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THE PRESIDENCY

No. 238

16 March 2007

It is hereby notified that the President has assented to the following Act, which is hereby published for general information:—

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



AIDS HELPLINE: 0800-123-22 Prevention is the cure

Act No. 19, 2006 ACCREDITATION FOR CONFORMITY ASSESSMENT,
CALIBRATION AND GOOD LABORATORY PRACTICE ACT, 2006

*(English text signed by the President.)
(Assented to 12 March 2007.)*

ACT

To provide for an internationally recognised and effective accreditation and monitoring system for the Republic by establishing SANAS as a juristic person; to recognise SANAS as the only accreditation body in the Republic for the accreditation of conformity assessment and calibration and monitoring of good laboratory practice; and to provide for matters connected therewith.

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 of ensuring that the accreditation system of the Republic continues to support the needs of our enterprises competing in a fast-paced global economy;
- the need to provide for the strengthening of the recognition of **SANAS** as the national accreditation authority for conformity assessment, calibration and good laboratory practice;
- the importance of supporting 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; and

IN ORDER TO—

- recognise **SANAS** as the sole body in the Republic responsible for carrying out accreditations in respect of conformity assessment, calibration and good laboratory practice;
- ensure an internationally recognised accreditation system;
- promote accreditation as a means of facilitating international trade and enhancing the economic performance and transformation of the Republic;
- promote the competence and equivalence of accredited bodies and of facilities which comply with good laboratory practice,

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B E IT THEREFORE ENACTED by the Parliament of the Republic of South Africa,
as follows:—

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CHAPTER 1

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INTERPRETATION AND PURPOSE

Definitions

1. In this Act, unless the context indicates otherwise—
- “**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; 10
- “**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); 15
- “**accreditation body logo**” means a logo used by an accreditation body to identify itself;
- “**accreditation certificate**” means a formal document or set of documents, stating that accreditation has been granted for the defined scope; 20
- “**accreditation symbol**” means a symbol issued by an accreditation body to be used by an accredited body to indicate its accredited status;
- “**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 realised by standards whatever their uncertainty; 25
- “**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; 30
- “**certificate of GLP compliance**” means a formal document or set of documents stating that GLP compliance has been demonstrated;
- “**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; 35
- “**GLP**” (good laboratory practice) 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;
- “**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 judgment, general requirements; 40
- “**laboratory**” means any specialised confined environment used for the performance of scientific work, including laboratories involved in testing work; 45
- “**Minister**” means the Minister of Trade and Industry;
- “**OECD**” means the Organisation for Economic Cooperation and Development;
- “**Public Finance Management Act**” means the Public Finance Management Act, 1999 (Act No. 1 of 1999);
- “**rating agency**” means an organisation that rates the status of enterprises in terms of broad-based black economic empowerment compliance; 50
- “**SANAS**” means the South African National Accreditation System established by section 3;

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“**verification laboratory**” means a body designated in terms of section 7(2) of the Trade Metrology Act, 1973 (Act No. 77 of 1973), to verify measuring instruments that are used in terms of the aforesaid Act in order to establish that they comply with all statutory requirements pertaining to such instruments as defined and provided for in that Act.

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Purpose

2. The purpose of this Act is to provide an internationally recognised and effective accreditation and GLP conpliance monitoring system for the Republic by—

- (a) establishing SANAS as a public entity;
- (b) recognising SANAS as the only accreditation body in the Republic for—
 - (i) conformity assessment and calibration; and
 - (ii) monitoring GLP compliance to OECD principles.

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CHAPTER 2

ESTABLISHMENT OF SANAS AS PUBLIC ENTITY

Establishment of SANAS

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3. (1) SANAS is hereby established as a juristic person.

(2) SANAS is a public entity for the purposes of the Public Finance Management Act.

(3) The establishment of SANAS by this section does not affect the validity of any action taken by SANAS as a non-profit organisation registered in terms of section 21 of the Companies Act, 1973 (Act No. 61 of 1973) (registration No. 199600354/08), prior to the commencement of this Act.

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Status of SANAS

4. (1) SANAS is recognised as the only national body responsible for carrying out accreditations in respect of conformity assessment, which includes accreditation of—

- (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.

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

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Functions and objects

5. (1) The objects of SANAS are to—

- (a) accredit or monitor for GLP compliance purposes, organisations falling within its scope of activity;
- (b) promote accreditation as a means of facilitating international trade and enhancing the Republic’s economic performance and transformation;
- (c) promote the competence and equivalence of accredited bodies; and
- (d) promote the competence and equivalence of GLP compliant facilities.

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(2) In order to achieve its objects, SANAS may—

- (a) promote SANAS as the sole national accreditation body in its scope of activity;

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- (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' scope of activity;
- (c) encourage and promote GLP compliance with principles adopted by the OECD for GLP facilities; 5
- (d) promote the acceptance of its activities and those of all bodies accredited by SANAS or its international counterparts;
- (e) promote recognition of accredited bodies by users of conformity assessment;
- (f) liaise with regional and international standard bodies and with technical regulatory and metrology organisations in respect of any matter related to accreditation; 10
- (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; 15
- (j) establish and maintain a register of all accredited organisations in the Republic;
- (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; 20
- (n) obtain and maintain membership of national or international organisations that may assist SANAS to achieve its objects and to actively participate in such organisations;
- (o) participate in formulating international and regional guidelines and standards to facilitate the accreditation process; 25
- (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 logos such as those of the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF); and 30
- (s) establish appropriate technical committees including the following: 35
- (i) Approval Committees to evaluate applications for accreditation;
- (ii) Specialist Technical Committees.
- (3) SANAS may do all that is necessary or expedient to perform its functions including—
- (a) acquiring or disposing of any right in or to property, but ownership in immovable property may be acquired or disposed of only with the consent of the Minister; 40
- (b) opening and operating banking accounts in the name of SANAS;
- (c) investing any of SANAS' money;
- (d) insuring SANAS against—
- (i) any loss, damage or risk;
- (ii) any liability it may incur in the application of this Act; 45
- (e) performing legal acts, including acts in association with or on behalf of any other person or organ of state;
- (f) subject to subsection (4), concluding agreements with organs of state and other persons;
- (g) instituting or defending any legal action. 50
- (4) An agreement concluded in terms of subsection (3)(f) may not conflict with any international requirement binding on SANAS.

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Application of Public Finance Management Act

6. (1) SANAS is required to comply with the provisions of the Public Finance Management Act 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; 5
 - (b) the Minister is the executive authority as contemplated by section 52 of the Public Finance Management Act; and
 - (c) any delegation of the Board's responsibilities in terms of the Public Finance Management Act must be in accordance with section 56 of that Act. 10

Application of international accreditation standards and criteria

7. SANAS is required to comply with international accreditation standards and criteria relevant to its scope of activity.

CHAPTER 3

BOARD OF SANAS 15

Appointment of Board and chairperson

8. (1) The Board consists of not less than 10 and not more than 15 members and is made up as follows:
- (a) The chief executive officer of SANAS by virtue of his or her office;
 - (b) not more than two members of the senior management of SANAS by virtue of their office; and 20
 - (c) the rest of the members, who are non-executive members and are appointed by the Minister.
- (2) When appointing members to the Board, the Minister must ensure that those members— 25
- (a) are broadly representative of the demographics of the country, including with regard to gender and disability; 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. 30
- (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 must be appointed by the Minister.

Term of office of members of Board 35

9. (1) Non-executive members of the Board hold office for a period not exceeding five years and are eligible for reappointment for one further term only.
- (2) If a member of the Board dies or vacates office the Minister may appoint any person in that member's place for the unexpired period of his or her office.
- (3) A member may resign by giving at least one month's written notice. 40

Disqualification of members of Board

10. (1) A person is not eligible to be appointed to or to continue to serve as a member of the Board if that person—
- (a) is an unrehabilitated insolvent;
 - (b) has at any time been convicted of an offence involving dishonesty; 45

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- (c) has, as a result of improper conduct, been removed from an office of trust; or
(d) has been declared by a court to be mentally ill or unfit.
- (2) A member of the Board must vacate his or her office if he or she is absent from three consecutive meetings of the Board without the prior leave of the chairperson.
- (3) The Minister may at any time, after consulting the Board, terminate the term of office of any member of the Board if there are good reasons for doing so. 5

Conditions of appointment of members of Board

11. (1) The conditions of appointment of members of the Board who are not in the employ of an organ of state are determined by the Minister.
- (2) The conditions of appointment may include remuneration and allowances payable by SANAS to the members of the Board as determined by the Minister after consultation with the Minister of Finance. 10
- (3) Members who are employed by an organ of state are not entitled to remuneration and allowances but must be reimbursed for out of pocket expenses by SANAS.
- (4) Non-executive members of the Board are appointed part-time. 15

Operating procedures of Board

12. (1) The Board must meet at least four times a year.
- (2) The first meeting of the Board must be held at the time and place determined by the Minister.
- (3) The chairperson of the Board decides when and where the Board will meet, but a majority of the members of the Board may request the chairperson in writing to convene a meeting at a time set out in the request. 20
- (4) If the chairperson is absent from a meeting, the Board may elect another member to preside at that meeting.
- (5) A majority of the members of the Board constitute a quorum for a meeting of the Board. 25
- (6) Decisions of the Board require a supporting vote of a majority of members present at a meeting.
- (7) The Board must keep minutes of its proceedings and decisions.
- (8) The Board may, by resolution, make rules to further regulate its proceedings. 30

Committees of Board

13. (1) The Board must establish the committees necessary to enable it to perform its functions.
- (2) The Board must determine the composition, rules and procedures of committees established in terms of subsection (1). 35
- (3) The Board may from time to time dissolve or reconstitute a committee.

Advisory forum

14. (1) (a) The Board must establish an advisory forum consisting of representatives of bodies with an interest in accreditation and of representatives of accredited bodies. 40
- (b) The Board must ensure that different interests are adequately represented in the advisory forum.
- (2) The advisory forum must advise the Board on—
- (a) matters in respect of which SANAS could play a role; and
- (b) any other matter on which the Board requests advice.
- (3) The Board must establish a constitution and, if necessary, rules for the advisory forum. 45

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CHAPTER 4

EXECUTIVE MANAGEMENT

Appointment of chief executive officer

15. (1) The Board, after consulting the Minister, must appoint a suitably qualified person as the chief executive officer. 5
- (2) The chief executive officer is an employee of SANAS and is accountable to the Board.
- (3) The chief executive officer is responsible for the efficient management of SANAS and must perform any duty assigned or delegated to the chief executive officer by the Board. 10
- (4) The chief executive officer holds office for an agreed term not exceeding five years and may be reappointed upon expiry of that term of office.
- (5) The chief executive officer may appeal to the Minister against a decision of the Board to terminate his or her contract of employment prior to its expiry
- (6) The appeal contemplated in subsection (5) must— 15
- (a) be lodged in writing within 14 days from the date of notification of the decision to terminate the contract; and
- (b) comply with any other requirements that may be prescribed in respect of an appeal.
- (7) If the chief executive officer is unable to perform his or her functions, the Board may appoint an acting chief executive officer to perform those functions. 20

Employment contract and performance agreement

16. (1) The employment contract of the chief executive officer must be in writing and must incorporate in an appropriate form the provisions of section 57 of the Public Finance Management Act. 25
- (2) The Board and the chief executive officer must conclude a performance agreement for the chief executive officer—
- (a) within a reasonable time after the appointment of the chief executive officer; and thereafter
- (b) annually within one month of the commencement of each financial year. 30
- (3) The performance agreement must include—
- (a) measurable performance objectives and targets that must be met and the time frames within which those performance objectives and targets must be met;
- (b) standards and procedures for evaluating performance and intervals for evaluation; and 35
- (c) the consequences of substandard performance.

Appointment of staff

17. The chief executive officer, after consulting the Board, may—
- (a) appoint staff to assist SANAS in carrying out its functions; and
- (b) determine the remuneration, allowances, benefits and other terms and conditions of appointment of members of staff taking into account the Public Service Act, 1994 (Proclamation No. 103 of 1994). 40

Services of non-employees

18. SANAS may enter into a contract with any person other than an employee to perform any of its functions for and on behalf of SANAS. 45

Delegation and assignment

19. (1) The Board may delegate any of its powers and assign any of its duties to the chief executive officer, excluding the power to make rules for the Board.

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(2) The chief executive officer may delegate any power conferred on him or her under or duty assigned to him or her by this Act to any other person with appropriate knowledge and experience who is under the control of the chief executive officer.

(3) A delegation or assignment under subsection (1) or (2) must be in writing and—

(a) may be subject to any conditions or restrictions determined by the Board or chief executive officer;

(b) does not prevent the exercise of that power by the Board or chief executive officer; and

(c) may be withdrawn or amended by the Board or chief executive officer.

CHAPTER 5

10

FINANCIAL MANAGEMENT

Funds and investments

20. (1) The funds of SANAS consist of—

(a) money appropriated by Parliament;

(b) accreditation fees;

(c) annual fees paid by accredited organisations;

(d) fees generated as a result of training or other projects;

(e) money received from any other source.

(2) SANAS may invest any of its funds not immediately required—

(a) subject to any investment policy that may be prescribed in terms of section 7(4) of the Public Finance Management Act; and

(b) in such a manner as may be approved by the Minister.

Financial year and accounting

21. The financial year of SANAS is from 1 April in any year to 31 March of the following year except that for the year in which it is established, the financial year will commence on the date that this Act comes into operation, and ends on 31 March next following that date.

CHAPTER 6

GENERAL PROVISIONS

Applications for accreditation or GLP compliance monitoring

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22. (1) Any person seeking accreditation or GLP compliance status from SANAS must apply in accordance with the procedures determined by the Board.

(2) SANAS must—

(a) evaluate every application for accreditation or GLP compliance monitoring in accordance with procedures and criteria determined by the Board and in accordance with the appropriate national or international criteria; and

(b) issue a certificate of accreditation or GLP compliance to applicants that meet required criteria, specifying any conditions applicable to the accreditation or GLP compliance monitoring.

(3) The Board may formulate and make publicly available rules consistent with the provisions of this Act on any matter necessary or expedient for the administration of this Act including—

(a) the form and procedure for applications for accreditation or GLP compliance;

(b) the fees applicable to different categories of accreditation or GLP compliance;

(c) the fees for training or other projects undertaken;

(d) the proper use within the Republic of the name, accreditation body logo or accreditation symbol of SANAS; and

(e) the proper use of regional and international logos such as those of ILAC and IAF.

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Accreditation certificates

23. (1) An accreditation certificate or certificate of GLP compliance issued in terms of section 22(2)(b), must be signed by the chief executive officer or a person with delegated authority to do so in terms of section 19.

(2) SANAS may authorise a person in the employ of SANAS to certify a copy of an accreditation certificate or a certificate of GLP compliance issued in terms of subsection (1) as being a true copy of the certificate. 5

(3) In any legal proceedings, a document that purports to be a certificate issued in terms of subsection (1) or a copy of such certificate certified in terms of subsection (2) is upon its production evidence of the facts contained therein. 10

(4) An accreditation certificate or certificate of GLP compliance is the property of SANAS and must be returned by an accredited body when requested to do so.

Maintenance of accreditation by accredited body

24. (1) Accredited bodies have a responsibility to comply at all times with SANAS accreditation criteria including the specific competencies specified in their accreditation certificate. 15

(2) Misuse of accreditation, including misrepresentation of data from an accredited body or misuse of the accreditation symbol, is an offence.

Certificate issued by accredited body

25. In any legal proceedings, a document that purports to be a certificate issued by an accredited body in terms of their approved accreditation and signed by a person deemed by SANAS as competent to do so is upon its production evidence of the facts contained therein. 20

Regulations

26. The Minister may make regulations concerning— 25

- (a) the scope of activity within which SANAS may grant accreditation or monitor compliance with OECD principles for GLP;
- (b) responsibilities of accredited bodies; and
- (c) generally, any other ancillary or incidental administrative or procedural matter that is necessary to prescribe for the proper implementation or administration of this Act. 30

Offences

27. (1) Any person who knowingly—

- (a) makes or assists in making a report, return, notice or any other document to be sent to any other person, as required by this Act, that contains an untrue statement of a material fact; or 35
- (b) omits to state a material fact in or on any of the documents referred to in paragraph (a),

is guilty of an offence.

(2) Any person who contravenes or who fails to comply with this section, section 24 or section 28 is guilty of an offence and is liable on conviction to a fine or to imprisonment for a period not exceeding 24 months or to both a fine and such imprisonment. 40

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Breach of confidence

28. (1) Any person who is or was involved in the performance of any function in terms of this Act shall not disclose any information which he or she obtained in the performance of such a function except—

- (a) to the Minister; 5
- (b) to any person who of necessity requires it for the performance of his or her functions in terms of this Act;
- (c) if he or she is a person who of necessity supplies such information in the performance of his or her functions in terms of this Act;
- (d) if such information is required in terms of any law or as evidence in any court of law; 10
- (e) to any competent authority which requires it for the institution, or an investigation with a view to the institution, of any criminal prosecution; or
- (f) by or on the authority of the Minister, the chairperson of the Board or the chief executive officer. 15

Liability of SANAS

29. (1) The State Liability Act, 1957 (Act No. 20 of 1957), applies in respect of SANAS, and in such application a reference in that Act to the Minister of a department concerned must be construed as a reference to the chief executive officer of SANAS.

(2) 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. 20

Transitional provisions

30. (1) For the purposes of this section:

- (a) “Companies Act” means the Companies Act, 1973 (Act No. 61 of 1973);
- (b) “effective date” means the date on which SANAS is established by section 3; and 25
- (c) “the Association” means the association not for gain established in terms of section 21 of the Companies Act (registration number 199600354/08), known as “South African National Accreditation System”.

(2) As from the effective date— 30

- (a) the Association ceases to exist as an association not for gain incorporated in terms of section 21 of the Companies Act;
- (b) all assets, liabilities, rights and obligations of the Association are deemed to be assets, liabilities, rights and obligations of SANAS;
- (c) the chief executive officer and all other employees of the Association are transferred to SANAS as if section 197 of the Labour Relations Act, 1995 (Act No. 66 of 1995), were applicable; 35
- (d) all accreditations by the Association that are valid immediately prior to the effective date are deemed to have been made by SANAS in terms of this Act.

(3) The Registrar of Companies must deregister the Association as a company in terms of the Companies Act with effect from the effective date. 40

(4) Any application for accreditation, appeal, complaint or other proceedings commenced prior to the effective date may be continued with as if they had been instituted in terms of this Act.

(5) Any committees of the Association established prior to the effective date are deemed to have been established by the Board in terms of this Act, provided that an audit committee must be established in terms of this Act within two years of the promulgation of this Act. 45

(6) The Minister may make regulations not inconsistent with this Act concerning any matter necessary or expedient for regulating the smooth transition of the Association from its status as an association not for gain established in terms of the Companies Act to a public entity. 50

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(7) (a) The transition of the Association to a public entity shall not affect any licences that have been granted prior to the transition.

(b) SANAS shall replace the Association as the licensee in all licence agreements.

(c) The effect of this subsection is a substitution of the licensee and does not constitute a sub-licence agreement.

5

Short title and commencement

31. This Act is called the Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act, 2006, and comes into operation on a date fixed by the President by proclamation in the *Gazette*.