R103 - GENERAL REQUIREMENTS: PROFICIENCY TESTING FOR ISO/IEC 17025 LABORATORIES

September 2013

A. Introduction

ISO/IEC 17025 requires a laboratory to have "*quality control procedures for monitoring the validity of tests and calibrations undertaken*." This means that laboratories must perform internal performance-based "quality control" checks in accordance with 5.9 of ISO/IEC 17025 as it applies to every test, technology and/or parameter on their Scope(s) of Accreditation in order to demonstrate compliance with ISO/IEC 17025 accreditation requirements.

Irrespective of and in addition to a lab's quality control activities, there is a separate and distinct requirement for all laboratories to participate in relevant and available proficiency testing (PT) as described in this document and the A2LA *R103a – Annex – Proficiency Testing for ISO/IEC 17025 Laboratories* document.

The ILAC requirements document specifying PT participation is entitled ***ILAC Policy for Participation in Proficiency Testing Activities*** (ILAC-P9). ILAC P9 requires that "*Accreditation bodies (ABs) seeking to sign or seeking to maintain their status as a signatory to the ILAC Multilateral Recognition Arrangement (MRA) shall demonstrate the technical competence of their accredited calibration and testing laboratories. One of the elements by which accredited laboratories can demonstrate technical competence is by satisfactory participation in PT activities where such activities are available and appropriate*."

Results from PT are an indication of a laboratory's competence and are an integral part of the assessment and accreditation process. PT programs may take many forms and standards for satisfactory performance vary depending on the field. Please visit the A2LA web site for a full listing of available PT programs (http://www.a2la.org/dirsearchnew/ptproviders.cfm).

It is recognized that there are areas of testing and calibration in which suitable PT is not available or practical. When such PT programs are not available or relevant to the scope of accreditation, A2LA will rely on the aforementioned "quality control" checks in accordance with clause 5.9.1 of ISO/IEC 17025:2005 for assuring the quality of testing and/or calibration results. Quality control checks may include (but are not limited to) the following types of activities: regular use of certified reference materials and/or internal quality control using secondary reference materials; replicate tests or calibrations using the same or different methods; re-testing or re-calibration of retained items; and correlation of results for different characteristics of an item. The results of these quality control checks do not need to be provided to A2LA. A representative sample of these internal checks will be reviewed on-site by the A2LA assessor during the full on-site assessments as a part of their usual assessment.

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

B. References

ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories

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

ILAC – P9 ILAC Policy for Participation in Proficiency Testing Activities

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

APLAC PT006 Proficiency Testing Frequency Benchmarks

C. Definitions

Interlaboratory comparison (ILC) is 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) is the evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.[1]

An *activity* is any test or calibration performed on an artifact provided by an accredited or an acceptable commercially available Proficiency Testing Provider in relation to their regularly scheduled and available proficiency testing schemes.

Discipline is the field of testing or calibration as defined on the scope of accreditation (e.g. Acoustics, Chemical, Electrical, etc.).[2]

Sub-discipline is a sub-field of testing or calibration as defined on the scope of accreditation (e.g. Tensile, Impact, Hardness, Corrosion/Environmental Simulation, etc. in the Mechanical field of testing; Chromatography, Combustion, etc. in the Chemical field of testing; 1D, 2D, 3D Dimensional in the Calibration field; etc.). For a listing of the specific sub-disciplines please see *R103a – Annex: Proficiency Testing for ISO/IEC 17025 Laboratories*. [3]

D. Sub-contracting

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

E. Laboratory Testing/Calibration Approach

(PT1) Laboratories shall conduct proficiency tests in accordance with their normal testing/calibration and reporting procedures, unless otherwise specified in the instructions from the proficiency test provider.

(PT2) Laboratories shall also ensure that proficiency testing samples are equally distributed among trained and qualified personnel and satellite locations (where applicable) for the relevant tests.

F. Applicable Only to Test/Calibrations on the Scope of Accreditation

When relevant and available, it is necessary to participate in PT only for the test methods, test technologies or calibrations for which accreditation is being sought and maintained.

G. Documented Plan & Minimum Coverage Over 4 Years

(PT3) Unless otherwise specified within this document or in A2LA* R103a – Annex – Proficiency Testing for ISO/IEC 17025 Laboratories*, at minimum, laboratories shall participate in at least two proficiency-testing activities per year, every year. Laboratories with 4 or less sub-disciplines on their scope are required to participate in at least one proficiency testing activity per year, every year. For laboratories accredited in calibration

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

[2] A2LA defined.
[3] A2LA defined.

and testing or in more than one field of testing, participation is required for at least two-proficiency testing activities per year, per overall accreditation, every year. Several programs (e.g. Environmental, Construction Materials, Food) specify the type and frequency of proficiency tests required.

(PT4) In fields without specific requirements, and in addition to meeting PT3, all accredited laboratories must participate in relevant and commercially available proficiency testing at a frequency sufficient to ensure that all sub-disciplines and materials/matrices/product types (as defined in each section of* R103a – Annex – Proficiency Testing for ISO/IEC 17025 Laboratories *document) on the scope(s) of accreditation are covered over a four year period.

Therefore, A2LA requires that laboratories have suitably implemented these requirements and ***(PT5) have a documented plan of how they intend to cover the applicable program requirements or the major sub-disciplines and materials/matrices/product types (as defined in* R103a – Annex – Proficiency Testing for ISO/IEC 17025 Laboratories *document) on their scope of accreditation over a four-year period***. ***(PT6) This plan shall cover any commercially available participation and any inter-laboratory organized studies, as applicable***. ***(PT7) The plan must also address the laboratory's process for submission of proficiency testing results and related corrective action responses to A2LA (see also PT10)***. ***(PT8) The plan shall be reviewed and updated, as necessary, as part of the laboratory's management review.*** This plan will be reviewed by the A2LA assessor during the on-site assessments and submitted to A2LA. Per A2LA *R102 – Conditions for Accreditation*, laboratories are obliged to inform A2LA of any changes to this plan.

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 (ISO/IEC 17025, section 4.9);
- Laboratory receipt of complaints of a technical nature;
- Poor performance in previous proficiency testing participation;
- Change in technical management.

H. Before Accreditation is Granted

(PT9) Applicant laboratories for A2LA accreditation shall demonstrate successful participation in at least one relevant and available 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.

I. Proficiency Testing Providers

Applicants and accredited laboratories are required to participate in relevant and available PT provided by organizations administering acceptable PT programs. A2LA ***strongly*** recommends that laboratories participate in

PT programs operated by accredited PT providers. Where appropriately accredited PT providers are not available, laboratories should use programs that follow ISO/IEC 17043 for PT programs.

Acceptable participation in PT programs is as follows:

- Programs that are available through commercial proficiency testing programs (see listing on the A2LA web site), and;
- Programs that are available through well-organized inter-laboratory comparisons (ILCs).

If these programs are suitable and relevant to the scope of accreditation, laboratories must participate in these programs.

ILCs should be designed, wherever possible, to follow ISO/IEC 17043. Acceptability of such programs will be made on a case-by-case basis by the assessor using the A2LA *A316 - Guidance for Review of Proficiency Testing Reports*, and will be based on the design of the program, its frequency, the suitability of the samples, and defined written criteria for data analysis and corrective action. For guidance on determining whether the PT summary reports of non-accredited PT providers meet ISO/IEC 17043, please consult the aforementioned 'Guidance' document.

There are also instances where PT providers are specified within an accreditation program recognized by regulation and participation in these PT programs is mandatory.

International Programs: Often, A2LA is made aware of relevant programs organized through our international counterparts. When possible, A2LA will notify accredited laboratories of the existence of these programs, which are often one-time studies for the purpose of comparing methodologies. If no other relevant programs exist that can demonstrate a laboratory's on going competency, laboratories will be asked to participate in these international comparison studies.

J. Providing A2LA with PT Results

(PT10) Laboratories are expected to record their analysis of all final results. Laboratories must submit the final results and analysis, or arrange for the direct submittal of the final results by the PT provider to A2LA, followed by subsequent analysis of all relevant proficiency testing participation to A2LA within 30 days upon receipt. **(Please note that the results of any internal performance-based quality control data do not need to be provided.)** ***(PT11) Detailed corrective action responses, including root cause analysis, for any outlying or unacceptable final results related to testing/calibration on their Scope of Accreditation must also be submitted***. A2LA may confer with assessors to discuss the results of such studies and assessors will 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, patterns of erratic results, successive failures, or other poor performance (as defined further in this document) in required PT programs may result in revocation of accreditation for affected tests/parameters and/or a required on-site surveillance visit by an A2LA assessor. The laboratory's scope of accreditation found on the A2LA web site will be revised to reflect any revocations. Failure to meet minimum participation requirements or failure to increase PT participation due to A2LA request (see Section G) or to respond to A2LA requests for information may result in an adverse accreditation action.

Unless defined elsewhere in this document, any test or measurement results that are evaluated as "unacceptable" by the PT scheme provider, using its stated evaluation protocol, requires a corrective action response. If results are not

evaluated, A2LA considers any results more than 3 standard deviations from the PT assigned value to be an outlying result and requires a corrective action response.

Remedial Actions: If unacceptable results are received on a formal PT program (e.g., CTS), the laboratory must enroll for the same analysis in the next available PT round and demonstrate acceptable performance. Failure to successfully analyze the sample in this "remedial" round will result in immediate revocation of the testing/calibration concerned from the laboratory's Scope of Accreditation. Accreditation will be reinstated only upon demonstration of acceptable performance on a future PT round or by satisfactory performance of the test/calibration as witnessed and attested by a qualified and approved A2LA assessor during an official A2LA on-site assessment.

It is understood that PT samples are occasionally not completely compatible with the materials and methods used by a laboratory. In these cases, a laboratory can decline to participate in a specific round of PT and justify their decision to A2LA.

K. Formatting of this Document

Requirements for PT in each of the fields offered by A2LA are described in A2LA *R103a – Annex – Proficiency Testing for ISO/IEC 17025 Laboratories*. Specialized categories within a certain field of accreditation contain specific PT requirements, which are subject to change based upon formal agreements between A2LA and other cooperating agencies (e.g., USEPA, USGA etc.). These special programs are also described here. Contact information (including addresses and telephone numbers) for the specific programs referenced in the Annex are contained on the A2LA web site (www.A2LA.org).

Summary of Requirements

(PT1) Laboratories shall conduct proficiency tests in accordance with their normal testing/calibration and reporting procedures, unless otherwise specified in the instructions from the proficiency test provider.

(PT2) Laboratories shall also ensure that proficiency testing samples are equally distributed among trained and qualified personnel and satellite locations (where applicable) for the relevant tests.

(PT3) Unless otherwise specified within this document or in A2LA* R103a – Annex – Proficiency Testing for ISO/IEC 17025 Laboratories*, at minimum, laboratories shall participate in at least two proficiency-testing activities per year, every year. Laboratories with 4 or less sub-disciplines on their scope are required to participate in at least one proficiency testing activity per year, every year.

(PT4) In fields without specific requirements, and in addition to meeting PT3, all accredited laboratories must participate in relevant and commercially available proficiency testing at a frequency sufficient to ensure that all sub-disciplines and materials/matrices/product types (as defined in each section of* R103a – Annex – Proficiency Testing for ISO/IEC 17025 Laboratories *document) on the scope(s) of accreditation are covered over a four year period.

(PT5) Laboratories shall have a documented plan of how they intend to cover the applicable program requirements or the major sub-disciplines and materials/matrices/product types (as defined in* R103a – Annex – Proficiency Testing for ISO/IEC 17025 Laboratories *document) on their scope of accreditation over a four-year period.

(PT6) This plan shall cover any commercially available participation and any inter-laboratory organized studies, as applicable.

(PT7) The plan must also address the laboratory's process for submission of proficiency testing results and related corrective action responses to A2LA.

(PT8) The plan shall be reviewed and updated, as necessary, as part of the laboratory's management review.

(PT9) Applicant laboratories for A2LA accreditation shall demonstrate successful participation in at least one relevant and available proficiency testing activity prior to receiving accreditation.

(PT10) Laboratories are expected to record their analysis of all final results. Laboratories must submit the final results and analysis, or arrange for the direct submittal of the final results by the PT provider to A2LA, followed by subsequent analysis of all relevant proficiency testing participation to A2LA within 30 days upon receipt. **(Please note that the results of any internal performance-based quality control data do not need to be provided.)**

(PT11) Detailed corrective action responses, including root cause analysis, for any outlying or unacceptable final results related to testing/calibration on their Scope of Accreditation must also be submitted.

APPENDIX A - Document Revision History

Date	Description
1/01/2013	- Removed reference to ILAC P1 in Part A; - Updated Part A to address ILAC P9-2010; - Added references and definitions sections, Parts B & C; - Expanded PT2 to include satellite locations, where applicable; - Expanded PT2 to specify that PT samples be equally distributed among all trained and qualified personnel; - Added provisions in Part G for A2LA to require more PT than in the lab's plan under certain conditions; - Updated PT7 to require the laboratory to provide the final results of their PT participation within 30 days upon receipt; - Added PT8 to require the PT plan to be reviewed and updated as part of the laboratory's management review; - Updated Part I to replace ASTM E1301 and ISO Guide 43 with ISO/IEC 17043; - Expanded on PT10 to address direct submittal of final PT results to A2LA by the provider; - Added statement to Part J that additional assessor charges may apply related to review of PT results; - Revised the 'Remedial' section of Part J to include a provision to have a method reinstated by satisfactory performance of the test as witnessed and attested by a qualified and approved A2LA assessor during an official A2LA on-site assessment.
9/19/2013	- *Editorial only* – PT7 clarified on what is required in the PT plan.