



MODULE 3

ACCREDITATION, MAINTENANCE AND REACCREDITATION PROCESSES

3.1 INITIAL ACCREDITATION

Laboratories wishing to obtain accreditation under any of the American Industrial Hygiene Association Laboratory Accreditation Programs (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 and 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 6A, Sections 6A.2.7 and 6A.3.6 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. An additional application fee may be required when the laboratory reapplies for accreditation in the FoT(s) initially 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 Modules 6A – 6F, and Appendices A-F by AIHA PAT Programs or an equivalent proficiency testing program approved by AIHA-LAP, LLC. 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. The cost of proficiency testing programs shall be borne by the participating laboratory.



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 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 maintained on the AIHA-LAP, LLC website (www.aihaaccreditedlabs.org). The accreditation application and Quality Manual 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. If the application is complete, it shall be forwarded to a site assessor for continuation of the accreditation process.

3.3.3 If the application is incomplete, AIHA-LAP, LLC staff shall work 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. If the laboratory requests that any of the submitted materials be returned to the laboratory, then AIHA-LAP, LLC shall make copies of the original materials and return the copies to the laboratory. The original 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 Quality Manual to the assigned site assessor for review. A laboratory shall be notified in advance of the site assessor's identity and shall be permitted one rejection of an assessor. If a laboratory believes that a particular assessor may represent a conflict of interest, the laboratory may reject any assessors assigned, 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. Staff shall then contact the laboratory, in writing, 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).

If the laboratory chooses to stop the accreditation process by not addressing the critical deficiencies, then the site assessor shall return all laboratory application materials to AIHA-LAP, LLC, who shall send a letter to the laboratory documenting the laboratory decision to stop the process. The application fee shall be forfeited and 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 AAB and the laboratory. The laboratory shall bear all costs associated with the site assessment based upon the current year's Fee Schedule maintained on the AIHA-LAP, LLC website (www.aihaaccreditedlabs.org). 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 shall be asked to complete a feedback form. 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 17025:2005 Standard and AIHA-LAP, LLC policy requirements, to evaluate the laboratory during the site assessment portion of the accreditation process. The AAB shall approve the laboratory site assessment checklist prior to use by the site assessor. 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 suggestions, 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 assessment to AIHA-LAP, LLC 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 Suggestions are recommended activities for improving laboratory performance. The laboratory shall address these issues with a response; however, suggestions do not require proof of conformity for accreditation.



3.5.3 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.

3.5.4 The laboratory shall respond in writing to all of the deficiencies and suggestions to the site assessor and AIHA-LAP, LLC within twenty (20) business days of completion of the site assessment. 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.

3.5.5 If the laboratory fails to respond to the site assessor and AIHA-LAP, LLC regarding deficiencies and suggestions within twenty (20) business days of completion of the site assessment, then AIHA-LAP, LLC may send a certified letter to the laboratory informing them that they have ten (10) business days from the date of the letter 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.

3.5.6 If the laboratory responses to the deficiencies and suggestions 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 and suggestions. 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.

3.5.7 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. 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 to the Chief Site Assessor that the laboratory be denied accreditation. If the Chief Site Assessor concurs with this recommendation to deny accreditation, then all laboratory records related to the accreditation process are submitted to the Technical Advisory Panel (TAP) for review and evaluation (see Section 3.6, *Technical Advisory Panel Review*).

3.5.8 A *Follow-Up Site Assessment* is an on-site check on the implementation of the laboratory's deficiency responses to the routine site assessment. The site assessor may recommend a follow-up assessment at the close of the routine assessment or after receiving the laboratory responses to the routine assessment. A follow-up assessment must be approved by the Director of AIHA Affiliate Laboratory Programs and, if approved, must be completed prior to granting accreditation or reaccreditation. A follow-up assessment may be required if the site assessment has revealed a large number of deficiencies, significant repeat deficiencies, or if 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.

3.5.9 A *Surveillance Site Assessment* is a site assessment performed between routinely scheduled assessments and after the granting of accreditation or reaccreditation. It may be a full assessment or focus on specific programs or problem areas. Surveillance site assessments may be required due to a credible complaint, high personnel turnover, a large number of deficiencies during the most recent routine assessment, repeat deficiencies, poor proficiency testing performance, or any other reason(s) that call into question the laboratory's compliance with accreditation requirements. The Analytical Accreditation Board 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 will bear all costs associated with the site assessment based upon a predetermined fee schedule. A laboratory must respond to all deficiencies found during a surveillance assessment in order to maintain their accreditation status.

All initially accredited laboratories shall undergo an on-site surveillance assessment within twelve (12) months of their approval by the AAB. All costs shall be borne by the laboratory.

3.6 TECHNICAL ADVISORY PANEL REVIEW

Some laboratories shall be subjected to a process/product quality review by the Technical Advisory Panel (TAP). 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. When there is an irresolvable discrepancy in findings between TAP and the site assessor, TAP shall return a recommendation to AIHA-LAP, LLC staff, noting the discrepancy. AIHA-LAP, LLC shall send all application and assessment materials to the AAB Vice Chair and Chief Site Assessor for resolution.

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. The selection of laboratories for the TAP review shall be based on pre-defined, selection criteria. The criteria are designed to ensure selection of laboratories for TAP review at the following minimum frequencies:

3.6.1 IHLAP - 100% initial accreditations including those for Beryllium, Pharmaceutical, and Compressed Breathing Air scope categories, and 20% for reaccreditations

3.6.2 ELLAP - 100% initial accreditations, 20% reaccreditations

3.6.3 EMLAP – 100% of initial accreditations, 20% reaccreditations

3.6.4 FoodLAP - 100% of accreditations and reaccreditations

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 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 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 Modules 6A through 6D), but has met all other accreditation requirements, then the following shall apply. 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).

3.7.2.1 Laboratories for Initial Accreditation

The AAB shall deny accreditation for a FoT(s) with a non-proficient PT status as applicable. When the laboratory attains a proficient status for the previously denied FoT(s), then the laboratory will be added to the next scheduled AAB ballot for a formal vote on initial accreditation for the FoT(s).

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.

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 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, 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 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 Modules 6B – 6F. 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 immediately.

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. The proficiency testing sample retest results shall replace the original results submitted by the laboratory and FoT proficiency shall be reevaluated based upon the proficiency testing retest results. Proficiency testing retest samples may be used only to regain a proficient status (i.e., cannot be used to achieve an initial proficient status on an accelerated basis).

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 Assistant Manager, 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 6A-F and Appendices A-F 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 or in the Miscellaneous 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 Policy Module 3, 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 Policy Module 3, Section 3.9, Addition of a Field of Testing (FoT).

3.11 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 as shown on the certificate of accreditation issued by AIHA-LAP, LLC. 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 (see Section 3.11.1).

3.11.1 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 and 3.3 except that the process must be completed before the expiration date of the current accreditation(s) and failure to submit a complete application may result in suspension of accreditation(s).

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.

3.11.2 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 revocation.

In rare cases, the AAB, with input from the site assessor, may require a follow-up visit or surveillance assessment to verify resolution of major deficiencies as identified in the site assessment performed as part of the (re)accreditation process. In this instance, laboratories shall be notified at the time of the (re)accreditation process site assessment of the requirement for a subsequent announced or unannounced surveillance assessment. Laboratories shall bear the cost of a required surveillance assessment.

3.11.3 Technical Advisory Panel Review

This review follows the same system defined in Section 3.6.

3.11.4 Granting of Reaccreditation

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



FIGURE 3-1 ACCREDITATION PROCESS

