Introduction

ISO/IEC 17025:2017, section 7.7.2, requires a laboratory to "monitor its performance by comparison with results of other laboratories, where available and appropriate"

Irrespective of and in addition to a lab's monitoring the validity of their results as required by ISO/IEC 17025:2017, section 7.7.1, there is a separate and distinct requirement for all laboratories to participate in available and appropriate proficiency testing (PT) and/or interlaboratory comparisons (ILC) as described in this document.

Results from PT and/or ILC are an indication of a laboratory's competence and are an integral part of the assessment and accreditation process. PT and/or ILC programs may take many forms and standards for satisfactory performance vary depending on the field.

It is recognized that there are areas of testing and calibration in which suitable PT and/or ILC programs are not available or appropriate. In these cases, A2LA will assess the justification provided by the laboratory, but this does not preclude the laboratory from performing other "quality control" activities in accordance with clause 7.7.1 of ISO/IEC 17025:2017 for ensuring the validity of results. Internal results obtained from activities listed in clause 7.7.1 of ISO/IEC 17025:2017 do not need to be provided to A2LA, unless required per specific A2LA program requirements (refer to section on Providing A2LA with PT Results). A representative sample of these records will be reviewed on-site by the A2LA assessor during usual assessment processes.

It is important to note that in some instances these proficiency testing requirements may also apply to accredited conformity assessment bodies under ISO 15189 (for medical testing laboratories), ISO/IEC 17020 (for inspection bodies), and/or ISO 20387 (for biobanks) accreditation programs. Please refer to their respective General Requirements documents for details.

Specific requirements found in this Policy are in **bold** type and numbered as in "**(PT1)**".

References

ISO 15189:2012 Medical Laboratories – Requirements for quality and competence

ISO/IEC 17020:2012 Conformity assessment – Requirements for the operation of various types of bodies performing inspection

ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories

ISO/IEC 17043:2010 Conformity assessment — General requirements for proficiency testing

ISO 20387: 2018 General requirements for biobanking

ILAC – P9 ILAC Policy for Participation in Proficiency Testing Activities

EA-4/18:2010 Guidance on the level and frequency of proficiency testing participation

Definitions

Interlaboratory comparison (ILC): the organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.[1]

Proficiency testing (PT): the evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.[1]

[1] ISO/IEC 17043:2010 Conformity assessment – General requirements for proficiency testing

Subcontracting

PT samples shall not be subcontracted to another laboratory for analysis.

Before Accreditation is Granted

(PT1) When appropriate and available proficiency testing exists, A2LA applicant laboratories shall demonstrate successful participation in at least one proficiency testing activity prior to receiving accreditation.

Applicant laboratories should enroll in suitable PT programs as early as possible to ensure that the completion of the accreditation process is not delayed.

On a case-by-case basis, as determined by A2LA Staff, evidence of enrollment in suitable PT programs may suffice **for the purpose of achieving initial accreditation.** This is normally done when the next scheduled round of the PT program will not occur for quite some time and the laboratory has demonstrated competence through internal performance-based data. Participation in at least one PT program is considered mandatory where available and appropriate, prior to receiving accreditation.

Laboratory Testing/Calibration Approach

(PT2) Laboratories shall conduct PT activities in accordance with their normal testing/calibration and reporting procedures, unless otherwise specified in the instructions from the PT provider.

(PT3) Laboratories shall also ensure that PT samples are equally distributed among trained and qualified personnel and satellite locations (where applicable) for the relevant tests/calibrations on the scope of accreditation.

Documented Plan

(PT4) In addition to laboratories with specific program requirements, all accredited laboratories must have a documented plan of how they intend to participate in appropriate and available PT programs to cover the tests/calibrations on their scope of accreditation and shall include participation within the accreditation cycle. **(PT5)** The documented plan shall include or be accompanied by a risk assessment of the level and frequency of the PT to be performed by the laboratory. *Note: PT5 has a 1-year transition period and becomes a mandatory requirement on July 1, 2022.* **(PT6)** This plan shall identify any commercially available participation and any interlaboratory comparisons, as applicable. **(PT7)** The plan shall be regularly reviewed and updated, as necessary, in response to changes in staffing, methodology, instrumentation, etc.

It may not be necessary in all cases to include on the plan every test, calibration or measurement technique listed on the laboratory's scope of accreditation. For further guidelines on creating a comprehensive PT plan, including risk assessment considerations, please review A2LA *G133 – A2LA Guide for Establishing Proficiency Testing Plans*

The laboratory's PT plan, along with PT participation and performance will be reviewed as part of the laboratory's regular assessment and annual review processes by A2LA assessors and staff.

A2LA reserves the right to request or require more frequent PT participation when the laboratory-developed plan is not considered suitable in relation to the scope(s) of accreditation. Examples of instances in which A2LA may request or require additional PT activity include:

- Due to the number and nature of technical deficiencies identified during an assessment;
- Due to the number and nature of laboratory documented nonconforming work;
- Laboratory receipt of complaints of a technical nature;
- Poor performance in previous proficiency testing participation;
- Change in technical management or essential/key personnel.

Proficiency Testing Providers

ISO/IEC 17025:2017 requires all laboratories, both applicant and accredited, to participate in appropriate and available PT provided by organizations administering acceptable programs. A2LA **strongly** recommends that laboratories participate in PT programs operated by accredited PT providers. Guidance on acceptable providers, and on acceptable PT participation to demonstrate the validity of measurement results, may be found in A2LA *G133 – A2LA Guide for Establishing Proficiency Testing Plans*

Laboratories are reminded that when selecting appropriate PT programs, the laboratory shall evaluate the competence of the provider and retain appropriate evidence to be assessed by A2LA, in accordance with section 6.6 of ISO/IEC 17025:2017.

Note: PT providers accredited to ISO/IEC 17043 by an ILAC recognized AB are considered competent and no additional evaluation by the lab is necessary or needed.

There are also instances where PT providers are specified within an accreditation program recognized by regulation and participation in these PT programs is mandatory. Please refer to the relevant A2LA program-specific requirement document for details.

Providing A2LA with PT Results

With the exception of laboratories accredited under program specific requirements, effective July 1, 2021 laboratories are only required to submit their documented plan and a summary of participation and performance as part of their regular assessment application (new or renewal) and annual review processes via the A2LA customer portal.

A2LA may confer with assessors to discuss the results of such studies and assessors may be instructed to review all data associated with these studies during each assessment. Additional charges for assessor review of this data and/or corrective actions may apply.

Failure to participate according to the documented plan, patterns of erratic results, successive failures, or other poor performance in PT programs may result in request by A2LA for additional PT participation, revocation of accreditation for affected tests/parameters, and/or a required on-site surveillance visit by an A2LA assessor. Failure to respond to A2LA requests may result in an adverse accreditation action.

(PT8) The laboratory shall initiate its corrective action process for any test or measurement results that are evaluated as "unacceptable" by the PT scheme provider, using its stated evaluation protocol. If results are not evaluated by the provider, A2LA considers any results more than 3 standard deviations from the PT assigned value to be an outlying result and requires corrective action.

Guidance for PT in each of the fields offered by A2LA are described in A2LA *G133 – A2LA Guide for Establishing Proficiency Testing Plans*. Specialized categories within a certain field of accreditation contain specific requirements, which are subject to change based upon formal agreements between A2LA and other cooperating agencies (e.g., USEPA, USGA etc.).

Summary of Requirements

(PT1) When appropriate and available proficiency testing exists, A2LA applicant laboratories shall demonstrate successful participation in at least one proficiency testing activity prior to receiving accreditation

(PT2) Laboratories shall conduct PT activities in accordance with their normal testing/calibration and reporting procedures, unless otherwise specified in the instructions from the PT provider.

(PT3) Laboratories shall also ensure that PT samples are equally distributed among trained and qualified personnel and satellite locations (where applicable) for the relevant tests/calibrations on the scope of accreditation.

(PT4) In addition to laboratories with specific program requirements, all accredited laboratories must have a documented plan of how they intend to participate in appropriate and available PT programs to cover the tests/calibrations on their scope of accreditation and shall include participation within the accreditation cycle.

(PT5) The documented plan shall include or be accompanied by a risk assessment of the level and frequency of the PT to be performed by the laboratory. *Note: PT5 has a 1-year transition period and becomes a mandatory requirement on July 1, 2022.*

(PT6) This plan shall identify any commercially available participation and any interlaboratory comparisons, as applicable.

(PT7) The plan shall be regularly reviewed and updated, as necessary, in response to changes in staffing, methodology, instrumentation, etc**.**

(PT8) The laboratory shall initiate its corrective action process for any test or measurement results that are evaluated as "unacceptable" by the PT scheme provider, using its stated evaluation protocol. If results are not evaluated by the provider, A2LA considers any results more than 3 standard deviations from the PT assigned value to be an outlying result and requires corrective action.

DOCUMENT REVISION HISTORY

Date	Description
10/14/19	➢ Updated Header/Footer to current version ➢ Updated format and font for consistency ➢ Added Qualtrax hyperlinks

06/24/21	➢ Complete rewrite to align with ISO/IEC 17025:2017