# 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 based on the Scope/PT Table maintained on the AIHA Laboratory Accreditation Programs, LLC (AIHA LAP) website, www.aihaaccreditedlabs.org.
In priority order:

1. Category 1: External PT through an AIHA LAP approved external PT program as outlined in 6.2. A list of approved PT programs for each FoT and exceptions (e.g., Diffusive Sampler see 6.6.2) can be found on the AIHA LAP website.

2. Category 2: Demonstration of Proficiency – Round Robin and Internal Proficiency Testing as outlined in 6.3.

3. Category 3: Demonstration of Proficiency – Internal Quality Control as outlined in 6.4.
   *Note: This option will be allowed only in very rare cases and through AIHA LAP approval.*

Samples from approved PT programs and round robin 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

**To find which PT program a laboratory should use based on FoT, review the Scope/PT Table on the AIHA LAP website. The PT plan shall be declared in the Accreditation Application for each FoT.**

Review the following sections in this policy for additional requirements based on program:

- 6.6 INDUSTRIAL HYGIENE ACCREDITED LABORATORIES
- 6.7 ENVIRONMENTAL LEAD ACCREDITED LABORATORIES
- 6.8 ENVIRONMENTAL MICROBIOLOGY ACCREDITED LABORATORIES
- 6.9 FOOD ACCREDITED LABORATORIES
- 6.10 UNIQUE SCOPE ACCREDITED LABORATORIES
- 6.11 BERYLLIUM FIELD/MOBILE ACCREDITED LABORATORIES

**6.2.1** For initial accreditation or initial FoT addition, the laboratory shall have participated in and passed the most recent reporting round from the PT provider for accreditation application consideration.

**6.2.2** AIHA LAP APPROVED EXTERNAL PROFICIENCY TESTING PROGRAM

AIHA LAP reviews and formally approves 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.

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

When approving proficiency testing programs, AIHA LAP will request and review 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 an appropriate statistic or other procedure acceptable to AIHA LAP.

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 robin 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 (2) 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 (4) 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 LAAF) and shall be made available to AIHA LAP or its agents (e.g., AAB, TAP, Site Assessors) upon request.

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

**6.5.2.1** The laboratory shall provide a scored report of proficiency sample results in accordance with the AIHA LAP accreditation requirements through the Data Management System (DMS). (Work instruction, DMS_WI_Proficiency_Testing, is available in the LAP Document Library.) The proficiency testing report provided shall contain adequate information to make a determination on FoT proficiency in accordance with stated criteria.

**6.5.2.2** A laboratory shall submit all scored reports of proficiency tests and comparison program results, including excused rounds, approximately 45 business days after results are received regardless of the outcome. LAAF-accredited labs, see 6.9.5.

### 6.5.3 Proficiency Status

AIHA LAP considers laboratories to be proficient when the laboratory has a passing score for the applicable PT analyte class in two (2) of the last three (3) consecutive PT rounds. An excused round will not be counted in the three (3) consecutive PT rounds, but the proficiency testing report showing an excused round shall be turned into the DMS portal.

**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. Accredited laboratories shall maintain proficiency for all applicable FoT.

**6.5.3.2** Laboratories that become non-proficient for any FoT shall adhere to the procedures outlined in Module 3, Section 3.8.2. Laboratories shall evaluate

their results and take appropriate actions. See Policies 2A.7.10, on nonconforming work and 2A.8.7 on 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 FoT for which accreditation is sought, according to the approved IHLAP Scope/PT Table on the AIHA LAP website.

**6.6.1** When two (2) FoTs are tied to a single proficiency testing analyte category, the laboratory must alternate analysis between the two (2) FoTs. The laboratory may elect to tie all methods in each FoT to the proficiency testing analyte category (e.g., silica under IHPAT for IR and XRD)

6.6.1.1 If an accredited laboratory fails to maintain proficiency in a given PT program to which they have elected to tie to two (2) FoTs, the accreditation shall be suspended for both FoTs, regardless of which FoT led to the non-proficiency status.

6.6.1.2 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 Section 6.3.

6.6.1.3 The laboratory may not elect to tie more than two (2) FoTs to any single proficiency testing analyte category.

**6.6.2** Diffusive Sampler Analysis Accredited Laboratories: IH Laboratories seeking or maintaining accreditation for Diffusive Sampler analysis shall participate and maintain proficiency in the AIHA PAT, LLC IHPAT – Diffusive Sampler Proficiency Testing.

**6.6.3** 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.

**6.6.4** 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), Environmental Lead Proficiency Analytical Testing (ELPAT) is a prerequisite to accreditation qualification under the AIHA LAP 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 FoT for which accreditation is sought, according to the approved ELLAP Scope/PT Table maintained on the AIHA LAP 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** 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). The laboratory must alternate analysis between the technologies.

**6.7.2** NLLAP Recognition

Analyses conducted by a laboratory in a non-proficient FoT 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 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 for which accreditation has been suspended. When a laboratory is suspended or rated non-proficient in a FoT/Method, AIHA LAP shall notify the laboratory that analysis conducted by that laboratory for the non-proficient or suspended FoT are not recognized by NLLAP.

## 6.8 ENVIRONMENTAL MICROBIOLOGY ACCREDITED LABORATORIES

Laboratories pursuing/maintaining accreditation in EMLAP are required to analyze samples for those FoT for which accreditation is sought, according to the approved EMLAP Scope/PT Table maintained on the AIHA LAP 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

Laboratories pursuing/maintaining accreditation in the Food Laboratory Accreditation Program (FoodLAP) shall participate in an AIHA LAP approved proficiency testing program as listed on the Scope/PT Table maintained on the AIHA LAP website. Laboratory accreditation for each Field of Testing (FoT) shall be defined by the extent of participation in an AIHA LAP 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.

**6.9.4** For LAAF-accredited labs and AOAC accredited labs, they shall demonstrate successful proficiency testing for every applicable test on their scope in a 12-month period.

**6.9.5** For LAAF-accredited labs, a laboratory must submit all proficiency testing results approximately 30 calendar days after results are received regardless of the outcome.

## 6.10 UNIQUE SCOPES ACCREDITED LABORATORIES

Laboratories pursuing/maintaining accreditation in the Unique Scopes program shall participate in an AIHA LAP approved proficiency testing program as listed on the Scope/PT Table maintained on the AIHA LAP website. Laboratory accreditation for each Field of Testing (FoT) shall be defined by the extent of participation in an AIHA LAP approved proficiency testing program.

**6.10.1** AIHA LAP may seek input from the AAB and the TAP during this approval process and have 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.

## 6.11 BERYLLIUM FIELD/MOBILE ACCREDITED LABORATORIES

Laboratories pursuing/maintaining accreditation in Be Field/Mobile are required to analyze samples for those FoT for which accreditation is sought, according to the approved Be Field/Mobile Scope/PT Table on the AIHA LAP website.