



## MODULE 6 PROFICIENCY TESTING (PT) AND ROUND ROBIN PROGRAMS

### 6.1 INTRODUCTION

For all Fields of Testing (FoT) in a laboratory's scope of accreditation, the laboratory shall demonstrate proficiency in one of the following categories, in priority order:

1. Category 1: External PT, through AIHA Proficiency Analytical Testing, LLC Program, or through an AIHA-LAP, LLC approved external PT program as outlined in 6.2.
2. Category 2: Demonstration of Proficiency via Round Robin and/or Demonstration of Proficiency via an Internal Proficiency Testing Program as outlined in 6.3
3. Category 3: Demonstration of Proficiency via Internal Quality Control as outlined in 6.4.  
*Note: This option will be allowed only in very rare cases and through the AIHA-LAP, LLC approval process.*

For a list of approved External PT providers and exceptions, refer to the Scope PT Table on the AIHA-LAP, LLC's website.

Samples from the AIHA PAT Programs, LLC, or other approved proficiency testing and round robin programs, shall be analyzed as specified by the program administrator, using the same preparation, analytical procedure and instrumentation combination used to test customer samples as far as practicable.

The results from all PT programs and Round Robins shall be shared with analysts.

### 6.2 CATEGORY 1 – EXTERNAL PROFICIENCY TESTING

#### 6.2.1 AIHA PAT Programs, LLC

AIHA PAT Programs, LLC offers programs that support AIHA-LAP, LLC laboratory accreditation and include the following programs: IHPAT, ELPAT, EMPAT, BAPAT, and BePAT. If the Laboratory chooses to use AIHA PAT Programs, LLC to maintain accreditation for a FoT/Method(s), or to add a Field of Testing as specified in Policy 3.9, then the laboratory shall comply with the following requirements:

- 6.2.1.1 The laboratory shall have participated and passed at least one (1) round of testing per FoT to be considered for initial accreditation.
- 6.2.1.2 When a single proficiency testing analyte category can be used to demonstrate proficiency for multiple FoTs, and the lab seeks accreditation for these FoTs, the laboratory may elect to use the analyte category for this scheme to demonstrate proficiency for only one FoT, and elect to demonstrate proficiency for the other(s) by choosing an option from Sections 6.3
- 6.2.1.3 When a single proficiency testing scheme analyte category can be used to demonstrate proficiency for two FoTs/technologies/matrices, and the lab seeks



accreditation for these FoTs, the laboratory may elect to tie all methods in each FoT to the Proficiency Testing (e.g. Organics under AIHA IHPAT for GC and GC/MS). Under ELLAP, the laboratory may use a single set of ELPAT samples to demonstrate proficiency for multiple technologies within a FoT/matrix (e.g. Paint under ELPAT for FAA and ICP).

- 6.2.1.4** The laboratory may not elect to tie more than two (2) FoTs/technologies to any single proficiency testing analyte category. For example, although IHPAT Silica may be used to demonstrate competency for XRD, UV/VIS, and IR, no laboratory could choose to link all three FoTs to the IHPAT Silica proficiency testing category.
- 6.2.1.5** When two (2) FoTs are tied to a single proficiency testing analyte category, the laboratory must alternate analysis of the AIHA-PAT Program samples between the two technology types.
- 6.2.1.6** If an accredited laboratory fails to maintain proficiency in a given proficiency testing category to which they have elected to tie to two (2) FoTs/Technologies, the accreditation shall be suspended for both FoTs and/or technologies, regardless of which FoT or technology led to the non-proficiency status.

## **6.2.2** AIHA-LAP, LLC APPROVED EXTERNAL PROFICIENCY TESTING PROGRAM

AIHA-LAP, LLC reviews and formally approves other proficiency testing programs for its accreditation programs and accepts data from these approved programs. Laboratories shall analyze all samples provided for a given scheme by the proficiency testing programs in which they are enrolled and participate.

NOTE 1: The general requirements noted above in Sections 6.2.1.1 -6.2.1.6, above, also apply to Non-AIHA-PAT Programs PT schemes.

### **6.2.2.1** Requirements for Approval of Other Proficiency Testing Programs

When approving other proficiency testing programs, AIHA-LAP, LLC will look for the following features:

- a) Proficiency samples and background matrices shall resemble real-world samples to the degree possible.
- b) Target concentrations of the proficiency testing samples shall be appropriate for the program in which they are being applied. For example, if the samples submitted to the laboratory are for occupational hygiene purposes, the target concentrations shall be relevant to evaluation of an occupational exposure guideline.
- c) The units of results for reported data shall be appropriate for the type of testing performed. Reported results shall be in units appropriate to the end use of the data, such as for comparison to target standards.



- d) All proficiency testing programs shall conclude with a performance rating, preferably a proficient or non-proficient rating based on a common statistic or other procedure acceptable to the AIHA-LAP, LLC.
- e) Samples taken from reference atmospheres (laboratory or field) are preferable to samples spiked using solutions or slurries.
- f) Samples shall be in, or on collection media, similar to media used in the field, to the degree possible.
- g) All proficiency testing programs shall have at least two (2) rounds per year or as specified by the appropriate accreditation module.
- h) For those programs not meeting the 2-round annual minimum, the laboratory shall augment their participation with a Demonstration of Proficiency Testing program as specified in Section 6.3 below.

### **6.3 CATEGORY 2 – DEMONSTRATION OF PROFICIENCY – ROUND ROBIN AND INTERNAL PROFICIENCY TESTING**

#### **6.3.1 Round Robin**

For FoTs where external PT is not available, the laboratory shall participate in a round robin program designed to allow for the accreditation of laboratories that share the same key analyte(s) of interest (e.g., formaldehyde and isocyanates) and meeting the requirements of Policies 6.3.1.1- 6.3.1.9. An independent vendor or one (1) of the participating laboratories' shall generate and distribute the round robin samples to other participating laboratories. A laboratory with multiple facilities may participate as individual entities with the stipulation that samples are analyzed and reported by each facility as a separate entity. Acceptable criteria shall be determined.

Actions to be taken in the event of an unacceptable result shall be described in the laboratory's management system documentation, per Policy Module 2A.

The following are requirements for round-robin programs:

- 6.3.1.1** Round robins samples shall consist of or resemble real-world samples to the degree possible.
- 6.3.1.2** Round robins shall include participation of at least three (3) laboratories.
- 6.3.1.3** All round robin programs shall have at least two (2) rounds per year, with each round completed within a six-month time frame.
- 6.3.1.4** Each round shall include a minimum of four samples at varying concentrations. Target concentrations of the round robin samples shall be appropriate for the program in which they are being applied.
- 6.3.1.5** When analysis includes subjective analyst evaluation (e.g., microscopic identification and/or quantitation) each laboratory shall have all analysts assess each round robin



sample independently and shall report all individual analyst's results separately.

- 6.3.1.6 The units of results for reported data shall be appropriate for the type of testing performed. Reported results shall be in units appropriate to the end use of the data, such as for comparison to target standards.
- 6.3.1.7 A designated laboratory shall be responsible for data collection and distribution.
- 6.3.1.8 Resulting data shall be evaluated using appropriate statistical methods.
- 6.3.1.9 The laboratories shall attempt to resolve any significant differences in results among laboratories.

### **6.3.2 Internal Proficiency Testing**

For FoTs where external PT is not available, and where a round robin is prohibited, proprietary, or impractical, the laboratory shall implement a comprehensive internal PT program for at least one method in the FoT.

- 6.3.2.1 A minimum of twenty (20) QC data points shall be obtained initially to determine upper and lower control limits at three (3) standard deviations.
- 6.3.2.2 The laboratory shall have at least two rounds per year, each round separated by approximately six months. For initial accreditation or addition of a FoT, the time between rounds of internal PT can be performed at a minimum of 15 days apart.
- 6.3.2.3 Each round shall consist of a minimum of four independently prepared blind spikes at varying levels with the resulting data treated as it would be in a round robin program. The spiking procedures, to include frequency, responsibility for implementation, statistical treatment of resultant data, acceptance criteria, and actions to be taken in the event of an unacceptable result, shall be fully described in the laboratory's management system documentation. The spiking must be performed on an appropriate matrix.

## **6.4 CATEGORY 3- DEMONSTRATION OF PROFICIENCY – INTERNAL QUALITY CONTROL**

In very rare cases, the laboratory may be permitted to demonstrate proficiency for a minimum of one (1) method per FoT through the implementation of internal quality control (internal QC)

Internal QC is defined as routine activities and checks, such as periodic calibration, duplicate analyses and matrix spikes that are included in routine internal procedures to control the accuracy and precision of measurements.



## 6.5 GENERAL PROFICIENCY TESTING INFORMATION

### 6.5.1 Documentation of Program Participation

All documentation between the participating laboratory and the proficiency testing program or round robin administrator shall be retained by the laboratory for three (3) years (five (5) years for ELLAP) and shall be made available to AIHA-LAP, LLC or its agents (e.g., AAB, TAP, Site Assessors) upon request. The laboratory shall have participated and maintained proficiency in at least one round to be considered for initial accreditation.

### 6.5.2 Reporting of Proficiency Testing Results and PT Data Reports

**6.5.2.1** AIHA-LAP, LLC receives regular reports on the status of the participating laboratories' proficiency testing from AIHA PAT Programs, LLC.

**6.5.2.2** For other proficiency testing programs and round robins that have been formally approved by AIHA-LAP, LLC the laboratory shall provide a report of proficiency sample results in accordance with the AIHA-LAP, LLC accreditation application requirements. The proficiency testing report provided shall contain adequate information to make a determination on FoT proficiency in accordance with stated criteria.

### 6.5.3 Proficiency Status

**6.5.3.1** Laboratories must be proficient in the selected proficiency testing program or round robin to obtain and maintain accreditation for the applicable FoT/Method(s). Accredited laboratories shall maintain proficiency for all applicable FoT/Method(s).

**6.5.3.2** Laboratories that become non-proficient for any FoT/Method shall adhere to the procedures outlined in Module 3, Section 3.8.2. Laboratories shall also evaluate their results and take documented corrective action in the event of an unacceptable result. See Policies 2A.4.9.1, 2A.4.9.2, and 2A.4.11.1 on nonconforming testing and corrective actions for proficiency testing failures, including outliers.

## 6.6 INDUSTRIAL HYGIENE ACCREDITED LABORATORIES

Laboratories in the IHLAP are required to analyze samples for those Fields of Testing (FoT)/Method(s) for which accreditation is sought, according to the approved IHLAP Scope/PT Table maintained on the AIHA-LAP, LLC's website

**6.6.1** Compressed/Breathing Air Analysis Accredited Laboratories: IH Laboratories seeking or maintaining accreditation for Compressed/Breathing Air analysis shall participate and maintain proficiency in the Compressed/Breathing Air Round Robin (CAPT) in accordance with the Protocol for Compressed Air Proficiency Testing (CAPT) Program.

**6.6.2** Pharmaceutical Accredited Laboratories: IH Laboratories seeking or maintaining accreditation for Pharmaceutical Analyses shall participate and maintain proficiency in the Pharmaceutical Round Robin Program in accordance with the Protocol for Pharmaceutical Round Robin Proficiency Testing Program.



## **6.7 ENVIRONMENTAL LEAD ACCREDITED LABORATORIES**

Participation in AIHA Proficiency Analytical Testing Programs (AIHA-PAT Programs), LLC Environmental Lead Proficiency Analytical Testing (ELPAT) is a prerequisite to qualification under the AIHA-LAP, LLC Environmental Lead Laboratory Accreditation Program (ELLAP). This program has adopted the National Institute for Occupational Safety and Health (NIOSH) Proficiency Analytical Testing Statistical Protocol as the ELLAP Standard. Laboratories in the ELLAP are required to analyze samples for those Fields of Testing (FoT)/Method(s) for which accreditation is sought, according to the approved ELLAP Scope/PT Table maintained on the AIHA-LAP, LLC's website.

Laboratories participating in an AIHA-LAP-approved proficiency testing program to seek accreditation for the ELLAP shall conform to all proficiency testing requirements as outlined in this module.

### **6.7.1 NLLAP Recognition**

Analyses conducted by a laboratory in a non-proficient FoT/Method are not recognized under the NLLAP until a proficient rating is achieved. Those laboratories that are NP following a main ELPAT round while waiting on the retest shall be removed from the AIHA-LAP, LLC accredited ELLAP labs listing and the NLLAP until such time as a proficient rating is achieved. A laboratory shall not be recognized under the NLLAP for a FoT/Method for which accreditation has been suspended. When a laboratory is suspended or rated non-proficient in a FoT/Method, AIHA-LAP, LLC shall notify the laboratory that analysis conducted by that laboratory for the non-proficient or suspended FoT/Method are not recognized by NLLAP.

## **6.8 ENVIRONMENTAL MICROBIOLOGY ACCREDITED LABORATORIES**

Participation in AIHA PAT Programs, LLC's Environmental Microbiology Proficiency Analytical Testing (EMPAT) program or an equivalent proficiency testing program approved by AIHA-LAP, LLC is a prerequisite to qualification under the AIHA-LAP, LLC Environmental Microbiology Laboratory Accreditation Program (EMLAP). Laboratories in the EMLAP are required to analyze samples for those Fields of Testing (FoT)/Method(s) for which accreditation is sought, according to the approved EMLAP Scope/PT list maintained on the AIHA-LAP, LLC's website.

Laboratories participating in an AIHA-LAP-approved proficiency testing program to seek accreditation for the EMLAP shall conform to all proficiency testing requirements as outlined in this module.

## **6.9 FOOD ACCREDITED LABORATORIES**

All laboratories pursuing/maintaining accreditation in the Food Laboratory Accreditation Program (FoodLAP) shall participate in an AIHA-LAP, LLC-approved proficiency testing program as maintained on the AIHA-LAP, LLC web site. Laboratory accreditation for each Field of Testing (FoT) shall be defined by the extent of participation in an AIHA-LAP, LLC approved proficiency testing program.

**6.9.1** Prior to becoming accredited, a laboratory shall have successfully analyzed a set of proficiency testing samples for each matrix/test/method and/or techniques for which the laboratory seeks accreditation.



**6.9.2** In order to maintain accreditation, the laboratory shall participate in an external, approved proficiency testing program at least one time per year, per matrix. At a minimum, the proficiency testing activities should cover one activity per method/test type and/or technology per year. The laboratory's entire scope should be covered over a four-year period.

**6.9.3** If no external proficiency testing program is available for a matrix, the laboratory will participate in a round robin, perform an inter laboratory comparison, or conduct internal proficiency testing specific to that matrix at least one time per year per matrix.

#### **6.10 UNIQUE SCOPE ACCREDITED LABORATORIES**

**6.10.1** All laboratories pursuing/maintaining accreditation in the Unique Scope program are required to participate in proficiency testing programs approved by AIHA-LAP, LLC as outlined in Sections 6.1, 6.2, 6.3, and 6.4 above. Approval is determined at time of application.

**6.10.2** The AIHA-LAP, LLC may seek input from the AAB and the TAP during this approval process and there is further review during the on-site assessment prior to accreditation. The purpose of the proficiency testing requirements is to ensure that accredited laboratories, and those seeking accreditation, meet established performance criteria.