

AIHA Laboratory Accreditation Programs, LLC
Analysis to Related Bodies
Revised: November 2009

Introduction

AIHA Laboratory Accreditation Programs, LLC (AIHA-LAP, LLC) operates a group of laboratory accreditation programs with the primary mission of establishing high standards of performance for laboratories to promote the production of quality data for use in evaluating exposures that impact public health, the environment and natural resources. AIHA-LAP, LLC was organized in November 2008 as a limited liability company, a registered and distinct legal entity, under the laws of the Commonwealth of Virginia in the United States. AIHA-LAP, LLC currently operates four accreditation programs: Industrial Hygiene Laboratory Accreditation Programs (IHLAP), Environmental Lead Laboratory Accreditation Programs (ELLAP), Environmental Microbiology Laboratory Accreditation Programs (EMLAP), and Food Laboratory Accreditation Programs (FoodLAP), all of which meet international program requirements established under ISO/IEC 17011:2004. The policies for operation of AIHA-LAP, LLC are publicly available on the AIHA-LAP, LLC website (www.aihaaccreditedlabs.org).

As stated in ISO/IEC 17011:2004, clause 4.3.7, Note 1, a related body is a separate legal entity that is linked by common ownership or contractual arrangements to the accreditation body. The American Industrial Hygiene Association (AIHA), a not-for-profit corporation organized under the laws of the State of Illinois, is the sole owner of AIHA-LAP, LLC. AIHA also is the sole owner of two separately organized and operated Virginia limited liability companies, AIHA Proficiency Analytical Testing, LLC (AIHA-PAT, LLC) and AIHA Registry Programs, LLC. These LLCs are considered AIHA's Affiliated Laboratory Programs.

AIHA-LAP, LLC organization, structure and relationship with AIHA

AIHA, the sole owner of AIHA-LAP, LLC, is a nonprofit association of approximately 10,000 members and was founded in 1939. AIHA is one of the largest international associations serving the needs of occupational and environmental health professionals practicing industrial hygiene in industry, government, labor, academic institutions, and independent organizations.

In order to ensure that an accreditation body has effective separation from related bodies, such that that the activities of its related bodies do not compromise the confidentiality, objectivity and impartiality of its accreditations, ISO/IEC 17011:2004 outlines four criteria:

- a) Different top management for the activities described in 4.2.5

Cheryl Morton is the Director of AIHA-LAP, LLC and has the authority for supervision of the finances for AIHA-LAP, LLC, contractual arrangements, and supervision of the implementation of the policies and procedures, and delegation of authority for certain activities on her behalf. The Director's

position description provides further details on these and other responsibilities. The Director of AIHA-LAP, LLC does not serve in a similar capacity with any of AIHA, AIHA-PAT, LLC or AIHA Registry Programs, LLC.

The Director of AIHA-LAP, LLC reports to the AIHA Executive Director, Peter O'Neil. The AIHA Executive Director is not involved with the day-to-day operations or the accreditation process, but is kept informed of the status of the accreditation programs by the AIHA-LAP, LLC Director.

The AIHA Board of Directors has fiscal responsibility and oversight of AIHA-LAP, LLC, and approves the AIHA-LAP, LLC budget. The AIHA Board of Directors also interfaces with the AIHA Executive Director, who hires the Director of AIHA-LAP, LLC.

There is a Professional and Administrative Service Agreement between AIHA and AIHA-LAP, LLC for technical staff, office space, and support/professional services. AIHA-LAP, LLC provides annual payments through a License Agreement with AIHA to use the AIHA name and brand.

AIHA-LAP, LLC has liability insurance for its staff, volunteers and site assessors.

- b) Personnel different from those involved in the decision-making process of accreditation

Accreditation decisions are made by AIHA-LAP, LLC's Analytical Accreditation Board (AAB). The AAB is currently comprised of volunteer technical experts representing primarily accredited laboratories. There are currently 11 voting members. AIHA-LAP, LLC has modified its governance to expand AAB membership to 15 voting members beginning January 2010. Four individuals will be added to the AAB to represent government, consultants, and academics. In the past, AAB members were elected through balloting, but that process was changed to an appointment process in 2009.

The staff of AIHA-LAP, LLC does not make accreditation decisions, nor does the AIHA Executive Director. In addition, the AIHA Board of Directors is not involved in the accreditation decisions.

The members of AIHA-LAP, LLC's AAB do not serve in any position with any of AIHA, AIHA-PAT, LLC or AIHA Registry Programs, LLC.

- c) No possibility to influence the outcome of an assessment for accreditation

All AIHA-LAP, LLC assessors are required to sign Conflict of Interest/Confidentiality forms. Assessors cannot serve on the AAB, which makes accreditation decisions.

The reports of site assessment submitted by the site assessors are considered by the AAB in accreditation decisions, but the assessors cannot influence the final accreditation decision.

The members of AIHA-LAP, LLC's AAB do not serve in any position with any of AIHA, AIHA-PAT, LLC or AIHA Registry Programs, LLC.

d) Distinctly different name, logos and symbols

The names, logos and symbols of AIHA, AIHA-LAP, LLC, AIHA-PAT, LLC and AIHA Registry Programs, LLC are distinctly different. AIHA-LAP, LLC's name includes AIHA's acronym in its name since AIHA accreditation is cited in several state and federal regulatory requirements.

AIHA-LAP, LLC's relationship with AIHA-PAT, LLC and AIHA Registry Programs, LLC

AIHA-PAT, LLC and AIHA Registry Programs, LLC are separate legal entities created in November/December 2008 under the laws of the Commonwealth of Virginia. AIHA is the sole owner of these limited liability companies. AIHA-PAT, LLC and AIHA Registry Programs, LLC have different top management from AIHA-LAP, LLC. The top manager for AIHA-PAT, LLC and the AIHA Registry Programs, LLC is the AIHA Director of Scientific and Technical Initiatives.

Employees and office space of AIHA-PAT, LLC and AIHA Registry Programs, LLC are contractually leased from AIHA. Resources shared with AIHA-LAP, LLC are:

- Data management system. AIHA-PAT, LLC provides Proficiency Testing (PT) reports to AIHA-LAP, LLC. PT data is only accessible to AIHA-PAT, LLC. The staffs of AIHA-PAT, LLC and AIHA Registry Programs, LLC do not have access to accredited laboratory information.
- Annual technical meeting for Affiliate Laboratory Program staff, volunteers, site assessors and vendors

Laboratories accredited by AIHA-LAP, LLC may participate in AIHA-PAT, LLC proficiency testing programs, but they also are free to use other approved proficiency testing programs or to demonstrate competency independently.

Each of AIHA-LAP, LLC, AIHA-PAT, LLC and AIHA Registry Programs, LLC has a:

- Distinct name that includes the AIHA acronym since AIHA is cited in several states and federal regulatory requirements
- Established and distinct legal identity and tax ID number
- Separate technical board (decision makers)
- Group of separate dedicated volunteers and strategic advisors
- Separate governance and operating agreements
- Separate set of policy documents outlining program requirements
- Separate fee schedules
- Separate budget and separately managed finances
- Separate vendor contracts
- Separate Web site

Summary

AIHA-LAP, LLC accreditation decisions are made by an independent board (AAB), with technical assistance from a separate and independent Technical Advisory Panel (TAP), and independent site assessors (who do not influence accreditation decisions). A group of (independent) strategic advisors is also being formed.

Proficiency Testing decisions are being made by a separate AIHA-PAT, LLC board that is completely independent of the accreditation decision makers (AAB). Laboratories are free to use another approved provider for proficiency testing.

Activities of AIHA-LAP, LLC's related bodies do not compromise the confidentiality, objectivity, or impartiality of accreditation decisions. The related bodies do not provide consultancy services that are related to the accreditation program.