

PROFICIENCY TESTING AND OTHER COMPARISON PROGRAMMES REQUIREMENTS FOR CALIBRATION LABORATORIES

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Table of Contents

	Page
1. PURPOSE AND SCOPE	3
2. DEFINITIONS	3
3. BACKGROUND.....	3
4. GENERAL REQUIREMENTS	4
4.1 On Application for Accreditation.....	4
4.2 Maintenance of Accreditation	4
4.3 PT/ILC Activity Plan	4
4.4 During Assessment	6
5. REFERENCES.....	7
APPENDIX – AMENDMENT RECORD	8

1. PURPOSE AND SCOPE

The purpose of this document is to define SADCAS' policy and specific requirements for participation in Proficiency Testing activities by applicant and accredited calibration laboratories.

2. DEFINITIONS

- 2.1 **Inter Laboratory Comparison (ILC)** is the design, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.
- 2.2 **Proficiency Testing (PT)** is the evaluation of participant performance against pre-established criteria by means of inter laboratory comparison.
- 2.3 **Proficiency Testing Scheme** is the proficiency testing designed and operated in one or more proficiency testing rounds for a specific area of measurement, testing, calibration, examination, sampling or inspection.
- 2.4 **Proficiency Testing Scheme Report** is the content of proficiency testing scheme reports which may vary depending on the purpose of a particular scheme but each report shall be clear and comprehensive and include data on the distribution of results from all participants, together with an indication of the performance of individual participants.

3. BACKGROUND

SADCAS shall ensure that its accredited laboratories participate in proficiency testing or other comparison programmes, where available and appropriate, and corrective actions are carried out when necessary. An applicant or accredited Calibration Laboratory is therefore required to plan and monitor its participation in PT and/or ILCs other than PT. The planning shall take into account the risks and opportunities of the calibration laboratory activity. This includes an evaluation of the level and frequency of participation in PT and/or ILCs other than PT.

It is recognized that there may be areas where appropriate PT schemes are not available or are not practical, in such cases appropriate alternative shall be proposed by the laboratory and agreed to by SADCAS. This agreement shall be documented.

A PT is considered available if it is offered by a competent PT provider and the required documents are provided in the national language of the participating calibration laboratory or a language understood by the calibration laboratory.

PT/ILC schemes can be regarded as technically appropriate, if the scope of activity being provided is similar to the current practice of the applicant or accredited calibration laboratory.

Applicant and Accredited laboratories shall ensure that where satisfactory performance is not achieved, appropriate root cause analysis is undertaken and corrective action is implemented and its effectiveness monitored. SADCAS shall assess the evidence of implementation of prompt and appropriate corrective actions.

4. GENERAL REQUIREMENTS

4.1 On Application for Accreditation

All applicant calibration laboratories are required to participate in appropriate proficiency testing or inter laboratory comparisons (PT/ILCs) for the scope of accreditation required and provide SADCAS with the relevant proof on application for accreditation. SADCAS shall assess to ensure that there is a representative and satisfactory participation in PT/ILCs regarding applicant scope before granting accreditation.

4.2 Maintenance of Accreditation

4.2.1 All accredited calibration laboratories are required to participate in PT/ILC schemes that to the extent possible, comply with the requirements of ISO/IEC 17043 in order to confirm their ongoing competence and measurement capabilities. The calibration laboratory shall satisfy itself on the competence of the PT providers whose schemes it voluntarily participates in. The case of small ILCs should comply to *EA-4/21 INF - Guidelines for the assessment of the appropriateness of small interlaboratory comparison within the process of laboratory accreditation*.

4.2.2 Links to Proficiency Scheme Providers or applicable ILCs are available on the SADCAS website www.sadcas.org, SADCA website www.sadca.org and the AFRAC website <https://www.intra-frac.com>

4.2.3 Where appropriate, all accredited calibration laboratories shall participate in PT/ILC for items on their schedule of accreditation including specific instruments or measurement devices where they have been separately listed. For example, each separate item may include DC Voltage, DC Current, Gauge Pressure and specific instruments may include Tachometers, Oscilloscopes and liquid in glass thermometers.

4.2.4 The laboratory shall investigate all measurement results that fail to meet the minimum acceptance criteria, including where there is evidence of consistent poor performance, and record the root cause analysis conducted and all corrective action(s) taken.

PT/ILC Activity Plan

4.2.5 All applicant and accredited calibration laboratories shall:

- define its level and frequency of participation after careful analysis of its other measures for ensuring the validity of results;

- submit a PT/ILC activity schedule that foresees a representative participation in PT / ILCs activities regarding any accreditation scope for consideration by SADCAS in relation to the activities performed under the laboratory's scope of accreditation.

NB: Additional guidance on determining level and frequency of PT participation can be found in **EA-4/18 G: 2021**

- 4.2.6 The PT/ILC plan shall be addressed in the laboratory's documented management system and the plan shall be subject to review in response to changes in staff, methodology or instrumentation, revision and approval as described.
- 4.2.7 The laboratory may incorporate in the plan participation in any other organized PT or other comparison programmes organized nationally, regionally or internationally.
- 4.2.8 Where no formal PT is practical or available, the laboratory shall indicate suitable alternative means by which performance will be assessed and monitored. This may include activities arranged by themselves (bilateral or multilateral comparisons, etc.).
- 4.2.9 SADCAS shall assess the justifications of the laboratory's alternative approaches when there are no available or appropriate PT / ILCs to cover the applicant or accredited scope. SADCAS shall verify that the alternative approach implemented by the laboratory ensures the validity of the results.
- 4.2.10 The laboratory's PT activity plan shall be available for evaluation during the assessment of the laboratory; additionally, SADCAS may request that a copy of the plan be submitted for evaluation at any time. The laboratory shall ensure that the plan is maintained and kept current.
- 4.2.11 The PT activity plan should address:
- Identification of participants and/or potential participants for ILC;
 - Name and/or identification of the PT schemes which the laboratory intends to participate;
 - Name and identification of reference material used;
 - The proposed measurement artifact or instrument;
 - The measurement parameters, including range and measurement points;
 - How the reference value is to be established;
 - The minimum acceptance criteria;
 - Responsibility for issue of the PT/ILC report;
 - Where applicable, the typical ranges that cover the scope of accreditation, particularly where measurements at extremities may pose specific measurement challenges i.e. high temperatures and low pressures;
 - Any issues experienced with participating in PT; and
 - Frequency of participation per time period justified by the laboratory.

4.2.12 Determining the suitability of calibration laboratory's PT Plan

The following aspects shall be taken into consideration by SADCAS when determining the suitability of an accredited calibration laboratory's PT participation plan. That is, its "level" and "frequency" of participation in PT in relation to the activities, performed under its accreditation scope:

- The accredited calibration laboratory should define its level and frequency of participation after careful analysis of other measures in place for ensuring the validity of results. The level of participation should be made dependent on the extent to which other measures have been taken.
- Risks and opportunities associated with the laboratory activities, in particular those that will prevent, or reduce, undesired impacts and potential failures in the laboratory activities.
- The level of risk presented by the accredited laboratory, the sector in which it operates or the methodology it is using. This can be determined, for example, by considering:
 - Number and frequency of calibrations/sampling/measurements undertaken;
 - Calibration intervals;
 - Complexity and robustness of the methodology;
 - Turnover of technical staff;
 - Experience and knowledge of technical staff;
 - Source of metrological traceability (e.g. availability of reference materials, national measurement standards, etc.);
 - Known stability/instability of the measurement technique;
 - Stability of the analyte and matrix, and the impact of storage and transportation;
 - Significance and final use of calibration/sampling data (e.g. forensic science, food safety and medical laboratories represent areas requiring a high level of assurance); and
 - Level of risk posed by biohazardous PT items used and the containment precautions required.

4.3 During an Assessment

4.3.1 The laboratory's participation in PT/ILC activities will be evaluated against the documented plan.

4.3.2 The laboratory shall make available to the assessment team all proficiency testing schemes and ILC reports and appropriate evidence of the competence of the PT/ILC provider to organise the PT/ILCs in accordance with the relevant requirements of ISO/IEC 17043.

NOTE: PT providers accredited to ISO/IEC 17043 by an Accreditation Body (AB) signatory of the ILAC MRA for PT providers or a PT provider accredited to ISO/IEC 17043 by an applicant AB or an AB non-signatory of the ILAC MRA for PT providers are considered appropriate and competent. Organisation of, or participation in, ILCs organised, in accordance with the relevant requirements of

ISO/IEC 17043, to determine the performance of accredited calibration laboratory by comparison with results of other laboratories is also considered appropriate to demonstrate the validity of results.

4.3.3 PT/ILC reports shall be clear and comprehensive and include at least the following minimum information:

- Identification of the participants;
- Measurement protocol;
- Identification of the measurement standard or artefact;
- The reference value(s) and how these were established;
- Evaluation of the measurement results;
- An indication of the performance of individual participants;
- Minimum acceptance criteria; and
- Conclusion.

4.3.4 The effectiveness of corrective action taken will be evaluated during the assessment and taken into consideration during the decision making process.

Note: Additional guidance on the evaluation of measurement results and preparation of PT/ILC scheme reports is available in ISO/IEC 17043.

5. REFERENCES

- SADCAS PM 01 - SADCAS Policy Manual.
- ISO/IEC 17011 - Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.
- ISO/IEC 17025 - General requirements for the competence of testing and calibration laboratories.
- ISO/IEC 17043 - Conformity assessment – General requirements for the competence of proficiency testing providers.
- EA-4/21 INF - Guidelines for the assessment of the appropriateness of small interlaboratory comparison within the process of laboratory accreditation.
- ILAC P 9: ILAC Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing.
- EA-4/18 G: 2021 – Guidance on the level and frequency of Proficiency Testing Participation.

APPENDIX - AMENDMENT RECORD

Revision Status	Change			Approved by	Effective Date
	Page	Clause/ Subclause	Description of Change		
Issue 1	-	-	-	CEO	2011-06-27
Issue 1	2	Title	Inserted "and other comparison programmes".	CEO	2013-04-24
	3	2	Added definitions for "interlaboratory comparison" and "Proficiency Testing".	CEO	2013-04-24
		3	Extended background to elaborate on what is to be done in the case where PT schemes are not available.	CEO	2013-04-24
	3 to 5	4	General Requirements restructured into 4 subclauses covering the requirements on application for accreditation, maintenance of accreditation, PT/ILC Activity Plan and during an assessment.	CEO	2013-04-24
	5 to 6	5	Deleted reference to ILAC G13	CEO	2013-04-24
Issue 2	6	5	Deleted "ILAC P 9:11/2010.....activities" and substituted with "ILAC P 9: ILAC Policy for Participation in Proficiency Testing Activities"	CEO	2014-09-29
Issue 3	Whole Document		Aligned the procedure with ILAC-P9:01/2024	CEO	2025-01-27