

المركز السعودي للاعتماد  
Saudi Accreditation Center



## SAAC Policy for Participation in Proficiency Tests and inter- Comparison Programs

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## 1 purpose

This document sets out the general policy of SAAC regarding CAB' participation in proficiency tests and inter-comparison programs.

## 2 Scope

The document is applied to conformity assessment bodies based on the scope of accreditation of testing and calibration laboratories, medical laboratories and inspection bodies (if applicable) accredited by SAAC.

## 3 Reference

- ISO / IEC 17011: 2017 (Conformity assessment - General requirements for accreditation bodies that accredit conformity assessment bodies)
- ISO / IEC 17025: 2017 General requirements for the competence of calibration and testing laboratories.
- ISO / IEC 17020: 2012 Conformity assessment - Activity requirements for different types of agencies providing inspection services.
- ISO 15189:2022 Medical laboratories - Requirements for quality and competence
- ISO / IEC 17043: 2010 Conformity assessment - General requirements for proficiency tests.
- ISO 13528: 2015, statistical methods used in proficiency and comparative tests.
- ILAC P9: 06/2014 ILAC Policy for Participation in Proficiency Testing Activities

## 4 terms and definitions

- **Proficiency tests:** evaluates the performance of the participants based on predetermined criteria through inter-comparisons.
- **Inter-Comparison programs:** are the organization, performance, and evaluation of measurements or tests on the same purpose that is calibrated or tested or similar by two or more laboratories according to predetermined conditions.
- **Property:** the quantity to be measured.
- **Measurement Technique:** a process of testing/calibration/characterization, including any pre-treatment required to prepare the sample, as received into the laboratory measuring instrument.
- **Product:** the purpose for which the measuring technology is applied.
- **Level of participation:** the number of sub-disciplines identified by the organization within its field, and thus the number of proficiency tests / specific comparison programs that should be considered for participation.
- **Frequency of participation:** The number of times the organization determines that it needs to participate in

proficiency tests or comparison programs in a particular sub-specialty, which may differ from one sub-specialty to another in the laboratory and between laboratories that have the same sub-specialization

- **Category:** the field of technical competence that is defined by a single measurement technique, property, or product.

## 5 Contents

### 5.1 General Requirements

5.1.1 This document explains the reasons for participating in the proficiency tests/comparison programs:

- To assess the technical feasibility of procedures related to an experiment, analysis, examination, calibration or inspection.
- To assess the accuracy, correctness and effectiveness of the equipment used to conduct the analysis, experiment, inspection or calibration in the conformity assessment body.
- To assess the accuracy, validity and effectiveness of the reference materials used in the conformity assessment body.
- To assess the competency of workers in the conformity assessment body.
- To compare the results of the conformity assessment body with its peers.
- To support CMC files for calibration laboratories.

5.1.2 CAB shall formulate and implement a policy and procedures related to its participation in proficiency tests/inter- comparison programs, and study their results and periodicity.

5.1.3 The CAB shall review all related policies and procedures periodically, provided that this review includes all the technical and organizational issues.

5.1.4 The policy and procedures shall include, but are not limited to, the following elements:

- List of tests, experiments, examinations, and calibrations concerned with proficiency tests/inter-comparison programs,
- Determine the responsibilities and personnel involved,
- The relevant authorities,
- The schemes of participation and its periodicity,
- Concerned procedures and specifications,

- list of tests, experiments, examinations, and calibrations not concerned with proficiency tests/comparison programs or for which comparisons (if any) cannot be carried out,
- Justifications for not participating in proficiency tests/comparison programs,
- Measures are taken to avoid deficiency resulting from not participating in proficiency tests/comparison programs.

5.1.5 The policy and procedures related to participation in proficiency tests/comparison programs should include indicators and criteria for evaluating results with the approved corrective measures.

5.1.6 5.1.6 The conformity assessment body shall participate in accredited proficiency testing/interlaboratory comparison programs according to ISO/IEC 17043 if applicable.

5.1.7 The CAB must determine the level and frequency of participation in proficiency tests according to risk level of the activity or sector in which it operates or the methodology it uses. By looking at:

- The number of tests/calibrations/measurements carried out
- Change in technical personnel
- Experience and knowledge of technical personnel
- The existence of a source of traceability of the measurements (such as availability of reference materials, national standards, etc.)
- How stable/unstable the measurement technique is
- Significance and end-use of test/calibration data

5.1.8 The results of participation in proficiency tests/inter-comparison programs must be satisfied before applying, and these results must not be more than one year old from the date of submitting a new application or expanding the scope and 2 years in the event of a renewal request.

The results of participation in proficiency tests/ inter-comparison programs must be satisfactory before applying the application, and the time range of these results must not exceed two years from the date of submitting a new application or expanding the scope, and three years in the event of a request for renewal of accreditation.

## 5.2 unsatisfactory results:

5.2.1 The CAB that obtains unsatisfactory results as part of its participation in proficiency tests/inter-comparison programs shall notify SAAC immediately with attached the corrective actions that it has taken or will take, explaining a comprehensive analysis of the source and reasons for this to happen. The entity submits it to take the appropriate action,

including conducting a field assessment of the entity to verify the continuity of its compliance with the accreditation requirements.

5.2.2 The CAB's failure shall notify SAAC of its unsatisfactory participation and authorizes SAAC to take appropriate decisions, including suspending the entity's accreditation certificate.

### **5.3 Participation in proficiency tests for laboratories (Medical/Testing/Calibration) and inspection bodies**

5.3.1 Each laboratory or inspection body accredited by SAAC or applying for accreditation shall participate in proficiency tests/interlaboratory comparison programs at the national, regional, or international level, covering the entire scope of accreditation of the laboratory or inspection body within accreditation cycle based on nature of the test and accreditation scope sub-disciplines.

5.3.2 Each laboratory or inspection body accredited by SAAC or applying for accreditation shall participate in proficiency tests/inter-comparison programs and fill out Form F-36 in the following order:

- 1- Upon availability of proficiency tests/inter-comparison programs accredited according to ISO / IEC 17043 by SAAC covering the field of approved tests, checks, and calibrations / to be approved for the laboratory or inspection body. (In the absence of availability, the transition will be made to the next case with proof of submission with the application)
- 2- When there are proficiency tests/inter-comparison programs accredited according to ISO / IEC 17043 at the national, regional, or international level, by an accreditation body that has signed a mutual recognition agreement covering the field of approved tests, checks and calibrations / to be approved for the laboratory or inspection body. (In the absence of availability, the transition will be made to the next case with proof of submission with the application)
- 3- Availability of proficiency tests/comparison programs accredited according to ISO / IEC 17043 at the national, regional, or international level, by an AB not a signatory of ILAC-MRA covering the field of approved tests, checks, and calibrations / to be approved for the laboratory or inspection body. (If this case is not available, then the transition to clause 5.3.3 shall be submitted with proof of submission with the application)

5.3.3 In the absence of any of the cases mentioned in clause 5.3.2 above, the laboratory or the accredited / advanced inspection body can apply for accreditation from SAAC after submitting evidence to participate in proficiency tests/inter-comparison programs not accredited.

### **5.4 Inter-laboratory comparisons**

If the cases mentioned in Clause 5.3 above are not available; CAB - after submitting evidence with the demand that there are no proficiency programs or comparison programs - can use one of the following methods:

- 1- Structured comparison tests between three laboratories or more.
- 2- Providing an internal sample or a product to one or more other external laboratories for data comparison.
- 3- The inspection bodies shall provide evidence that they internally monitor the quality of the inspection results in accordance with Guide No. G-I-04.

Provided that the regulator has documented procedures for conducting the comparison and conducting statistical analysis, based on the specifications of ISO 17043 and ISO 13528, and the regulator must obtain the approval of SAAC before carrying out the comparison.