REPUBLIC OF SOUTH AFRICA

ACCREDITATION FOR CONFORMITY ASSESSMENT, CALIBRATION AND GOOD LABORATORY PRACTICE BILL

(As introduced in the National Assembly (proposed section 75); Explanatory summary of Bill published in Government Gazette No. 29170 of 31 August 2006) (The English text is the official text of the Bill)

(MINISTER OF TRADE AND INDUSTRY)

[B 29—2006] ISBN 0-9802545-4-X

BILL

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,

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

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CHAPTER 1

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;
 - "accredited body" means an organisation or facility that has been accredited by SANAS or by a member of the recognition arrangements of the International 10 Laboratory Accreditation Co-operation (ILAC) or the International Accreditation Forum (IAF):
 - "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 15 that accreditation has been granted for the defined scope;
 - "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 20 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;
 - "certification body" means an organisation that certifies other organisations in respect of the compliance of their management systems, schemes or products with 25 recognised specifications or standards;
 - "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 30 other relevant and validated documentation has been fulfilled;
 - "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;

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- **"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;
- **"laboratory"** means any specialised confined environment used for the performance of scientific work, including laboratories involved in testing work;
- "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;
- "SANAS" means the South African National Accreditation System established by section 3:
- "verification laboratory" means a body that certifies the accuracy of measuring 50 instruments that are used in terms of the Trade Metrology Act, 1973 (Act No.77 of 1973), in order to establish that such instruments comply with all statutory requirements pertaining to them.

Purpose

2. The purpose of this Act is to provide an internationally recognised and effective 55 accreditation and GLP compliance 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.

CHAPTER 2

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ESTABLISHMENT OF SANAS AS PUBLIC ENTITY

Establishment of SANAS

- **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 10 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.

Status of SANAS

- **4.** (1) SANAS is recognised as the only national body responsible for carrying out 15 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

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- (e) any other type of body that may be added to SANAS' scope of activity.
- (2) SANAS is recognised as the national body to monitor GLP compliance with principles adopted by the OECD for GLP facilities.

Functions and objects

5. (1) The objects of SANAS are to—

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- (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. (2) SANAS may do all that is necessary or expedient to perform its functions
- - (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 35 the Minister;
 - (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;

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- (ii) any liability it may incur in the application of this Act;
- (e) performing legal acts, including acts in association with or on behalf of any other person or organ of state;
- subject to subsection (3), concluding agreements with organs of state and other persons;

(g) instituting or defending any legal action.

- (3) An agreement concluded in terms of subsection (2)(f) may not conflict with any international requirement binding on SANAS.
 - (4) In order to achieve its objects, SANAS may—
 - (a) promote SANAS as the sole national accreditation body in its scope of 50
 - (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;

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	ourage and promote GLP compliance with principles adopted by the	
(d) pron	CD for GLP facilities; note the acceptance of its activities and those of all bodies accredited by	
(e) pron (f) liaise regu	MAS or its international counterparts; note recognition of accredited bodies by users of conformity assessment; e with regional and international standard bodies and with technical latory and metrology organisations in respect of any matter related to editation;	5
(g) liaise (h) pron (i) advi accre	e with national regulators in respect of any matter related to accreditation; note the use of accredited bodies to facilitate trade; se national, regional and international organisations on the conditions for editation and on other issues related to accreditation;	10
Rep	blish and maintain a register of all accredited organisations in the ublic;	
(l) supp	ate, negotiate, conclude and maintain mutual recognition arrangements; port government in activities on mutual recognition agreements;	15
(n) obta that	stigate methods of facilitating trade through accreditation; in and maintain membership of national or international organisations may assist SANAS to achieve its objects and to actively participate in organisations;	20
(o) parti to fa	icipate in formulating international and regional guidelines and standards icilitate the accreditation process; inulate and implement national guidelines and standards to facilitate the	
	editation process; note recognition of and protect the use of the SANAS logo nationally and	25
(r) pron those	rnationally; note and protect regional and international arrangement logos such as e of the International Laboratory Accreditation Cooperation (ILAC) and	
(s) estab (i)	International Accreditation Forum (IAF); and blish appropriate technical committees including the following: Approval Committees to evaluate applications for accreditation; Specialist Technical Committees.	30
Application o	f Public Finance Management Act	
Management A (2) For the j (a) the I	AS is required to comply with the provisions of the Public Finance Act applicable to national public entities. purposes of the Public Finance Management Act—Board is the accounting authority as contemplated by section 49(2)(<i>a</i>) of Public Finance Management Act;	35
(b) the Publ (c) any	Minister is the executive authority as contemplated by section 52 of the lic Finance Management Act; and delegation of the Board's responsibilities in terms of the Public Finance tagement Act must be in accordance with section 56 of that Act.	40
Application o	f international accreditation standards and criteria	
	is required to comply with international accreditation standards and nt to its scope of activity.	45
	CHAPTER 3	
	BOARD OF SANAS	
Appointment	of Board and chairperson	
made up as fo	Board consists of not less than 10 and not more than 15 members and is llows: chief executive officer of SANAS by virtue of his or her office;	50
(b) not r their	more than two members of the senior management of SANAS by virtue of office; and	
	est of the members, who are non-executive members and are appointed by Minister.	55

- (2) When appointing members to the Board, the Minister must ensure that those members—
 - (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.

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(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

- **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.

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 not a citizen of the Republic;
 - (b) is an unrehabilitated insolvent;
 - (c) has at any time been convicted of an offence involving dishonesty;
 - (d) has, as a result of improper conduct, been removed from an office of trust; or
 - (e) 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 25 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.

Conditions of appointment of members of Board

- **11.** (1) The conditions of appointment of members of the Board who are not in the mploy of an organ of state are determined by the Minister, after consultation with the Minister of Finance.
- (2) The conditions of appointment may include remuneration and allowances payable by SANAS.
- (3) Members who are employed by an organ of state are not entitled to remuneration 35 and allowances but must be reimbursed for out of pocket expenses by SANAS.

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.
- (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.
- (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.

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).

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(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.
- (b) The Board must ensure that different interests are adequately represented in the 10 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 15 forum.

CHAPTER 4

EXECUTIVE MANAGEMENT

Appointment of chief executive officer

- **15.** (1) The Board, after consulting the Minister, must appoint a suitably qualified 20 person as the chief executive officer.
- (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 25 Board.
- (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—
 - (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.

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 40 Finance Management Act.
- (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.
 - (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 50 evaluation; and
 - (c) the consequences of substandard performance.

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Appoint	ment of staff	
(a)	e chief executive officer, after consulting the Board, may—appoint staff to assist SANAS in carrying out its functions; and 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).	5
Services	of non-employees	
	aNAS may enter into a contract with any person other than an employee to any specific act or function.	
Delegation	on and assignment	10
chief exe (2) Tho or duty knowledg (3) A o	The Board may delegate any of its powers and assign any of its duties to the cutive officer, excluding the power to make rules for the Board. It chief executive officer may delegate any power conferred on him or her under assigned to him or her by this Act to any other person with appropriate ge and experience who is under the control of the chief executive officer. It lelegation or assignment under subsection (1) or (2) must be in writing and—may be subject to any conditions or restrictions determined by the Board or chief executive officer;	15
<i>(b)</i>	does not prevent the exercise of that power by the Board or chief executive officer; and	20
(c)	may be withdrawn or amended by the Board or chief executive officer.	20
	CHAPTER 5	
	FINANCIAL MANAGEMENT	
Funds a	FINANCIAL MANAGEMENT and investments	
20. (1) (a) (b) (c)	The funds of SANAS consist of— money appropriated by Parliament; accreditation fees; annual fees paid by accredited organisations;	25
20. (1) (a) (b) (c) (d) (e) (2) SA (a)	The funds of SANAS consist of— money appropriated by Parliament; accreditation fees;	25
20. (1) (a) (b) (c) (d) (e) (2) SA (a) (b)	The funds of SANAS consist of— money appropriated by Parliament; accreditation fees; annual fees paid by accredited organisations; fees generated as a result of training or other projects; money received from any other source. NAS may invest any of its funds not immediately required— subject to any investment policy that may be prescribed in terms of section 7(4) of the Public Finance Management Act; and	
20. (1) (a) (b) (c) (d) (e) (2) SA (a) (b) Financia 21. The following	The funds of SANAS consist of— money appropriated by Parliament; accreditation fees; annual fees paid by accredited organisations; fees generated as a result of training or other projects; money received from any other source. NAS may invest any of its funds not immediately required— subject to any investment policy that may be prescribed in terms of section 7(4) of the Public Finance Management Act; and in such a manner as may be approved by the Minister.	30
20. (1) (a) (b) (c) (d) (e) (2) SA (a) (b) Financia 21. The following	The funds of SANAS consist of— money appropriated by Parliament; accreditation fees; annual fees paid by accredited organisations; fees generated as a result of training or other projects; money received from any other source. NAS may invest any of its funds not immediately required— subject to any investment policy that may be prescribed in terms of section 7(4) of the Public Finance Management Act; and in such a manner as may be approved by the Minister. Il year and accounting the financial year of SANAS is from 1 April in any year to 31 March of the great year except that for the year in which it is established, the financial year will	30
20. (1) (a) (b) (c) (d) (e) (2) SA (a) (b) Financia 21. The following	The funds of SANAS consist of— money appropriated by Parliament; accreditation fees; annual fees paid by accredited organisations; fees generated as a result of training or other projects; money received from any other source. NAS may invest any of its funds not immediately required— subject to any investment policy that may be prescribed in terms of section 7(4) of the Public Finance Management Act; and in such a manner as may be approved by the Minister. Il year and accounting the financial year of SANAS is from 1 April in any year to 31 March of the gyear except that for the year in which it is established, the financial year will be on the date that this Act comes into operation.	30
20. (1) (a) (b) (c) (d) (e) (2) SA (b) Financia 21. The following commends	The funds of SANAS consist of— money appropriated by Parliament; accreditation fees; annual fees paid by accredited organisations; fees generated as a result of training or other projects; money received from any other source. NAS may invest any of its funds not immediately required— subject to any investment policy that may be prescribed in terms of section 7(4) of the Public Finance Management Act; and in such a manner as may be approved by the Minister. Il year and accounting the financial year of SANAS is from 1 April in any year to 31 March of the great year except that for the year in which it is established, the financial year will be on the date that this Act comes into operation. CHAPTER 6	30

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- 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 45 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 10 accreditation symbol of SANAS; and
 - (e) the proper use of regional and international logos such as those of ILAC and IAF.

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.

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- (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.
- (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.
- (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. 25

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.
- (2) Misuse of accreditation, including misrepresentation of data from an accredited 30 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 35 therein.

Regulations

- 26. The Minister may make regulations concerning—
 - (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.

Offences 45

- **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
 - (b) omits to state a material fact in or on any of the documents referred to in 50 paragraph (a),

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.

(2) Any person who contravenes or who fails to comply with section 24(1) or (2) or 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.

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;
 - (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:
 - (e) to any competent authority which requires it for the institution, or an 15 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.

Liability of SANAS

- **29.** (1) The State Liability Act, 1957 (Act No. 20 of 1957), applies in respect of 20 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.

Transitional provisions

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- **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
 - (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—
 - (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;
 - (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.
- (4) Any application for accreditation, appeal, complaint or other proceedings 4: 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 50 of this Act.
- (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.

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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.

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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*.

MEMORANDUM ON THE OBJECTS OF THE ACCREDITATION FOR CONFORMITY ASSESSMENT, CALIBRATION AND GOOD LABORATORY PRACTICE BILL, 2006

1. BACKGROUND

- 1.1 This Bill emanates from the Department of Trade and Industry (*dti*) project to restructure the South African Technical Regulatory Infrastructure and to optimise the South African Standards, Quality Assurance, Accreditation and Metrology System (SQAM).
- 1.2 The aim of restructuring the South African Technical Infrastructure is to align the infrastructure with international best practice.
- 1.3 Part of the restructuring is the reconstitution of the South African National Accreditation System (SANAS), which currently operates as a section 21 company, as a public entity and the introduction of the Bill.
- 1.4 Experience over the past ten years has indicated the need to recognise and strengthen government's recognition of SANAS as the national accreditation authority for calibration, conformity assessment and good laboratory practice (GLP).
- 1.5 The Bill aims to establish a national accreditation body that is internationally recognised for calibration, conformity assessment and good laboratory practice as a public entity.
- 1.6 This entity will assist government interventions through legislative measures by means of objective verification of the credibility and competence of private and public conformity assessment service providers, for example laboratories, certification bodies and rating agencies, in order to support public policy objectives in terms of health, safety and broad-based black economic empowerment compliance issues.
- 1.7 The new role that is proposed for SANAS provides for the strengthening of Government's recognition of SANAS as the national accreditation authority for calibration, conformity assessment and good laboratory practice.
- 1.8 The Bill provides for the maintenance of SANAS as an internationally recognised accreditation body as a crucial element of a well-functioning technical infrastructure.
- 1.9 The Bill makes provision for the dti's responsibility to ensure that SANAS operates optimally in pursuit of the national interest and that it has strategic direction and is coordinated.
- 1.10 The Bill has been revised following comments received from a wide range of organisations, interest groups and individuals.

2. OBJECTS OF BILL

The Bill is drafted in line with the modernisation of the Technical Infrastructure Policy and seeks to recognise SANAS as the only body in the Republic responsible for carrying out accreditation in respect of conformity assessment which includes accreditation for 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 and monitoring good laboratory practice compliance with the principles adopted by the Organisation for Economic Cooperation and Development for GLP facilities.

3. ORGANISATIONAL AND PERSONNEL IMPLICATIONS

The Bill provides for transitional arrangements, including the transfer of all staff and the CEO from the current section 21 company to the public entity, as well as the transfer of assets and liabilities. The Bill also provides for the appointment of a Board by the Minister.

4. FINANCIAL IMPLICATIONS FOR STATE

The dti has made budget allocations for SANAS. The current baseline of R6,787 million will need to be increased to R12,5 million as from the 2007/2008 budget cycle in order to provide for additional financial implications associated with the establishment and restructuring of SANAS as a public entity.

5. COMMUNICATION IMPLICATIONS

The dti will implement a communication strategy to ensure that all affected parties are aware of the establishment of and services offered by the new accreditation body as a public entity.

6. CONSTITUTIONAL IMPLICATIONS

None.

7. OTHER DEPARTMENTS/COMMITTEES/BODIES CONSULTED

National Treasury has been formally consulted in line with the PFMA on the establishment of SANAS as a public entity. Other stakeholders consulted are—

• Departments of:

Labour;

Transport;

Agriculture;

Housing;

Health;

Environmental Affairs and Tourism;

Minerals and Energy;

Science and Technology;

Provincial and Local Government;

- The Presidency;
- SABS;
- · CSIR;
- · Industry and other interested parties; and
- · Nedlac.

The Bill was also published in the Gazette for general public comment.

8. PARLIAMENTARY PROCEDURE

- 8.1 The State Law Advisers and the Department of Trade and Industry are of the opinion that this Bill must be dealt with in accordance with the procedure established by section 75 of the Constitution since it contains no provision to which the procedure set out in section 74 or 76 of the Constitution applies.
- 8.2 The State Law Advisers are of the opinion that it is not necessary to refer this Bill to the National House of Traditional Leaders in terms of section 18(1)(a) of the Traditional Leadership and Governance Framework Act, 2003 (Act No. 41 of 2003), since it does not contain provisions pertaining to customary law or customs of traditional communities.