PROFICIENCY TESTING AND OTHER COMPARISON PROGRAMME REQUIREMENTS FOR TESTING AND MEDICAL LABORATORIES AND BLOOD TRANSFUSION SERVICES

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SANAS Executive Committee
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1. **Purpose and Scope**

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

This document applies to all testing laboratories, which includes mechanical and physical, chemical and microbiological, medical, veterinary, pharmaceutical, forensic testing laboratories and blood transfusion services (excluding donor clinics).

2. **References and Definitions**

2.1 **References**

<table>
<thead>
<tr>
<th>Reference</th>
<th>Title</th>
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<tbody>
<tr>
<td>SANAS PM 01</td>
<td>SANAS Policy Manual</td>
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<tr>
<td>SANAS A01</td>
<td>References, Acronyms and Definitions</td>
</tr>
<tr>
<td>ISO 15189:2012</td>
<td>Medical laboratories – Requirements for quality and competence</td>
</tr>
<tr>
<td>Standards of Practice for Blood Transfusion in South Africa</td>
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<tr>
<td>ISO/IEC 17011</td>
<td>Conformity Assessment – General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies.</td>
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2.2 **Definitions**

2.2.1 **Interlaboratory 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.

2.2.2 **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 interlaboratory comparison.

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

2.2.2 **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 SANAS.

2.3 **Abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>PT</td>
<td>Proficiency Testing</td>
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<tr>
<td>ILC</td>
<td>Interlaboratory Comparison</td>
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3. **Background**

SANAS shall ensure that its accredited laboratories participate in proficiency testing or other comparison programmes, where available and appropriate. SANAS 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 SANAS. This agreement shall be documented.
Accredited laboratories shall 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

4.1.1 All applicant testing 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 reports with results falling outside of the specified measurement uncertainty stated on the report. 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.

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

4.1.2 Proficiency Testing activities may include:

i) an external proficiency testing scheme, preferably operated in accordance with ISO/IEC 17043;

ii) an Inter-laboratory comparison scheme (where two or more laboratories are used);

iii) suitable alternative to PT/ILC, as agreed to by SANAS, where PT schemes are not available or are not practical.

4.2 Maintenance of Accreditation

4.2.1 All accredited testing 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 in.

4.2.2 SANAS Accredited Proficiency Scheme Providers are available on the SANAS website. A register of non-accredited proficiency scheme providers and specific inter-comparison schemes are included on the SANAS website for information purposes only but will not imply that any of these schemes meet any recognized criteria.

4.2.3 Where appropriate, all accredited Testing 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 ICP analysis may include Fe, Mn, Zn.

4.2.4 Laboratories can from time to time be invited to participate in international proficiency testing schemes. Such participation is usually above and beyond that as required by SANAS and is at the discretion of the Testing Laboratory and / or SANAS.
4.2.5 The laboratory shall review their own performance and 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 preventative action(s) taken.

4.3 PT/ILC Activity Plan

4.3.1 All accredited testing 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 SANAS 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 organised PT or other comparison programmes organised 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. These may include activities such as intra laboratory comparisons, the use of reference materials or other comparisons. SANAS 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 SANAS. Such alternatives must still comply with the reporting requirements in 4.4.3.

4.3.6 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.

4.3.7 The PT activity plan should address:

- A breakdown of the parameters for which PT is conducted;
- Proficiency testing type (Inter-laboratory comparison; Intra-laboratory comparison; Use of a Reference material, PT scheme);
- Identification and number of participants, and/or potential participants for ILC;
- The name/s and or identification of the PT schemes which the laboratory intends to participate;
- Name and make of reference material used;
- The proposed measurement artefact or instrument;
- The measurement parameters, including range and measurement points;
- How the reference or consensus value 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;
- Any issues experienced with participating in PT;
- 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 or suitable alternatives to PT, as agreed by SANAS, will be evaluated against their plan. Failure of laboratories to show effective participation, or that the use of alternatives to PT has been agreed on by SANAS, could result in suspension of the tests concerned.

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

4.4.3 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.

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.
# ADDENDUM 1: AMENDMENT RECORD

<table>
<thead>
<tr>
<th>Proposed By:</th>
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<th>Change</th>
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| QM           | 2.1     | Corrected reference to the outdated version of ILAC P9  
Removed reference to obsolete ILAC G22  
Added reference to ISO 15189 and Standards of Practice for Blood Transfusion in South Africa |
| QM           | 4.4.3   | Reference to ILAC G22 replaced by ISO/IEC 17043 |
| Stakeholder  | 1       | Added “blood transfusion services (excluding donor clinics)” |
| QM           | 2.2.1   | Added Note |
| QM           | 2.2.2   | Added “Where reference to PT/ILC is made in this document, it will also include alternatives to PT/ILC, as agreed on by SANAS.” |
| Assessor     | 2.3     | Abbreviations added |
| AM           | 4.1.1   | 2nd & 3rd paragraphs added |
| QM           | 4.1.2 (iii) | 3rd bullet added |
| AM           | 4.2.5   | Added “review their own performance and” |
| Assessor     | 4.3.5   | Added last sentence |
| Assessment specialist | 4.3.7 | Added “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 “and number” |
| QM           | 4.4.1   | Added “or suitable alternatives to PT, as agreed by SANAS,” “or that the use of alternatives to PT has been agreed on by SANAS,” “the tests concerned.” Replaced “accreditation” |
| QM           | 4.4.3   | ISO/IEC 17043 replaced ILAC G22 |