

***The Role of SANAS in Support of South African
Regulatory Objectives***

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Outline of Presentation

- **INTRODUCTION**
- **STATUS OF SANAS**
- **TECHNICAL INFRASTRUCTURE**
- **TECHNICAL COMPETENCE**
- **SUPPORTING GOVERNMENT OBJECTIVES**
- **MUTUAL RECOGNITION ARRANGEMENTS**
- **THE INTERNATIONAL PICTURE**
- **MRA BENEFITS FOR REGULATORS**
- **INTERNATIONAL RECOGNITION**
- **CONCLUSION**

Who is SANAS?

- **The South African National Accreditation System**
- ***SANAS is currently the ninth largest, internationally recognized, national accreditation body in the world. It was inaugurated in 1996 (as a section 21 company).***
- ***The creation of a single national accreditation body, SANAS, allowed S.A to remain competitive nationally and internationally due to the ability to independently confirm competence of its Technical Infrastructure***
- **Accreditation is increasingly being used by S.A Regulators, as part of managing local regulatory risk, to ensure both the competence and consistency of outcomes of service providers used in the local regulatory domain**

Status of SANAS



SANAS is recognized as the only national body responsible for carrying out accreditation in respect of conformity assessment, which includes:

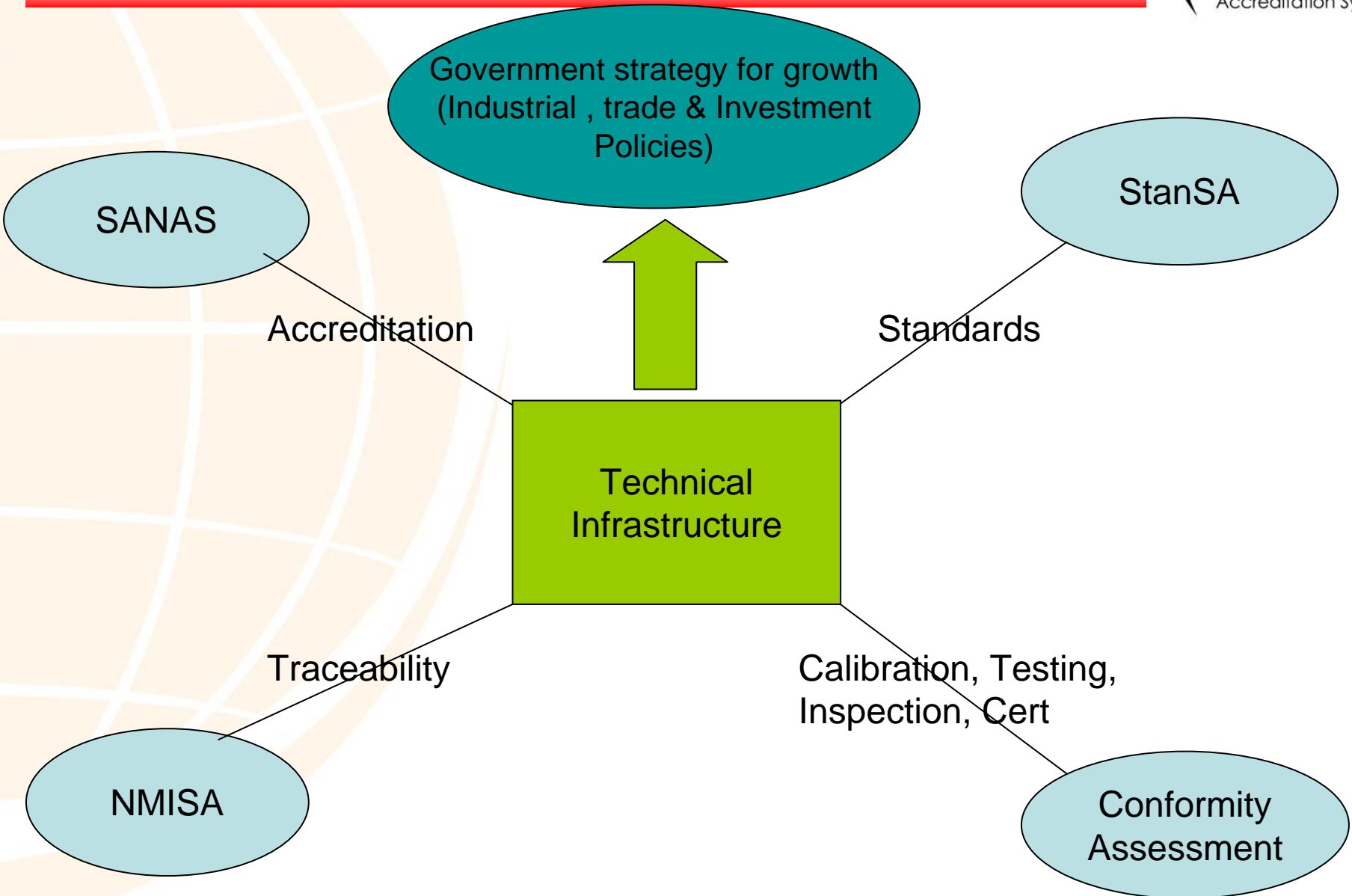
- **Calibration, testing and verification laboratories:**
- **Certification Bodies;**
- **Inspection Bodies;**
- **Rating agencies; and**
- **Monitoring of GLP compliance with principles adopted by the OECD**

The Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act, 19 of 2006

TECHNICAL INFRASTRUCTURE

- **Accreditation, together with Metrology, Standards and Conformity assessment are referred to as the Technical infrastructure**
- **Globalization is increasing the demands on countries to demonstrate that they have the Technical Infrastructure to guarantee that products originating in their territories are safe and fit for purpose**
- **Technical Infrastructure is required to meet the standards and measurement challenges required by health and safety considerations, environmental consideration as well as considerations of interoperability (necessary for globally dispersed manufacturing platforms)**

TECHNICAL INFRASTRUCTURE



TECHNICAL COMPETENCE

Many countries now rely on **Accreditation** as a means of determining technical competence.

Accreditation uses transparent and impartial criteria and procedures based on appropriate national and/or international standards, specifically developed to determine technical competence.

Specialist technical assessors conduct a thorough evaluation of all factors in a laboratory, inspection body or certification body that affect the result of test, calibration and inspection data and/or production processes.

TECHNICAL COMPETENCE

Accreditation bodies such as **SANAS** assess factors relevant to a organisation's ability to produce precise, accurate test, calibration and inspection data, **including the:**

- technical competency of staff;
- validity and appropriateness of methods;
- traceability of measurements to national standards;
- suitability, calibration and maintenance of equipment;
- suitable environmental conditions;
- handling of test / inspection items;
- quality assurance processes

SUPPORTING GOVERNMENT OBJECTIVES

Sound Technical Infrastructure to meet the standard & measurement challenges required by health and safety considerations

Contribute towards building skills, technology and infrastructure platforms from which enterprises can benefit

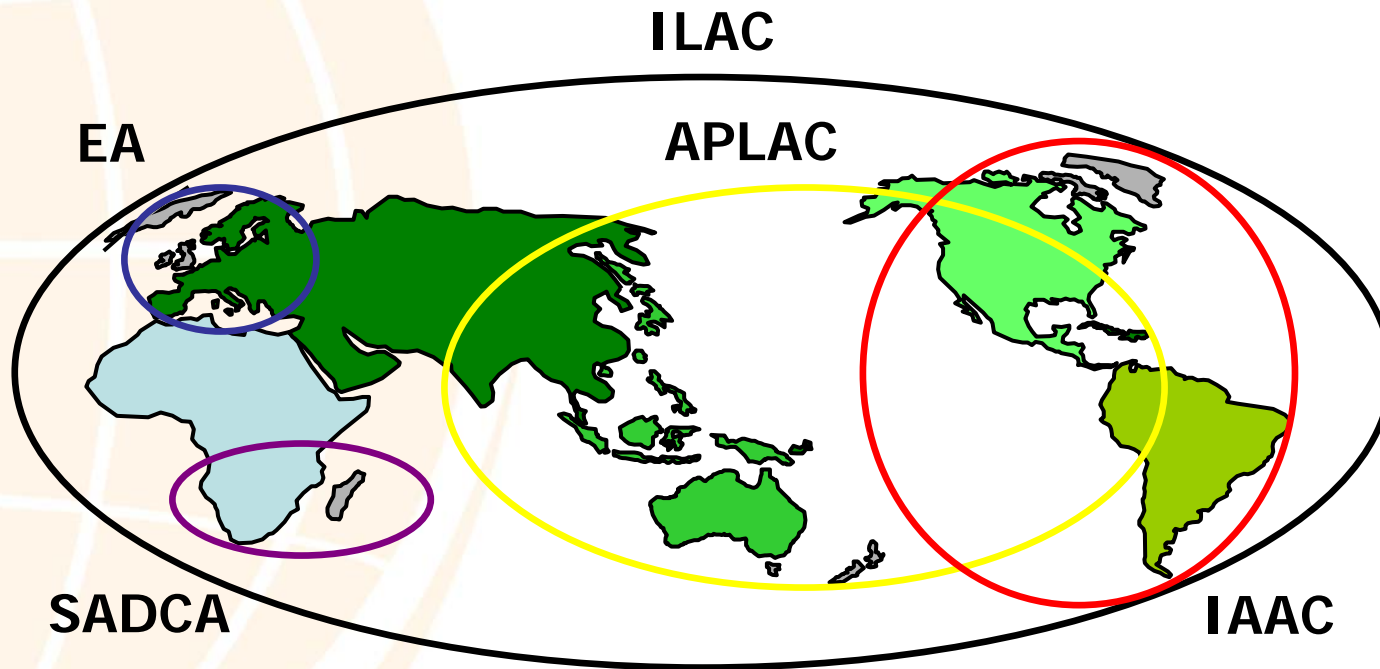
Increase market access opportunities for and export of South African goods and services

MRA_s BETWEEN ACCREDITATION BODIES

The Fundamental Purpose

Organisation accredited by one partner is recognised as possessing equivalent competence to an organisation accredited by the other(s)

THE INTERNATIONAL PICTURE



EA

European co-operation for Accreditation

APLAC

Asia Pacific Laboratory Accreditation Cooperation

IAAC

Inter-American Accreditation Cooperation

SADCA

Southern African Accreditation Cooperation

MRAs BENEFITS FOR REGULATORS

Two types of MRAs

Government to Government

Voluntary sector (eg ILAC Arrangement)

Access to multiple providers of compliance data

domestic laboratories

foreign laboratories

Reduced needs for Government compliance testing

Allows appropriate harmonisation / recognition of equivalence of regulatory requirements

INTERNATIONAL RECOGNITION LABORATORIES

- Through ILAC, (Dec. 2000) mutual recognition of SANAS certificates in Argentina, Australia, Austria, Belgium, Brazil, Canada, China, Chinese Taipei, Costa Rica, Cuba, Czech Republic, Denmark, Egypt, Finland, France, Germany, Greece, Hong Kong, India, Indonesia, Ireland, Israel, Italy, Japan, Korea, Malaysia, Mexico, New Zealand, Netherlands, Norway, Portugal, Romania, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland, Chinese Taipei, Thailand, Turkey, United Kingdom, United States of America, Vietnam.
- This represents 59 AB's in 46 economies

INTERNATIONAL RECOGNITION CERTIFICATION BODIES

- Signed the International Accreditation Forum (IAF) Multilateral Agreement in October 1998 for QMS; EMS & Product Cert. in Oct 2004
- . Gives recognition in Australia, Austria, Belgium, Brazil, Canada, China, Chinese Taipei, Czech Republic, Denmark, Finland, France, Germany, India, Indonesia, Ireland, Italy, Japan, Korea, Malaysia, Mexico, New Zealand, Netherlands, Norway, Philippines, Singapore, Poland, Portugal, Slovakia, Spain, Sweden, Switzerland, Thailand, Turkey, United Kingdom, United States of America, Vietnam.
- This represents 40 economies

WHAT MAKES SANAS ACCEPTABLE



- We have to comply with international criteria (includes Quality Management system criteria and demonstration of our technical competence with regard to the various sectors we accredit in).
- SANAS has a formal documented complaints procedure for both its own activities as well as those with whom it has formal mutual recognition arrangements.
- Constant international interaction and benchmarking.

BENEFITS OF BECOMING ACCREDITED

- Impartial feedback from independent examinations by experts against a defined scope of activity
- Comparisons of technical ability against similar facilities
- Customer has access to independent complaint mechanism
- National and International recognition of competence
- International benchmarking

HOW CAN WE TELL IF AN ORGANISATION IS ACCREDITED



Accredited organisations issue test or calibration reports bearing the **SANAS logo** indicating their accreditation.

A potential customer can also check with the laboratory as to what **specific tests or measurements** they are accredited for, and for what ranges or uncertainties.

This is specified in their **Scope of Accreditation**, which should be supplied by the laboratory upon request.

SANAS has a published **directory** of the facilities they have accredited (see www.sanas.co.za),

This directory contains :

An organisation's **contact details** and information on their **specific capabilities**.

CONCLUSION

Regulators need confidence in test and inspection data

Accreditation provides independent technical appraisal:

- Domestic Confidence
- Confidence in Foreign Bodies

CONCLUSION

South Africa has established a world class Technical Infrastructure which supports both local and International requirements

Accreditation provides the confidence to the regulators and importing countries that results of conformity assessment bodies are credible

It is unlikely that the Nuclear industry will be treated differently w.r.t conformity assessment regime, rather it will be integrated into the current system by up-skilling the accredited CABs with relevant expertise

The End

Thank you

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