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REPUBLIC OF SOUTH AFRICA

**ACCREDITATION FOR CONFORMITY ASSESSMENT,  
CALIBRATION AND GOOD LABORATORY PRACTICE  
BILL, 2006**

**(As introduced in the National Assembly as a section 75 Bill;  
Explanatory summary of Bill published in Government Gazette  
No.\*\*\* of 2006; The English text is the official text of the Bill)**

**(Minister of Trade and Industry)**

**[B\*\* of 2006]**

## **BILL**

**To provide for an internationally recognised and effective accreditation and monitoring system for South Africa by establishing SANAS as a public entity and recognising same as the only accreditation body in South Africa for the accreditation of conformity assessment, calibration and monitoring of good laboratory practice**

### **PREAMBLE**

#### **RECOGNISING –**

- the need for an internationally recognised national accreditation system as a crucial element of a well-functioning technical infrastructure that is aligned with international best practice;
- the importance to ensure that South Africa's accreditation system continues to support the needs of our enterprises competing in a fast-paced global economy;
- a need to provide for the strengthening of the recognition of SANAS as the national accreditation authority for calibration, conformity assessment and good laboratory practices;
- the importance to support public policy objectives in terms of health, safety and broad-based black economic empowerment compliance issues; and
- that government is committed to providing a supportive legal environment for accreditation of conformity assessment, calibration and good laboratory practice.

#### **IN ORDER TO—**

- recognise SANAS as the sole body in South Africa responsible for accrediting for its scope of activity in respect of conformity assessment;
- ensure an internationally recognised accreditation system;
- promote accreditation as a means of facilitating international trade and enhancing South Africa's economic performance and transformation;
- promote the competence and equivalence of accredited bodies and of compliant GLP facilities.

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## INTERPRETATION AND PURPOSE

### 1 Definitions

In this Act, unless the context indicates otherwise,

- (a) "accreditation body" means a body responsible for third party attestation related to conformity assessment and calibration facilities conveying formal demonstration of their competence to carry out tasks against specified criteria, including criteria in International Guides and Standards;
- (b) "accredited body" means an organisation or facility that has been accredited by SANAS or by a member of the recognition arrangements of the International Laboratory Accreditation Co-operation (ILAC) or the International Accreditation Forum (IAF);
- (c) "accreditation body logo" means a logo used by an accreditation body to identify itself;
- (d) "accreditation certificate" means a formal document or set of documents, stating that accreditation has been granted for the defined scope;
- (e) "accreditation symbol" means a symbol issued by an accreditation body to be used by an accredited body to indicate their accredited status;
- (f) "calibration laboratory" means a body that performs a set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or reference material, and corresponding values realized by standards whatever their uncertainty;
- (g) "certification body" means an organisation that certifies other organisations in respect of the compliance of their management systems, schemes or products with recognised specifications or standards;
- (h) "certificate of GLP compliance" means a formal document or set of documents stating that GLP compliance has been demonstrated;
- (i) "conformity assessment" means the procedure used to determine, directly or indirectly that the relevant requirement in technical regulations, standards, or any other relevant and validated documentation has been fulfilled;



- (j) "Good Laboratory Practice (GLP)" means a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded and reported. Its principles apply to all non-clinical health and environmental safety studies required by regulations for the purpose of registering or licencing pharmaceuticals, pesticides, food and feed additives, cosmetic products, veterinary drug products and similar products and for the regulation of industrial products;
- (k) "inspection body" means an organisation that performs examination of a product design, product, service, process or plant, and determination of their conformity with specific requirements or, on the basis of professional judgement, general requirements;
- (l) "laboratory" means any specialised confined environment used for the performance of scientific work, including laboratories involved in testing work;
- (m) "Minister" means the Minister of Trade and Industry;
- (n) "rating agency" means an organisation that rates the status of enterprises in terms of broad-based black economic empowerment compliance;
- (o) "SANAS" means the South African National Accreditation System established as a public entity in terms of this Act;
- (p) "Verification laboratory" means a body that certifies the accuracy of measuring instruments that are used in terms of the Trade Metrology Act, in order to establish that they comply with all statutory requirements pertaining to such instruments.

## 2 Purpose

The purpose of this Act is to provide an internationally recognised and effective accreditation and GLP compliance monitoring system for South Africa by –

- (a) establishing SANAS as a public entity;
- (b) recognising SANAS as the only accreditation body in South Africa for conformity assessment and calibration;
- (c) monitoring GLP compliance to Organisation for Economic Cooperation and Development (OECD) principles.

## **ESTABLISHMENT OF SANAS AS PUBLIC ENTITY**

### **3 Establishment of SANAS as public entity**

- (1) SANAS is hereby established as a public entity.
- (2) SANAS is a juristic person and must operate and perform its functions in accordance with the provisions of this Act.
- (3) The establishment of SANAS as a public entity does not affect the validity of any action taken by SANAS prior to the commencement of this Act.

### **4 Status of SANAS**

- (1) SANAS is recognised as the sole body in South Africa for accrediting for its scope of activity in respect of conformity assessment which includes:
  - (a) Calibration, testing and verification laboratories;
  - (b) certification bodies;
  - (c) inspection bodies;
  - (d) rating agencies; and
  - (e) any other type of body that may be added to SANAS' scope of activity.
- (2) SANAS is recognised as the sole body in South Africa for monitoring GLP compliance to OECD principles for GLP facilities.

### **5 Functions and objects**

- (1) The objects of SANAS are to:
  - (a) accredit or monitor for GLP compliance purposes, organisations falling within its scope of activity subject to them complying with relevant criteria;
  - (b) promote accreditation as a means of facilitating international trade and enhancing South Africa's economic performance and transformation;
  - (c) promote the competence and equivalence of accredited bodies; and
  - (d) promote the competence and equivalence of compliant GLP facilities.
- (2) In order to achieve its objects, SANAS must:
  - (a) promote SANAS as the sole national accreditation body in its scope of activity;

- (b) encourage and promote the accreditation of calibration, testing and verification laboratories, certification bodies, inspection bodies, rating agencies and any other type of body that may be added to SANAS's scope of activity;
- (c) encourage and promote the monitoring of GLP compliance to OECD principles for GLP facilities;
- (d) promote the acceptance of its activities and those of all bodies accredited by SANAS, or as appropriate its international counterparts, by regulatory authorities;
- (e) promote recognition of accredited bodies by users of conformity assessment;
- (f) liaise with regional and international standards, technical regulatory and metrology organisations in respect of any matter related to accreditation;
- (g) liaise with national regulators in respect of any matter related to accreditation;
- (h) promote the use of accredited bodies to facilitate trade;
- (i) advise national, regional and international organisations on the conditions for accreditation and on other issues related to accreditation;
- (j) establish and maintain a register of all accredited organisations in South Africa;
- (k) initiate, negotiate, conclude and maintain mutual recognition arrangements;
- (l) support Government in activities on mutual recognition agreements;
- (m) investigate methods of facilitating trade through accreditation;
- (n) obtain and maintain membership of national or international organisations that may assist SANAS to achieve its objects and to actively participate in such;
- (o) participate in formulating international and regional guidelines and standards to facilitate the accreditation process;
- (p) formulate and implement national guidelines and standards to facilitate the accreditation process;
- (q) promote recognition and protect the use of the SANAS logo nationally and internationally;
- (r) promote and protect regional and international arrangement logo's such as ILAC and IAF;
- (s) establish appropriate technical committees as follows:
  - (i) Approval Committees to evaluate applications for accreditation;
  - (ii) Specialist Technical Committees.

## **6 Application of the Public Finance Management Act**

- (1) SANAS is required to comply with the provisions of the Public Finance Management Act of 1999 applicable to national public entities.
- (2) For the purposes of the Public Finance Management Act –
  - (a) the Board is the accounting authority as contemplated by section 49(2) (a) of the Public Finance Management Act;



- (b) the Minister is the executive authority as contemplated by section 52 of the Public Finance Management Act;
- (c) any delegation of the Board's responsibilities in terms of the Public Finance Management Act must be in accordance with the provisions of section 56 of that Act.

## **7 Application of international accreditation standards and criteria**

- (1) SANAS is required to comply with international accreditation standards and criteria relevant to its scope of activity.

### **BOARD OF SANAS**

## **8 Appointment of the Board and Chairperson**

- (1) The Minister must appoint a Board of not less than ten, and not more than fifteen, members including:
  - (a) the Chief Executive of SANAS by virtue of his or her office;
  - (b) a maximum of two members of SANAS senior management by virtue of his or her office;
- (2) When appointing the members of the Board, the Minister must ensure that the members of the Board –
  - (a) are broadly representative of the population of the Republic; and
  - (b) have sufficient knowledge, experience or qualifications relating to the functions of SANAS and the responsibilities of the Board including, in particular, business management, finance, marketing, international or regional accreditation, standardisation and technical regulatory matters.
- (3) The chairperson of the Board must be selected by the members of the Board from amongst their number at the first meeting of a newly appointed board and be appointed by the Minister.

## **9 Terms of office**

- (1) Non-executive Members of the Board hold office for a period not exceeding five years and are eligible for reappointment.
- (2) A person appointed to fill a vacancy holds office for the remaining portion of the term of the vacating member.
- (3) A member may resign by giving at least one month's written notice.