SDAC Policy for Participation in Proficiency Testing Activities

HISTORY OF THE DOCUMENT

Version number	Reason(s) of revision	Scope of the revision
Ver 1.0:2/2020	- Replaces SDAC-PT-23 - Update of layout	Full revision

1.PURPOSE

A regular independent assessment of the technical performance of a laboratory is necessary to assure the validity of measurements or tests and should be part of an overall quality strategy. A common approach to this independent assessment is the use of independent Proficiency Testing (PT) schemes. Proficiency testing is a tool to demonstrate laboratory competence and to assist in maintaining the quality of the laboratory performance

According to ISO/IEC 17025 laboratories shall have a procedure for monitoring the results validity of tests and calibrations undertaken. This monitoring includes the participation in inter laboratory comparisons or proficiency testing programs.

This document defines the SDAC's policy for implementation of Proficiency Testing by accredited and applicant laboratories.

2. SCOPE

This policy applies to the Laboratory accreditation schemes (Calibration, Testing and Medical) and to Laboratories included in inspection and product certification bodies.

3. REFERENCES AND DEFINITIONS

ISO/IEC 17025:2017 Laboratories.	General Requirements for the Competence of Testing and Calibration
ISO/IEC 17043:2010	Conformity assessment – General requirements for Proficiency Testing
ISO 15189:2012	Medical laboratories – Requirements for quality and competence
ILAC-P9/06:2014	ILAC Policy for Participation in Proficiency Testing Activities.

4. DEFINITIONS

Inter laboratory Comparison (ILC):
Organisation, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.

Proficiency Testing (PT):
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. Note: In Medical Laboratories, PT is often referred to as EQA (External Quality Assurance)

Proficiency Testing Scheme:
Proficiency testing designed and operated in one or more rounds for a specific area of testing, measurement, calibration or inspection. Where reference to PT/ILC is made in this document, it will also include alternatives to PT/ILC, as agreed on by SDAC.

5. ROLE(S) AND RESPONSIBILITY
Accredited and applicant laboratories: compliance

6. POLICY

6.1 PT AND OTHER METHODS FOR PROOF OF COMPETENCE

6.1.1 The most preferred mean for demonstration of competence is the successful participation in a PT offered by an ISO/IEC 17043 accredited PT provider where PT is available and appropriate.

6.1.2 It is recognized that there are areas of testing and calibration for which suitable PT does not exist or is not practical. The means listed below are considered suitable alternatives but shall be used only if evidence is given that a PT does not exist or participation is not practical and approval is obtained from SDAC.

These alternative means in order of preference are:

a) use of PT from a non-accredited PT provider. However, the laboratory shall satisfy itself on the competence of the PT providers whose schemes it participates in.
b) inter laboratory comparisons (ILC) according to pre-determined conditions and methods
c) comparison of results between labs on mutual agreement
d) participation in the determination of properties of a (potential reference) material where the mean value determined will be considered as property
e) participation in the determination of performance characteristic of a method where the mean value determined will be considered as property
f) sending samples to other accredited labs for test/calibration on own costs and initiative
g) using CRM or reliable reference materials
h) intra laboratory comparisons

6.2 LEVEL AND FREQUENCY OF PARTICIPATION

6.2.1 Before granting accreditation, SDAC requires at least one successful PT/ILC participation in each technical area for which accreditation is sought. The identification of the main technical area can be done in collaboration with SDAC. It is required to prove that those results are referring to relevant methods and facilities as requested in the application.

6.2.2 When the laboratory is accredited, SDAC requires at least one successful PT/ILC participation during the accreditation cycle (3 years) in each technical area for which accreditation is granted as listed on the schedule of accreditation.

However, the CABs may and are encouraged to participate in proficiency testing programs more than the minimum required frequency i.e. once within 3-years.

There are also certain aspects needed to be considered by the CAB when determining the extent and the frequency of participation in proficiency tests. Such aspects may include:

- Legislative requirements set by the regulators, industry or professional sectors.
- Internal measures for quality assurance as the use of CRM, use control charts, application of different methods for the determination of the same parameter, etc.;
- The potential risk of false results within the respective category;
- The quantity of the performed tests/calibrations/inspections and also the significance and the effect on the final use of the results;
- The qualification of the personnel.

6.2.3 CABs are encouraged to participate proficiency testing schemes in the frame work of SDAC cooperation with the regional accreditation bodies (AFRAC, ARAC,……) in the fields of calibration , testing and medical laboratories. The nomination of CAB is made through SDAC according to the pertinence of the technical areas.

6.3 PT/ILC ACTIVITY PLAN

6.3.1 All accredited testing laboratories shall have available PT / ILC plans covering the overall scope in a period of one accreditation cycle (3 years).

6.3.2 Where PT/ILC are not available or applicable, the CAB shall enlist the other means it selects to ensure the validity of the results

6.3.3 The laboratory is required to incorporate in the plan participation in PT or other comparison programmes organised nationally, regionally or internationally

6.3.4 The laboratory has to define an adequate frequency for the review and update of PT/ILC plan and take into consideration changes in staff, methodology or instrumentation etc. It shall subject to revision and approval and be part of management review.

6.3.5 The laboratory shall make available the form SDAC-F-60 for evaluation during the assessment of the laboratory; the laboratory shall ensure that the form is maintained and kept current.

6.4 EVIDENCE OF PARTICIPATION IN PT/ILC

6.4.1The laboratory shall make available to the assessment team all proficiency testing scheme and ILC results certificate reports. Proficiency testing / 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;
- Measurement results;
- 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;
- Conclusion.

6.4.2 The CAB is required to create a brief summarizing all proficiency tests. The participation has to be evaluated with respect to each parameter. The summary has to contain at least the following information, if available:

- Name of test/parameter/activity
- Date of execution of the proficiency test;
- Proficiency test provider;
- Product/matrix;
- Non successful/passed parameters – where possible including z-score or 'En number';
- Corrective actions with root cause analysis for unsatisfactory results.

The laboratory shall send its summary report to SDAC when applying, and before each visit.

6.4.3 The records of the lab reviewing its own performance, investigating all unsatisfactory measurement results and the implemented corrective measures in case of non-successful participation have to be available easily on-site and provided to the assessment team.

6.5 ASSESSMENT AND DECISION MAKING

6.5.1 The suitability of the scope of participation and the adequacy of chosen proficiency testing or inter laboratory comparisons shall be estimated by the assessment team during the assessment procedure.

6.5.2 The laboratory's participation in PT / ILC activities or suitable alternatives to PT, as agreed by SDAC, will be evaluated against their plan. Failure of laboratories to show effective and sufficient participation, or that the use of alternatives to PT has been agreed on by SDAC, could have consequences for the CAB accreditation. In principle insufficient participation in a single proficiency test does not have immediate consequences for the accreditation

6.5.3 The results, the result analysis, as well as any possible actions deriving from the result of participation in PT/ILCs, shall in constitute an obligatory part of review during each surveillance/assessment visit.

6.5.4 In case of non-successful participation the effectiveness of corrective and preventative action taken will be evaluated during the assessment, and taken into consideration during the decision making process.

6.5.5 Insufficient or unsuccessful participation results need to be processed as nonconformity.

6.5.6 When a laboratory's participation is insufficient or unsuccessful, and the appropriate action has not been taken in proper time, or when a laboratory has unsuccessfully participated several times in a sequence, SDAC may:
-require another participation in a similar comparison;
-undertake an extraordinary surveillance visit; or
- withdraw or suspend partially or completely the accreditation scope

6.6 AVAILABILITY OF PT SCHEMES

For information about available PT schemes laboratories can:

- refer to the EPTIS database (www.eptis.bam.de) ;
- check accredited PT Providers whose accreditation information is published by accreditation bodies;
- ask peer laboratories that already participate in PTs.

7. RELATED FORMS

SDAC-F-60 Proficiency Testing plan and Metrological Traceability