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

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Table of Contents

Page

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 medical laboratories and testing laboratories which includes mechanical and physical, chemical and microbiological, veterinary, pharmaceutical, forensic testing laboratories etc.

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)/External Quality Assessment (EQA)** 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. An applicant or accredited Testing/Medical 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 testing/medical 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 an 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 testing/medical laboratory or a language understood by the testing/medical laboratory.

PT 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 testing/medical laboratory.

Applicant and Accredited testing/medical 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

4.1.1 All applicant testing/medical 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 representative and satisfactory participation in PT/ILCs regarding applicant scope before granting accreditation.

4.2 Maintenance of Accreditation

4.2.1 All accredited testing/medical laboratories shall participate in proficiency testing schemes/programmes that to the extent possible, comply with the requirements of ISO/IEC 17043. The testing/medical laboratory shall satisfy itself on the competence of the PT providers whose schemes it voluntarily participates.

4.2.2 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 and the AFRAC website https://www.intra-afrac.com

4.2.3 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.

4.2.4 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/medical laboratory and/or SADCAS.

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

4.2.6 All medical laboratories shall assess the clinical significance of non-conformances as they relate to patient samples. Where it is determined that the impact is clinically significant, a review of the patient results that could have been affected shall be conducted and users advised as appropriate.

4.3 **PT/ILC Activity Plan**

4.3.1 All applicant and accredited testing/medical laboratories shall develop PT/ILC plans that foresees a representative participation in PT/ILC activities regarding any accreditation scope.

4.3.2 The plan shall cover the scope of accreditation 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. Additional guidance on determining level and frequency of PT participation can be found in **EA-4/18 G: 2021**

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 suitable/appropriate formal PT is available, the testing/medical laboratory shall use alternative methodologies to monitor examination method/test performance. The testing/medical laboratory shall justify the rational for the chosen alternative and provide evidence of its effectiveness.

4.3.6 SADCAS shall assess the justifications of the testing/medical laboratory's alternative approaches. SADCAS shall verify that the alternative approach implemented by the laboratory ensures the validity of the results.

4.3.7 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.

4.3.8 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 Determining the suitability of testing/medical laboratory's PT Plan

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

- The accredited testing/medical 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 tests/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 test or measurement technique;
    - Stability of the analyte and matrix, and the impact of storage and transportation;
    - Significance and final use of test results (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.

4.5 During an Assessment

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

4.5.2 The laboratory shall make available to the assessment team all proficiency testing schemes and/or ILC reports and provide appropriate evidence of the competence of the PT Provider.

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 laboratory by comparison with results of other laboratories is also considered appropriate to demonstrate the validity of results.

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

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

4.5.4 The effectiveness of corrective 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 15189 – Medical Laboratories – Requirements for Quality and Competence
- ISO/IEC 17043 - Conformity assessment – General requirements for the competence of proficiency testing providers
- 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	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
Issue 4	Whole Document		Aligned the procedure with ILAC-P9:01/2024	CEO	2025-01-27