



MODULE 4

SUSPENSION, DENIAL, OR WITHDRAWAL OF ACCREDITATION

4.1. INTRODUCTION

AIHA-LAP, LLC staff shall continuously monitor the accreditation/reaccreditation application process, performance in the proficiency programs, and other pertinent information obtained from AIHA-LAP, LLC site assessors and stakeholders, to identify situations of nonconformity. If a laboratory fails to maintain conformity to accreditation requirements, then AIHA-LAP, LLC may initiate the following processes to suspend, deny, or withdraw accreditation.

4.2. DEFINITIONS

- 4.2.1** Suspension - A temporary removal of the laboratory's accreditation status for any or all FoTs.
- 4.2.2** Denial - The decision not to grant a laboratory initial accreditation.
- 4.2.3** Withdrawal - The removal of a laboratory's existing accreditation.

4.3. GROUNDS

AIHA-LAP, LLC may suspend, deny, or withdraw accreditation if any of the following circumstances apply. Denial or withdrawal of accreditation requires a vote of the AAB for all circumstances listed. Suspension of accreditation for 4.3.1 through 4.3.4 requires a vote of the AAB in accordance with the process set forth in Section 4.5; 4.3.5 through 4.3.15 are grounds for immediate suspension upon decision of AIHA-LAP, LLC staff or suspension may be imposed by AAB vote.

An initial applicant laboratory may be immediately denied accreditation of an initial application in the event that the laboratory knowingly reports fraudulent or erroneous data.

- 4.3.1** The laboratory fails to comply with any of the requirements of AIHA-LAP, LLC, as detailed in Modules 1 through 8, and Appendices G and H.
- 4.3.2** The laboratory submits, as its own, results for proficiency testing that were analyzed by another laboratory.
- 4.3.3** The laboratory misrepresents material information in an application (initial or reaccreditation) or in any written correspondence with AIHA-LAP, LLC.
- 4.3.4** The owner of the laboratory, laboratory key personnel or the laboratory itself has been convicted of a violation of federal/state statutes or regulations related to the accreditation program in question.
- 4.3.5** The laboratory knowingly reports fraudulent or erroneous data.
- 4.3.6** The laboratory misrepresents its accreditation through false or misleading advertising as defined in Module 7, communication (written or verbal), or in any other form.



- 4.3.7 The laboratory uses its accreditation in any manner that brings disrepute to AIHA-LAP, LLC.
- 4.3.8 The laboratory is no longer in the business of conducting analyses associated with its specific scope of accreditation(s).
- 4.3.9 The laboratory fails to respond to a written request for information within the specified time frame (e.g., reaccreditation application, corrective action(s) response, etc.).
- 4.3.10 The laboratory fails to conform to the requirements as specified in the laboratory assessment report by the assessor, within the required time frame.
- 4.3.11 The laboratory fails to maintain FoT proficiency (as applicable) based on proficiency testing sample performance, as defined in these policies.
- 4.3.12 The laboratory fails to notify AIHA-LAP, LLC of changes in ownership, laboratory location for fixed site facilities, or laboratory key personnel within the specified time frame.
- 4.3.13 The laboratory alters the AIHA-LAP, LLC Laboratory Accreditation Certificate in any way.
- 4.3.14 The laboratory refuses to allow an unannounced site assessment.
- 4.3.15 The laboratory does not submit the required AIHA-LAP, LLC fees by the required due date.

4.4. ADDITIONAL SUSPENSION INFORMATION

Suspension is a temporary removal of the laboratory's accreditation status for any or all FoTs when it is found to not be in conformity with specific program requirements. Suspension may occur at any time for cause.

- 4.4.1 Suspension may be initiated upon the recommendation of the AAB Chairperson, the Chief Site Assessor, or AIHA-LAP, LLC management.
- 4.4.2 A laboratory may elect to voluntarily suspend its accreditation status for any or all FoTs for a predetermined period of time. The laboratory shall submit, in writing, its request providing the reason and timeframe for the suspension.
- 4.4.3 AIHA-LAP, LLC shall notify a laboratory of the reasons for and conditions of the suspension, the action(s) required for reinstatement, and the deadline for satisfactory completion of the action(s). In the case of a voluntary suspension, AIHA-LAP, LLC shall formally respond to the request and provide the reasons for and conditions of the suspension, the actions(s) required for reinstatement and the deadline for satisfactory completion of the actions(s).
- 4.4.4 During the suspension, the laboratory may not advertise that it is accredited for the suspended FoT(s). The laboratory may advertise that it is accredited in other FoT(s), but must advise their customers that analyses within the suspended FoT(s) are not covered under AIHA- LAP, LLC accreditation. This notification shall be given to the customer upon receipt of the sample(s) and noted on the report. Additionally, upon the change of the laboratory's accreditation status for the accreditation/FoT(s) in question, these accreditation/FoT(s) will be removed from the listing of accredited laboratories on the AIHA-LAP, LLC web site and additional notifications and information may appear on the AIHA-LAP, LLC website.



- 4.4.5 Suspension shall be lifted upon resolution of the initial cause to the satisfaction of AIHA-LAP, LLC.
- 4.4.6 Suspension may proceed to withdrawal if the action(s) required for reinstatement are not met by the deadline, as determined by AIHA-LAP, LLC.
- 4.4.7 AIHA-LAP shall notify the laboratory, in writing, of any action at the conclusion of the suspension period.

4.5. PROCESS FOR SUSPENSION, DENIAL, OR WITHDRAWAL OF ACCREDITATION

The AIHA-LAP, LLC staff shall continuously monitor the accreditation/reaccreditation application process, performance in the proficiency programs, and other pertinent information obtained from AIHA-LAP, LLC stakeholders, to identify situations of nonconformity. If a laboratory fails to maintain conformity to accreditation requirements, then AIHA-LAP, LLC may initiate the following process to suspend, deny, or withdraw accreditation, as outlined in Figure 4-1. This process need not apply in cases of immediate suspension imposed by AIHA-LAP, LLC staff for reasons set forth in 4.3.5 through 4.3.15.

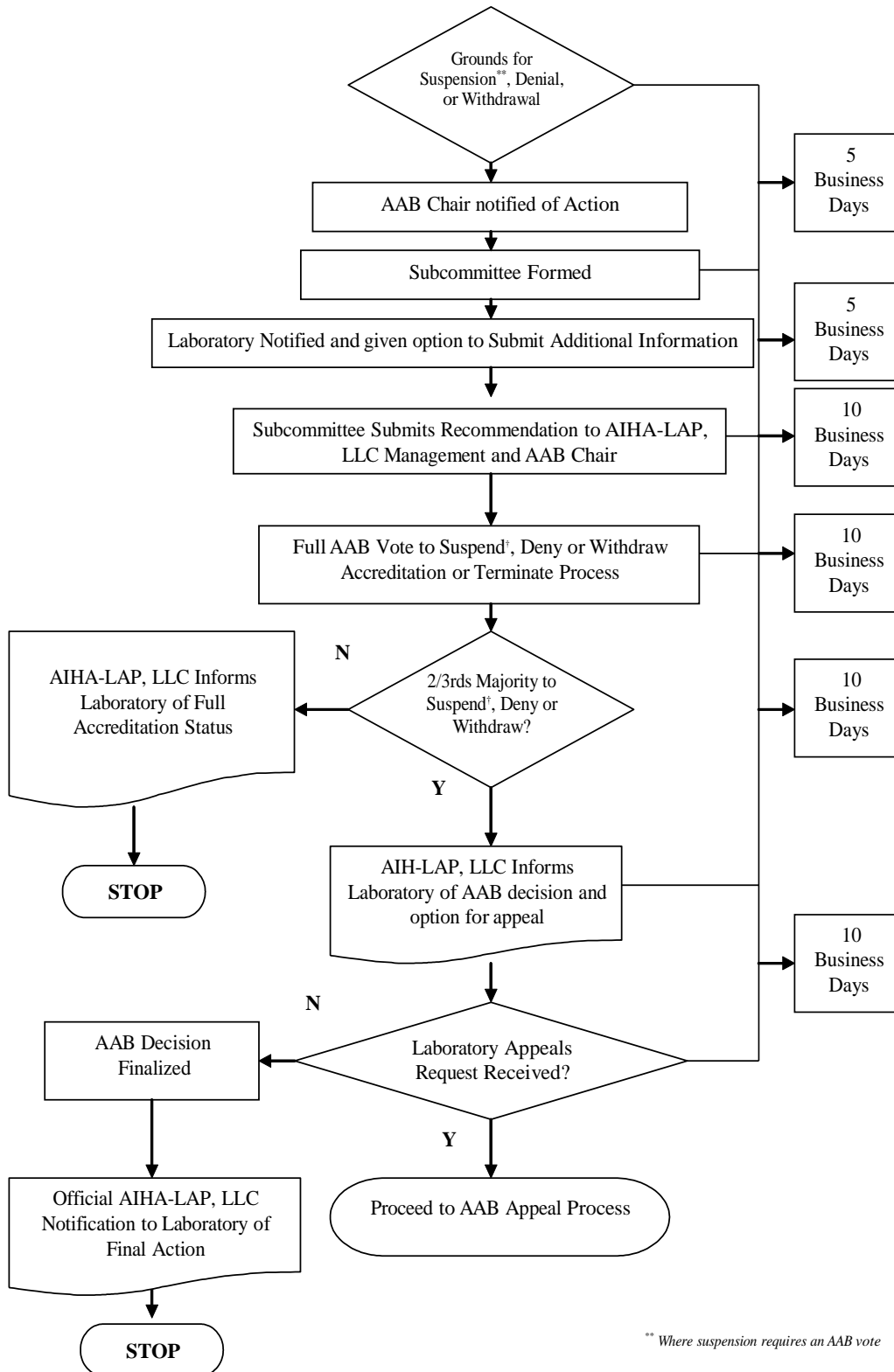
- 4.5.1 AIHA-LAP, LLC shall immediately notify the AAB Chairperson of the nonconformity indicating the laboratory identity; grounds for suspension, denial, or withdrawal; and all pertinent supporting or background information.
- 4.5.2 Within five (5) business days of AAB Chairperson notification, a subcommittee consisting of the most recent site assessor (if applicable), Chief Site Assessor, AIHA-LAP, LLC staff and two TAP members, will be formed.
- 4.5.3 The laboratory shall be notified of the initiation of the process for suspension, denial, or withdrawal and given five (5) business days to submit additional information, or a statement of its position as to why the action is not warranted.
- 4.5.4 Within ten (10) business days of receipt of additional information, or upon the expiration of the five (5) business day response window, the subcommittee shall be given all pertinent information needed to make a recommendation.
- 4.5.5 The subcommittee shall provide a recommendation within ten (10) business days. The findings of the subcommittee shall be forwarded to the AAB Chairperson.
- 4.5.6 AIHA-LAP, LLC shall submit all necessary information to the AAB via ballot and a vote of the full AAB voting membership (see Module 1, Section 1.2.1) on the suspension, denial, or withdrawal action shall be taken within ten (10) business days.
- 4.5.7 Within ten (10) business days from completion of the AAB vote, the AIHA-LAP, LLC shall notify the laboratory, in writing, of the AAB decision to:
 - 4.5.7.1 Continue or grant accreditation; or
 - 4.5.7.2 Affirm the recommendation to suspend, deny, or withdraw accreditation and offer the laboratory the right to appeal the AAB Decision (see Policy Module 5). The laboratory



shall have ten (10) business days from the date of receipt of this notification to provide the AIHA-LAP, LLC management with a written request to appeal.

- 4.5.8** Absent an appeals request, the AAB suspension, denial, or withdrawal decision is final. AIHA-LAP, LLC shall take the necessary steps to officially suspend (Section 4.2) or withdraw the accreditation status of accredited laboratories for the specified FoT(s), consistent with the AAB decision, and shall provide official notification to the laboratory of such actions.
- 4.5.9** If accreditation is denied or withdrawn, a laboratory may reapply for initial accreditation at any time upon satisfaction of conditions established by the AAB and/or AIHA-LAP staff.

FIGURE 4-1 SUSPENSION, DENIAL, OR WITHDRAWAL PROCESS



** Where suspension requires an AAB vote