



## **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 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. Additional relevant information shall be provided to applicant laboratories upon request.



- 3.3.1** The completed Accreditation Application and supporting documentation shall be submitted to the AIHA LAP, LLC office, in accordance with the accreditation application instructions, with the required fees as set forth in the Fee Schedule. All application materials must be submitted in English.
- 3.3.2** AIHA LAP, LLC staff shall have twenty (20) business days to complete the application review. The review includes a completeness check of the application, a preliminary evaluation of critical components to verify conformance, and verification of proficiency testing participation and proficiency status based on the scope of accreditation selected by the laboratory.
- 3.3.3** If the application is incomplete, AIHA LAP, LLC staff works with the laboratory to obtain the necessary information to continue with the application process. The laboratory shall provide all required information within thirty (30) business days of the request. Failure to do so shall result in the loss of the application fee and the laboratory shall be required to resubmit a completed application for consideration.
- 3.3.4** The application materials, used to prepare for the site assessment, are the property of AIHA LAP, LLC and shall be treated with appropriate confidentiality. The application materials shall remain in AIHA LAP, LLC files as an official record.

### **3.4 SITE ASSESSOR REVIEW**

The AIHA LAP, LLC staff shall forward one copy of the completed application and supporting documentation 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. Where the assessment cannot be conducted in a timely manner, this shall be communicated to the laboratory. If the laboratory delays the process by failing to cooperate with the site assessor's scheduling requirements, then they shall have no basis for complaint to AIHA LAP, LLC.

- 3.4.1** The site assessor shall complete a comprehensive technical review of the application. If the site assessor finds all components of the application to be in order, then a site assessment will be scheduled with the laboratory for the earliest possible date.
- 3.4.2** If any critical 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 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 given the opportunity to provide feedback on both the assessment and AIHA LAP, LLC staff. This feedback will be used to facilitate continuous improvement efforts at AIHA LAP, LLC and to evaluate the site assessor's performance.

- 3.5.1** The site assessor shall utilize a checklist, based on the ISO/IEC 17025:2017 Standard and AIHA LAP, LLC policy requirements, to evaluate the laboratory during the site assessment portion of the accreditation process. Conformity with all checklist items is required for a laboratory to be considered for accreditation.
- 3.5.2** Once the site assessment is complete, the site assessor shall submit a summary report, with 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. The laboratory shall provide an analysis of the extent and cause (e.g. root cause analysis) of any deficiency noted. 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, withdrawal 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. In addition, the Site Assessor shall submit the completed checklist to the laboratory at this time.
- 3.5.5** The laboratory shall respond in writing to all of the 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 accreditation or reaccreditation.

**3.5.10** A *Surveillance Site Assessment* is a site assessment performed between routinely scheduled assessments and after the granting of accreditation or reaccreditation. All initially accredited laboratories shall be contacted for site assessment assignment and scheduling within six 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 assessment as a condition of the granting of accreditation.

Surveillance assessments may be announced or unannounced. For announced surveillance assessments, the laboratory shall be contacted for site assessment assignment and scheduling within six (6) to nine (9) months of their approval by the AAB. The laboratory will bear all costs associated with the site assessment based upon a predetermined fee schedule. Surveillance assessments follow the same processes outlined in 3.5.1 to 3.5.8, but are typically limited to one day and may be extended at AIHA LAP, LLC discretion.

The surveillance assessment focuses on those issues outstanding from the scenarios listed above, but the laboratory may have new 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 technical review by the Technical Advisory Panel (TAP).

The Site Assessor may recommend a TAP review at the close of the assessment or upon final recommendation. Upon the site assessor's discretion, those laboratories with a large number of methods shall have a TAP review assigned to ensure a thorough review of the laboratory's scope has been conducted. Upon review of the assessment report, AIHA LAP, LLC may also request that the package be forwarded for TAP Review. All initial accreditation and surveillance 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 accreditation with suspension, then AIHA LAP, LLC shall remove the suspension.

### **3.7.2.2** Laboratories for Reaccreditation

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

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

## **3.8 MAINTENANCE OF ACCREDITATION**

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

### **3.8.1** Reporting of Significant Changes

Any changes in laboratory ownership, location (except for mobile and field operations laboratories), management, laboratory key personnel, or any other change that significantly affects the laboratory's capability, scope of accreditation, or ability to meet the policy requirements, shall be reported in writing to AIHA LAP, LLC within twenty (20) business days of the change. Any absence of personnel for a period in excess of twenty (20) consecutive working days, that impacts the laboratory's ability to perform its scope of testing, shall be reported to AIHA LAP, LLC within twenty (20) business days. This notification requirement shall be in effect if any laboratory key personnel are absent for reasons of extended family leave, illness, temporary disability, etc.

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

### **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.

### **3.8.5** Complaints

If requested, the laboratory shall assist AIHA LAP, LLC in the investigation and resolution of any accreditation related complaints regarding the laboratory.

## **3.9 ADDITION OF A FIELD OF TESTING (FoT)**

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

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

For FoT additions at the time of assessment, the laboratory must first give sufficient notice to the site





assessor (a minimum of ten (10) business days) notice, subject to agreement by the assessor.

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

### **3.10 ADDITION OF A METHOD**

An accredited laboratory that wishes to add a method within a field 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(s). Additionally, the laboratory shall notify AIHA LAP, LLC in writing of its intentions not to seek reaccreditation, in lieu of submitting an application for consideration of reaccreditation.



### **3.12.1 Reapplication**

The reaccreditation process shall begin with the laboratory completing the Accreditation Application. Nine (9) months prior to the expiration of the existing accreditation(s), AIHA LAP, LLC shall notify the laboratory, in writing, requesting that the laboratory 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 may be charged for the site assessment. Refusal to allow an unannounced laboratory assessment may be grounds for immediate suspension and eventual withdrawal of accreditation.

In rare cases, the AAB, with input from the site assessor, may require a surveillance assessment to verify resolution of major 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**

