R 03-09

NOMINATED REPRESENTATIVE AND SIGNATORIES: RESPONSIBILITIES, QUALIFICATIONS AND APPROVAL

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Reviewed By:	SANAS Management and Stakeholders
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CONTENTS

1. Purpose and Scope

This document describes the responsibilities, registration / certification and qualifications of Nominated Representatives and Technical Signatories of accredited / compliant Conformity Assessment Bodies (CABs), and the procedure for approval of Nominated Representatives and Technical Signatories.

2. Definitions and References

"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); [Act 19, 2006]

The terms 'accredited body' and 'conformity assessment body' (CAB) are synonymous.

Act 19, 2006	Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act, 2006
SANAS PM	SANAS Policy Manual
SANAS A01	References, Acronyms and Definitions
SANAS F147	Terms and Conditions of Accreditation
SANAS F199	Terms and Conditions of GLP/GCP Compliance

3. General

3.1 The staff of accredited bodies (CABs) as defined in Act 19 of 2006 must have the appropriate qualifications, training and / or experience in order to competently perform the tasks for which the CAB is accredited. They must be able to demonstrate their competence to an assessor for the scope(s) for which the CAB is accredited. Accredited CABs shall ensure that all signatories to certificates / reports are approved.

Note: "Approval" by SANAS means that SANAS has confirmed the competence, as declared by the CAB, of the relevant signatory / personnel member.

3.2 The lack of appropriately qualified and competent staff shall result in a CAB failing to initially obtain or losing existing accreditation.

3.3 For the application of approval of a person as Nominated Representative (NR) and/or Technical Signatory (TS) and/or Contracted Technical Signatory (CTS), a CAB should be aware of the criteria for approval.

3.4 These criteria are based on the desire of SANAS to:

a) provide the NR with the necessary authority within the CAB to represent the CAB on all matters pertaining to their accreditation and to ensure that the accreditation requirements and standards are complied with;
b) define desirable capabilities and aptitudes, which the NR should have to actively promote SANAS and its declared objectives; and
c) define requirements to aid an accredited CAB in selecting/ appointing a TS and CTS based on technical competence.

4. Nominated Representative (NR) (however named)

4.1 All Accredited CABs and Compliant Facilities shall formally appoint a NR (however named, in some cases referred to as the Management Representative or Contact Person) who as the duly authorised representative of the CAB shall have the authority and responsibility for all matters relating to accreditation and/or compliance and for maintaining the link and all communication between the CAB and the Accreditation Body. Refer to the SANAS Terms and Conditions of Accreditation and the Terms and Conditions of GLP/GCP Compliance.

4.2 The Nominated Representative shall:

4.2.1 have an in-depth knowledge and understanding of all requirements relating to accreditation / compliance including those specified in any accreditation standard, guide, regulation and/or any IAF/ILAC/AFRAC mandatory document as well as any SANAS policies, procedures and requirements, which apply to the CAB. In addition, the NR shall have a clear understanding of the Accreditation of Conformity Assessment, Calibration and Good Laboratory Practices Act,2006 (Act 19 of 2006), the SANAS Terms and Conditions of Accreditation and/or Terms and Conditions of Compliance (as applicable);

4.2.2 know what accreditation / compliance is and have a positive attitude toward accreditation / compliance and its processes;

4.2.3 irrespective of other duties and responsibilities, have a defined responsibility and authority to ensure that:

i) the CAB meets its obligations as specified in the Terms and Conditions of Accreditation (F147) and/or Terms and Conditions of GLP/GCP Compliance (F199) (as applicable);
ii) the CAB complies with all the applicable Accreditation Requirements; and
iii) the management system / principles are implemented and followed at all times to support their current scope of accreditation / compliance (in the case of accredited CABs, this includes ensuring results released are authorized by the approved signatory).

4.2.4 have direct access to the highest level of management at which decisions are made on the CAB's policy or resources;

4.2.5 notify the relevant SANAS Accreditation Manager of significant changes relevant to the CAB's accreditation / compliance status in writing at least four (4) weeks prior to them taking effect, the failure of which may result in the suspension of the CAB. (Refer to R51 "Suspensions, Reduction, Withdrawals and re-instatement of accredited / GLP Compliant organisations).

4.2.5.1 Changes in location

i) A change in physical location may mean a change from one room to another or from one building to another. The CAB shall take into consideration the impact the change in location will have on its ability to produce reliable results.

ii) The CAB, depending on the type, may be required to go under suspension until they are able to verify their capability in line with their scope of accreditation. Where applicable, validation records must contain evidence of acceptable comparative data from before and after the change of location. In addition, where environmental

conditions such as temperature and humidity are critical for the accredited parameters, records of such conditions at the new premises shall be maintained and made available on request by SANAS. SANAS may decide to conduct an on-site assessment, to verify that the original accreditation requirements have been maintained, the costs of which shall be for the account of the CAB.

iii) Medical laboratories that change location are required to conform to all the requirements in R 72 "Requirements for Relocation of SANAS Accredited Medical Laboratories" to maintain their accreditation status.

4.2.6 At an assessment of a satellite / branch facility, provide the Team Leader with information on the actions that have been taken to ensure that non-conformances raised at the Head Office by SANAS have also been addressed at the satellite / branch facility, as appropriate.

Note: This information must preferably be provided at the start of the assessment, in order for the assessment team to verify implementation of any such corrective actions in the branch / satellite, as appropriate.

5. Signatories

Not applicable to Medical laboratories (refer to clause 5.1.5), GLP/GCP Compliant organisations or Certification Bodies.

5.1 Technical Signatory (TS)

5.1.1 A TS is a person whose competency, as declared by the CAB, is confirmed by the accreditation body, and whose signature confers validity on the CAB's certificates, reports and/or results issued under its accreditation. Technical signatories include those individuals authorised by regulations to sign certificates/reports (i.e. IPE Inspectors, Competent Persons, Verification Officers etc.) however they must also be confirmed as competent by the accreditation body to sign results issued under accreditation.

Note: With Proficiency Testing Scheme Providers, the scheme coordinator and scheme manager is equivalent to a technical signatory.

The Technical Signatory shall:

a) accept responsibility for the contents (i.e. results and/or measurements) of the Certificate/Report which he/she is signing or authorising;

b) have sufficient current knowledge of the method used, as well as the objectives of the test/calibration/inspection;

c) be able to assess and interpret the data;

d) be confident when authorising results or measurements, that all the necessary checks had been completed as required by the management system to ensure the quality of the results;

e) have an in-depth knowledge of all SANAS requirements relating to accreditation / compliance, including those specified in any accreditation

standard, guide, regulation and/or any IAF/ILAC/AFRAC mandatory document which applies to the CAB, and those specific to the responsibilities of technical signatories and to the scope of accreditation; and

f) be conversant with the management system implemented within the CAB.

5.1.2 All technical signatories (excluding CTS) must be fulltime or formally employed (e.g. fixed-term contract) employees fulfilling the requirements as defined in the Labour Relations Amendment Act 12 of 2002. For the purposes of this requirement, owners, shareholders, members, sole-proprietors, directors and partners who are active in the accredited activities of the CAB are also considered as employees of the CAB. (Refer to 5.2.4)

5.1.3 In the case of accredited Calibration Laboratories, technical signatories shall be either:

a) certified as a metrologist or expert metrologist by the National Laboratory Association – South Africa (NLA-SA) as part of the "MetCert" certification program. The "Metcert" certification programme replaces the SANAS "Certificate of Competence";

b) registered with the Engineering Council of South Africa (ECSA) as either a professional engineering technician, technologist, engineer, or certificated engineer in an applicable discipline;

c) registered with the South African Council for Natural Scientific Professions (SACNASP) as either a professional or certified natural scientist (level A or B) in an applicable field of practice; or

d) registered with the Health Professions Council of South Africa (HPCSA) as a Medical Physicist.

5.1.4 In addition to compliance with the requirements listed in clause 5.1.1 a) to f) all accredited Inspection Bodies operating under a regulation, technical signatories must possess the necessary qualification/s as required by the relevant regulation or national standard. Registration with an applicable professional body may also be a requirement, details of qualifications, experience and registration are specified in the inspection field specific TR documents.

Examples of registration requirements for Inspection Bodies include:

a) Occupational Hygiene – registered with the SAIOH as an occupational hygienist;

b) Lift Inspection – registered with the Engineering Council of South Africa (ECSA) as a lift inspector;

c) Pressure Equipment Regulations (Design) – registered with the Engineering Council of South Africa (ECSA) as a professional technologist, engineer or certificated engineer;

d) Pressure Equipment Regulations (Inspection) – registered with the South African Institute of Welding in the category SAQCC IPE (South African Qualification and Certification Committee – Inspector of Pressurised Equipment) including Competent Persons for Vessels – CP-PV and Steam Generators – CP-SG.

5.1.5 In addition to technical signatories complying with all the requirements listed in clause 5.1.1 a) to f), technical signatories in Verification Laboratories are required to be certified by the National Regulator for Compulsory Specifications (NRCS) as a verification officer (VO). Applicant technical signatories must include a copy of their VO certificate before inclusion on the Scope of Accreditation.

Note: In terms of the specification as defined in SANS 10378, clause 5.2.1.3, technical signatories may not appear on more than one Scope of Accreditation at any one time.

5.1.6 Signatories in Medical Laboratories are required to be registered with the Health Professions Council of South Africa (HPCSA) and are those persons who are appropriately qualified and competent in a specific discipline and may issue results and sign reports in that discipline, as defined in the scope issued by the HPCSA. These signatories are approved by the HPCSA for a specific discipline, SANAS will monitor the competence of the signatories during assessment. Medical Laboratories shall have a procedure that identifies and controls the process of signing of reports. This will be verified during the assessment process.

5.1.7 All Technical Signatories (including CTS) should be evaluated by SANAS at least once within the accreditation cycle. (Refer to P41 “Sampling for Assessment Purposes)

5.2 Contracted Technical Signatory (CTS)

Not applicable to Verification Laboratories or BBBEE Verification agencies

5.2.1 The use of CTS is an interim arrangement to aid an accredited CAB in the unexpected situation of being without a SANAS approved Technical Signatory on its staff. The period of using a CTS may not exceed 1 year.

5.2.2 In addition to the CTS complying with all requirements as defined in 5.1 above, the Accredited CAB intending to make use of a CTS shall:

a) inform SANAS of its intent to obtain approval for a CTS;

b) have a formal agreement covering the arrangements, including confidentiality and conflict of interest between the accredited CAB and the contracted person/ external body;

c) take full responsibility for authorisations made by the CTS on its behalf;

d) ensure that the CTS meets all the requirements as defined in 5.1 above;

e) have records of the proof of competence of the CTS permanently available at the premises where the CTS operates;

f) ensure that the CTS has sufficient presence within the accredited CAB to be able to demonstrate satisfactory control of his/her function;

g) ensure that the CTS repeats or reconstructs a specified number of tests/calibrations for which he/she is signatory where all these are not performed by the CTS;

h) ensure that where all work is not performed by the CTS (not applicable to *Pressure Equipment Regulation* Inspection Bodies), the CTS is required to review the competence of those performing work in his/her absence prior to implementation of the contract and then on a regular basis thereafter; and

i) In addition to a) to h) above, Inspection Bodies and Gas Test Station CTS shall have a formal agreement covering the arrangements for the period that the inspection body requires them, including confidentiality and conflict of interest between the accredited CAB and the contracted person/ external body.

5.2.3 It is the responsibility of the accredited CAB wishing to use a CTS to have documented procedures covering the abovementioned requirements as well as maintaining records to demonstrate full implementation thereof.

5.2.4 Technical Signatories who are employed on a regular but not full-time basis (i.e. 2 days per week) are not considered as contracted technical signatories, but may be considered as employees provided they meet the applicable requirements (refer to 5.1.2), and therefore may be registered as Technical Signatories.

5.3 Management Signatory (MS)

Certification Bodies certify compliance to a specific standard. Since their processes also require the involvement of a decision-making committee, there is no need for a TS. Senior management responsible for running the certification scheme are required to have knowledge of certification and this is sufficient to allow the Management Signatory's signature to confer validity on the certificate. The signatory to a SANAS endorsed certificate needs to be "approved" by SANAS.

6. Application and Approval Procedure

6.1 The CAB must apply for approval of TS, CTS and NR (or contact person / management representative) by completing the relevant sections of the SANAS application and submitting it together with a detailed and current CV for each applicant. Applicant TS and CTS are also required to include a signed declaration of competence for the methods applied for.

6.2 Where the personnel evaluation is required to take place during the initial or surveillance assessment visit, the completed application must be forwarded to the SANAS Office at least 6 weeks prior to the planned visit.

6.3 For an application for a NR (or Contact Person) of an already accredited /GLP compliant CAB, or a MS of an already accredited Certification Body, the relevant SANAS Accreditation Manager would, based on the information supplied, either arrange to assess the applicant by interview or approve the application, deferring the interview to the next planned visit to the CAB. For a new application this interview will take place at the initial assessment.

6.4 Based on the information supplied for an application for a TS or a CTS, the relevant Accreditation Manager would normally appoint an Assessor(s) to assess the applicant's organisation. This may be done by interview, witnessing, evaluation of relevant competency records generated by the applicant, or a combination of these. This will be for the CAB's account.

6.5 The Approval Committee (AC) or Accreditation Manager (AM) review process, as applicable, shall review the credentials of the applicant signatories for approval. The AM review or AC may decide to approve a signatory based on the information supplied on the

application. Where the AM or AC is not satisfied with the competence of the applicant signatory, it may require a technical assessor to re-confirm the technical competence of the applicant signatory. This confirmation is usually done on-site through a witnessing assessment, all costs of which are for the account of the CAB. Signatories for new CABs are assessed during the initial assessment. New applications for signatory in an existing accredited CAB may be assessed during the surveillance where practical or by an additional visit to the CAB. CABs will be charged additionally for these visits.

6.6 A Technical Signatory applicant in a calibration laboratory, who holds the applicable MetCert certification, may be recommended by an existing technical signatory, who is him or herself a holder of the MetCert certification (in the same discipline). This recommendation shall confirm that the applicant:

a) is fully conversant with the laboratories documented management / quality system;

b) is competent and capable to operate all laboratory equipment, measuring instruments, artefacts and standards used in the laboratory;

c) has been evaluated and found competent to perform the calibrations and or measurements for which he or she is being recommended;

The Accreditation Manager (AM) may then approve the Technical Signatory with the proviso that the approval may not extend beyond those items or calibrations for which the person making the recommendation is approved. The AM may request additional information necessary to support the application. If in doubt the AM may require the laboratory to undergo an assessment, where the applicant technical signatory will be evaluated at the cost of the laboratory. During the next scheduled assessment, the approved technical signatory may undergo evaluation on some or all of the calibrations for which accreditation was approved, and if found not to be competent will have the technical signatory status revoked.

ADDENDUM 1: Amendment Record

Proposed By:	Section	Change
QM	3.1	"fields" replaced by "scope(s)" Last sentence added "/ reports"
QM	3.4 a)	Changes from "…ensure that accreditation standards are upheld"
QM	4.1	1st sentence added "formally" 2nd sentence added "as the duly authorised representative of the CAB" 3rd sentence added "all matters relating to accreditation and/or compliance and for"
QM	4.2.1	Added "/ÄFRAC"
QM	4.2.3	Added point i) and ii)
QM	4.2.3 iii)	Changes from "…current accreditation / compliance (in the…"
QM	4.2.4	Deleted 2nd Paragraph based on informing SANAS without delay and in writing of any changes which may affect CAB's compliance
QM	4.2.5	Changes from "…Notifying SANAS of changes to the CAB" Deleted "The relevant SANAS Accreditation Manager must be notified of any such significant changes" Last sentence added ", Reduction…. / GLP Compliant"
QM	4.2.5.1	Added title "Changes in location"
QM	4.2.5.1 ii)	Changes from "In the case of change of location, the CAB will..." 3rd sentence added "Where applicable" 5th sentence "move" replaced by "change of location
QM	4.2.5.1 iii)	Deleted "physical"
QM	4.2.7	Deleted "a report on the findings raised by SANAS at the last Head Office assessment, including" "e corrective actions carried out" replaced by "that non-conformances raised" Last sentence changes from "Head Office have been implemented in the specific…" Note comment: "opening meeting of the day" replaced by "start"
QM	5.1.1 a)	Added "/AFRAC"
QM	5.1.2	Added "or formally employed"
AM	5.1.4 d)	Added "including Competent Persons for Vessels – CP-PV and Steam Generators – CP-SG."
QM	6.5	1st sentence changes from "The appropriate Approval Committee…" "contained in the completed section "Application for recognition as technical signatory / nominated representative" of" replaced by "supplied on" "laboratories and inspection authorities" replaced by "CABs"