A GENERAL DESCRIPTION OF SANAS

Approved By: Chief Executive Officer: Ron Josias
SANAS Executive Committee

Revised By: Chief Executive Officer Ron Josias

Date of Approval: 2016-01-28
Date of Implementation: 2016-01-28
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1. **Introduction**

This document provides an overview of SANAS and how the organisation operates with respect to granting accreditation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks. It covers all the activities of SANAS in limited detail, but references other SANAS documents where appropriate.

2. **Definitions and References**

SANAS PM  SANAS Policy Manual  
SANAS A 01  References, Acronyms and Definitions  
Act 19 of 2006: Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act 19 of 2006

3. **Background on SANAS**

SANAS’ history spans over four (4) decades, starting in 1974, with the establishment of the National Calibration Service (NCS), whose focus was on the accreditation of calibration laboratories. In 1992, the NCS became the National Laboratory Accreditation (NLA), when the accreditation of Testing Laboratories was included.

On 17 January 1996, the NLA became SANAS, a registered non-profit organisation registered in terms of Section 21 of the Companies Act 61 of 1973, and recognised by government as the National Accreditation Body for South Africa. On 1 May 2007, SANAS’ recognition was formally enacted through the promulgation of the Act, changing its legal status to that of a public entity.

The Accreditation Act recognises SANAS as the only national accreditation body for the Republic of South Africa for conformity assessment, calibration, monitoring of Good Laboratory Practice.

SANAS is a Schedule 3A Public Entity in terms of the Public Finance Management Act 1 of 1999 (PFMA).

3.1 **SANAS’ Mandate**

SANAS is mandated through the Act to provide an internationally recognised and effective accreditation and monitoring system for the Republic of South Africa to:

- Accredit, or monitor for GLP compliance purposes, organisations falling within its scope of activity;
- Promote accreditation as a means of facilitating international trade and enhancing the Republic’s economic performance and transformation;
- Promote the competence and equivalence of accredited bodies; and
- Promote the competence and equivalence of GLP compliant facilities.
3.2 SANAS’ Policy Framework

SANAS operates in accordance with the requirements, criteria, rules and regulations as laid down in the following documents:

1. The Accreditation Act;
2. The PFMA;
3. Requirements of the international standard ISO/IEC 17011 “General requirements for bodies providing assessments and accreditation of conformity assessment bodies”;
4. Requirements as stipulated in the various Memoranda of Agreement with international bodies and national regulatory bodies; and
   • Requirements for national bodies to monitor GLP compliance with principles adopted by the OECD for GLP facilities.

One of SANAS’ core values is the national, regional and international acceptance of its accredited conformity assessment body’s results facilitated through a network of co-operations and entities. To facilitate and expand the recognition of our accredited conformity assessment body’s results/reports SANAS:

- Maintains Mutual Recognition Arrangements (MRA’s) with the International Accreditation Forum (IAF), the International Laboratory Accreditation Cooperation (ILAC) and the African Accreditation Cooperation (AFRAC);
- Maintains its national body status to monitor GLP compliance with principles adopted by the Organisation of Economic Co-operation and Development (OECD) for GLP facilities; and
- Establishes and maintains memorandum of understandings with various South African government departments using accreditation to support their health, safety and environmental protection obligations.

3.3 Funding

SANAS’ finances and procurement is executed within the framework of the PFMA. SANAS base its fee structure on a cost recovery basis for accreditation services rendered. Matters of national interest such as new programme development, expanding and maintaining international recognition, functions performed on behalf of the Republic of South Africa, such as SANAS’ involvement in regional integration and national projects, are funded by government.

Fees charged for services are reviewed annually and approved by the SANAS Board of Directors. The approved fee structure is formalised in SANAS’ fee document (P14“SANAS Fees”), which is available on the SANAS website.

Financial and performance monitoring are reported on a quarterly basis to SANAS’ Board of Directors and Department of Trade and Industry (the dti).

SANAS’ income is derived from:
- Government grant through the dti;
- Accreditation income (Application, initial and annual fees);
- Training income; and
- Projects income.
3.4 Governance

3.4.1 The SANAS Board of Directors is the Accounting Authority of SANAS. The SANAS Board of Directors is appointed by the Minister of the dti, who is the Executive Authority of SANAS.

The SANAS Board provides strategic direction for SANAS. The Board, in consultation with the Minister of the dti appoints the Chief Executive Officer of SANAS (CEO), who is responsible for the day to day functioning of SANAS. The CEO, together with the SANAS Executive Committee and SANAS’ Board of Directors sets the strategy for SANAS on a short and long-term basis.

3.4.2 The Advisory Forum

The Advisory Forum is a forum made up of stakeholder members.

The Advisory Forum is responsible for advising SANAS’ Board of Directors on all matters in which SANAS could play a role and any other matter on which the SANAS Board of Directors requests advice. Membership to the Advisory Forum is open only to associations, NGO’s, Professional Bodies, and Trade Unions at association level and State Departments with an interest in accreditation. The Advisory Forum has no executive powers in terms of SANAS. SANAS’ Board of Directors considers recommendations from the Advisory Forum.

3.4.3 SANAS Executive

SANAS is composed of four (4) separate functional units with 4 Executive positions. The Executives report directly to the CEO, and under the direction of the CEO, are responsible for the management of SANAS.

<table>
<thead>
<tr>
<th>FUNCTIONAL UNIT</th>
<th>FUNCTION</th>
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<tbody>
<tr>
<td>The Finance Unit</td>
<td>The Finance Unit is headed by the Chief Financial Officer, and is responsible for all financial and fiscal management aspects of SANAS’ operations in accordance with the PFMA and National Treasury regulations/guidance. This includes providing leadership, co-ordination and reporting in the administrative, business planning, accounting and budgeting efforts of SANAS.</td>
</tr>
<tr>
<td>Corporate Services</td>
<td>Corporate Services Unit is responsible for providing legal advisory/compliance services, company secretarial services and providing supervision of internal corporate support functions which includes IT services, HR, Quality, Marketing and Communication and office management.</td>
</tr>
<tr>
<td>Accreditation Unit</td>
<td>The Accreditation unit is responsible for all technical and administrative aspects of accreditation including the management of the Assessment specialists, assessors, assessment teams and assessments, as well as ensuring the technical integrity, consistency and impartiality in the assessment process is maintained.</td>
</tr>
<tr>
<td>Strategy and Development</td>
<td>The Strategy and Development unit is responsible for managing all International and Regional Liaisons, such as AFRAC, SADCA and the Tripartite (COMESA, SADC and EAC), Knowledge Transfer functions and areas of growth and development within the accreditation arena (New programme development).</td>
</tr>
</tbody>
</table>
3.5 Committees

3.5.1 Specialist Technical Committees (STC’s)

The STC’s role is to support the technical credibility of accreditation activities, SANAS has STC’s for each discipline in which we accredit. These STC’s determine special technical criteria for specific areas. The term of reference for the STC’s is captured in SANAS document P19 “The Responsibilities and Duties of the SANAS Specialist Technical Committees”.

3.5.2 Approval Committee (AC)

To ensure transparency and avoid possible prejudice in the decision making process, SANAS uses individuals who were not involved in the assessment of the entity under review. The AC advises the Chairperson regarding the granting or rejection of accreditation. The terms of reference of the SANAS AC are captured in the SANAS document P20 “The Responsibilities and Duties of the SANAS Approval Committees and Accreditation Managers in the approval and decision on accreditation / GLP compliance”.

3.6 Scope of Accreditation

SANAS is recognised as the only national body responsible for carrying out accreditation in respect of conformity assessment, which includes accreditation of:

(a) Calibration, testing and verification laboratories;
(b) Certification bodies;
(c) Inspection bodies;
(d) Proficiency Testing Service Providers
(e) Producers of Certified Reference Materials
(f) Rating agencies; and
(g) Any other type of body that may be added to SANAS’ scope of activity.

SANAS is also recognised as the national body to monitor GLP compliance with the principles adopted by the OECD for GLP facilities.

SANAS operates accreditation schemes in both the voluntary and regulatory sectors. Table 1 below outlines the scope of accreditation that is offered by SANAS and indicates the International or National Standards that must be complied with in order to be accredited.

<table>
<thead>
<tr>
<th>Scopes of Accreditation &amp; (SANAS Document)</th>
<th>Accreditation Standard/ Scheme</th>
<th>Voluntary or Regulatory Domain</th>
<th>Validity period of Certificate of Accreditation</th>
<th>Accreditation is granted for:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Testing Laboratories (P04)</strong></td>
<td>ISO/IEC 17025</td>
<td>Voluntary</td>
<td>5 years</td>
<td>• Tests performed on specified materials or products to specified test methods;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Techniques for specified instrument(s) using specific chemical and / or physical methods, to identify and / or determine a physical property of a material or species contained within.</td>
</tr>
<tr>
<td><strong>Medical Laboratories (P04)</strong></td>
<td>ISO 15189</td>
<td>Voluntary</td>
<td>4 years</td>
<td>• Tests performed on human biological materials to specified test methods.</td>
</tr>
<tr>
<td>Scopes of Accreditation &amp; (SANAS Document)</td>
<td>Accreditation Standard/ Scheme</td>
<td>Voluntary or Regulatory Domain</td>
<td>Covered by:</td>
<td>Validity period of Certificate of Accreditation</td>
</tr>
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<td>------------------------------------------</td>
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</tbody>
</table>
| Calibration Laboratories (P04)          | ISO/IEC 17025                  | Voluntary                     | ILAC MRA    | 5 years                                       | • Specified types of measurements performed, measurement range and calibration and measurement capability (CMC).  
• The transfer of traceability from national standards. |
| Certification Bodies (P05)               | ISO/IEC 17021 and IAF mandatory documents, as applicable | Voluntary                     | IAF MLA     | 3 years                                       | • QMS Certifiers for certifying organisations to ISO 9001.  
• EMS Certifiers for organisations to ISO 14001.  
• Hazards Critical Control Points (HACCP) certified to SANS10330.  
• Food Safety Management System (FSMS) certified to ISO/IEC 22000  
• Occupational Health and Safety System (OHSAS) certified to ISO/OHSAS 18001.  
• Responsible Tourism certified to SANS 1162  
• Risk Based Inspection (RBI) certified to specific standards in SANS 347  
• Energy Management Systems (EnMS) certified to ISO/IEC 50001  
• Road Transport Management System (RTMS) certified to SANS 1395 |
<p>| ISO/IEC 17024 and IAF Mandatory documents | Voluntary                     | Not signatory to IAF          | 3 years     | • Personnel Certifiers for certification of persons |
| ISO/IEC 17065, and any relevant IAF mandatory documents | Voluntary                     | IAF MLA                       | 3 years     | • Certifiers for certifying products, processes or services in accordance with various national and international standards as specified by the Certification Scheme (E.g.: Globalgap, PEFC) |
| ISO/IEC 14065 and IAF mandatory documents, where applicable | Voluntary                     | Not signatory to IAF          | 3 years     | • Greenhouse Gas (GHG) certified to ISO/IEC14065 |
| GLP / GCP Facilities (P16)              | OECD Principles of GLP / VICH Principles of GCP | Voluntary                     | OECD        | 2 years                                       | • GLP compliance monitoring, according to the Organisation for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice for facilities conducting non-clinical environmental health and safety studies |
| Blood Transfusion Laboratories (P04)    | ISO/IEC 17025                  | Voluntary                     | National Programme | 4 years | • The operation of PT schemes |
| Proficiency Testing (PT) Providers (P04) | ISO/IEC 17043                 | Voluntary                     | No          | 4 years                                       | • The operation of PT schemes |</p>
<table>
<thead>
<tr>
<th>Scopes of Accreditation &amp; (SANAS Document)</th>
<th>Accreditation Standard/Scheme</th>
<th>Voluntary or Regulatory Domain</th>
<th>Covered by:</th>
<th>Validity period of Certificate of Accreditation</th>
<th>Accreditation is granted for:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Producers of Certified Reference Materials (CRM) (P07)</td>
<td>ISO Guide 34 (ISO/IEC 17025 a prerequisite)</td>
<td>Voluntary</td>
<td>No</td>
<td>5 years</td>
<td>The production and assignment of property values of CRM</td>
</tr>
<tr>
<td>Inspection Bodies (P15)</td>
<td>ISO/IEC17020 and/or the National Standards specific to the field of inspection</td>
<td>Voluntary / Regulatory</td>
<td>ILAC MRA or National Programme</td>
<td>4 years</td>
<td>The performance of inspections in a specified field, e.g.: Gas Test Station; Major Hazard Installation; Food Inspection; Textiles, Clothing, Leather and Footwear; PER – Manufacturing; PER – In-service; Legal Metrology Inspection; Explosives; Electrical Inspection (Regulation R242); Gaming and Gambling; X-Ray Equipment; Automotive Inspection; Electrotechnical (NRCS); Energy Efficiency; Occupational Hygiene Inspection; Construction Inspection (Structures); Lift Inspection; Abattoir Inspection; Steel Structure Inspection, Consignment Inspection.</td>
</tr>
<tr>
<td>Verification Laboratories (P17)</td>
<td>SANS 10378 NRCS requirements</td>
<td>Regulator</td>
<td>National Programme</td>
<td>4 years</td>
<td>Verification of measurement instruments used for trade. Note: Laboratories assessed to SANS 10378 are not allowed to perform commercial calibrations to ISO/IEC 17025 unless their accreditation certificate specifically indicates they are accredited for this. The Regulator recognised this exclusion.</td>
</tr>
<tr>
<td>Broad Based Black Economic Empowerment (BBBEE) Verification (P24)</td>
<td>SANAS R47 and competence to the BBBEE Codes of Good Practice.</td>
<td>Regulator</td>
<td>National programme</td>
<td>3 years</td>
<td>Accreditation is granted for Verification Agencies verifying an organisation’s compliance to the BBBEE codes and the sector codes.</td>
</tr>
</tbody>
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4. Procedure for Accrediting Organisations

The table below describes the format of the Accreditation Process. Procedures are in place to describe the specific requirements for the various accreditation programs with the necessary responsibilities included.

**The Application Process**

- **Application for Accreditation**
  - The application criteria and process is described in the programme specific documents (P04, P05, P15, P16; P17 and P24). Applicants will be required to make a formal application on the relevant F14 Application form, which will list the information required by SANAS on application.
  - SANAS will review each application in order to ensure that it has the necessary resources and competence in order to conduct the assessment.

- **Initial Assessment Process**
  - The applicant’s documents will be reviewed by an appointed Assessment Specialist / Lead
| **Assessment** | Assessor, if deficiencies are identified, the CAB will be required to correct these deficiencies prior to the initial assessment.  
- Pre-assessment visits may be requested in the voluntary arena, where deficiencies in the system may be identified.  
- It is a mandatory requirement that pre-assessments will be carried out in the regulatory domain. |
| **Allocation of the Assessment Team** | An assessment team will be appointed, which will include an Assessment Specialist and/or Lead Assessor and the required number of technical assessors with the appropriate expertise for each specific scope. |
| **Initial Assessment** | The assessment team will conduct an assessment in accordance with SANAS procedures at the applicants’ Head Office and all other premises of the CAB from which key activities are performed, and which are covered by the scope of accreditation.  
The applicant CAB must satisfy the SANAS Assessment Specialist and/or assessors that it complies with all relevant ISO/IEC Standard/Guide and any International interpretation thereof, and SANAS accreditation requirements to enable the assessment team to make a positive recommendation to the Approval Committee (AC).  
CABs that wish to be accredited for on-site activities shall, where relevant, comply with the additional requirements that may be applicable for that specific field. Additional criteria for on-site accreditation are given in SANAS Requirement or Technical Requirement documents where such additional requirements exist. |
| **The Decision-making process** | The AC evaluates the adequacy of information provided by the assessment team, and determines whether requirements for accreditation have been fulfilled, and whether accreditation can be granted. The final decision on whether accreditation can be granted or not, is made by the Approval Committee Chairperson, based on the information gathered, submitted and recommendation of the relevant assessment team. (Refer to P20 for procedures of the Approval Committee) |
| **Issue of Certificate and Schedule of Accreditation** | If accreditation is granted by SANAS, an accreditation certificate signed by the CEO, with a schedule detailing the scope of accreditation signed by the relevant Accreditation Manager will be issued to the CAB.  
Accreditation will remain valid as long as the organisation continues to comply with SANAS requirements. All certificates will be issued with a validity date, subject to changes which can impact the CAB’s status. (E.g. change to scope of accreditation, range of measurements / tests or changes in location, phone number, senior staff, etc.)  
Refer to P10 “Accreditation / GLP Compliance Certificate”, which describes the format and procedures for the issue and maintenance of Certificates and schedules. |
| **Continued Compliance with accreditation and SANAS requirements** | It will be the responsibility of the accredited CAB to ensure that it complies with all accreditation criteria at all times. The accredited CAB will be required to report any possible non-compliance with criteria to SANAS immediately. Should an accredited CAB fail to continue to comply with accreditation criteria at any time before the expiry of the certificate the accreditation shall be withdrawn by SANAS. Once withdrawn the accredited CAB shall comply with all requirements in terms of the conditions of the withdrawal.  
Note: The GLP compliance monitoring process is fully described in the document P16 “Good Laboratory Practice (GLP) Compliance Monitoring Program”. |

**Maintenance of Accreditation**

| **6-month follow-up Assessment** | SANAS will verify continued compliance/competence by conducting follow-up visits to all newly accredited CABs approximately 6 - 12 months after the date of initial accreditation. This will normally be undertaken by the Assessment Specialist / Lead assessor unless otherwise delegated by the Accreditation Manager. |
Surveillance Assessments

- Surveillance assessments will be scheduled from 12 to no longer than 24 month intervals. (Refer to the program-specific P-documents)
- Surveillance visits will follow the initial assessment format but on a sampling basis (Refer to SANAS P 41 “Sampling for Assessment Purposes”). Each surveillance visit will involve a technical assessment of the CAB together with an assessment of the Quality Management System.
- The program specific P-documents (P04, P05, P15, P16; P17 and P24) detail the surveillance assessment process and intervals of the assessments.
- All Technical Signatories must be available at each assessment, or be available at the planned assessments as per the agreed on cycle plan, if relevant. SANAS will assess each technical signatory at least once in an accreditation cycle the selection of who will be assessed will be made by SANAS. Technical managers shall also be available at each assessment in the Inspection programme.

Re-assessments

- On successful re-application by the CAB, re-assessments will be arranged for approximately 3 months prior to the expiry date of the Certificate of Accreditation, and in the case of Inspection Bodies, 6 months prior to the expiry date of the Certificate of Accreditation (Refer to Table 2 for the Validity period of certificates)
- The next cycle will begin with assessments carried out at 12-month to no longer than 24-month intervals, depending on the length of the cycle. SANAS can unilaterally make changes to the assessment interval at any stage of the process, but intervals will not be longer than 24 months;
- Re-assessment visits involve a comprehensive on-site re-examination of the CAB’s management system and assessment activities and will be similar in format and content to the initial assessment, except that previous history will be taken into account (Refer to SANAS P 41 “Sampling for Assessment Purposes”).
- The decision-making process and re-issue of the Certificate and Schedule of Accreditation will follow the Re-assessment, as for the initial assessment.

Extension of Accreditation

- Extensions of accreditation will follow the same process as for initial accreditation.
- Applications for extension shall be made at least six (6) weeks prior to the on-site visit.
- P05 “The Assessment of Certification Bodies” will include procedures for extension(s) in the product certification field for specification addition in an existing accredited EAC code.

Personnel Evaluations

- SANAS Requirement document R03 will define the requirements for the responsibilities, qualifications and approval of Nominated Representatives and Signatories. As part of the assessment, the SANAS team will assess the competence of personnel in the performance of their functions and in their understanding and implementation of SANAS’ requirements. Approval of personnel as signatories or Nominated Representatives will follow the decision-making process as defined above.

5. Retention of Records

SANAS maintains records associated with each accredited organisation. Access to some or all of the records may be deemed to be confidential and only SANAS personnel will have access.

The records maintained amongst others are:

- Applications for accreditation and extensions;
- Assessment documentation and reports;
- Details of accredited facilities and technical signatories;

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• Records of decision-making;
• Records of assessors / Assessment specialists used to conduct assessments;
• SANAS fees paid or outstanding.

6. Limitation of Legal Liabilities

A SANAS accredited organisation is entitled to carry on any SANAS endorsed report, a statement to limit its legal liabilities for mistakes. SANAS is not responsible for the results of possible errors made by an accredited organisation. All accredited organisations are required to absolve SANAS of any such liabilities by signing the appropriate section of the SANAS application form for accreditation.

7. SANAS Publications

SANAS disseminates information by means of publications, which are available from the SANAS office or on the SANAS website. These include:

• SANAS Directory of Accredited Organisations;
• SANAS Annual report;
• Whatsup@SANAS (quarterly);
• SANAS Bulletin (monthly);
• SANAS A News (annually)
• SANAS Annual Report.
**ADDENDUM 1: Amendment Record**

<table>
<thead>
<tr>
<th>Proposed By</th>
<th>Section</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>QM, CEO</td>
<td>All</td>
<td>Entire re-write of document</td>
</tr>
</tbody>
</table>
| QM          | All     | Changed titles: Field Manager to Accreditation Manager  
|             |         | Added reference to Assessment Specialists |

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