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

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R103 - General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories

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 Annex to the A2LA General Requirements for Proficiency Testing document. ILAC-P1 ***ILAC Mutual Recognition Arrangement: Requirements for the Evaluation of Accreditation Bodies*** states “*Proficiency testing is one of the important tools used by laboratories and Accreditation Bodies for monitoring test and calibration results and for verifying the effectiveness of the accreditation process. As such, it is an important element in establishing confidence in the competence of Signatories and their accredited laboratories covered by this Arrangement.*” P1 further mandates Accreditation Bodies (AB) “... *to demonstrate the technical competence of its accredited laboratories by their satisfactory participation in Proficiency Testing Activity.*”

The ILAC requirements document defining PT participation is the ***ILAC Policy for Participation in National and International Proficiency Testing Activities*** (ILAC-P9) and defines PT as “*the determination of the calibration or testing performance of a laboratory ... by means of interlaboratory comparison.*”

Results from proficiency testing are an indication of a laboratory’s competence and are an integral part of the assessment and accreditation process. Proficiency testing 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 proficiency testing programs (<http://www.a2la.org/dirsearchnew/ptproviders.cfm>).

When such proficiency testing 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 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. Sub-contracting

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

C. 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 personnel trained and qualified for the relevant tests.

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D. Applicable to Test/Calibrations on Scope Only

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

E. Documented Plan & Minimum Coverage Over 4 Years

(PT3) Unless otherwise specified within this document or in the Annex to the A2LA General Requirements for Proficiency Testing, at a minimum, proficiency testing participation is required for 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 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.

In fields without specific requirements, ***(PT4) all accredited laboratories must participate in relevant and available proficiency testing at a frequency sufficient to ensure that all major sub-disciplines and materials/matrices/product types (as defined in each section) on the scope(s) of accreditation are covered over a four year period.***

Per ISO/IEC 17025, Section 5.9.1;

- the laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken.
- this monitoring shall be planned ...


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 the Annex to the A2LA General Requirements for Proficiency Testing 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 promptly upon receipt.*** This plan will be reviewed by the A2LA assessor during the on-site assessments and submitted to A2LA. Per the *A2LA Conditions for Accreditation*, laboratories are obliged to inform A2LA of any changes to this plan.

F. Before Accreditation is Granted

(PT8) Applicant laboratories for A2LA accreditation must be able to demonstrate successful participation in at least one relevant and available proficiency testing activity (i.e. study) prior to receiving accreditation.

Applicant laboratories should enroll in suitable proficiency testing 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 proficiency testing 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.

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G. Proficiency Testing Providers

Applicants and accredited laboratories are required to participate in relevant and available proficiency testing provided by organizations administering acceptable proficiency testing programs. A2LA **strongly** recommends that laboratories participate in proficiency testing programs operated by accredited proficiency testing providers. Where appropriately accredited proficiency testing providers are not available, laboratories should use programs that follow ASTM E1301 or ISO Guide 43 for proficiency testing programs.

Acceptable participation in proficiency testing 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 ASTM E1301 or ISO Guide 43. Acceptability of such programs will be made on a case-by-case basis by the assessor using the *A2LA 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 Guide 43, please consult the aforementioned ‘Guidance’ document.


There are also instances where proficiency-testing providers are specified within an accreditation program recognized by regulation and participation in these proficiency-testing 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.

H. Providing A2LA with PT Results

(PT9) Laboratories are expected to document their analysis of all results, and to submit the results, and the subsequent analysis, of all relevant proficiency testing participation to A2LA promptly upon receipt. (Please note that the results of any internal performance-based quality control data do not need to be provided.) (PT10) Detailed corrective action responses for any outlying or unacceptable results related to testing/calibration on their Scope of Accreditation must also be submitted. To facilitate A2LA review, laboratories must complete the Proficiency Testing Data Submission Form (F104) along with the data and corrective actions. *This form can be provided to you in either hard copy or electronic format by contacting A2LA or can be downloaded from our web site.* 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.

Failure to participate, patterns of erratic results, successive failures, or other poor performance (as defined further in this document) in required proficiency testing programs may result in revocation of accreditation for affected parameters and/or a required on-site surveillance visit by an A2LA assessor. The laboratory’s scope of accreditation

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found on the A2LA web site will be revised to reflect any revocations. Failure to meet minimum participation requirements or to respond to A2LA requests for information may result in an adverse accreditation action.

Unless defined elsewhere in this document, A2LA considers a test result outside of three standard deviations of the mean of test results to be an outlying result and requires a corrective action response. 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. In addition, any test result outside of the laboratory’s claimed estimation of measurement uncertainty shall be considered an outlying result.

Remedial Actions: If unacceptable results are received on a formal proficiency testing program (e.g., CTS), the laboratory must enroll for the same analysis in the next available proficiency-testing round and demonstrate acceptable performance. Failure to successfully analyze the sample in this “remedial” round will result in immediate revocation of the testing concerned from the laboratory’s Scope of Accreditation. Accreditation will be reinstated only upon demonstration of acceptable performance on a future proficiency testing round.

It is understood that proficiency-testing 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 proficiency testing and justify their decision to A2LA.

I. Formatting of this Document

Requirements for proficiency testing in each of the fields offered by A2LA are described in the Annex to the A2LA Proficiency Testing Requirements. Specialized categories within a certain field of accreditation contain specific proficiency testing 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 personnel trained and qualified for the relevant tests.

(PT3) Unless otherwise specified within this document or in the Annex to the A2LA General Requirements for Proficiency Testing, at a minimum, proficiency testing participation is required for at least two proficiency-testing activities per year, every year.

(PT4) all accredited laboratories must participate in relevant and available proficiency testing at a frequency sufficient to ensure that all major sub-disciplines and materials/matrices/product types (as defined in each section) on the scope(s) of accreditation are covered over a four year period.

(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 the Annex to the A2LA General Requirements for Proficiency Testing document) on their scope of accreditation over a four-year period.

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(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 promptly upon receipt.

(PT8) Applicant laboratories for A2LA accreditation must be able to demonstrate successful participation in at least one relevant and available proficiency testing activity (i.e. study) prior to receiving accreditation.

(PT9) Laboratories are expected to document their analysis of all results, and to submit the results, and the subsequent analysis, of all relevant proficiency testing participation to A2LA promptly upon receipt.

(PT10) Detailed corrective action responses for any outlying or unacceptable results related to testing/calibration on their Scope of Accreditation must also be submitted.

APPENDIX A - Document Revision History

Date	Description
08/28/2000	Original Issue of this document.
01/11/2001	<p>Description of the proficiency testing requirements related to the A2LA Automotive Electromagnetic Compatibility Accreditation Program (AEMCLAP) revised to reflect current practice.</p> <p>Document Revision History section added.</p> <p>No other changes made.</p>
10/01/2003	<p>Revised format and content of the Introduction. Specifically:</p> <ul style="list-style-type: none"> - Added reference to similar methods/technologies/calibrations - Added hierarchy of preference for PT programs - Added reference to corporate inter-laboratory programs. - Specified that evidence of enrollment may suffice for the purposes of initial accreditation on a case-by-case basis. - Added the specific requirement that after January 1, 2004, laboratories must have a documented plan for PT coverage over 4 years. - Addressed qualitative testing - Added consistency across programs with respect to prompt return of PT results (minimum quarterly), participation “at least” twice per year, and covering all testing sub-disciplines listed on a laboratory’s scope - Added reference to <i>A2LA Proficiency Testing Data Submission Form</i> <p>Clarified Putting Green Materials PT requirements</p> <p>Reference to the Kentucky UST Program and the Wyoming LAUST Program added.</p> <p>Updated references to <i>A2LA Food Testing Program Requirements</i> in Biological and Chemical sections.</p>



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	Removed Appendix A that specified PT programs and instead added direction to the A2LA web site
01/05/04	Added sub-disciplines under Calibration section Clarified “A2LA Sponsored” Calibration PT activities
07/28/04	Updated Dimensional sub-discipline under Calibration section Added Dimensional sub-discipline under Mechanical section Minor editorial changes
07/26/05	Description of PT Assessor Checklist for determining compliance to the A2LA Proficiency Testing Requirements as well as an evaluation of the compliance of PT summary reports to ISO Guide 43 for non-accredited PT providers added Reduced the participation requirements for labs with less than 4 sub-disciplines Clarified the hierarchy for acceptable participation Removed redundancies under fields of testing Reference to the Texas (TXDOH IAQ) Program added. Removed the reference to the USEPA EMSL-Las Vegas Radiochemistry Program.
9/13/05	Updated to reference ISO 17025:2005
07/03/07	Defined proficiency testing and quality checks and the differences between them. Further clarified the intent of the document to be exclusively a proficiency testing document to meet ILAC proficiency testing requirements for testing and calibration laboratories. Placed the sub-disciplines and materials/matrices/product types into the Annex to the A2LA General Requirements for Proficiency Testing.
04/09/08	Numbered the requirements for ease of reference. No other changes made.
11/06/2009	Changed “less than 4 sub-disciplines” to “4 or less sub-disciplines” [section E, (PT3)] Removed requirement to explain when PT isn’t applicable and what is done in lieu of PT Removed PT12