



PM 01-09

## SANAS POLICY MANUAL

<b>Approved By:</b>	The SANAS Board of Directors Chief Executive Officer:	Ron Josias
<b>Reviewed By:</b>	Quality Manager:	Yolanda Vinnicombe
<b>Date of Approval:</b>		
<b>Date of Implementation:</b>		

**CONTENTS**

1.	Purpose and Scope.....	4
2.	Definitions and References .....	4
3.	SANAS Policy Statement .....	5
4.	General Requirements .....	7
4.1.	Legal Entity.....	7
4.2	Terms and Conditions for Accreditation / GLP Compliance.....	13
4.3	Use of Accreditation Symbols and Other Claims of Accreditation .....	14
4.4	Impartiality Policy.....	14
4.5.	Financing and Liability .....	16
4.6	Establishing Accreditation Schemes .....	18
5.	Structural Requirements.....	19
5.1	Council of Trade and Industry Institutions (COTII) .....	19
5.2	SANAS' Structure .....	20
5.3	SANAS Operational Structure.....	23
5.4	Committees of SANAS .....	27
6.	Resource Requirements.....	28
6.1.	Competence of Personnel .....	28
6.2.	Personnel Involved in the Accreditation Process .....	33
6.3.	Personnel Records .....	35
6.4.	Outsourcing .....	35
7.	Process Requirements.....	36
7.1.	Accreditation Requirements.....	36
7.2.	Application for Accreditation .....	36
7.3.	Resource Review .....	37
7.4.	Preparation for assessment .....	37
7.5.	Review of Documented Information.....	37

7.6.	Assessment .....	38
7.7.	Accreditation Decision-making .....	38
7.8.	Accreditation Information .....	39
7.9.	Accreditation Cycle .....	39
7.10.	Extraordinary Assessments .....	40
7.11.	Extending Accreditation .....	41
7.12.	Suspending, Withdrawing or Reducing Accreditation .....	41
7.12.	Complaints and Appeals .....	42
8.	Information Requirements .....	42
8.1.	Confidential Information .....	42
8.2	Publicly Available Information .....	43
9.	Management System Requirements .....	45
9.1.	General.....	45
9.2.	Management System.....	45
9.3.	Document Control.....	46
9.4.	Record Control .....	47
9.5.	Nonconformities and Corrective Actions .....	47
9.6.	<b>Improvement</b> .....	48
9.7.	Internal Audits.....	48
9.8.	Management reviews.....	49
<b>10.</b>	<b>Cross Frontier Accreditation</b> .....	49
11.	Proficiency Testing / Inter-Laboratory Comparisons for Laboratories .....	50
12.	Traceability.....	50
13.	Reference Materials .....	51
14.	Professional Judgment / Opinions .....	51
15.	Transfer of Accreditation / GLP Compliance Status and Franchising.....	51
16.	Electronic Signatures .....	51
	APPENDIX A – Amendment Record .....	53

## 1. Purpose and Scope

The purpose of the South African National Accreditation System (SANAS) Policy Manual is to establish and outline the general policies governing our management system, which is appropriate for the type, range and volume of our work. These are the top-level policies representing our plans and protocols for achieving management control, consistency, legal compliance and customer satisfaction.

All our procedures and requirements must conform to and reflect these policies. Any changes to policies and procedures must be reviewed to ensure that there are no conflicts with the content of this Policy Manual (PM).

The Policy Manual is applicable to all our staff, members of the SANAS Board of Directors, our committees, contracted personnel (assessors and technical experts), stakeholders and accredited conformity assessment bodies (CAB), all of whom shall ensure that they understand the policies and relevant procedures set out in this manual and that it is implemented and maintained at all times.

This Policy Manual is available to all staff via our document management system and to the public and relevant stakeholders via our website ([www.sanas.co.za](http://www.sanas.co.za)).

## 2. Definitions and References

ISO/IEC 17011:	Conformity Assessment – General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies
ISO/IEC 27001:	Information technology – Security techniques – Information security management systems - Requirements
ILAC/IAF A2:	Requirements and Procedures for Evaluation of a Single Accreditation Body
ILAC/IAF A3:	Narrative Framework for Reporting on the Performance of an Accreditation Body: A Tool for the Evaluation Process.
Act No. 19 of 2006:	Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act, 2006 (The Accreditation Act)
Act No. 1 of 1999	Public Finance Management Act (PFMA)
Act No. 20 of 1957	State Liability Act
SANAS ICT 06	Information Security Manual
SANAS A01	References, Acronyms and Definitions
SANAS Website:	<a href="http://www.sanas.co.za">www.sanas.co.za</a>
AFRAC Website:	<a href="http://www.intra-frac.com">www.intra-frac.com</a>
SADCA Website:	<a href="http://www.sadca.org">www.sadca.org</a>
ILAC Website:	<a href="http://www.ilac.org">www.ilac.org</a>
IAF Website:	<a href="http://www.iaf.nu">www.iaf.nu</a>
OECD Website:	<a href="http://www.oecd.org">www.oecd.org</a>

### 3. SANAS Policy Statement

The strategic objectives of SANAS is to improve its operational efficiency and service delivery; to contribute to industrial development and the protection of health, safety and the environment; to promote the acceptance of SANAS-accredited results amongst global partners to advance South African exports; to support economic development objectives and regional integration; and to establish relationships to advance South Africa's industrial policy and economic development objectives.

To facilitate and expand the recognition of our accredited CAB's results nationally, regionally and internationally through a network of co-operations and entities we:

- Maintain Mutual Recognition Arrangements (MRA's) with the International Accreditation Forum (IAF), the International Laboratory Accreditation Cooperation (ILAC), the African Accreditation Cooperation (AFRAC), and Southern African Development Community Cooperation in Accreditation (SADCA);
- Where necessary, conclude and maintain MRA's as required from time to time;
- Maintain our national body status to monitor GLP compliance with principles adopted by the Organisation of Economic Co-operation and Development (OECD) for GLP facilities; and
- Establish and maintain memorandum of understandings with various South African government departments using accreditation to support their health, safety environment protection obligations.

To effectively implement our mandate and objectives, achieving management control, consistency and customer satisfaction, we:

- operate in accordance with the requirements, criteria, rules and regulations as laid down in the:
  - Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act, 2006 (Act 19 of 2006), hereafter referred to as "The Accreditation Act";
  - Requirements of the international standard ISO/IEC 17011:2017 "General requirements for bodies providing assessments and accreditation of conformity assessment bodies";
  - Guidance and mandatory documents from IAF, ILAC, AFRAC and SADCA;
  - Requirements for national bodies to monitor GLP compliance with principles adopted by the OECD for GLP facilities;
  - Requirements of the international standard ISO/IEC 27001 "Information Technology – Security Techniques - Information Security Management Systems"; and
  - Requirements as stipulated in the various Memoranda of Agreement with international bodies and national regulatory bodies.
- ensure the availability of competent staff, assessment personnel and decision-makers to provide confidence in accredited services; and

- Periodically reviews its management system for continual improvement.

SANAS is committed to providing credible and cost-effective value-adding accreditation services and continuously strives to improve the scope of our service to satisfy the needs of stakeholders and regulators.

SANAS ensures that its core values that are based on the principles of Excellence, Integrity, Innovation, Dedication and Social are reflected in its policies and procedures and upheld in its operations and service delivery.

SANAS' Top Management ensures that this policy is communicated, understood, implemented and maintained at all levels of the organization and by all concerned.

***This Policy Statement is approved by the SANAS Chief Executive Officer.***

## 4. General Requirements

### 4.1. Legal Entity

#### 4.1.1. Background

SANAS' history spans over 3 decades, starting in 1974, with the establishment of the National Calibration Services (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 the South African National Accreditation System (SANAS), a registered non-profit organisation registered in terms of Section 21 of the Companies Act, No. 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 Accreditation Act, changing its legal status to a level 3A public entity.**

The SANAS Office is situated at:

Libertas Office Park:  
Cnr Libertas and the Highway str.  
Equestria  
0184

#### 4.1.2. Authority and Legal Responsibility

The Accreditation Act recognises SANAS as the only National Accreditation Body for the Republic of South Africa for conformity assessment and monitoring of Good Laboratory Practice, and to provide for matters connected therewith. SANAS will expand its scope of work as required.

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

- Accredite, 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.

As a public entity, we ensure compliance with the following Acts:

- Act No. 19 of 2006      Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act

- Act No. 1 of 1999            Public Finance Management Act
- Act No.103 of 1994        Public Services Act
- Act No. 20 of 1957        State Liability Act
- Act No. 66 of 1995        Labour Relations Act
- Any other Act or regulation that is and may be applicable to SANAS and accreditation.

#### 4.1.3. SANAS Mission Statement

*Our mission is to create an impartial and transparent mechanism for organisations to independently demonstrate their competence and facilitate the beneficial exchange of goods, services and knowledge and provide a service that is recognised as equitable to best international practice while reflecting the demographics of South Africa in all that we do.*

#### 4.1.4. SANAS Objectives

SANAS' objectives help channel employees toward a common goal to concentrate and conserve valuable resources in the organisation and to work efficiently and effectively in a timely manner. Therefore, we set 5- and 3-year objectives and on an annual basis, review our strategic objectives. These objectives are captured in the SANAS 5-year Strategic Plan (SB06), 3-year Annual Performance Plan (SB01), and the 1-year Business Plan (SB02).

**SANAS' current Strategic Objectives are to:**

- Provide accreditation support for industrial development and the protection of the health and safety of the public and the South African environment;
- Promote the acceptance of SANAS-accredited results nationally and amongst global partners to advance South Africa's trade and economic development objectives;
- Support regional integration and relations in order to advance South Africa's trade, industrial policy, and economic performance objectives; and
- Improve SANAS' operational efficiency to deliver services with a spirit of excellence.

#### 4.1.5. SANAS Vision

**SANAS vision is to pioneer and lead the future of accreditation in Africa and deliver services with a spirit of excellence.**

#### 4.1.6. Company Values

**In its service delivery, SANAS upholds the following five (5) core values:**

<b>Excellence</b>	<b>We are a company dedicated to excellence in service delivery through investing in a competent knowledge base institution aimed at exceeding customer expectations</b>
-------------------	--

<b>Integrity</b>	We understand that our strength is based on trust and therefore are consistent in our deeds, principles and outcomes, and act with honesty and respect without compromising the truth
<b>Innovation</b>	We are a forward-thinking company and have the courage and confidence to come up with creative ways in accreditation development
<b>Dedication</b>	As a team we are committed and passionate about our work and take ownership in all that we do
<b>Social</b>	We are a company that cares, therefore invest in our people, our communities, and environment

#### 4.1.7. SANAS Services

SANAS provides accreditation services and training in accreditation related activities.

##### 4.1.7.1. Accreditation services

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

- Calibration, testing and verification laboratories;
- Certification bodies;
- Inspection bodies;
- Proficiency Testing Service Providers
- Producers of Certified Reference Materials
- Rating agencies; and
- 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.

<b>Accreditation Scheme (SANAS Document)</b>	<b>Accreditation Standard</b>	<b>Voluntary or Regulatory Domain</b>	<b>Covered by:</b>	<b>Accreditation is granted for:</b>
<b>Testing Laboratories (P04)</b>	ISO/IEC 17025	Voluntary & Regulatory	ILAC MRA	<ul style="list-style-type: none"> <li>• Tests performed on specified materials or products to specified test methods;</li> <li>• 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.</li> </ul>
<b>Medical Laboratories (P04)</b>	ISO 15189	Voluntary	ILAC MRA	<ul style="list-style-type: none"> <li>• Tests performed on human biological materials to specified test methods.</li> </ul>
<b>Calibration Laboratories (P04)</b>	ISO/IEC 17025	Voluntary	ILAC & AFRAC MRA	<ul style="list-style-type: none"> <li>• Specified types of measurements performed, measurement range and calibration and measurement capability (CMC).</li> <li>• The transfer of traceability from national standards.</li> </ul>
<b>GLP / GCP Facilities (P16)</b>	OECD Principles of GLP / VICH Principles of GCP	Voluntary	OECD	<ul style="list-style-type: none"> <li>• 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</li> </ul>
<b>Blood Transfusion Laboratories (P04)</b>	ISO/IEC 17025	Voluntary	National Programme	
<b>Proficiency Testing (PT) Providers (P04)</b>	<ul style="list-style-type: none"> <li>• ISO/IEC 17043</li> </ul>	Voluntary	No	<ul style="list-style-type: none"> <li>• The operation of PT schemes</li> </ul>
<b>Producers of Certified Reference Materials (CRM) (P07)</b>	<ul style="list-style-type: none"> <li>• ISO/ 17034</li> <li>• (ISO/IEC 17025 a prerequisite)</li> </ul>	Voluntary	No	<ul style="list-style-type: none"> <li>• The production and assignment of property values of CRM</li> </ul>

<b>Accreditation Scheme (SANAS Document)</b>	<b>Accreditation Standard</b>	<b>Voluntary or Regulatory Domain</b>	<b>Covered by:</b>	<b>Accreditation is granted for:</b>
<b>Inspection Bodies (P15)</b>	• ISO/IEC17020 and/or the National Standards specific to the field of inspection	Voluntary / Regulatory	ILAC & AFRAC MRA or National Programme	<ul style="list-style-type: none"> <li>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; Lift Inspection; Abattoir Inspection; Steel Structure Inspection</li> </ul>
<b>Verification Laboratories (P17)</b>	SANS 10378 NRCS requirements	Regulatory	National Programme	<p>Verification of measurement instruments used for trade.</p> <p>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.</p>
<b>Broad Based Black Economic Empowerment (BBBEE) Verification (P24)</b>	SANAS R47 and competence to the BBBEE Codes of Good Practice.	Regulatory	National programme	Accreditation is granted for Verification Agencies verifying an organisation's compliance to the BBBEE codes and the sector codes.

<b>Certification Accreditation Schemes (SANAS Document P05)</b>	<b>Accreditation Standard (Level 3)</b>	<b>Voluntary or Regulatory Domain</b>	<b>Covered by:</b>	<b>Sub-scopes (Levels 4 and 5):</b>
Management System Certification	ISO/IEC 17021 and IAF mandatory documents, as applicable	Voluntary	IAF <b>MLA</b> & AFRAC <b>MRA</b>	<ul style="list-style-type: none"> <li>QMS Certifiers for certifying organisations to ISO 9001.</li> <li>EMS Certifiers for organisations to ISO 14001.</li> <li>Food Safety Management System (FSMS) certified to ISO/TS 22003</li> </ul>

			National or International Programme	<ul style="list-style-type: none"> <li>• Energy Management Systems (EnMS) certified to ISO 50003</li> <li>• Food Safety System Certification (FSSC) and FSSC 22000</li> <li>• Hazards Critical Control Points (HACCP) certified to SANS10330.</li> <li>• Information Security Management System (ISMS) and ISO/IEC 27006</li> <li>• Information Technology Service Management System (ITSMS) and ISO/IEC 20000-1</li> <li>• Occupational Health and Safety System (OHSAS) and OHSAS 18001 / ISO 45001</li> <li>• Risk Based Inspection (RBI) - Specific standards in SANS 347 (ASME; API)</li> <li>• Road Transport Management Systems to SANS 1396-1</li> <li>• Medical Devices and In-vitro Diagnostics (IVD) and ISO/IEC 13485</li> <li>• Road Traffic Safety (RTS) – ISO/IEC 39001</li> </ul>
Certification of persons	ISO/IEC 17024 and IAF Mandatory documents	Voluntary	Not signatory to IAF	<ul style="list-style-type: none"> <li>• No applicable</li> </ul>
Product Certification	ISO/IEC 17065, and any relevant IAF mandatory documents	Voluntary	IAF MLA	<ul style="list-style-type: none"> <li>- GLOBALGAP: Integrated Farm Assurance (IFA) General Regulations: GLOBALG.A.P IFA Control Points and Compliance Criteria (Option 1, 2 or 3)</li> <li>• Responsible Tourism certified to SANS 1162</li> <li>- PEFC ST 2003; PEFC ST 2001 PEFC and PEFC ST 2002 – Chain of Custody</li> <li>- Scheme rules/requirements established by the scheme owner including methods of measuring and identifying conformity (refer to ISO 17067) and National/International product/process/service specifications used to establish conformity of the defined commodity to be certified</li> </ul>
Greenhouse gas Validation & Verification	ISO/IEC 14065 and IAF mandatory documents, where applicable ISO/IEC 14064-3; ISO/IEC 14066	Voluntary	Not signatory to IAF	<ul style="list-style-type: none"> <li>• Not applicable</li> </ul>

Note: "National Programme" encompasses compliance to any nationally imposed requirement e.g. regulations, sector specific standard etc.

#### 4.1.7.2. Training services

The SANAS Knowledge Transfer department provides generic training on accreditation related courses. In order not to compromise its impartiality principles and status in training service delivery, SANAS does not give specific advice for the development of an organization's

operations. Furthermore, the training delivered or facilitated by SANAS are not a pre-condition of accreditation neither do they guarantee accreditation by SANAS.

The following training services are provided:

- Management system courses in the different accreditation standards;
- Documenting the system course;
- Internal auditing courses;
- Nominated representative and technical signatory workshops;
- Technical assessing techniques;
- Team Leader Courses.

Besides the above courses, SANAS may also offer other accreditation related courses depending on clients' needs, provided that such courses do not compromise SANAS' impartiality. The training courses are designed to create awareness on the benefits and importance of accreditation and to promote an understanding of the requirements of the key accreditation standards.

#### 4.1.8. Regional and International Connections

SANAS is:

- A full member of the International Laboratory Accreditation Cooperation (ILAC) and signatory to the ILAC MRA.
- An accreditation body member of the International Accreditation Forum (IAF) and signatory to the IAF MLA.
- An arrangement member of the African Accreditation Cooperation (AFRAC) and signatory to the AFRAC -MRA
- An ordinary member of SADC Cooperation in Accreditation (SADCA).

## 4.2 Terms and Conditions for Accreditation / GLP Compliance

Understanding the roles and responsibilities of SANAS and the CAB / GLP/GCP facility, as well as the terms and conditions for granting and maintaining, suspending, reducing or withdrawing accreditation is important so as to avoid future misunderstandings and possible litigation. We have therefore concluded legally enforceable agreements through the Terms and Conditions of Accreditation (F147) and Terms and Conditions of GLP/GCP Compliance (F199). These Terms and Conditions detail our obligations regarding to accreditation provision and the requirements, obligations and duties of an applicant and accredited CAB / GLP compliant facility.

The Terms and Conditions become binding with effect from the date on which an Application Declaration Form is signed by the CAB and remains binding throughout the duration of the Accreditation and including any periods of suspension. Upon formal agreement to the Terms and Conditions, the CAB shall be deemed to understand and shall be obliged to adhere to the Terms and Conditions at all times.

### 4.3 Use of Accreditation Symbols and Other Claims of Accreditation

The R 04 document sets out the conditions for SANAS accredited CABs to use:

- The SANAS accreditation symbols; or reference to SANAS accreditation; and
- The SANAS accreditation symbol together with either the International Accreditation Forum (IAF) or the International Laboratory Accreditation Cooperation (ILAC) Mark, as applicable, referred to as the “Combined Mark”.

The R 04 document is to be used in conjunction with the requirements for the use of the accreditation symbol and/or reference to accreditation as specified in the Terms and Conditions of Accreditation / Terms and Conditions of GLP / GCP Compliance.

The conditions contained in the R 04 document must be met by all SANAS accredited CABs using the SANAS Accreditation symbol or Combined Mark. SANAS takes appropriate action in those instances where its accreditation symbol and/or the combined mark has been misused.

SANAS is the sole proprietor of its corporate logo and accreditation symbol which have been registered and are therefore legally protected. The SANAS accreditation symbol confirms a CAB's competence to the accreditation requirements, thereby providing a level of confidence to the market. To prevent the misuse of the accreditation symbol or the ILAC/IAF combined marks, or misrepresentation of accreditation which could adversely impact on the integrity of SANAS and accreditation, we have documented the requirements for the use and protection of the SANAS accreditation symbol and the IAF and ILAC marks in *R 04 “Conditions for Use of Accreditation Symbols, Reference to Accreditation and Combined Marks*.

#### **References:**

- *R 04 “Conditions for Use of Accreditation Symbols, Reference to Accreditation and Combined Marks*
- *F 112 Agreement for the use of the Accredited CAB Combined ILAC MRA Mark*
- *F 111 Sub-license agreement for the use of the IAF MLA Mark*
- *ILAC P 8: ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements and Guidelines for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories and Inspection Bodies*
- *ILAC R 7: Rules for the use of the ILAC MRA Mark*

### 4.4 Impartiality Policy

Safeguarding impartiality, transparency, objectivity and independence of all SANAS' operations and accreditation activities is paramount in instilling confidence and trust in the integrity of SANAS' services to its clients and stakeholders. The CEO bears the overall accountability for the safeguarding of impartiality and the Executive Committee ensures that these values are upheld.

This is achieved by applying its policies and procedures in a manner that:

- is non-discriminatory, where its services are offered to all CABs in a fair and equitable manner regardless of size, its membership to any association or groups, the number of organisations already accredited, whether from the public sector or private sector and provided that the application is within the scope of accreditation as offered;
- manages conflict of interest and any potential conflict of interest in our decision-making processes;
- ensures an impartial complaints and appeals procedure (P12) which is open and accessible to all stakeholders and the public;
- avoids the provision of services that affects its impartiality, such as consultancy services or suggesting the use of consultants, nor to participate in or offer any conformity assessment services that CABs perform;
- avoids compromising its impartiality and status in training service delivery, by offering generic training courses which do not give specific advice for the development of an organization's operations, and furthermore, not offering training courses as a precondition or guarantee of accreditation;
- only offers support, training and twinning opportunities to other developing accreditation bodies in terms of meeting the necessary criteria for obtaining international recognition; and
- ensures that the principles of impartiality and non-discrimination are upheld within our Committees to protect the integrity of the system, which must as a minimum include:
  - Ensuring the effective involvement of interested parties through balanced representation, so that no one party dominates the committee;
  - Being impartial in terms of their affiliation(s);
  - Having no conflict of interests, to minimise and control bias in advice and decision making; and
  - Possessing the relevant competencies required.

SANAS is organised in such a manner as to ensure that impartiality requirements are met as a public entity, and the National Accreditation Body formally enacted through the promulgation of the Accreditation Act.

The SANAS Board of Directors, its personnel, committee members and contracted personnel commit to act objectively and declare any actual or potential commercial, financial, political or other pressures that could compromise the impartiality of the accreditation process, whenever it may arise, through the signing of the relevant confidentiality, impartiality and non-disclosure agreements.

Any staff member or contracted personnel member who are found not to comply with these impartiality requirements will be sanctioned.

SANAS continuously evaluates the risks to impartiality arising from its activities and from any conflicts arising from its or its personnel's relationships and interactions with other organisations, through various mechanisms such as internal and external audits, management reviews, complaints and customer satisfaction surveys. SANAS analyses, evaluates, treats and monitors all identified risks, and determines whether any residual risks are within an acceptable level of risk. SANAS does not provide accreditation in areas where an unacceptable level of risk is identified, and which cannot be mitigated to an acceptable level.

SANAS' signed Impartiality policy statement is available on the SANAS website at [www.sanas.co.za](http://www.sanas.co.za)

Procedures for the management of impartiality are defined in P 07 "Management of Impartiality". We ensure the involvement of interested parties, such as our specialist technical committee members, assessors and accredited CABs in the safeguarding of impartiality through their contributions in the review of this document, and in the identification and any risks to impartiality.

#### **References:**

- *SB 03 SANAS Risk management strategy*
- *SB 04 Risk assessment plan*
- *P 07 Management of Impartiality*
- *P 19 Terms of reference, registration and responsibilities of specialist technical committees*
- *P 20 The responsibilities and duties of the approval committees and field managers in the approval and decision on accreditation*
- *OP 15 Requirements for Assessors, inspectors and Experts*
- *FP 13 Gifts, donations and sponsorship policy*
- *F 22, F73, F73 Confidentiality, impartiality and non-disclosure agreements*
- *F 218 Declaration of interest by SANAS Executive Committee members*
- *F 63 Employee business interest declaration*
- *F 177 Board of Directors declaration of interest*
- *F 53 Independent Contractor Agreement between SANAS and Assessors/ Technical / GLP Inspector / Expert*
- *F 147 Terms and conditions of Accreditation*
- *F 199 Terms and conditions of GLP and GCP Compliance*

## **4.5. Financing and Liability**

### **4.5.1. Financing**

Our finances and procurement are executed within the framework of the Public Finance Management Act (PFMA). We base our fees, as far as possible, 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 our involvement in regional integration and national projects, are funded by a government grant.

As far as possible, we ensure that our fees do not discriminate or create unnecessary barriers to organisations in obtaining accreditation, therefore fees charged for services are reviewed annually and approved by the SANAS Board of Directors. Financial and performance monitoring are reported on a quarterly basis to the Board and **the dti**.

**SANAS' income is derived from:**

- Government grant through the Department of Trade and Industry;
- Accreditation -income (Application, initial and annual fees);
- Training income; and
- Projects income.

The approved fee structure is formalised in our fee document (P14 "SANAS Fees") and is publicly available via the SANAS website.

**SANAS accreditation services are priced fairly and equitably to recover all direct and indirect costs associated with its services. The SANAS Board of Directors monitors SANAS' finances through its Audit and Risk Committee and financial reports.**

#### 4.5.2. Liability

SANAS does not accept liability for **errors** made by **accredited CABs** or **errors** on certificates or reports issued by our accredited **CABs**. All applicant **and accredited CABs** are required to **absolve SANAS of any such liabilities** by accepting the SANAS Terms and Conditions of Accreditation (F147) or the Terms and Conditions of GLP/GCP Compliance (F199), as relevant, through the signing of the relevant "Application for Accreditation Form", which includes clauses on Liability, and reference the State Liability Act, 1957 (Act No. 20 of 1957).

Assessors / GLP Inspectors / Experts are required to sign the SANAS Independent Contractor Agreement (F53) which include clauses on Liability and reference the State Liability Act 20 of 1957. **No person is liable for anything done or omitted in good faith when performing a function or exercising a power in terms of this Act.**

Liability is limited to our assets. **SANAS has** obtained insurance to cover general liability and professional indemnity for the **Board of Directors**, permanent staff and contract personnel. The cover must be appropriate to the risk, and the risk are reviewed annually.

**References:**

- **SANAS Business Plan**
- **SANAS Annual Performance Plan**
- **SANAS Strategic Plan**

- P 14 SANAS Fees

#### 4.6 Establishing Accreditation Schemes

4.6.1. SANAS offers the following accreditation schemes in accordance with the relevant adopted international standards:

- Calibration laboratories to ISO/IEC 17025;
- Testing laboratories to ISO/IEC 17025;
- Medical laboratories to ISO 15189;
- Inspection bodies to ISO/IEC 17020;
- Proficiency Testing Service Providers to ISO/IEC 17043;
- Producers of Certified Reference Materials to ISO 17034;
- Management systems certification bodies to ISO/IEC 17021-1;
- Product certification bodies to ISO/IEC 17065;
- Personnel certification bodies to ISO/IEC 17024;
- Greenhouse Gas (GHG) to ISO/IEC 14065; and
- GLP / GCP facilities to OECD Principles of GLP / VICH Principles of GCP

4.6.2. In addition, SANAS offers the following accreditation schemes developed in accordance with the relevant national requirements and/or regulatory requirements:

- Broad Based Black Economic Empowerment (BBBEE) Verification to the BBBEE Codes of Good Practice;
- Verification laboratories to the SANS 10378 and NRCS requirements;
- Blood Transfusion Laboratories, Blood Banks and Donor clinics to ISO/IEC 17025 and the Blood Transfusion Standard of Practice
- Management System certification bodies to ISO/IEC 17021 and applicable national programmes for:
  - 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

4.6.3. SANAS will broaden its scope of accreditation as the need arises, based on the needs of the country and/or stakeholders.

4.6.4. When needed, through its various Specialist Technical Committees, SANAS develops Technical Requirements and/or Technical Guidance documents. These documents shall neither contradict nor exclude any of the requirements included in the relevant international standards, normative documents or national regulations, as applicable.

4.6.5. SANAS P 43 "Development of Accreditation Schemes" defines the procedures to determine the suitability of conformity assessment schemes and standards for accreditation purposes and includes the process for extending existing accreditation schemes into new areas.

4.6.6. In discontinuing accreditation schemes SANAS considers the views of interested parties, contractual duties and transition arrangements, and communicates with stakeholders concerning any discontinuations.

**Reference:** P 43 Development of Accreditation Schemes

## 5. Structural Requirements

### 5.1 Council of Trade and Industry Institutions (COTII)

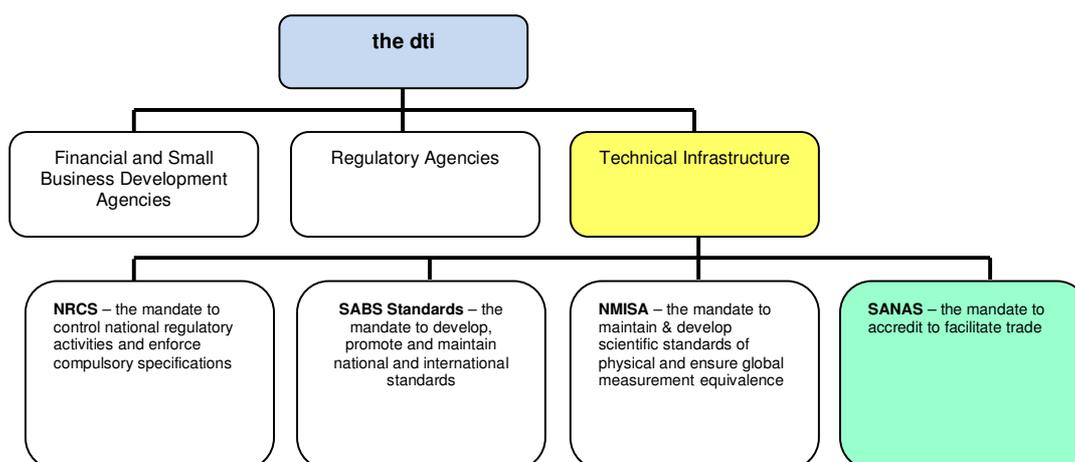
SANAS is an agency of The Department of Trade and Industry's (**the dti**) Council of Trade and Industry Institutions (COTII). **The dti** relies on us in support its economic growth, employment and equity ideals. COTII is grouped into three main clusters, one of which is **the dti** Specialist Services Agencies, responsible for Standards, Accreditation, Metrology and regulation of compulsory specifications, known as the South African Technical Infrastructure. The Specialist Services Agencies consist of the following organisations:

- The South African National Accreditation System (SANAS)
- The National Regulator for Compulsory Specifications (NRCS)
- The South African Bureau of Standards (SABS)
- The National Metrology Institute of South Africa (NMISA)

The Minister of Trade and Industry is the Executive Authority of all the above institutions. Each one of the institutions is a separate legal entity, with a separate Board of Directors as their Accounting Authority.

SANAS has put into place the required fire walls to ensure that possible conflict of interest does not exist in our relationships with these related bodies. There will be instances where a perceived conflict of interest cannot be avoided, in such cases, we ensure that we have processes and procedures in place to mitigate the possible associated risks. **SANAS remains responsible for all accreditation decisions and which are not subject to approval by any other person or organisation within the COTII framework.**

The organogram below shows the relationship we have with organisations which are considered related bodies. These related bodies shall not perform any of the activities for which we have been mandated to perform in accordance with the Accreditation Act; however, they may have CAB's accredited by us.



## 5.2 SANAS' Structure

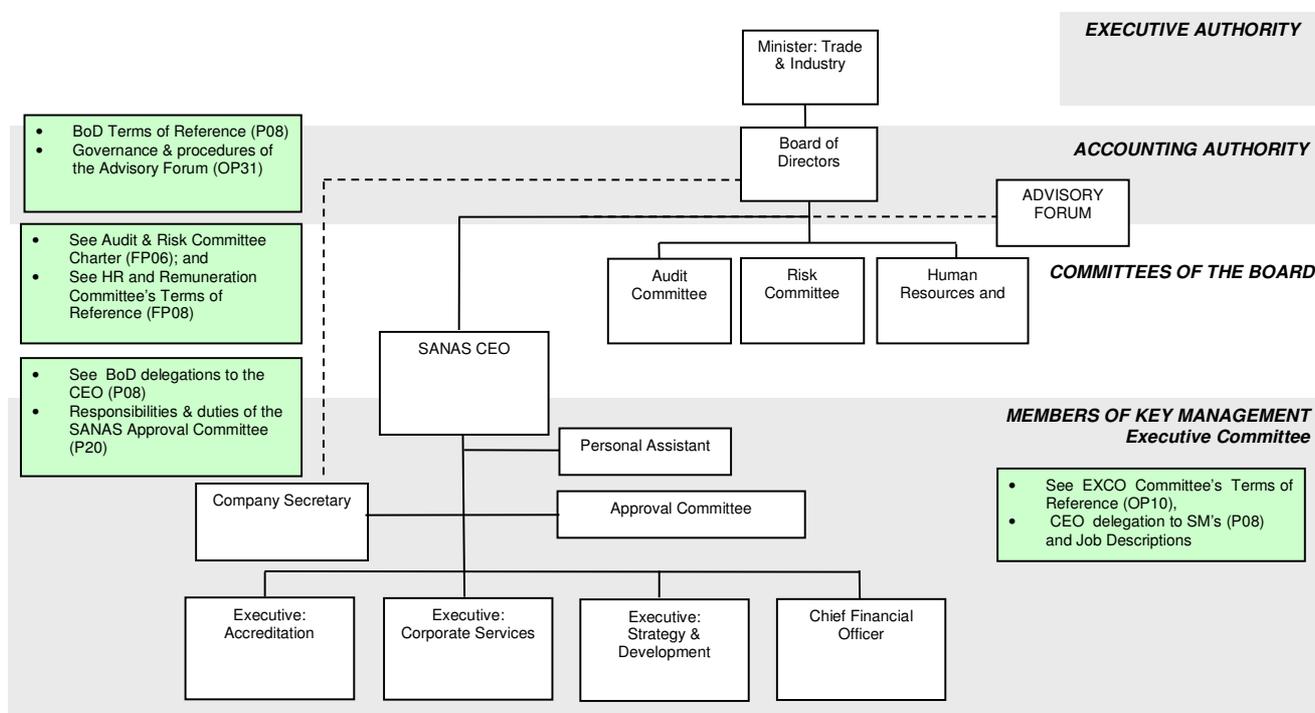
Our structure provides guidelines for the system of reporting that drives our mandate. The structure is divided into areas that are responsible for certain aspects of our mandate and include the relationships between areas and individuals needed to achieve more efficient operations while attaining our goals **and safeguarding impartiality**.

SANAS' organisational structure comprises of a governance structure and an operational structure.

### 5.2.1 SANAS Governance Structure

The Minister of Trade and Industry is our Executive Authority, who is empowered to appoint the SANAS Board of Directors (BOD). Our Board of Directors is the Accounting Authority, and in consultation with the Minister of Trade and Industry, appoints the Chief Executive Officer (CEO) and Executives of SANAS. The Board is supported by Committees as required to effectively implement good governance, e.g., the Advisory Forum, the Human Resource and Remuneration Committee, the Audit and the Risk Committees. The CEO is supported by an Executive Committee, consisting of the Executives.

**Figure 1** below presents our governance structure and provides a short summary and reference of the position's functions.

**Figure 1: Governance Structure**

The responsibilities of the governance structure is as follows:

#### 5.2.1.1 The Minister of Trade and Industry

In accordance with the Accreditation Act, the Minister of Trade and Industry:

- Appoints the non-executive members of the Board;
- Approves ownership or disposal of immovable properties;
- In consultation with the Board, terminates the terms of office of any member of the Board;
- Approves the allowance payable to Board members;
- Approves investment of funds not immediately required;
- May make regulations concerning the implementation of the Accreditation Act;
- Concludes **an annual** renewable shareholder compact agreement with SANAS; and
- **Approves the SANAS five-year Strategic Plan and Annual Performance Plan (APP).**

**Reference:** *Accreditation Act*

#### 5.2.1.2 The SANAS Board of Directors

The Board provides strategic direction for the daily operations of SANAS and executes and delivers on the Shareholder Compact with the Minister of **the dti**.

**Reference:** P 08 *Governance and procedures of the SANAS Board and delegations to the CEO*

#### 5.2.1.3 *The Chief Executive Officer (CEO)*

The Chief Executive Officer (CEO) is accountable to the Board of Directors. The Board delegates to the CEO the responsibility of implementing the Board approved Strategic Plan. The CEO **is accountable for** and **bears** the overall responsibility for **contractual arrangements, ensuring adequate resources,** decision making and for the **development of the** SANAS Management System **policies** in accordance with ISO/IEC 17011 and relevant ILAC/IAF/OECD/AFRAC/SADCA requirements. This responsibility includes its **establishment,** documentation, implementation, maintenance and improvement and all authorities and necessary responsibilities for the direction and day-to-day management of SANAS.

The CEO appoints an acting CEO in his/her absence. However, where the period of absence exceeds one month, the Board of Directors appoints an acting CEO. The appointment will be distributed to relevant persons within SANAS via email. Heads of units are responsible for SANAS activities within their own units.

**Reference:** P 08 *Governance and procedures of the SANAS Board and delegations to the CEO*

#### 5.2.1.4 *The SANAS Executive Committee (EXCO)*

The EXCO consists of the Executives and is led by the CEO. The EXCO is mandated by the **Board to support the CEO,** to execute the strategic plan and to direct and manage SANAS to deliver performance in line with the Board approved strategic and business **plans while ensuring the safeguarding of impartiality in all aspects of SANAS' operations.**

**Reference:** OP 10 *Executive Committee Governance and Procedures*

### 5.2.2 **Committees of the Board**

Our Board ensures that it has access to the necessary expertise to advice on good corporate governance and the effective execution of their responsibilities. This is done through the establishment **by the Board** of various committees that complies with the corporate governance requirements as captured in the shareholder compact agreement with government and the relevant requirements of **King IV** (Corporate Governance Standards) and the protocol on corporate governance.

**The committees of the Board consist of:**

#### 5.2.2.1 *The Advisory Forum*

The Advisory Forum consists of representatives of bodies with an interest in accreditation and accredited bodies, who advises the Board on matters in respect of which SANAS could play a role and any other matter on which the Board requests advice.

**References:** OP 31 *Governance & procedures of the Advisory Forum*

#### 5.2.2.2 *The Audit Committee*

The Audit Committee reviews, controls and monitors the financial performance of SANAS.

**References:** FP 06 *Audit & Risk Committee Charter*

#### 5.2.2.3 *The Risk Committee*

The Risk Committee reviews, controls and monitors the risks of SANAS.

**References:** FP 06 *Audit & Risk Committee Charter*

#### 5.2.2.4 *The Human Resource (HR) and Remuneration Committee*

The HR & Remuneration Committee controls, monitors and approves SANAS HR and Remuneration policies.

**References:** FP 08 *HR and Remuneration Committee's Terms of Reference (FP08)*

### 5.3 **SANAS Operational Structure**

The operational structure of SANAS is shown in **Figure 2** and shows the lines of authority and responsibility.

The duties, roles and responsibilities of personnel within our operational units are defined in each personnel member's job description. The purpose and responsibilities of the units are defined in the applicable procedures.

#### 5.3.1 *The Finance Unit*

The Finance Unit is headed by the Chief Financial Officer (CFO) and is responsible for **the supervision of** all financial and fiscal management aspects of SANAS' operations in accordance with the PFMA and National Treasury regulations/guidance. This includes, but is not limited to providing

leadership, co-ordination and reporting in the administrative, business planning, accounting and budgeting efforts of SANAS.

### 5.3.2 Accreditation Unit

The Accreditation unit is headed by the Executive: Accreditation and is responsible for all technical and administrative aspects of the accreditation process including, but not limited to the management of the assessors, assessment teams and the performance of assessments, as well as ensuring the provision of adequate assessor resources, the technical integrity, consistency and impartiality in the assessment process is maintained.

### 5.3.3 Strategy and Development

The Strategy and Development unit is headed by the Executive: Strategy & Development and is responsible for assisting the CEO in managing all International and Regional Liaisons, such as AFRAC, SADCA and the Tripartite (COMESA, SADC and EAC), Strategic support, Knowledge Transfer functions and areas of growth and development within the accreditation arena (New programme development).

#### 5.3.3.1 Knowledge Transfer (KT)

The SANAS Knowledge Transfer is headed by the Manager: Knowledge Transfer, who supports the main objectives of SANAS through developing and presenting generic courses to industry. These courses excludes giving specific training towards the development and implementation of the management system, competence of a CAB and /or operational procedures.

The KT unit is responsible for, but not limited to, developing and presenting training courses to SANAS staff, Assessors, GLP Inspectors on SANAS' policies, procedures and the development and maintenance of the required competencies to perform accreditation functions.

#### 5.3.3.2 New Programme Development (NPD)

The NPD unit is headed by the Projects Research manager who is responsible for the development or adoption of activities for the various accreditation schemes provided by SANAS.

### 5.3.4 Corporate Services

The Corporate Services Unit is headed by the Executive: Corporate Services and is responsible for providing supervision of internal corporate support functions which includes IT services, HR, Quality, Marketing and Communication and office management.

#### 5.3.4.1 Quality Management

The Quality Management unit is headed by the Quality Manager who carries operational responsibilities for the control, maintenance and supervision of the implementation of the policies, processes and procedures of the SANAS Management System in accordance with ISO/IEC 17011 requirements, ILAC/IAF/OECD/AFRAC, the relevant National regulations and guidelines. The Quality Manager reports to top management on the performance of the management system and any need for improvement and ensures the timeous handling of complaints and appeals.

The QM is the liaison SANAS representative for all national and international inputs and enquiries.

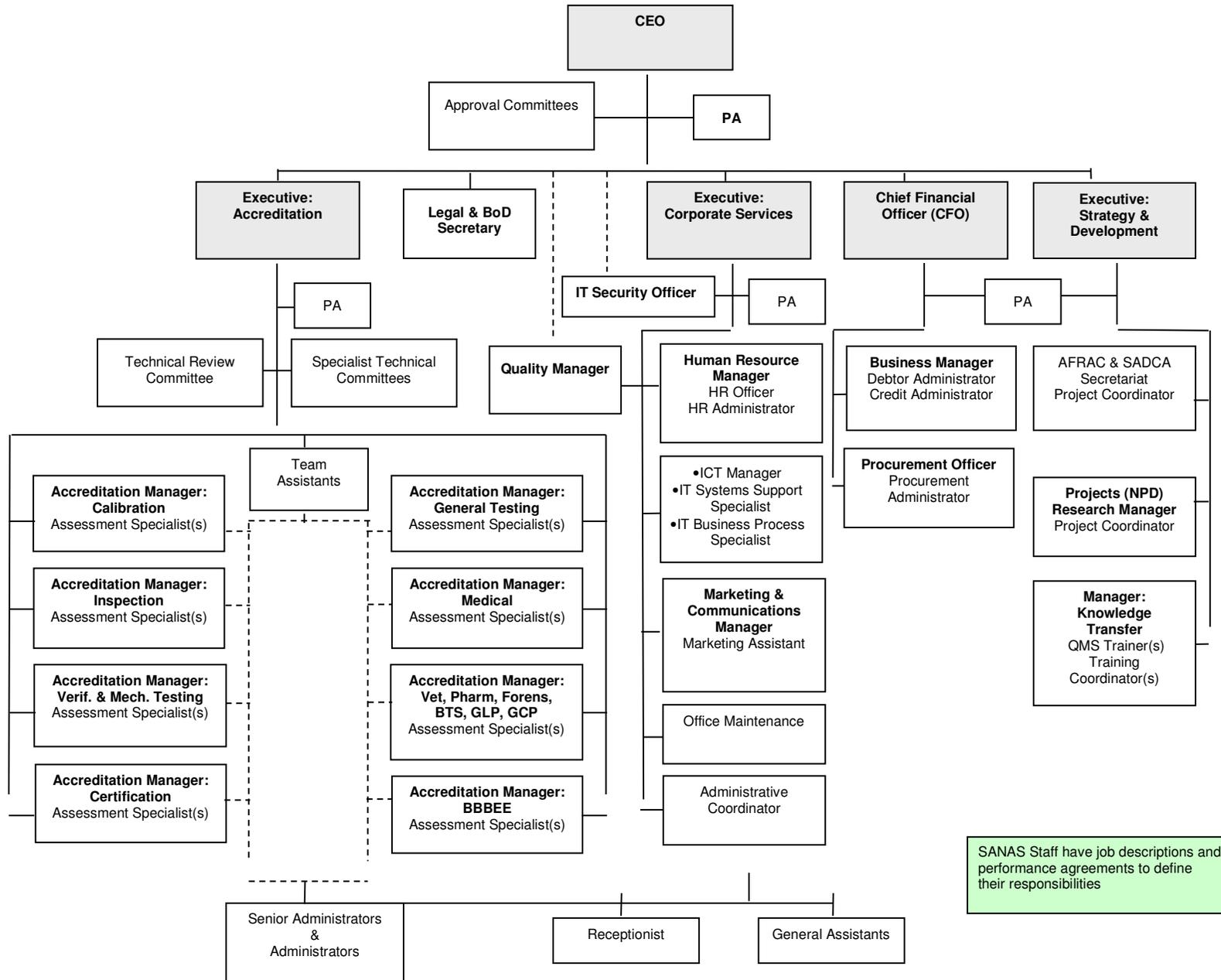
#### 5.3.4.2 Human Resources

The HR unit is headed by the HR Manager who is responsible for the effective and efficient administration of all SANAS' human resources. This includes, but not be limited to, ensuring that SANAS has a sufficient number of internal personnel with the appropriate qualifications, training, knowledge, experience and skills for the effective and efficient performance of the volume and type of functions, as well as the execution of performance evaluations.

#### 5.3.5 Legal Affairs and Board Secretary

The Company Secretary advises the Board of Directors and CEO on corporate governance, compliance issues and legal matters.

Figure 2 – SANAS Organisational Structure



SANAS Staff have job descriptions and performance agreements to define their responsibilities

## 5.4 Committees of SANAS

Through the establishment of various committees and/or working groups as needed from time to time, SANAS ensures that it has access to the relevant expertise to advise, guide and assist us, as applicable, in various accreditation related matters. Formal rules for the appointment, terms of reference, composition and operation of each of its Committees is documented in various procedures to ensure that impartiality requirements are met.

### 5.4.1 Approval Committee (AC)

Approval Committee members are appointed by the CEO and consists of competent individuals who are familiar with the accreditation process and have a broad knowledge of the area of assessment to be evaluated, including any applicable regulatory requirements.

The purpose of the Approval Committee is to advise the chairperson concerning the granting, maintaining, extending, reducing, suspending, re-instating or withdrawing of accreditation, on the basis of the information gathered and the recommendation made by the relevant assessment team. The Approval Committee chairperson shall be a permanent employee of SANAS. SANAS is responsible for all accreditation decisions and does not contract or delegate such decisions to any other organization or person.

The committee's scope of work is normally be limited to initial assessments, re-assessments, new scope extensions, re-instatements, withdrawals and suspensions of accreditation. The Approval Committee also provides feedback on the performance of the assessment team members, and where required, advices on additional training needs for assessment teams.

**Reference:** P20 "The responsibilities and duties of the Approval Committees and Accreditation Managers in the approval and decision on accreditation."

### 5.4.2 Specialist Technical Committee (STC)

Specialist Technical Committee members are approved by the Executive: Accreditation and their Chairs by the CEO. STC members consist of:

- national experts in specific technical scopes;
- members with legislative responsibility (where required);
- representatives of accredited organisations with the relevant technical experience and expertise; and
- Interested stakeholders from independent associations.

In some categories of membership, participation through the provision of written input is accepted.

SANAS ensures that the appropriate technical expertise and an appropriate balance of interests is maintained for each of its STCs. The role of the STC is to provide guidance to SANAS on technical matters pertaining to accreditation, in their specific scope of expertise.

**Reference:** P19 Terms of reference, registration and responsibilities of Specialist Technical Committees.

#### 5.4.3 Working Groups

SANAS may from time to time appoint temporary working groups who will be tasked to support SANAS in dealing with specific issues that might require input from experts. In certain cases this function might be allocated to STC's.

#### 5.4.4 Technical Review Committee (TR)

Technical Review Committee members consist of the Executive: Accreditation, Accreditation Managers and Assessment Specialists. Other members of staff may be invited from time to time as required. The TR's role is to address any accreditation related challenges, and provide input into SANAS' policies, procedures and processes.

## 6. Resource Requirements

### 6.1. Competence of Personnel

#### 6.1.1. General

The availability of sufficient, qualified, competent human resources forms the backbone of a credible accreditation service. SANAS therefore employs/contracts personnel who have the appropriate knowledge and skills relevant to the accreditation schemes and geographic areas in which it operates to enable them to competently undertake the work for which they are employed/ contracted for.

#### 6.1.2. Determination of Competence Criteria

SANAS ensures that all its personnel and assessors involved in the accreditation and/or assessments process have the required competencies, knowledge and skills applicable to their areas of responsibility in order to deliver a trusted service of high standard. The competency criteria required for each of the following types of personnel is determined and documented in SANAS HR 22 "Competence procedure for staff involved in the Accreditation process":

##### 6.1.2.1 SANAS Administrative personnel:

The roles and responsibilities of the SANAS Administrative personnel are defined in their job descriptions as well as SANAS OP19 "SANAS Administration Processes".

The competency requirements for Administrators considers the knowledge and skills required for their responsibilities in the administration of the pre- and post- assessment processes, and which includes as a minimum:

- Knowledge of the SANAS accreditation processes;
- Knowledge of the ISO/IEC 17011:2017 requirements;
- Knowledge of the roles and responsibilities of the Team Assistants, Assessment Specialists, Accreditation Managers, Assessment Personnel, the Specialist Technical Committees and the Approval Committee; and
- Skills in administrative functions

#### 6.1.2.2 SANAS Team Assistants:

The roles and responsibilities of the SANAS Team Assistants are defined in their job descriptions as well as SANAS OP19 "SANAS Administration Processes".

The competency requirements for Team Assistants considers the knowledge and skills required for their responsibilities in supporting the Accreditation Managers in the administrative aspects of their responsibilities, and which includes as a minimum:

- Knowledge of the SANAS' rules and processes, including the accreditation processes;
- Knowledge of SANAS financial processes;
- Knowledge of the ISO/IEC 17011:2017 requirements;
- Knowledge of the roles and responsibilities of the Administrative personnel, Assessment Specialists, Accreditation Managers, Assessment Personnel, the Specialist Technical Committees and the Approval Committee; and
- Skills in administrative functions

#### 6.1.2.3 SANAS Assessment Specialists and Accreditation Managers:

SANAS Assessment Specialists are the permanently employed Team Leaders, who, in addition to the responsibilities as Team Leader, assists the Accreditation Managers in various aspects of their functions, which includes the review of application documentation, review of assessment reports and decision-making. The roles and responsibilities of the Assessment Specialists are therefore defined in the relevant SANAS procedures.

SANAS Accreditation Managers are responsible for the management of the activities of the Accreditation Programmes (Schemes) to which they are assigned, and are supported by Team Assistants, Administrative personnel and Assessment Specialists. Accreditation Managers must be trained and qualified as Team Leaders and Approval Committee members and Chairpersons of the Approval Committee. Their responsibilities include the review of applications, selection of assessment team members, review of documents and assessment reports and decision-making. The roles and responsibilities of the Accreditation Managers are defined in their job descriptions and relevant SANAS procedures.

The competency requirements for Assessment Specialists and Accreditation Managers considers the knowledge and skills required for their responsibilities in the various aspects of the accreditation activities, and which includes as a minimum:

- Knowledge of the SANAS' rules and processes, including the accreditation processes;
- Knowledge of assessment principles, practices and techniques;
- Knowledge of general management system principles and tools;
- Knowledge of accreditation and applicable accreditation scheme requirements, including the relevant guidance and application documents;
- Knowledge of Conformity assessment scheme requirements, other procedures and methods used by the CAB;
- Knowledge of risk-based assessment principles;
- Knowledge of general regulatory requirements related to the conformity assessment activities;
- Knowledge of SANAS financial processes;
- Knowledge of the ISO/IEC 17011:2017 requirements;
- Note/minute-taking and report-writing skills;
- Understanding of the roles and responsibilities of the Administrative personnel, Team Assistants, Assessment Specialists, Accreditation Managers, Assessment Personnel, the Specialist Technical Committees and the Approval Committee; and
- Management of meetings.

#### 6.1.2.4 Decision-makers:

The SANAS Approval Committee is responsible for decisions regarding the granting, extending, reducing, suspending or withdrawing of accreditation from the information gathered, submitted and recommended by the assessment team. Their responsibilities and competence criteria is defined in SANAS P20 "The responsibilities and duties of the Approval Committees and Accreditation Managers in the approval and decision on accreditation"

#### 6.1.2.5 Assessment Personnel:

Assessment personnel include internal Assessment Specialists, and external Team Leaders and Technical Assessors drawn from industry, academia and accredited CABs, based on our need for assessors, their personal attributes, qualifications, experience, competence in the relevant accreditation scheme and compliance with specified criteria, trained, qualified and registered as assessors by SANAS.

Assessment personnel meeting the specified criteria but who have not been trained, qualified and registered as SANAS assessors, are called Experts.

Due to the technical nature of our work, technical assessors and experts need to maintain their competence within a given field. SANAS therefore does not employ full time technical assessors/experts but uses SANAS registered, contracted external Technical Assessors / experts on a need-be basis.

SANAS keeps a database of assessors and experts, specifying the scopes for which they have been authorised to assess.

An assessment team normally consists of a team leader and an appropriate number of assessors / experts to cover the scope of accreditation.

The responsibilities and procedures for the **competence criteria**, training, qualification, selection and contracting of assessment personnel is defined in SANAS procedure OP15 “Requirements for SANAS assessors / experts / GLP inspectors”.

SANAS ensures that **assessment personnel** are aware of their duties, responsibilities and authorities. **Table 6.1** describes the types of **assessment personnel** and their function. Specific responsibilities and methods of conducting assessments are defined in procedures listed below:

- P39 “The SANAS Technical Assessor and Expert Information and Guidance Handbook”
- P04 “Accreditation of Laboratories and Proficiency Testing Scheme Providers”
- P05 “The Assessment of Certification Bodies”
- P15 “Accreditation of Inspection Bodies – Regulatory and Voluntary Domain”
- P17 “Accreditation of Verification Laboratories”
- P24 “Assessment Process of BEE Verification Agency”
- P06 “Preparation of Reports”
- P37 “Management of Extraordinary Events or Circumstances and Conditions for Terminating Assessments”
- P41 “Sampling for Assessment Purposes”

**TABLE 6.1: Types of Assessment Personnel and their overall function**

TYPE OF ASSESSOR	OVERALL FUNCTION
<b>Team Leader / GLP Inspector</b>	<p>A leader of an assessment team who is given the overall responsibility for specified assessment activities such as:</p> <ul style="list-style-type: none"> <li>• Preparing the assessment plan;</li> <li>• Making decisions relating to the conduct of the assessment;</li> <li>• Representing the assessment team with the CAB's management;</li> <li>• Conducting assessment of the Management Requirements; and</li> <li>• Coordinating and submitting the final assessment pack.</li> </ul> <p>A <b>Team Leader</b> may sometimes also act as a Technical Assessor during the same assessment, provided he possesses the necessary technical competence in the required <b>scheme</b> assessed.</p>
<b>Technical Assessor</b>	<p>A team member, who conducts the assessment of the technical competence of the CAB for specific area(s) of the desired scope of accreditation. These include:</p> <ul style="list-style-type: none"> <li>• Conducting the assessment of the Technical Requirements and scope of activity by various methods as defined in SANAS procedures, such as witnessing, performing vertical assessments etc.</li> <li>• Assessing competence of the technical personnel for approval as Technical Signatories by SANAS.</li> <li>• Reports to the Team Leader.</li> </ul>
<b>Technical Expert</b>	<p>A team member who conduct assessments of the technical competence the CAB during an assessment, <b>providing specific knowledge or expertise with respect to the scope of accreditation</b>. Technical experts <b>work under the responsibility of</b> a qualified assessor <b>and do not assess independently</b>.</p>

TYPE OF ASSESSOR	OVERALL FUNCTION
<b>Monitor</b>	A <b>qualified assessor</b> who is tasked to evaluate the performance of an assessor, trainee assessor or technical expert and who recommends appropriate follow-up actions to improve performance. A monitor may also be tasked to assist a Technical Expert during an assessment with the assessment process, including completion of assessment documentation and interpretation of accreditation requirements.
<b>Mentor</b>	A <b>qualified assessor</b> who is tasked to tutor a newly qualified assessor, trainee assessor or technical expert throughout an assessment.

The Competence criteria for the assessment team, as a minimum, includes:

- Knowledge of the SANAS' rules and processes, including the accreditation processes;
- Knowledge of assessment principles, practices and techniques;
- Knowledge of general management system principles and tools;
- Knowledge of accreditation and applicable accreditation scheme requirements, including the relevant guidance and application documents;
- Knowledge of Conformity assessment scheme requirements, other procedures and methods used by the CAB;
- Knowledge of risk-based assessment principles;
- Knowledge of general regulatory requirements related to the conformity assessment activities;
- Knowledge of practices and processes of the CAB's business environment;
- Communication skills appropriate to interact with all levels within the CAB;
- Note/minute-taking and report-writing skills;
- Opening & closing meeting skills;
- Interviewing skills; and
- Assessment management skills.

SANAS maintains a record of the competence through demonstrated performance for each personnel member involved in the management and performance of assessments.

### 6.1.3. Competence Management

SANAS ensures the initial and on-going monitoring of its personnel involved in the accreditation process in order to provide reasonable assurance that our personnel project the required level of professionalism, competence and expertise and to allow us an opportunity to identify appropriate follow-up actions to improve performance where necessary.

#### 6.1.3.1 Monitoring of SANAS internal personnel

Newly appointed SANAS internal personnel are required to undergo the SANAS induction and training programme, which is followed by a competency evaluation period. Once their competency is

evaluated and confirmed in the relevant areas of their responsibility, their competence and performance will be monitored on an on-going basis.

Through the performance management process, SANAS identifies individual training needs on an annual basis and provides access to specific training initiatives for all personnel to ensure continuous growth, development and improvement of its personnel.

**References:** HR 07 "SANAS Performance Management Handbook".  
HR 20 "SANAS Induction and Training Programme".

#### 6.1.3.2 Monitoring of Assessment personnel

Assessment personnel's conduct, depth of expertise and consistent interpretation and application of the relevant Standard/Guides used, contributes largely to the image and reputation of SANAS. Newly qualified assessors will be monitored at their first on-site assessment, and thereafter regular monitoring of the assessor will be conducted. Various methods of monitoring of all our assessors are used, which includes on-site monitoring of performance of an assessment, review of assessment data and reports, feedback from assessed CAB's and independent customer satisfaction surveys. Feedback arising out of any such monitoring will be recorded, appropriate corrective actions taken if needed and where necessary included in the agenda of an assessor conclave.

**Reference:** OP15 "Requirements for SANAS assessors / experts / GLP inspectors".

#### 6.1.3.3 Monitoring of Approval Committee members

The CEO approves the Approval Committee members on receipt of evidence of training in the decision-making process, and confirmation from the relevant Accreditation Manager or in the case of the Accreditation Manager, the Executive, their satisfactory performance after a mentoring and monitoring stage. Registered Approval Committee (AC) members will thereafter be monitored at least once in every 3 years, to provide confidence in their continued competence, independence and professionalism. Where monitoring indicates a need for improvement, appropriate measures will be effected.

**Reference:** The Responsibilities and duties of the Approval Committees and Accreditation Managers in the Approval and Decision on Accreditation / GLP Compliance".

## 6.2. Personnel Involved in the Accreditation Process

- 6.2.1. SANAS ensures that it has the necessary access to a sufficient number of competent personnel to manage and support each area of its business and the different accreditation schemes in which it offers accreditation.

An assessor gap analysis is conducted on an annual basis to highlight areas where additional assessors / experts need to be sourced and/or qualified. Assessor and accreditation statistics are

monitored on an on-going basis to ensure a proactive approach in ensuring the availability of sufficient assessment personnel.

SANAS implements a talent management programme for its internal personnel to assist in:

- identifying internal competency gaps and developing employees to close the gaps;
- identifying core contributors and implementing processes to retain and continuously develop them;
- identifying successors and strategies to retain employees in an endeavour to ensure access to a sufficient number of competent personnel in all areas of its business.

**References:**

- SANAS HR 19 SANAS Succession Plan Procedure
- SANAS HR 04 SANAS Procedures on Recruitment, Selection, Appointment and Retention
- OP15 "Requirements for SANAS assessors / experts / GLP inspectors".

- 6.2.2. All SANAS staff are provided a job description which outlines his/her roles and responsibilities and sign an employment contract on appointment.

SANAS contracted assessment personnel, including trainee assessors, are required to sign the F53 "SANAS Independent Contractor Agreement" on their registration, that specifies their agreement to comply with SANAS' requirements as assessor, and which includes their responsibilities in terms of confidentiality, impartiality and non-conflict of interest. In addition, each assessment personnel member is required to sign the F22 "Confidentiality, Impartiality and Non-disclosure agreement" prior to each assessment in which they participate, declaring any relationship they may have or have had with the CAB being assessed.

SANAS Approval Committee members are required to sign a Confidentiality and Non-disclosure agreement with each decision-making process undertaken to ensure that no conflict of interest exists with the CAB being considered.

**References:**

- SANAS Employee Contracts
- F53 "SANAS Independent Contractor Agreement"
- F22 "Confidentiality, Impartiality and Non-disclosure agreement"
- F08 "Approval Committee and Accreditation Manager decision on accreditation"

- 6.2.3 SANAS normally arranges annual Assessor Conclaves, and where required, internal and external workshops, training sessions and/or information sessions to ensure that its staff and assessment personnel remain up to date with the accreditation processes and procedures.

The SANAS Quality Manager ensures that its staff, Committee Members and Assessment Personnel have access to the relevant policies, procedures, processes, forms and requirements by publishing the documentation on the internal document management system, and where applicable to the CAB, assessment personnel, committee members and other stakeholders, on the SANAS website.

**References:**

1. SANAS OP 02 SANAS Document control procedure

**6.3. Personnel Records**

SANAS maintains an up-to-date set of records for all staff members, contracted personnel and committee members, the record requirements of which are specified in the relevant procedures.

As a minimum, the records retained must include:

- a) A Curriculum Vitae;
- b) Training records in the areas of responsibility;
- c) Copies of Qualifications;
- d) Monitoring / performance reports, including any corrective measures undertaken;
- e) Professional status and affiliations, if relevant.

**References:**

- OP15 "Requirements for SANAS assessors / experts / GLP inspectors",
- P 20 "The Responsibilities and Duties of the Approval Committees and Accreditation Managers in the approval and decision on accreditation"
- P19 "Terms of reference, registration and responsibilities of Specialist Technical Committees")

**6.4. Outsourcing**

SANAS normally carries out assessments itself. However, it may be necessary to outsource parts of or whole of, an assessment of a specific CAB. SANAS will in such cases remain with the total responsibility for the assessment process.

SANAS does not outsource the decision-making process, whether the assessment was conducted by SANAS, or whether it was outsourced.

SANAS has bilateral agreements with other recognised accreditation bodies that are members of the ILAC, IAF and/or AFRAC MRA/MLA's. These bilateral agreements allow SANAS to perform assessments on behalf of these organisations for their clients operating services in South Africa and allows SANAS to outsource assessments to these accreditation bodies, where required.

The details of each bilateral agreement will indicate the scope and degree of cooperation between the foreign accreditation body and SANAS.

Accreditation assessments will only be outsourced to Accreditation Bodies with the required scope(s) that are signatories to the relevant multilateral arrangements with IAF, ILAC or AFRAC, and only on prior written consent by the CAB. The outsourced accreditation body personnel involved with the assignment will be required to sign the relevant SANAS Nondisclosure/Confidentiality Statements.

SANAS outsources various functions including website maintenance, IT services providers, training providers, events coordinators, cleaning and security services. Subcontractors who may have access to confidential information must sign the necessary SANAS confidentiality statements which are maintained by SANAS.

**References:**

- SANAS F 74: Confidentiality and Non-disclosure agreement for service providers and contractors
- FP 02 Supply Chain Management Manual
- P26 Cross Frontier Accreditation

## 7. Process Requirements

A general description of the accreditation process is summarised in A03 “General Information on the Accreditation Process”.

### 7.1. Accreditation Requirements

The accreditation requirements for CAB's used by SANAS are those set out in the relevant International / National standards, applicable normative documents and any ILAC/IAF/AFRAC guidance or interpretations thereof.

The applicable accreditation criteria for the different accreditation schemes, and which CABs must fully comply with in order to obtain and maintain accreditation are specified in clause 4.1.7.1 – Table 1.

### 7.2. Application for Accreditation

An authorised representative of an applicant CAB seeking accreditation must apply to SANAS by completing the relevant application form in the prescribed format which is available on the SANAS website at [www.sanas.co.za](http://www.sanas.co.za). The application must be submitted to SANAS with the supporting information / documentation as required in the application, which must include information demonstrating that the requirements of the relevant international standard are addressed.

The relevant procedures as referenced below, describes the application process, including the process for the review of the application information submitted by SANAS.

The F147 Terms and Conditions for Accreditation specifies the conditions under which applications will not be accepted by SANAS.

### 7.3. Resource Review

All applications for accreditation received are reviewed by SANAS to determine whether the application criteria have been fulfilled, whether SANAS offers the scope of accreditation applied for, and whether SANAS has the necessary resources and competence to carry out the assessment.

The Application will be valid for one (1) year. SANAS will review the information provided in the application and determine the CABs readiness and its ability to carry out the initial assessment within the validity period of the application, and where this will not be possible, the reasons will be communicated to the applicant.

### 7.4. Preparation for assessment

SANAS ensures that a suitable number of assessment team members with the required knowledge, skills and expertise for the scope to be assessed are appointed from the database of registered assessors.

SANAS informs the CAB of the appointed assessment team members and their affiliation with any organisations or institutions in order to provide the CAB with the opportunity to object to any member of an assessment team. Such objections will however only be considered if the CAB is able to prove that a conflict of interest exists. Procedures for objections to any member(s) of an assessment team are defined in the relevant programme specific procedures, as referenced below.

Assessment team members are required to know, understand and implement the procedures for the preparation and planning of the assessment of the competence of a CAB, including the process of sampling activities representative of the scope of accreditation.

Each assessor will be provided with the required assessment forms in order to document the findings of the assessment. Any technical requirements or technical guidance documents are accessible via the SANAS website. Each assessor is required to have in their possession a copy of the relevant accreditation standard, which they would have obtained during their assessor training course, or on revision of the standard, as relevant.

The relevant application documentation and any non-conformances raised at the previous assessment of the CAB will also be provided to the assessment team members. The assessment team shall not accept applications or requests from the CAB made on the day of the assessment.

### 7.5. Review of Documented Information

The information and documentation submitted by the CAB on application is reviewed by the assessment team prior to the on-site assessment to evaluate the CABs management system for compliance with the relevant accreditation standard, where applicable the regulatory requirements, and other requirements for accreditation.

The results of the document review and a recommendation on the way forward, including justification for a decision not to proceed with any further assessment will be provided to the CAB within the timelines specified by SANAS. The CAB will be provided with an opportunity to correct any deficiencies after which an on-site assessment can be scheduled.

## 7.6. Assessment

To ensure uniformity and consistency, SANAS has documented detailed procedures for the assessment process and the various assessment techniques used in the programme specific procedures, as referenced below. The procedures define the processes from onset of the assessment to its finalisation, including the management of the corrective action process, where required, after the assessment. The various roles, responsibilities and timelines are included.

### References:

- SANAS P04 - Accreditation of laboratories, proficiency testing scheme providers and producers of certified reference materials
- SANAS P05 – The assessment of Certification Bodies
- SANAS P15 – Accreditation of Inspection Bodies, Regulatory and Voluntary Domain
- SANAS P16 – Good Laboratory Practice (GLP) Compliance Monitoring Programme
- SANAS P17 – Accreditation of Verification Laboratories
- SANAS P24 – Assessment process of a BEE Verification Agency
- SANAS F147 – Terms and Conditions of Accreditation
- SANAS OP19 – Administrative Processes

## 7.7. Accreditation Decision-making

Due to the high risk associated with granting, maintaining, extending, reducing, suspending, reinstating or withdrawing of an organisation's accreditation status, SANAS applies two methods of decision-making to mitigate this risk. These methods are:

- For high-risk decision-making emanating from initial, re-assessments and extension of new scopes of accreditation, including any assessment team's recommendations for reducing, suspending or withdrawing of accreditation, the CEO delegates decisions on to the Approval Committee chairperson, on advice from the approval committee members.
- For surveillance assessments, extension of existing scopes of accreditation, additional signatories of existing accredited CABs, assessments to verify transition to a new standard / guide, recommendations for on-site clearance of findings (COF) or recommendations for reinstatement of accreditation following suspension, decisions are made by SANAS Accreditation Managers (AM) or the Assessment Specialists, as delegated.

Accreditation decisions are not outsourced.

The composition of the Approval Committee ensures impartiality and independence in decision making at all times. AC members will not be assigned to evaluate an assessment of which he/she was a member of the team or where he/she may have any other conflicts of interest with the matter under review.

SANAS has documented procedures for the competency criteria for Approval Committee members, the decision-making process, the type of information on which decisions are based and the reporting of the outcome of the decision to the CAB.

**References:**

- SANAS P20 “The Responsibilities and Duties of the Approval Committees and Accreditation Managers in the approval and decision on accreditation
- SANAS R51 “Suspensions, Withdrawals and Re-instatement of accredited or GLP/GCP compliant organisations”
- F147 “Terms and Conditions of Accreditation” and
- F199 “Terms and Conditions of GLP/GCP Compliance”.

## 7.8. Accreditation Information

SANAS issues an Accreditation Certificate to each CAB to which it grants accreditation in accordance with the procedures defined in SANAS P10 “Accreditation / GLP Compliance Certificate and Scope of Accreditation”.

The SANAS Accreditation certificate consists of two parts, namely the:

- Certificate which bears the formal accreditation status of an accredited CAB, signed by the Accounting Officer as delegated by the SANAS BoD; and
- the Scope of accreditation which contains details of the scope for which accreditation has been granted, signed by the relevant Accreditation Manager as delegated by the Accounting Officer.

The Accreditation Certificate is valid for a defined period and which is aligned to the applicable accreditation cycle (refer to clause 7.9). SANAS reserves the right to withdraw the Accreditation Certificate at any time for transgressions of the SANAS Terms and Conditions of Accreditation (F147 / F199).

The Accreditation Certificates are published on the SANAS website.

## 7.9. Accreditation Cycle

The SANAS accreditation cycle begins on the date that accreditation has been granted by SANAS and shall not be longer than the periods as stipulated below, unless otherwise prescribed by a regulation or other legal instrument:

Accreditation Programme	Validity period
Calibration and Testing Laboratories	5 years
Certification Bodies	3 Years
Inspection Bodies	4 Years
Verification Laboratories	4 Years
Medical Laboratories	4 Years
GLP/GCP facilities	2 years
Producers of Certified Reference Materials	5 years
Blood Transfusion laboratories, donor clinics and blood banks	4 years
Proficiency Testing Providers	4 years
Broad Based Black Economic Empowerment (BBBEE) Verification Agencies	4 years

The following procedures describe SANAS' processes and procedures used in applying periodic scheduled on-site assessments, which shall not exceed 2 years, to verify that the conformity assessment activities representative of the scope of accreditation at the relevant locations are assessed during the accreditation cycle:

- P04 "Accreditation of Laboratories and Proficiency Testing Scheme Providers"
- P05 "The Assessment of Certification Bodies"
- P15 "Accreditation of Inspection Bodies – Regulatory and Voluntary Domain"
- P17 "Accreditation of Verification Laboratories"
- P24 "Assessment Process of BEE Verification Agency"

At least 3 months before the end of the accreditation cycle (and 6 months in the case of Inspection Bodies), subject to receiving an application for renewal of accreditation from the CAB, a reassessment will be planned and conducted to re-confirm the competence of the CAB in all the requirements of the standard, for the scope for which they are accredited.

Should the application for renewal of accreditation not be submitted within the above-mentioned timelines, a re-assessment may not be conducted prior to the end of the accreditation cycle, resulting in the expiry of the CAB's accreditation. Should the CAB wish to continue with accreditation, the CAB will have to re-apply as a new applicant. All application fees and timeframes will be applied for the re-application.

## 7.10. Extraordinary Assessments

SANAS reserves the right to conduct unscheduled and/or unannounced extraordinary assessments over and above the planned assessments and at any time during the assessment cycle in order to:

- follow up on the investigation and resolution of a complaint against a CAB;
- follow up on significant changes relevant to the accreditation of the CAB which may have an effect on the CAB's accreditation / compliance status; or
- For any other reason that SANAS may deem necessary to confirm on-going compliance to accreditation requirements.

Such extraordinary assessments are conducted in accordance with the requirements as detailed in SANAS R 76 “Extraordinary (unscheduled) assessments to SANAS Accredited Facilities”. The extraordinary assessment will be at the cost of the CAB should SANAS confirm any transgression/contravention of the accreditation requirements.

### 7.11. Extending Accreditation

There are 2 types of extensions to the scope of accreditation:

- i) A whole new scope including the conformity assessment activities within that scope;
- ii) Conformity assessment activities added to an existing accredited scope.

SANAS handles applications for extensions to a CAB's scope of accreditation in accordance with procedures defined in:

- *P04 “Accreditation of Laboratories and Proficiency Testing Scheme Providers”*
- *P05 “The Assessment of Certification Bodies”*
- *P15 “Accreditation of Inspection Bodies – Regulatory and Voluntary Domain”*
- *P17 “Accreditation of Verification Laboratories”*
- *P24 “Assessment Process of BEE Verification Agency”*

### 7.12. Suspending, Withdrawing or Reducing Accreditation

To ensure compliance to accreditation requirements, applicable regulatory requirements, safeguard the integrity of the accreditation and the reliability of results produced by an accredited CAB, SANAS applies various sanctions to accredited CABs who have failed to meet the applicable accreditation requirements or abide by the rules of accreditation.

Sanctions may include suspension of CABs accreditation or part thereof, or where warranted, reduction or withdrawal of CAB's accreditation status.

Suspension, reduction or withdrawal of accreditation may also be voluntary requested by the CAB.

The procedures and criteria for such sanctions including re-instatement of accreditation after a period of suspension are defined in SANAS R51 “Suspensions, Reductions, Withdrawals and Re-Instatement of Accredited/GLP Compliant Organisations”

## 7.12. Complaints and Appeals

Complaints against the services or accreditation activities of SANAS are considered as opportunities for improvement as SANAS understands the link between complaint resolution, and customer loyalty and satisfaction. SANAS therefore encourages customer feedback and aims to address any valid complaints promptly and effectively.

Where appropriate, SANAS ensures that complaints against the services of its applicant or accredited CAB are first addressed by the CAB through their own complaint procedure, failing which, the complaint may be referred to SANAS.

Complaints against the validity or reconsideration of non-conformance(s) raised during an assessment are handled as disputes. Disputes must be submitted in writing to SANAS within 5 working days after the assessment.

An applicant or accredited CAB is entitled to submit an appeal for the reconsideration of any adverse accreditation decision related to its accreditation status.

Complaints, appeals and disputes must be submitted in writing to the responsible SANAS authority within the stipulated timeframes.

Responsibilities and procedures for the submission, receipt, evaluation of validity, investigation and decision-making of complaints, appeals and disputes are defined in P12 "Handling of Complaints and Appeals", and which is available on the SANAS website.

SANAS ensures that the investigation and decision on complaints and appeals do not result in any discriminatory actions against the complainant.

## 8. Information Requirements

### 8.1. Confidential Information

SANAS maintains a high level of confidentiality in our operations. An undertaking, through, but not limited to the following legally enforceable agreements, as relevant, will be obtained from the Board Members, Committee Members, Employees, Assessment Personnel, any other Contracted Personnel and other third parties, to the maintenance and disclosure of confidential information:

- i) The Terms and Conditions for Accreditation (F147) / GLP Compliance (F199);
- ii) Independent Contractor Agreement Between SANAS and Assessor / GLP Inspector / Expert (F53);
- iii) Confidentiality, Impartiality and Non-Disclosure Agreements (F22, F73, F74);
- iv) SANAS Employment Contracts.

Any breach of confidentiality is viewed in a very serious manner and we will use whatever remedies are available to deal with such breach.

Any person requesting information from SANAS must do so in accordance with the procedures specified in SANAS P42 "Section 14 Manual in Terms of the Promotion of Access to Information Act 2 of 2000", which serves both as an index of records held by SANAS as a public body and as a guide for requesters. The procedure contains information on the type of information that is made publicly available, the information that may be requested, and the information that SANAS refuses access to. Confidential information shall only be disclosed in accordance with the Accreditation Act, as enforced under chapter 6, section 28 of the Accreditation Act.

## 8.2 Publicly Available Information

Communication is a necessary tool to network, spread ideas, and promote accreditation. The importance of communication is crucial to the success of SANAS in fulfilling our mission. We therefore use communication tools such as our website, reports, policies and procedures, assessor conclaves, communication meetings, workshops and the media.

SANAS makes the following categories of records / information publicly and freely available through its website at [www.sanas.co.za](http://www.sanas.co.za):

Document Category	Description of the Document / Records
The Accreditation Act	Sets out the legal framework of SANAS
SANAS Policy Manual (PM01)	Contains SANAS' governing policies, information about the authority under which SANAS operates, its activities, means by which SANAS obtains financial support, a description of its rights and duties, and the Mutual Recognition Arrangements/Multilateral Arrangements that SANAS is involved with
SANAS Advisory Documents (A - Documents)	Contains general information on aspects concerning SANAS.
SANAS Assessment Forms (F - Documents)	Forms used for assessment purposes to capture information
SANAS Procedural Documents (P - documents)	Describes the formalities and requirements for obtaining accreditation.
SANAS Requirement Documents (R - documents)	Describes additional mandatory aspects that together with the relevant ISO/IEC documents must be complied with across all technical fields in order to obtain and maintain SANAS accreditation.
SANAS Technical Requirement Documents (TR - documents)	Describes the additional mandatory aspects in specific technical fields of expertise.
SANAS Technical Guidance Documents (TG - documents)	Contains technical information and specific guidance to best practices in specific fields of expertise.
SANAS Annual Reports, Pamphlets, Information Brochures, Communiqué and Monthly Newsletters	Contains performance recordings and general communication with stakeholders
Details of Accredited CABs	Includes details of the current status of the accreditations it has granted, including information on suspension or withdrawal of

	accreditation
SANAS Courses	Contains information and dates of courses presented by SANAS

In addition, SANAS uses the following forums as communication tools for its stakeholders and interested parties:

Communication Documents	<ul style="list-style-type: none"> <li>• Whatsup@SANAS: Publication for all stakeholders</li> <li>• Bulletin: To convey changes in requirements – target audience are the CAB's and Assessors</li> <li>• A-News: Assessor newsletter</li> <li>• Annual report: For all stakeholders</li> <li>• Insight: Internal newsletter distributed to staff members</li> </ul>
Conclaves & Workshops	<ul style="list-style-type: none"> <li>• Assessors / GLP Inspectors conclave held as required. This meeting is used to: <ul style="list-style-type: none"> <li>○ discuss and highlight changes in accreditation requirements</li> <li>○ address issues of concern, with the focus on improving consistency in the assessment / GLP inspection process</li> </ul> <p>The conclaves are is therefore beneficial for the improvement and performance of the assessor / GLP inspector.</p> </li> <li>• Workshops held as needed, to ensure assessors are aware of specific accreditation scheme requirements and/or developments</li> </ul>
Communication meetings	<ul style="list-style-type: none"> <li>• Communications meeting, where representatives of accredited CABs, interested parties and stakeholders are invited, are conducted as required. This meeting is used to discuss and highlight issues that need to be addressed in the coming year. The main focus of these meetings is to communicate changes, notifications, resolutions and other matters concerning requirements for accreditation and the interface between SANAS and the various role players and is therefore beneficial for the improvement and sustainability of the CAB's performance.</li> <li>• Marketing activities as identified in the Marketing Strategy</li> </ul>
Regulator Meetings	<ul style="list-style-type: none"> <li>• Meetings are held with representatives of Regulatory Bodies as needed, the main focus of which is to: <ul style="list-style-type: none"> <li>○ discuss current regulations and the involvement of SANAS in any new or existing regulations, and subsequent accreditation requirements;</li> <li>○ make them aware of the benefits of accreditation and the accreditation processes</li> </ul> </li> </ul>

Following the publication of any new or amended accreditation requirements, SANAS will verify that each accredited CAB conforms to the new or amended requirements, as applicable.

## 9. Management System Requirements

### 9.1. General

The SANAS Management System is established, documented, implemented and maintained in a manner that is capable of supporting and demonstrating the consistent compliance with the requirements of ISO/IEC 17011, the Accreditation Act and the requirements stipulated by our Board of Directors. Policies and objectives related to competence, consistency of operation and impartiality are established. Our policies and accreditation criteria shall be consistent with the policies and guidance from ILAC, IAF, AFRAC and SADCA, after due consideration of their relevance and impact.

We implement a system for the measurement of quarterly targets based on annual objectives, which is based on our strategic objectives as required by government and the Accreditation Act. These measurable outcomes are monitored by the Executive Committee and reported to the Board and the dti on a quarterly basis.

The policy manual and all our related documentation is made electronically available to all staff members. The documentation relevant to the accreditation activities is made available publicly on our website ([www.sanas.co.za](http://www.sanas.co.za)).

### 9.2. Management System

The SANAS Management System consists of the Policy Manual, supported by various procedures and forms used for the recording of information. The effectiveness and efficiency of the Management System are continuously monitored through various mechanisms, which include:

- Internal audits;
- Document reviews;
- Management Reviews;
- Risk Assessments;
- Performance reviews;
- Complaints;
- Customer feedback and
- External Customer Surveys;

Any needed improvements identified through these mechanisms will be implemented and monitored to ensure the continuous improvement of the Management System.

### 9.3. Document Control

**SANAS** develops, reviews, maintains and controls all documentation in accordance with our procedure OP 02: “The Numbering, Approval and Control of SANAS Documentation”. This procedure defines the controls needed for:

- the approval of documents for adequacy prior to use;
- the review and update of documents as needed;
- the identification of changes and the current revision status of documents;
- the availability of current versions of applicable documents at points of use;
- the identity and legibility of documents;
- the prevention of use of obsolete documents; and
- safeguarding of the confidentiality of documents, as relevant.

The Quality Manager ensures that only current valid versions of documents are made available to all staff internally and on the SANAS website. It remains the responsibility of all staff and contracted personnel, accredited CABs, stakeholders and interested parties to ensure that they use only the current versions of documents and destroy all superseded documents.

International Standards and Guides:

It is the responsibility of each accredited / GLP compliant facility to ensure that it uses the most recent issue of the international standard/guide applicable to its area of accreditation and / or the national equivalent. This includes all IAF/ILAC/AFRAC guidance and mandatory documents on the above guides and standards where relevant.

The hierarchy of SANAS documentation is given in the **Table 3.7** below.

**TABLE 3.7: The hierarchy of SANAS Documents**

DOCUMENT CATEGORY	PREFIX	USE	DISTRIBUTION
<b>The Accreditation Act</b>		The Accreditation Act contains the terms of reference for the operation and duties of the SANAS Board and its interaction with Government. The Accreditation Act is the highest level of document	Internal/External
<b>SANAS Policy Manual</b>	PM	Describes the overall policies and objectives of SANAS.	Internal/External
<b>SANAS Strategic and Budget Documents</b>	SB	Describes both the basic broad framework within which SANAS operates, as well as strategic intent.	Internal
<b>SANAS Human Resource Documents</b>	HR	Describes the internal human resource policies and procedures of SANAS	Internal
<b>SANAS Information and Communication Technology Documents</b>	ICT	Describes the internal information and communication policies and procedures of SANAS	Internal
<b>SANAS Operational</b>	OP	Describe the internal operational procedures of the SANAS	Internal

DOCUMENT CATEGORY	PREFIX	USE	DISTRIBUTION
<b>Procedures</b>		office	
<b>SANAS Financial Procedures</b>	FP	Describes the internal financial policies and procedures of SANAS	Internal
<b>SANAS Procedural Documents</b>	P	Describes the formalities and requirements for obtaining accreditation	Internal/ External
<b>SANAS Requirement Documents</b>	R	Describes additional mandatory aspects that together with the relevant ISO/IEC documents must be complied with across all technical fields in order to obtain and maintain SANAS accreditation	Internal/External
<b>SANAS Technical Requirement Documents</b>	TR	Describes the additional technical mandatory aspects in specific areas, which were generated by the STC that together with the relevant ISO/IEC documents must be complied with in order to obtain and maintain SANAS accreditation. These are compulsory documents.	Internal/External
<b>SANAS Technical Guidance Documents</b>	TG	Contains technical information and specific guidance to best practices in specific fields of accreditation. These are not compulsory documents.	Internal/External
<b>SANAS Forms</b>	F	Used for the capturing of data.	Internal/External
<b>SANAS Advisory Documents</b>	A	Contains additional information on aspects concerning SANAS	Internal/External

#### 9.4. Record Control

The controls needed for the efficient and reliable management of information through proper identification, storage, protection, retrieval, retention and disposal of all its records, including records of its applicant and accredited CABs are defined in procedure OP01 "SANAS Records".

SANAS' records are held in a secure, access controlled and confidential manner **that supports:**

- the quick and comprehensive retrieval of relevant information;
- sound decision making;
- its compliance to the relevant legal, evidential and accountability requirements such as the:
  - effective financial management as required in terms of the Public Finance Management Act (Act No. 1 of 1999);
  - access to information as required by the Promotion of Access to Information Act, Act No. 2 of 2000 (Refer to P42 "and
  - the facilitation and regulation of electronic communications and transactions as required by the Electronic Communications and Transactions Act, Act No 25 of 2002.

#### 9.5. Nonconformities and Corrective Actions

Nonconformities against our own operations can be identified through different mechanisms which include, but are not limited to, complaints, customer feedback or surveys, internal audits, review of procedures and monitoring of staff / assessor performance.

Where nonconformities have been identified, the necessary corrective actions, appropriate to the impact of the problems, are taken to correct and control the nonconformity. Any actions taken must eliminate the causes of nonconformities in order to prevent recurrence.

Responsibilities and procedures for the identification and management of non-conformances and the effective implementation of corrective actions appropriate to the impact of the problems encountered are defined in:

- OP07 “Internal Audits”
- P12 “Handling of Complaints and Appeals”.

## 9.6. Improvement

The mechanisms that SANAS has established to identify non-conformities, are also used to identify opportunities for improvement, to identify risks and to take the appropriate actions to initiate improvements and/or to mitigate the risks identified.

It is the responsibility of all staff, contracted personnel and CABs to identify opportunities for improvement and/or risks, and report these to the Quality Manager to allow for the review and improvement of our processes and assist in preventing a potential non-conformance.

SANAS has developed a risk profile which is reviewed annually by the Board of Directors with measures being put in place to militate against the identified risks.

## 9.7. Internal Audits

To verify continued compliance to all the requirements of our Management System, ISO/IEC 17011 and the mandatory requirements of ILAC / IAF / AFRAC / SADCA, and to confirm the effective and efficient implementation of our policies and procedures, we schedule and conduct internal audits normally once a year.

Responsibilities and procedures for scheduling and conducting of internal audits, the identification of non-conformances / areas of improvement and reporting are defined in SANAS OP07 “Internal Audits”.

In accordance with the Public Finance Management Act (PFMA), the Board of Directors appoint independent External and Internal Auditors to review our corporate governance and operational compliance to the relevant Acts, standards and procedures.

## 9.8. Management reviews

Continuous review of the SANAS management **system and operations** is undertaken to determine whether all requirements and objectives of our Management System have been adequately and effectively met and to ensure that any deviations are identified and correct timeously.

We therefore implement a system of management meetings that allows for the various aspects of the Management System to be reviewed and improved on, on an on-going basis. These meetings comprise of:

- i) *Technical Review meetings*: to address any accreditation related challenges, whether technical or administrative, and provides input into SANAS policies, procedures and processes.
- ii) *Executive Committee meetings* to report on and monitor Strategic issues affecting the performance of SANAS across all business units; to report on the current performance and opportunities for improvement of the management system, SANAS' service and accreditation process; to identify the need for resources; and to approve accreditation requirements and procedures; and make decisions. (Refer: OP10 "Executive Committee Governance and Procedures";
- iii) *Divisional Strategic Planning Meetings* to review the focus and implementation of the outcomes identified for the strategic objectives for the year and to propose goals and objectives, as required, for the year(s) ahead; and
- iv) *The Annual Strategic Board Meeting* to provide direction to SANAS, and to approve strategic objectives for year(s) ahead.

Responsibilities and procedures for the scheduling, conduct and outcomes of the management review meetings are defined in SANAS procedure OP08 "Management Review".

## 10. Cross Frontier Accreditation

The International Accreditation Forum (IAF) and the International Laboratory Accreditation Co-operation (ILAC) strongly advises CABs to obtain domestic accreditation, however there may be reasons why a CAB may seek accreditation from Accreditation Bodies (AB) outside of their own country instead of or as well as the domestic accreditation.

SANAS handles all applications received from CABs' outside of its borders in accordance with SANAS P26 "Cross Frontier Accreditation.

## 11. Proficiency Testing/Inter Laboratory Comparisons for Laboratories

Proficiency testing (PT), inter-laboratory comparisons and other means of demonstrating a CAB's technical competence are crucial to the integrity and reliability of results. Applicant and accredited laboratories, and where applicable, Inspection Bodies, must provide SANAS with sufficient evidence of participation in PT activities **or inter-laboratory comparisons and other means of demonstrating technical competence**. We realise that there will be instances where SANAS may have to assist in the provision of such proficiency testing programmes, however these could be considered a conflict of interest if PT schemes are available or already accredited by SANAS. We therefore:

- a) Refrain from providing PT schemes where there is an easily accessible scheme available nationally and in the region;
- b) Provide a list of all SANAS accredited PT schemes and other schemes available nationally, regionally and internationally. SANAS however does not endorse unaccredited schemes; and
- c) Ensure that all PT schemes supported by SANAS are managed independently.

### **References:**

- *R48 Proficiency Testing and other Comparison Programme Requirements for Calibration Laboratories*
- *R80 Proficiency Testing and other Comparison Programme Requirements for Testing and Medical Laboratories*
- *TG74 Guidelines for Inter-laboratory Quality Control in Accredited Medical Laboratories*

**Note:** The above requirements are not applicable to GLP Compliant Facilities.

## 12. Traceability

Accredited CABs are required to demonstrate that calibration of critical equipment, and hence the measurement results generated by that equipment, relevant to their scopes of accreditation, are traceability to the International System of Units (SI units). Where this is not possible traceability shall be to certified reference materials provided by a competent supplier and/or to other specified methods or consensus standards.

Metrological traceability can be demonstrated by having calibrations performed either in National Metrology Institutes (e.g. NMISA) or in calibration laboratories accredited by SANAS or by Accreditation Bodies which are signatories of the ILAC Arrangement.

The acceptance of other National Metrology Institutes other than those of the CIPM MRA partners will be at the discretion of the CEO of SANAS after due consultation with the appropriate STC and NMISA counterpart. Should any such organisations be acceptable, a record will be maintained of its acceptability and the reasons for the acceptability.

Calibration certificates issued by non-accredited facilities must provide sufficient information regarding the process of the calibration as required by the criteria defined in TR25 and are only accepted where no accredited provider of these calibration services exists. This is to ensure that no aspect of the calibration could have a detrimental effect on the traceability. (Refer to TR 25 "Criteria for performing calibration and intermediate checks on equipment used in accredited CABs".

For legal compliance, measurement traceability as defined in Chapter 3 of the National Measurement Units and Measurement Standards Act, Act 18 of 2006 applies.

### **13. Reference Materials**

SANAS accredited testing laboratories shall have a programme and procedure in place for the calibration of its reference standards. Reference standards shall be calibrated by a body that can provide traceability.

### **14. Professional Judgment / Opinions**

CABs may include in their test/inspection reports and calibration/inspection certificates a section that provides their professional judgment, opinion or interpretation based on the measurement results. The test/inspection report / calibration/inspection certificate shall indicate that these professional judgments, opinions or interpretations, although contained in the report certificate, fall outside the CAB's scope of accreditation.

### **15. Transfer of Accreditation / GLP Compliance Status and Franchising**

Accreditation shall not be transferable from one entity to another. We do not allow an accredited / compliant facility to franchise their accreditation activities to other CABs or organisations. The requirements concerning transfer of accreditation are detailed in SANAS R01 "Transfer of Accreditation / GLP Compliance and Franchising".

### **16. Electronic Signatures**

Technology has developed over the years making electronic signatures possible. However electronic signature can be open to abuse or fraudulent use, if not strictly controlled. South Africa has published the required legislation regarding the acceptance of electronic signatures. We therefore accept the usage of electronic signatures from South African accredited CABs, provided these signatures meet the requirements as specified in the Electronic Communication and Transactions Act, Act 25 of 2002.

Where a CAB accredited by SANAS is registered in a country other than South Africa, these CABs will be required to demonstrate that the advanced electronic signature complies with their national

legislation concerning electronic signatures. The discretion to accept or reject the use of such signatures however remains that of SANAS.

**APPENDIX A – Amendment Record**

<b>Proposed by</b>	<b>Section</b>	<b>Change</b>
QM	All	Complete review and alignment of the Policy Manual to ISO/IEC 17011:2017