PROFICIENCY TESTING AND OTHER COMPARISON PROGRAMMES REQUIREMENTS FOR TESTING AND MEDICAL LABORATORIES

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1. PURPOSE AND SCOPE

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

This document applies to all testing laboratories which includes mechanical and physical, chemical and microbiological, veterinary, pharmaceutical, forensic testing laboratories, medical laboratories etc.

2. DEFINITIONS

2.1 **Inter Laboratory 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.

2.2 **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 inter laboratory comparison.

2.3 **Proficiency Testing Scheme** is the proficiency testing designed and operated in one or more rounds for a specific area of testing, measurement, calibration 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. SADCAS is also required to specify the minimum amount and frequency of proficiency testing participation by laboratories.

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

Accredited laboratories shall ensure, where necessary, that appropriate root cause analysis, corrective actions and preventive actions are carried out.

4. GENERAL REQUIREMENTS

4.1 On Application for Accreditation

4.1.1 All applicant testing/medical laboratories are required to participate in appropriate proficiency testing or inter laboratory comparisons for the scope of accreditation required and provide SADCAS with the relevant proof on application of participation and satisfactory performance.

4.1.2 Proficiency Testing may include:

(i) An external proficiency testing scheme, preferably operated in accordance with ISO/IEC 17043; and
(ii) Inter laboratory comparison scheme (where two or more laboratories are used).

4.2 Maintenance of Accreditation

4.2.1 All accredited testing/medical laboratories must preferably participate in proficiency testing schemes that have been independently shown to comply with the requirements of ISO/IEC 17043. Participation in other unaccredited schemes is acceptable until such time that there are sufficient accredited schemes in the various disciplines. The laboratory shall satisfy itself on the competence of the PT providers whose schemes it voluntarily participates.

4.2.2 All accredited medical laboratories shall participate in proficiency testing at least twice per year (minimum of 2 cycles per year covering all accredited parameters). However, the adequacy of participation shall be evaluated based on risk assessment.

4.2.3 All accredited testing laboratories shall participate in proficiency testing at least once per year.

4.2.4 Links to Proficiency Scheme Providers are available on the SADCAS website www.sadcas.org. A list of Proficiency Scheme Providers is also available on the SADCA website www.sadca.org.

4.2.5 Where appropriate, all accredited testing/medical laboratories shall participate in PT/ILC for items on their schedule of accreditation including specific tests or methods where these have been separately listed. These shall be addressed in the PT activity plan. For example, separate items under Inductively Coupled Plasma (ICP) analysis may include Fe, Mn, Zn.

4.2.6 Laboratories can from time to time be invited to participate in international PT schemes. Such participation is usually above and beyond that as required by SADCAS and is at the discretion of the Testing Laboratory and/or SADCA.

4.2.7 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 and preventive action(s) taken.

4.3 **PT/ILC Activity Plan**

4.3.1 All accredited testing/medical laboratories shall have available PT/ILC plans for at least 2 accreditation cycles, i.e. the activity schedule for the past accreditation cycle (where possible) and the plan for the subsequent accreditation cycle.

4.3.2 The plan shall cover all activities as specified above and shall be accomplished in a period not exceeding 1 accreditation cycle.

Note: The frequency and extent of participation shall be justified by the laboratory to SADCAS for each accredited method and shall be included in the plan.

4.3.3 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.

4.3.4 The laboratory may incorporate in the plan participation in any other organized PT or other comparison programmes organized nationally, regionally or internationally.

4.3.5 Where no formal PT is practical or available, the laboratory shall indicate suitable alternative means by which performance will be assessed and monitored. They may include activities such as intra laboratory comparisons, the use of reference materials or other comparisons. SADCAS will consider these alternative arrangements as part of the laboratory's planned activities. The onus is on the laboratory to provide the details of the plan and its justification thereof and obtain approval from SADCAS.

4.3.6 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.

4.3.7 The PT activity plan should address:

- A breakdown of the parameters for which PT is conducted;
- PT type (inter laboratory comparison; intra laboratory comparison);
- 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 artefact 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.

4.4 **During an Assessment**

4.4.1 The laboratory's participation in PT/ILC activities will be evaluated against their plan. Failure of laboratories to show effective participation could result in suspension of accreditation.

4.4.2 The laboratory shall make available to the assessment team all proficiency testing schemes and ILC reports.

4.4.3 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.

4.4.4 The effectiveness of corrective and preventive 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 ILAC G 22.

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 proficiency testing
- ILAC P 9: ILAC Policy for Participation in Proficiency Testing Activities

APPENDIX - AMENDMENT RECORD

Revision Status	Change			Approved by	Effective Date
	Page	Clause/ Subclause	Description of Change		
Issue 1	-	-	-	CEO	2011-06-27
Issue 1	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 2	1	Title	Deleted "Calibration" and substituted with "Testing and Medical	CEO	2018-11-15
Issue 3	4	4.2	Specified the minimum PT participation frequency for testing and medical laboratories	CEO	2023-09-22