

THE CONFORMITY ASSESSEMENT POLICY OF THE NATIONAL REGULATOR FOR COMPULSORY SPECIFICATIONS (NRCS)

Compiled by	Regulatory Research and Development			
Approved by	The Chief Executive Officer : Mr E Mamadise			
Signature	tomer			
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1. POLICY STATEMENT

This policy establishes the general principles for recognition of the competency of conformity assessment bodies located within and outside South Africa; and specifies the minimum criteria for acceptance of conformity assessment results (testing, calibration, inspection, verification and certification) produced by those bodies.

The policy applies to the conformity assessment of any material, commodity, product, installation, process, system, person or body for the purposes of demonstrating compliance against the NRCS's mandatory standards and requirements that are specified in Compulsory Specifications and Technical Regulations.

2. OBJECTIVES

The objectives of this policy are to achieve the following:

- 2.1 Establish the criteria for the recognition and acceptance of conformity assessment results such as test reports and other conformity assessment certificates that are produced within South Africa and in other jurisdictions.
- 2.2 Assess and confirm whether conformity assessment results have been generated in appropriate ways that are in accordance with the mandatory standards and requirements as specified in Compulsory Specifications and Technical Regulations.
- 2.3 Monitor continued suitability and competence of the organisations performing testing, calibration, verification, inspection and certification.
- 2.4 Provide information on CA requirements and procedures to ensure transparent conformity assessment process for equal treatment of all applicants.
- 2.5 Support international trade through the removal of unnecessary technical barriers through elimination or minimisation of duplication of testing for the purposes of approvals where such of products or commodities have been tested and attested to conform against similar or equivalent standards in other jurisdiction



3. NORMATIVE REFERENCES

- 3.1 National Regulator for Compulsory Specifications Act, 2008 (Act 5 of 2008) as amended and Regulations published under the Act.
- 3.2 Legal Metrology Act, 2014 (Act 9 of 2014) and Regulations published under the Act.
- **3.3** Compulsory specification and Technical Regulations as applicable to a specific material, commodity, product, installation, process, system, person or body.
- 3.4 The Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act (2006), Act 19 of 2006.
- 3.5 SANS (ISO/IEC) 17020: Conformity assessment Requirements for the operation of various types of bodies performing inspection
- **3.6 SANS (ISO/IEC)17021**: Requirements for bodies providing audit and certification of management systems
- 3.7 SANS (ISO/IEC) 17025: General requirements for the competence of testing and calibration laboratories
- **3.8 SANS (ISO/IEC) 17065**: Conformity assessment Requirements for bodies certifying products, processes and services
- 3.9 SANS (ISO/IEC) 17043: Conformity assessment General requirements for proficiency testing
- 3.10 SANS 10378: General requirements for the competence of verification laboratories

4. INFORMATIVE REFERENCES

- 4.1 ISO/IEC 17000 Series on Conformity assessment as applicable:_
 - 4.1.1 SANS (ISO/IEC) 17000 :Vocabulary and general principles
 - **4.1.2 SANS (ISO/IEC) 17011:** General requirements for accreditation bodies accrediting conformity assessment bodies
 - 4.1.3 SANS (ISO/IEC) 17030: General requirements for third-party marks of conformity
 - **4.1.4 SANS (ISO/IEC) 17040:** General requirements for peer assessment of conformity assessment bodies and accreditation bodies
 - **4.1.5 SANS (ISO/IEC) 17050-1:** Supplier's declaration of conformity Part 1: General requirements
 - **4.1.6 SANS (ISO/IEC) 17050-2:** Supplier's declaration of conformity Part 2: Supporting documentation



4.1.7 ISO/IEC 17067: Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes

4.2 ISO/IEC Conformity Assessment Guides:-

- **4.2.1 ISO/IEC Guide 23:** Methods of indicating conformity with Standards for third Party certification Systems
- **4.2.2 ISO/IEC Guide 28:** Conformity assessment Guidance on a third-party certification system for products
- **4.2.3 ISO/IEC Guide 60:** Conformity assessment Code of good practice
- **4.2.4 ISO/IEC Guide 68:** Arrangements for the recognition and acceptance of conformity assessment result

5. ABBREVIATIONS/ACRONYMS

5.1	CAB	Conformity Assessment Body
5.2	IEC	International Electrotechnical Commission
5.3	ISO	International Standardisation Organisation
5.4	IAF	International Accreditation forum
5.5	ILAC	International Laboratory Accreditation Co-operation
5.6	NRCS	National Regulator for Compulsory Specifications
5.7	SANAS	South African National Accreditation System
5.8	SANS	South African National Standard
5.9	TR	Technical Regulation
5.10	VC	Compulsory Specification



6. **DEFINITIONS**

6.1 Accreditation

Attestation by SANAS or other accreditation bodies affiliated to the International Accreditation Forum (IAF) and/or International Laboratory Accreditation Co-operation (ILAC) related to a conformity assessment body giving formal recognition of its competence to carry out specific conformity assessment tasks.

6.2 Attestation

The issuing of a statement, based on a decision following review that fulfilment of specified requirements has been demonstrated.

6.3 Conformity assessment

- a) As defined in the NRCS Act: 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.
- b) As defined in SANS 17000: demonstration that specified requirements relating to a commodity, product process, system or body are fulfilled.

6.4 Conformity Assessment Body

A body that performs conformity assessment services, i.e. testing, calibration, inspection, verification and/ or certification.

6.5 Conformity Assessment Activities

Activities such as testing, inspection, accreditation, certification, calibration and verification; performed to establish if compliance to specified regulatory requirements and/or conformity to an international or national standards as pertaining to any particular material, commodity, product, installation, process, system, person or body have been met.

6.6 The National Regulator for Compulsory Specifications (NRCS)

The NRCS as established by the National Regulator for Compulsory Specifications Act, 2008 (Act No. 5 of 2008) as amended.

6.7 Mutual Recognition Agreement

An agreement that establishes procedures for the acceptance of the results of conformity assessment procedures conducted by conformity assessment bodies located in the territory of another country with the objective of facilitating economic activity related to such.



6.8 Technical Acceptance Agreement

An agreement between the NRCS and competent authorities of exporting countries that provides for reciprocal/mutual acknowledgement and acceptance of the validity of each other's' conformity assessment results. The Agreement will clearly specify the exact documentation (certificates/ issuances) to be accepted by each authority and the procedures to be followed between the authorities.

6.9 Recognition of conformity assessment results

The acknowledgement of the validity of a conformity assessment results by the NRCS.

6.10 South African National Accreditation System

The National body responsible for carrying out accreditations in respect of conformity assessment, as mandated through the Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act (Act 19 of 2006).

6.11 Third-party conformity assessment

Conformity assessment activity that is performed by a person or body that is independent of the person or organisation that provides the object and of user interests in that object.

7. GENERAL RULES

- 7.1 The NRCS <u>recognises</u> Conformity Assessment Bodies (CABs) that are accredited by SANAS or other Accreditation bodies that are affiliated to the IAF and/or ILAC as <u>competent</u> to provide conformity assessment activities that specified in their accreditation certificate.
- 7.2 The NRCS shall <u>accept</u> conformity assessment results issued by CABS accredited by SANAS or an ILAC or IAF affiliated organisation as a valid demonstration of appropriate and proficient technical assessment of the conformity of any material, commodity, product, installation, process, system, person or body with the requirements of VCs or TRs.
- 7.3 Conformity assessment results pertaining to any regulated material, commodity, product, installation, process, system, person or body, for standards other than those specified in a VC or a TR shall only be accepted if it is proven, in the form of a declaration report by an accredited CAB to be technically equivalent to the applicable South African National Standard (SANS).



- 7.4 The NRCS shall make use of accredited CABs for the purposes of its own conformity assessment activities unless otherwise specified within the related regulatory context which must be fully communicated to all stakeholders.
- 7.5 Proof of conformity of material, commodity, product, installation, process, system, person or body with standards that are specified in a VC or a TR shall be presented in the form of a test report or conformity certificates that are issued by accredited third-party CAB, unless otherwise specified by the NRCS.
- **7.6** The Manufacturer or Importer shall on request, provide the NRCS with the required evidence of conformity, and ongoing evidence of conformity, at own cost.
- 7.7 Where specifically required by a compulsory specification, the Manufacturer or Importer shall also provide evidence of conformity of production at own cost.
- **7.8** Any additional requirements prescribed in VC and TR must also be complied with to comply fully with the requirements of a VC or TR.
- 8. SPECIFIC REQUIREMENTS FOR CONFORMITY ASSESSMENT BODIES AND ACCEPTANCE OF CONFORMITY ASSESSMENT RESULTS
- 8.1 A CAB shall be accredited by SANAS or other Accreditation bodies that are affiliated to the IAF and/or ILAC in respect of competency to determine the conformity of material, commodity, product, installation, process, system, person or body with the requirements of a compulsory specification.
- 8.2 A CAB shall possess a valid accreditation certificate issued by SANAS or other bodies/organisation affiliated to the International Accreditation Forum (ILAC) and/or International Laboratory Accreditation Co-operation (ILAC) attesting conformity to the following standards as applicable:
 - **8.2.1 SANS (ISO/IEC) 17025**: General requirements for the competence of testing and calibration laboratories
 - **8.2.2 SANS (ISO/IEC)17021**: Requirements for bodies providing audit and certification of management systems
 - **8.2.3 SANS (ISO/IEC) 17065**: Conformity assessment Requirements for bodies certifying products, processes and services



8.2.4 SANS (ISO/IEC) 17043: Conformity assessment — General requirements for proficiency testing

8.2.5 SANS 10378: General requirements for the competence of verification laboratories

8.3 The NRCS may at its own discretion require a CAB to make available the accreditation

certificate for the purposes of verifying the CAB's accreditation status.

In the absence of evidence of appropriate accreditation, or successful independent peer 8.4

review/mutual acceptance, the CAB shall provide satisfactory evidence of compliance with the

requirements of ISO/IEC 17025 or ISO/IEC 17020, as applicable, which satisfies the NRCS.

9. MUTUAL RECOGNITION AGREEMENTS AND TECHNICAL ACCEPTANCE AGREEMENTS

9.1 Where South Africa is a signatory to a Mutual Recognition Agreement (MRA), the terms and

conditions stated in such mutual acceptance arrangement as to the acceptance of conformity

assessment, shall be upheld by the NRCS.

Where the NRCS is a signatory to Technical Acceptance Agreement, the terms and conditions 9.2

stated in the arrangement as to the acceptance of conformity assessment, shall be upheld by

the NRCS.

10. REPLACEMENT AND WITHDRAWAL

This policy replaces Doc No: NRCS-CPO 112-00

11. REVISION PARTICULARS

This document becomes effective on the date it is approved by the Chief Executive Officer of the

NRCS.

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