Georgian Accreditation Centre

Policy on Participation of Laboratories and Inspection Bodies in Proficiency Testing Activities

PL - 03

Elaborated by:	Reviewed by:	Approved by:
Nestan Mgeladze:		**Malkhaz Kharebava**
Head of Accreditation service:	**Accreditation Committee**	Acting General Director:

1. Introduction

1.1 According to ISO/IEC 17025 [5] a laboratory shall have quality control procedures to demonstrate the credibility of testing and calibration results. This monitoring may include the participation in interlaboratory comparisons or proficiency testing programs. Other methods are also acceptable for regular use of standard samples, to conduct repeated examinations and calibration, using the same or other methods. By implementing these methods, the laboratory can submit proofs of their competence to the customer, interested parties and the accreditation body.

ISO 15189 [6] standard also requires that medical laboratories seek confirmation for confidence in their results through participation in suitable interlaboratory comparisons.

2. Scope

2.1 The Accreditation Center is based on the requirements of the use of qualification testing and interlaboratory comparisons presented in EA-4/21 INF:2018 [9] and ILAC P9:06/2014 [2] standards, which determines the credibility of the results obtained by the work carried out by the laboratories and where relevant inspection bodies .

2.2 In the context of this document, “laboratories” implies all laboratory types – i.e. testing, calibration and medical laboratories.

2.3 If inspection bodies executes measurements, then the requirements for ISO/IEC 17025 are mandatory for them. Therefore, the term "laboratory" - should be understood as any organization, which produces measurements for conformity assessment.

2.4 The Guidelines for the Document by the Accreditation Bodies, aims to consider relevant elements of ISO/IEC 17043 standard requirements during the evaluation, even during the small interlaboratory comparisons.

3. Terminology

3.1 Proficiency testing (PT) is the determination of the calibration or testing performance of a laboratory or the testing performance of an inspection body against pre-established criteria by means of interlaboratory comparison ISO / IEC 17043 point 3.7.

3.2 Interlaboratory comparison (ILC) is the organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories or inspection bodies in accordance with predetermined conditions ISO/IEC 17043 point 3.4.

3.3 Small interlaboratory comparison (small ILC) is interlaboratory comparison, which is organized between 7 or less laboratories;

3.4 Interlaboratory comparison test items (ILC test items) are: sample, product, artefact, referential material, part of the device, measuring standard, data or other information used for qualification testing (Adapted to ISO/IEC 17043 3.8.).

4. GAC Policy

4.1 Laboratories and, were relevant, inspection bodies should monitor validity of tests/examinations/calibrations/measurements and demonstrate the competence of their activity by the way of participation in the relevant PTs or ILC programs provided by competent national or international PTs/ILCs providers. GAC supports the use of appropriate PT programs which meet essential requirements of ISO/IEC 17043 [1], where applicable. GAC recommends participation in PT and ILC programs provided by accredited bodies. Where such ILC or PT are not accessible or are not provided, the comparisons between two or more laboratories/inspection bodies (small ILC) are acceptable if the basic conditions and requirements of ISO/IEC 17043 [1] are met and the results of comparisons are properly evaluated. GAC, during the assessments/surveillances, can use measurement audit, in which calibrated item, reference material or characterized item by other means can be used to check the performance of laboratory or inspection body. Such approach can be used for various reasons and can be considered as bilateral comparison if there is no accessible other ILC or PT.

4.2 GAC requires for successful participation of laboratories and, was relevant, inspection bodies in suitable PTs/ILCs programs where PTs/ILCs are available and appropriate:

4.2.1 At least once prior to gaining accreditation (including the scope extension). PTs/ILCs programs shall cover all areas or disciplines of desirable for accreditation.

4.2.2 At least once in between two subsequent accreditation assessments (e.g. initial assessment and the following first reassessment or in between two subsequent reassessments) in the course of validity of the relevant accreditation certificate, covering all types of tests/examinations/measurements, which are indicated in the accreditation scope. Corresponding tests/examinations/measurements can be grouped into the corresponding sub-disciplines and within these sub-disciplines, participation in one ILC/PT is required covering one or more methods. In subsequent accreditation circles, it is required to participate in ILC/PT with different methods or different measured parameters.

4.3 Laboratories and proper inspection bodies, which are already accredited or in the process of accreditation, shall prepare a plan for participation in PTs/ILCs, which provides the activities of the conformity assessment bodies, risks, quality control of the technical process and quality assurance issues. This strategy should be developed for a single accreditation cycle. At least once a year it must be revised and if necessary it should be upgraded. The strategy for participation in PT will be reviewed by the Accreditation Center. When planning, the accredited activity can be grouped according to the groups (sub-disciplines) of sets of measurement techniques, properties and products on which the outcome of a PT for one of these sets can be directly correlated to the others sets of measurement techniques, properties and products contained within the group [4].

4.4 Where PTs/ILCs are not available or not appropriate, laboratories, and where relevant inspection bodies, shall use and demonstrate other means for monitoring of the validity of tests and calibrations. For calibration and testing laboratories, the alternative approaches are specified in the clause 7.7 of ISO/IEC 17025 [5] and for medical laboratories in 5.6 of ISO 15189. Those means may include, but not be limited, to the following: 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; retesting or recalibration of retained items, etc.

4.5 PT/ILC is considered as a demonstration of competence and maintaining the quality of technical activity of laboratories and inspection bodies (where relevant). For this reason during the assessments GAC's assessment teams shall evaluate whether laboratory and, where relevant, inspection body participated in the PTs/ILCs and whether participation was relevant to their scope of accreditation and also results obtained. It is a mandatory issue to be evaluated during each assessment.

4.6 Participation of laboratories or, were relevant, inspection bodies in PTs/ILCs and the results obtained are used as one of the criteria in evaluation of the quality of the work performed by the laboratory or inspection body and of the competence of the personnel.

4.7 GAC, evaluating participation of laboratories or, were relevant, inspection bodies in PTs/ILCs uses the document EA-03/04 [3]. In the decision making process on the granting or maintaining of accreditation GAC takes into consideration the results of participation in PTs/ILCs.

4.8 If the results of participation of the laboratories or, were relevant, inspection bodies in PTs/ILCs are unacceptable, GAC requires laboratories or inspection bodies to review/analysis of unsatisfactory results and carry out corrective actions. If the corrective actions were not implemented or not acceptable GAC can ask to take additional actions: e.g., to check means on internal quality control; if possible, to take part repeatedly in PTs/ILCs or to carry out other means, seeking to demonstrate the effectiveness of the corrective actions.

4.9 CAB shell to present to GAC the PT/ILC plan, which shell cover all areas or disciplines per 4 years.

4.10 Repetitive unacceptable results of participation in PTs/ILCs may result in the suspension of accreditation of the laboratories or reduction of the scope of accreditation.

4.11 Information on PTs/ILCs providers are published in the GAC website by the following address: www.gac.gov.ge.

5. References

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

[2] ILAC –P9:06/2014 - *ILAC Policy for Participation in Proficiency Testing Activities*

[3] EA-03/04 G:2001 - *Use of Proficiency Testing as a Tool for Accreditation in Testing*

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

[5] ISO/IEC 17025:2017 - *General Requirements for the Competence of Testing and Calibration Laboratories*

[6] ISO15189: 20012 - *Medical laboratories - Particular requirements for quality and competence*

[7] ISO/IEC 17020:2012 - *Conformity assessment -- Requirements for the operation of various types of bodies performing inspection*

[8] ILAC P15:07/2016 - *Application of ISO/IEC 17020:2012/2013 for the Accreditation of Inspection Bodies*

[9] EA-4/21 INF:2018 - *Guidelines for the assessment of the appropriateness of small interlaboratory comparisons within the process of laboratory accreditation.*

List of changes

Revision	**Actual Chapter**	**Date**	Content
	Chapter 4. p. 4.9	25.02.2019	Add - CAB shell to present to GAC the PT/ILC plan, which shell cover all areas or disciplines per 4 years.

List of familiarizing with document

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