4.13.3** Computer records are satisfactory without hard copy files, provided copies can be produced as needed and data edits are documented within the computer files.

**2A.4.13.4** Corrections to laboratory records shall be dated.

**2A.4.13.5** 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 Internal Audits (See ISO/IEC 17025:2005, Section 4.14)**

**2A.4.14.1** Internal quality assurance audits shall be conducted at least annually.

**2A.4.14.2** Internal quality assurance audits shall verify compliance with AIHA-LAP, LLC requirements.

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**2A.4.14.3** Audit results shall be shared, as appropriate, with laboratory personnel.

**2A.4.15 Management Reviews (See ISO/IEC 17025:2005, Section 4.15)**

**2A.4.15.1** Management reviews shall be conducted at least annually.

**2A.4.15.2** Management review results shall be shared, as appropriate, with laboratory personnel.

**2A.4.15.3** 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** Personnel shall meet the following minimum criteria in order for the laboratory to be accredited or re-accredited. The AAB shall consider individuals not meeting the following criteria on a case-by-case basis.

### 2A.5.2.1.1 Technical Manager

The laboratory shall provide day to day supervision of its technical operations by designating at least one Technical Manager (TM) per program. The TM shall be an employee of the laboratory. The TM shall possess a bachelor's degree in an applicable physical or biological science. The TM shall 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. The TM shall authorize and document that all analyses for which the laboratory is accredited are completed by personnel with appropriate education and/or technical background. The TM shall ensure that adequate supervision is provided for all laboratory technical personnel. The Technical Manager or their designee shall function as the approved signatory. Specific TM qualifications for each program are given in modules 2B through 2F.

**2A.5.2.1.2** Quality Manager (QM) The individual who functions as the Quality Manager of the laboratory shall possess a bachelor's degree in an applicable basic or applied science and have at least one year of nonacademic analytical or quality control experience appropriate to the types of analyses performed by the laboratory; or in lieu of a bachelor's degree, four years of nonacademic analytical or quality control experience. The Quality Manager shall have documented training in statistics or laboratory quality assurance/quality control. The Quality Manager may be a part-time employee or a consultant.

NOTE Appropriate documentation of training in statistics or laboratory quality assurance/quality control shall include at least one of the following: 1) College level course in statistics; 2) Continuing education in laboratory quality assurance/quality control (e.g., AIHA-LAP, LLC or equivalent course); or 3) Relevant experience – documented examples of the level of quality assurance/quality control used in applicable work experience.

### 2A.5.2.1.3 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 must be documented. Analysts shall be responsible for complying with all quality assurance and quality control requirements pertaining to their technical functions.

Program specific requirements for analytical staff, such as secondary education, advanced degrees, years of experience, or other specific training requirements, if applicable, may be found in Modules 2B-2F.

Note: Laboratory Information Management Systems (LIMS) Specialist is a position recommended for laboratories with sophisticated data handling systems; however, it is

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- Deleted: minimum experience required for each LQAP is defined in Modules 2B-2F for each program. This employee shall be responsible for all technical operations, as well as the functioning and administration of the laboratory in such a manner that provides the necessary resources needed to ensure the required quality of laboratory operations. This individual shall also be responsible for the implementation of any corrective actions performed at the laboratory. He/she shall be available during at least 50 percent of the laboratory operating hours to address technical issues for laboratory staff and customers and acceptable onsite supervision must be demonstrated.

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not required for accreditation. The LIMS Specialist is the individual responsible for the operation, validation, and implementation of the laboratory information management system. LIMS consist of the computer and software used to identify, schedule, prioritize, perform calculations, generate reports, store results, and perform any other computerized function necessary to control the flow of samples through the laboratory. This person should have a bachelor's degree and/or appropriate laboratory and/or computer skills and education.

#### 2A.5.2.1.5 Combined Positions

The laboratory staff may consist of a Technical Manager, a Quality Manager, laboratory analyst(s), and technician(s), as needed. If a single individual serves in more than one position, then this individual must meet all position qualifications and responsibilities. If this individual also performs analytical work, then his/her analytical work must be reviewed on-site by a second qualified individual. See definition of "Qualified Individual (for data review)" in Module 9 – Glossary.

**Note:** In large laboratories, a first line supervisor, however named, may be designated as a Technical Manager.

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**2A.5.2.2** The laboratory shall have sufficient personnel to allow for all QA/QC to be performed on site. Quality Manager's responsibilities may be fulfilled by qualified designees.

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**2A.5.2.3** Job descriptions shall include required qualifications, experience, education, training and managerial duties.

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**2A.5.2.4** 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.

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**2A.5.2.5** Training shall be documented in laboratory records and include a description of the content and duration of the program.

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

**2A.5.3.1** All chemicals, compressed gases, glassware and waste materials, etc. shall be appropriately stored and/or contained.

**2A.5.3.2** Ventilation hood face velocities shall be appropriate and shall be measured and recorded at least semiannually (annually, if alarmed).

**2A.5.3.3** Work surfaces shall be nonporous or have a nonporous coating.

**2A.5.3.4** Lunch areas, if provided, shall be separate from the testing area. Consumption of food or beverages shall not be permitted in the testing areas. Smoking shall not be permitted in the testing area.

**Note:** The ventilation system should be adequate for controlling chemical exposure to employees consistent with requirements of OSHA standards or equivalent national or

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international standards.

**Note.** All electrical circuits should be grounded and ground fault interrupted (GFI) circuits should be available where appropriate.

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

**2A.5.4.1** Procedures recommended by the Environmental Protection Agency (EPA), the National Institute for Occupational Safety and Health (NIOSH), ASTM International (formerly American Society for Testing and Materials), AOAC International (formerly Association of Official Analytical Chemists), the American Public Health Association (APHA), the Occupational Safety and Health Administration (OSHA), or other national or international agencies may be acceptable if the laboratory has verified acceptable method performance applicable to the FoT. Alternate procedures and/or modifications of existing methods may be used if they have been validated and documented by the laboratory.

**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, and have no uncertainty requirements. For quantitative tests, laboratories shall determine measurement uncertainty using appropriate statistical techniques. Refer to the AIHA-LAP, LLC guidance document, Guidelines for Uncertainty Estimation, 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** An equipment log shall be maintained for each major item of equipment. Records shall be maintained in the equipment log that documents preventive maintenance and repairs, including those performed by laboratory personnel. The name or initials of the person performing the maintenance or repair shall be recorded.

**2A.5.5.2** Equipment critical to the generation of the test results shall be subject to

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performance checks prior to use for analysis of samples. Such checks may include evaluation of instrument sensitivity, alignment, linearity, noise level and/or response levels versus historical values. Acceptance criteria for these checks shall be stated in the analytical method.

**2A.5.5.3** Results of the function and calibration status checks required for equipment that goes outside the direct control of the laboratory (see ISO/IEC 17025:2005, Section 5.5.9) shall be documented.

**2A.5.5.4** Calibration procedures shall specify frequency of calibration checks.

**2A.5.5.5** When possible, any external calibration service used must be a calibration laboratory accredited to ISO/IEC 17025:2005 by a recognized accreditation body.

**2A.5.5.6** Where appropriate, cleaning procedures for glassware and apparatus shall be specified by the laboratory and shall be appropriate for the method specifications.

#### **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** Reference materials shall have a certificate of analysis that shows specific NIST-traceability, or equivalent, and uncertainty, when possible. The certificate must show the specific SRM<sup>®</sup> used for traceability.

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**2A.5.6.6** 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.

**Note:** Refer to the [AIHA-LAP, LLC](#) guidance document, [Guidelines for Traceability](#), for additional information on traceability.

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

**2A.5.7.1** Information regarding sampling materials, sampling containers, preservatives, and shipping instructions shall be available to clients through the laboratory.



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**2A.5.7.2** Where appropriate, the laboratory shall request that customers submit field blanks with their samples.

**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.5.8.2** A sample log (computerized or handwritten) shall be used to record the receipt of all samples and blanks. This log shall contain, at a minimum, the following:

- a) Sample and batch identification
- b) Date received
- c) Customer identification

**2A.5.8.3** If a batch identification system is used, each sample shall be identified by a unique identifier.

**2A.5.8.4** The laboratory shall confirm that the requested test can be performed on the sample according to the laboratory's standard operating procedures.

**2A.5.8.5** The sample storage, retention and disposal procedures of the laboratory shall be stated. These policies shall include the manner and duration of sample retention and disposal.

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**2A.5.8.6** Laboratories are expected to follow all federal, state and local regulations regarding environmental contamination and waste disposal.

**2A.5.8.7** Stable samples may be retained for use in the laboratory's internal quality control program.

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

**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. Deviations that result in nonconforming work shall be immediately evaluated. 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 Accuracy and Bias**

Accuracy studies are performed to determine how close a measurement comes to an actual or a theoretical value. Regular use of certified reference materials (CRM) is required. 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



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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.

#### 2A.5.9.1.2 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.5.9.1.3 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. Customers of the laboratory should supply specimens of blank sampling media from the same source lot as was used for collecting the field samples.

#### 2A.5.9.1.4 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. Some methods have listed acceptance criteria for applicable analytes based on determinations by a single laboratory, or the compilation of data from many laboratories, or limits that are assumed or expected. Laboratories should realize these method performance limits might be too broad to define accurate acceptance criteria for their particular laboratory conditions. These limits are best used as guidelines during the initial phases of method use and are superseded when the laboratory has collected sufficient self-generated data for proper statistical evaluation.

#### 2A.5.9.1.5 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 in place 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) Modification to the test method, if applicable
- c) Date of sample receipt
- d) Page numbers on each page, and either "x of y" page numbering or a clear indication of the end of the report.

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#### 2A.5.10.2 The approved signatory shall be the Technical Manager or his/her designee.



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**2A.5.10.3** Test results not covered under AIHA LAP, LLC accreditation shall be clearly identified on the final test report.

**2A.5.10.4** 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.5.10.5** The final report shall state the measured quantitative result of the analysis of any blank samples submitted to the laboratory. Also, a statement must be made that discloses whether or not the sample results have been corrected for contamination based on the field blank or other analytical blank.

**2A.5.10.6** The number of significant figures reported should reflect the precision of the analysis.

**2A.6 SAFETY AND HEALTH**

Laboratories are expected to follow applicable federal, state and local regulations regarding safety and health, for example, OSHA Standard 29 CFR 1910.1450, "Occupational Exposures to Hazardous Chemicals in Laboratories." 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 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.

- Reagents and Standards
- Equipment Calibration and Maintenance Procedures
- Analytical Methods
- Data Reduction, Validation and Reporting
- Internal Quality Control Procedures
- Internal Audits
- Corrective and Preventive Actions
- Customer Communications
- Quality Assurance Reports
- Document Control and Control of Records
- Sample Retention and Disposal
- Reference to other Management System Documentation

**2A.4.3.1 The document control policies of the laboratory shall be stated.**

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