



# R 48-05 Draft 1

## PROFICIENCY TESTING AND OTHER COMPARISON PROGRAMME REQUIREMENTS FOR CALIBRATION LABORATORIES

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## 1. Purpose and Scope

The purpose of this document is to define the proficiency testing requirements which form part accreditation criteria to be met by applicant and accredited calibration laboratories. This document is applicable to accredited bodies in this discipline and as defined in the Accreditation Act, Act No. 19 of 2006 [7]. ~~The purpose of this document is to define SANAS' policy and specific requirements for participation in Proficiency Testing activities by accredited and applicant Calibration Laboratories.~~

## 2. References, Definitions and Abbreviations

### 2.1 References

- |     |                    |   |
|-----|--------------------|---|
| [1] | ISO/IEC 17025:2017 | General requirements for the competence of testing and calibration laboratories.                                |
| [2] | ILAC-P9/06:2014    | ILAC Policy for Participation in Proficiency Testing Activities.  |
| [3] | SANAS PM01         | SANAS Policy Manual.  |
| [4] | ISO/IEC 17043:2010 | Conformity assessment – General requirements for proficiency testing.   |
| [5] | ISO/IEC 17011      | Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies. |
| [6] | SANAS A01          | References, Acronyms and Definitions  |
| [7] | Accreditation Act  | No. 19 of 2006: Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act, 2006     |

### 2.2 Definitions

#### 2.2.1 Interlaboratory Comparison:

Organisation, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions. [4]

#### 2.2.2 Proficiency Testing:

~~Evaluation of participant performance against preestablished criteria by means of interlaboratory comparisons. [1]. 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 interlaboratory comparison.~~

#### 2.2.3 Proficiency Testing Scheme:

Proficiency testing designed and operated in one or more rounds for a specific area of testing, measurement, calibration or inspection. [4]

#### ~~2.2.4 National Measurement Audit:~~

~~Proficiency testing scheme managed and operated by the National Metrology Institute of South Africa NMISA on behalf of SANAS, used to confirm the ongoing capability and competence of accredited calibration laboratories.~~

### 2.3 Abbreviations

CMC:	Calibration and Measurement Capability
PT:	Proficiency Testing
ILC:	Interlaboratory Comparison
NMISA:	National Metrology Institute of South Africa
UoM:	Uncertainty of Measurement

### 3. Background

ISO/IEC 17025:2017 requires all laboratories including laboratories seeking accreditation to participate in proficiency testing where available and appropriate. ~~SANAS shall ensure that their accredited facilities participate in proficiency testing or other comparison programmes, where available and appropriate.~~

The laboratories management system shall address the risk associated with the level and frequency of proficiency testing planned and undertaken. [1]

SANAS is also required to specify the minimum amount and frequency of proficiency testing participation by laboratories. [2] [5]

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 SANAS. This agreement shall be documented.

Accredited laboratories shall use the results of proficiency testing to identify opportunities for improvement and shall implement any necessary actions. [1] ensure, where necessary, that appropriate root cause analysis, corrective actions and preventative actions are carried out.

### 4. General Requirements

#### 4.1 On Application for Accreditation

All applicant calibration laboratories are required to participate in *appropriate* proficiency testing or Interlaboratory comparisons for the scope of accreditation required and provide SANAS with the relevant proof on application of participation and satisfactory performance.

'Appropriate' participation can be described as that level of participation which will result in an acceptable level of risk, i.e. risk that the laboratory may issue certificates and/or reports with results falling outside of the specified measurement uncertainty stated on the certificate.

The SANAS policy requires that laboratories undertake proficiency testing or ILC's for all items or parameters listed on their proposed schedule of accreditation, covering a large portion of their proposed range and at a consummate level of uncertainty.

The policy does not require that PT participation always cover the entire measurement range nor that the uncertainty of the reference value always be considerably smaller than the CMC's proposed by the applicant, *however* where measurements are at range extremities (e.g. very high pressures and temperatures) or CMC's are relatively smaller than uncertainties typically available, then this is an indication of increased risk, and evidence of successful ILC or PT participation must be made available, to support the application.

Whilst this policy accepts that there may be areas where ILC or PT's are not commercially available, in cases where there is increased risk, then the lack of *commercially* available ILC's or PT is not *necessarily* considered a valid reason for non-participation.

#### 4.2 Maintenance of Accreditation

- ~~4.2.1 All accredited calibration laboratories are required to participate in the National Measurement Audit in order to confirm their ongoing competence and measurement capabilities, where such audits are arranged.~~
- 4.2.1 It is recognized that National Metrology Institutes i.e. NMISA may be faced with challenges in participation in routine PT activities due to the infrequency of suitable International inter-comparisons, in such cases the institute shall propose suitable alternatives to confirm their on-going competence.
- 4.2.2 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 these have been separately listed. These items, instruments or measuring devices shall be addressed in the PT activity plan. 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. Calibration laboratories should also consider including different methods into their ILC/PT plans.
- 4.2.3 The laboratory **shall** review their own performance and investigate all measurement results that fail to meet the minimum acceptance criteria and record the root cause analysis conducted and all corrective and preventative action(s) taken.

#### 4.3 PT/ILC Activity Plan

- 4.3.1 All accredited calibration laboratories shall have available a PT / ILC activity schedule that covers the past 5-year period (historic - where possible) and the plan for the subsequent 5 year period.
- 4.3.2 The plan **shall** cover all activities as specified above and shall be accomplished in a period not exceeding 5 years.
- 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, revision and approval as described.
- ~~4.3.4 The laboratory may incorporate in the activity plan participation in the National Measurement Audit program, and participation in any other organized PT activity, or PT arranged by regional / international organizations.~~
- 4.3.4 Where no formal PT is available, the laboratory shall indicate other interlaboratory activities in which they intend to participate. These may include activities arranged by themselves (bilateral or multilateral inter-laboratory comparisons etc.) with other laboratories in order to satisfy this requirement. Such laboratory arranged ILC (e.g. bilateral comparisons) must still comply with the reporting requirements in 4.4.
- 4.3.5 The laboratory's PT activity plan **shall** be available for evaluation during the assessment of the laboratory; additionally, SANAS 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.

4.3.6 The PT activity plan should address:

- Identification of participants, and/or potential participants for ILC;
- The name/s and or identification of the PT schemes which the laboratory intends to participate;
- The proposed measurement artefact or instrument;
- The measurement parameters, including range and measurement points;
- How the reference or consensus value is to be established;
- **How the uncertainty of the reference value or the uncertainty of the inter-laboratory comparison is to be established;**
- The minimum acceptance criteria;
- Responsibility for issue of the PT / ILC report, and who will act as the referee in the event there are only 2 participants and there is a disagreement in the results;
  - 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.
  - **It is accepted that the detail in the plan will be more comprehensive for current and flowing year, than activity scheduled only for 4- or 5-years' time.**

4.4 *During an Assessment*

4.4.1 Laboratory's participation in PT / ILC activities will be evaluated against their plan.

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

4.4.3 Proficiency testing scheme / 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.

4.4.4 The effectiveness of corrective and preventative 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 17043:2010 [4].*

**ADDENDUM 1: AMENDMENT RECORD**

<b>Proposed By:</b>	<b>Section</b>	<b>Change</b>
AM	References	Updated to latest ILAC P9 document
Assessor	2.3	Removed reference to NLA
AM	4.1	Details added to describe 'appropriate' – 2 <sup>nd</sup> , 3 <sup>rd</sup> & 4 <sup>th</sup> paragraphs
AM	4.2.1	Added 'where such audits are arranged' with reference to National Audits
Assessor	4.2.3	Added last sentence
AM	4.2.4	Added "review their own performance and"
Assessor	4.3.5	Added last sentence
AM & assessment specialist	4.3.7	"or consensus" added ", and who will act as the referee in the event there are only 2 participants and there is a disagreement in the results;" added
AM	1	Purpose and Scope – Updated to include reference to the Accreditation Act.
AM	2.1	References – Updated reference to current version of ISO/IEC 17025, Added reference to the accreditation Act.
AM	3	Updated text.
AM	4.3.6	PT Plan – Added bullet points, requirement for the uncertainty of the reference value, or assigned ILC uncertainty to be defined. Added clarification of the detail required on the PT Plan.
AM		References to the National Measurement Audit removed.