



# ACCREDITATION OF CONFORMITY ASSESSMENT BODIES ENABLES CONFIDENCE AND TRUST

Calibrated, tested,  
certified or inspected  
once; accepted  
everywhere





## About SANAS

SANAS is South Africa's sole national accreditation body that provides an internationally recognised and effective accreditation system in respect of conformity assessment, calibration and monitoring of good laboratory practice (GLP).

## SANAS provides accreditation support to:

- South African manufacturers and exporters, and
- Government regulators and industry bodies that ensure public health and safety, and that protect the environment.

## In South Africa, SANAS works with the following institutions or bodies:

- Department of Trade and Industry (**the dti**);
- Council of Trade and Industry Institutions (COTII);
- South African Technical Infrastructure, namely;
  - > NMISA - National Metrology Institute of South Africa
  - > SABS - South African Bureau of Standards
  - > NRCS - National Regulatory Of Compulsory Specifications
- National Government departments such as: the Departments of Labour; Health, Agriculture Forestry and Fisheries, Minerals and Energy, Environmental Affairs and Tourism.

## Who gives SANAS its mandate?

SANAS is mandated by government through the Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act (Act No. 19 of 2006) to provide accreditation services in South Africa.

SANAS's primary role is to serve South Africans by providing a reliable, internationally recognised accreditation infrastructure to government, industry and the wider community.

# What

## **What is SANAS accreditation?**

SANAS accreditation is a formal process of assessing and recognising whether a conformity assessment body (CAB) is technically competent to provide the services it offers.

It is also an attestation that a conformity assessment body is competent to carry out specific conformity assessment tasks.

SANAS recognition is used by such conformity assessment bodies to illustrate to their clients, regulators and government that they are competent to provide the services as stated on the schedule of accreditation issued by SANAS.

## **What is a conformity assessment body?**

This is a body or organisation that performs conformity assessments and can be the object of accreditation. These may include calibration, testing and verification laboratories, certification bodies, inspection bodies, rating agencies and any other type of body that may be added to SANAS's scope of activity.

## **Why do we need SANAS accreditation in South Africa?**

South African organisations, including manufacturers and exporters, often have to prove that their products and services comply with the compulsory technical regulations set by governments or the private specifications set by those who procure from them.

Clients of SANAS-accredited conformity assessment bodies use the certificates and test reports issued to prove that their products or services are competently tested and comply with all relevant requirements.

## **What is SANAS doing at an international level?**

In support of its national accreditation activities, SANAS is a signatory to the multilateral arrangements of both the International Laboratory Accreditation Co-operation (ILAC) and International Accreditation Forum (IAF).

These arrangements promote the global acceptance of technical test, inspection and calibration data as well as certificates issued by certification bodies. ILAC and IAF signatories are spread over 61 economies. For South African manufacturers and exporters, SANAS accreditation implies the elimination or reduction in the need for re-testing or re-certification to an importing country that is a signatory to the arrangement.

## Whom does SANAS accredit?

### CALIBRATION LABORATORIES AND PROFICIENCY TESTING SCHEMES

The calibration programme provides a service to all of the Industrial Policy Action Plan (IPAP) priority sectors, including metals fabrication, aerospace, automotive, green industries, agro processing, biofuels, pharmaceuticals and chemicals.

These laboratories provide metrological traceability in South Africa, as required by the Measurements Units and Measurement Standards Act, Act No. 18 of 2006. SANAS-accredited laboratories form an integral part of the metrological chain whenever physical measurements are performed for manufacturing and exports, safety or scientific purposes, for law enforcement purposes or to ensure that South African manufacturers remain globally competitive.

Although relatively smaller, the proficiency-testing scheme, which is essential for proof of accuracy of measurements and to demonstrate competency, is also one of the key programmes.

### TESTING LABORATORIES

The testing programme provides a service to the IPAP priority sectors including metals fabrication, aerospace, automotive, green industries, agro processing, biofuels, pharmaceuticals and chemicals.

Testing laboratories play an important role in supporting South African manufacturing and export by providing manufacturers with objective evidence that a product or service conforms to certain customer requirements or specifications.

The number of accredited testing laboratories has been steadily growing over the past few years.



## **PHARMACEUTICAL LABORATORIES**

The pharmaceutical programme provides an important service to the South African pharmaceutical industry, in particular, for chemical and microbiology testing. The industry constitutes around 33% of all the pharmaceutical sales in Africa. As such, the pharmaceutical laboratories play a vital role in fighting numerous diseases, including tuberculosis and HIV/AIDS.

## **INSPECTION BODIES**

The inspection programme provides services to all of the IPAP priority sectors, including metals fabrication, aerospace, automotives, green industries, agro processing, biofuels, pharmaceuticals and chemicals that have to comply with health, safety and environmental regulations.

Inspection mainly operates within the regulatory domain where regulators, industry and citizens need the confidence that inspection bodies, especially those inspecting work place health and safety requirements in accordance with the Occupational Health and Safety Act and those inspecting compulsory standards in accordance with the National Regulator for Compulsory Specifications Act, are competent to do so.

## **LEGAL METROLOGY VERIFICATION LABORATORIES**

The purpose of the verification laboratories, which fall under the domain of legal (trade) metrology, is to protect consumers from unfair trade practices. These laboratories perform verifications on volume, mass and length measuring instruments in accordance with the requirements of the Trade Metrology Act and other related technical regulations.

## **CERTIFICATION BODIES**

The certification programme provides support to all the IPAP priority sectors including metals fabrication, aerospace, automotive, green industries, agro processing, biofuels, pharmaceuticals and chemicals.

In terms of certification, the focus is on ensuring that an organisation has the necessary procedures and controls in place to provide confidence to the customer that a certain product falls within specified requirements.

Accredited certification bodies certify other organisations with regard to the compliance of their management system with recognised standards, such as quality management (ISO 9000), environmental management (ISO14000), occupational health and safety management systems (OHSAS 18000), food safety management system requirements (ISO 22000). Certification bodies also validate and verify GHG emission of organisations and projects (ISO 14065).

## **MEDICAL TESTING LABORATORIES**

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The credibility of medical pathology laboratories is paramount to the health and safety of the patients who rely on the testing services provided by these laboratories. Laboratory tests are an integral part of the treatment of any patient and constitute up to 80% of a physician's diagnosis and treatment choice. As medical doctors base their diagnosis on the results issued by medical laboratories, it is important that these results be accurate and reliable.

## **VETERINARY LABORATORIES AND GOOD CLINICAL PRACTICE: GCP - COMPLIANT FACILITIES**

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It is important for South Africa to have a strong and competent veterinary laboratory industry for the diagnosis of diseases, especially emerging diseases such as bovine spongiform encephalopathy (BSE) (mad cow disease) and testing the safety of meat and other animal products.

## **GOOD LABORATORY PRACTICE: GLP-COMPLIANT FACILITIES**

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SANAS is the official GLP monitoring authority. Its main duty is to inspect test facilities and conduct audits to ascertain their degree of compliance to the OECD principles of GLP.

These principles were developed to promote the quality and validity of test data used to determine the safety of chemicals and chemical products. Quality test data forms the basis for mutual acceptance of data among countries. The application of these principles helps avoid the creation of barriers to trade and improves the protection of human health and the environment.

A large, stylized, light gray graphic of a human figure in a dynamic, jumping or dancing pose, positioned on the right side of the page. The figure is composed of simple geometric shapes: a circle for the head, a rounded rectangle for the torso, and curved lines for the limbs. The background is a gradient of gray, darker at the top and bottom, and lighter in the middle.

## **FORENSIC LABORATORIES**

Forensic laboratories are crucial to our criminal justice system as they provide useful information that aids in the investigation and prosecution of crime through the scientific examination of physical evidence.

## **BLOOD TRANSFUSION LABORATORIES**

The primary goal of a blood transfusion facility is the transfusion of safe units of blood. Accreditation plays a vital role in ensuring that the personnel involved in all the activities (donor registration, blood collection, testing, processing and storage) involved in a blood transfusion service are competent and that national and/or international standards are properly adhered to.

## **B-BBEE VERIFICATION AGENCIES**

In 2005, SANAS initiated its broad-based black economic empowerment (B-BBEE) verification accreditation programme, which supports Government's national objective to allow for the broader participation of previously disadvantaged people in the mainstream economy.



## What is SANAS's responsibility?

SANAS assesses factors that show whether a conformity assessment body is able to produce precise, accurate tests, calibration, certification, inspection results, including measurement, verification and validation of data and proficiency testing.

### These factors are:

- The technical competency of the conformity assessment body;
- The validity and appropriateness of methods used by the conformity assessment body;
- The traceability of measurements to national and international standards;
- The suitability, calibration and maintenance of equipment;
- The suitability of environmental conditions;
- The handling of test/inspection calibration and verification items;
- The quality assurance processes of conformity assessment bodies; and
- The reporting of results by the conformity assessment body.

## What is SANAS doing in Africa?

In support of government's objective of regional integration, SANAS continues to play an important role in the Southern African Development Community (SADC) by hosting the SADC accreditation secretariat and holding the regional coordinator position.

SANAS is presently assisting the newly established SADC Accreditation Services (SADCAS) by partnering with that body. SANAS also continues to provide Chairmanship and secretariat services to the African Accreditation Cooperation (AFRAC). AFRAC is working towards the establishment of an African accreditation mutual recognition arrangement that will provide for the acceptance of technical test and calibration data, as well as certificates issued by conformity assessment bodies in Africa.



# What SANAS accreditation is not:

## It is important to understand what SANAS accreditation is not.

- It is not merely a means of registering or listing personnel, products and processes;
- It is not a management system assessment/audit that is merely enhanced by scientific/technical elements;
- It is not the recognition of reputation/affiliation; these things change over time;
- It is not the recognition of future capabilities;
- It is not the recognition of an individual's qualifications;
- It is not broad approval of every activity that a conformity assessment body might engage in.



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