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MODULE 4 SUSPENSION, REVOCATION OR DENIAL OF ACCREDITATION

4.1 GROUNDS

The AIHA-LAP, LLC may suspend, revoke, or deny accreditation if any of the following circumstances apply:

4.1.1 The laboratory fails to comply with any of the requirements of AIHA-LAP, LLC, as detailed in Modules 1 through 8.

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4.1.2 The laboratory is no longer in the business of conducting analyses associated with its specific scope of accreditation(s).

4.1.3 The laboratory fails to respond to a written request for information within the specified time frame (e.g., annual update, reaccreditation application, corrective action(s) response, etc.).

4.1.4 The laboratory fails to conform to the requirements as specified in the laboratory assessment report by the assessor, within the required time frame.

4.1.5 The laboratory fails to maintain FoT proficiency (as applicable) based on proficiency testing sample performance, as defined in these policies.

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4.1.6 The laboratory fails to notify AIHA-LAP, LLC of changes in ownership, laboratory location for fixed site facilities, or management personnel (Technical Manager, approved signatories or Quality Manager) within the specified time frame.

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4.1.7 The laboratory submits, as its own, results for proficiency samples that were analyzed by another laboratory.

4.1.8 The laboratory misrepresents material information in an application (initial or reaccreditation) or in any written correspondence with AIHA-LAP, LLC.

4.1.9 The owner of the laboratory, laboratory management (Technical Manager or Quality Manager) or the laboratory itself has been convicted of a violation of federal/state statutes or regulations related to the accreditation program in question.

4.1.10 The laboratory knowingly reports fraudulent or erroneous data.

4.1.11 The laboratory misrepresents its accreditation and/or participation in a PT program through false or misleading advertising, or communication (written or verbal), or in any other form.

4.1.12 The laboratory alters the AIHA-LAP, LLC Laboratory Accreditation Certificate in any way.

4.1.13 The laboratory uses its accreditation in any manner that brings disrepute to AIHA-LAP, LLC.

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4.1.14 The laboratory refuses to allow an unannounced site assessment.

4.1.15 The laboratory does not submit the required AIHA-LAP, LLC fees by the required due date.

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4.2 SUSPENSION

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. Reasons for suspension are listed in Section 4.1.

Conditions of suspension include:

4.2.1 Suspension may be initiated upon the recommendation of the AAB Chairperson, the Chief Site Assessor, or the AIHA-LAP, LLC management. A finite period for the suspension shall be clearly defined.

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4.2.2 A majority vote of the AAB (see Module 1, Section 1.2.1) to suspend must be obtained for those suspension actions that are not automatic (administrative and proficiency issues).

4.2.3 A laboratory's accreditation status for any or all FoTs shall be immediately suspended upon notification of the initiation of the revocation process.

4.2.4 A laboratory may elect to voluntarily suspend its accreditation status for any or all FoTs with the agreement of the AAB Chairperson for just cause and for a predetermined period of time.

4.2.5 AIHA shall notify a laboratory by certified mail, return receipt requested, 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).

4.2.6 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, the laboratory's accreditation status for the FoT(s) in question will be listed on the AIHA-LAP, LLC web site as suspended.

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4.2.7 Suspension shall be terminated by the AAB Chairperson upon resolution of the initial cause.

4.2.8 Suspension shall proceed to revocation if the action(s) required for reinstatement are not met by the deadline. This action shall be authorized and initiated by the AAB Chairperson.

4.2.9 AIHA-LAP, LLC shall notify the laboratory, in writing, of any action (reinstatement or revocation) at the conclusion of the suspension period.

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4.3 REVOCATION

The AIHA-LAP, LLC staff shall continuously monitor the 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



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requirements, then AIHA-LAP, LLC may initiate the following revocation process, as outlined in Figure 4-1.

4.3.1 AIHA-LAP, LLC shall immediately provide the AAB Chairperson with a written notification of the nonconformity indicating the laboratory identity, grounds for revocation, and all pertinent supporting documentation.

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4.3.2 Within five (5) business days, the AAB shall establish a two-person subcommittee, chosen from the TAP membership, to conduct a procedural (or process) review.

4.3.3 The AAB subcommittee shall be responsible for reviewing the actions taken thus far by AIHA-LAP, LLC to determine conformity to procedural requirements. It shall not be the responsibility of the two-person AAB subcommittee to review the technical merits of the revocation action. Within ten (10) business days of appointment, the subcommittee shall submit a written determination of procedural conformity.

4.3.4 If the findings of the AAB subcommittee indicate that procedural requirements were not followed, then this written determination shall be forwarded to the AAB Chairperson for reconsideration of the revocation action.

4.3.5 If the findings of the AAB subcommittee support the revocation action, from a procedural conformity perspective, then AIHA-LAP, LLC shall immediately notify the laboratory that its accreditation status for any or all FoTs is suspended until final action on the revocation is completed. The AAB Chairperson shall submit all necessary information to the AAB members to investigate the technical merit of the revocation process. A vote of the full AAB voting membership (see Module 1, Section 1.2.1) on the revocation action shall be taken within ten (10) business days.

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4.3.6 Within ten (10) business days from completion of the AAB vote, the AIHA-LAP, LLC shall send a letter using a documented delivery process to the laboratory informing it of the AAB's decision to either:

4.3.6.1 Terminate the revocation process, remove the suspension and reinstate the laboratory's accreditation status for specified FoT(s), or

4.3.6.2 Continue the suspended accreditation status for the specified FoT(s) and offer the laboratory the right to appeal the AAB decision to revoke accreditation (see AIHA-LAP, LLC 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. The laboratory shall also be informed of its monetary responsibilities should it choose to appeal.

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<#>The AAB shall notify the AIHA Board Coordinator for the LQAP of the revocation decision within ten (10) business days from completion of the AAB vote. ¶

4.3.7 If the laboratory submits a formal request for appeal within the given time frame (see Section 4.3.6.2), then the suspended accreditation status for the specified FoT(s) continues until the AAB affirms the revocation decision through the appeals process (see Module 5).

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4.3.8 Absent an appeals request, the AAB revocation decision is final. AIHA-LAP, LLC shall take the necessary steps to officially revoke the accreditation status for the specified FoT(s),

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consistent with the revocation decision, and shall provide official notification to the laboratory of such actions.

4.4 PROCESS FOR DENIAL OF ACCREDITATION

If a laboratory fails to meet the requirements of the AIHA-LAP, LLC accreditation process as defined in Module 3, fails to complete the accreditation process, or meets any of the grounds defined in Section 4.1, the AAB may deny accreditation to the laboratory.

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FIGURE 4-1 REVOCATION PROCESS

