

AN OVERVIEW OF  
**SANAS**  
 (South African National Accreditation System)

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**Outline of Presentation**

- INTRODUCTION
- LEGISLATION
- TECHNICAL INFRASTRUCTURE
- TECHNICAL COMPETENCE
- WTO/TBT & ACCREDITATION
- SUPERVISION IN THE MARKET
- SUPPORTING GOVERNMENT OBJECTIVES
- MUTUAL RECOGNITION ARRANGEMENTS
- INTERNATIONAL RECOGNITION
- CONCLUSION

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**Introduction**

**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

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## LEGISLATION



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

Act 19 of 2006

**Purpose:** establish SANAS as a public entity; recognize SANAS as the sole accreditation body for conformity assessment, calibration and GLP compliance.

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## 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 Consumer Protection

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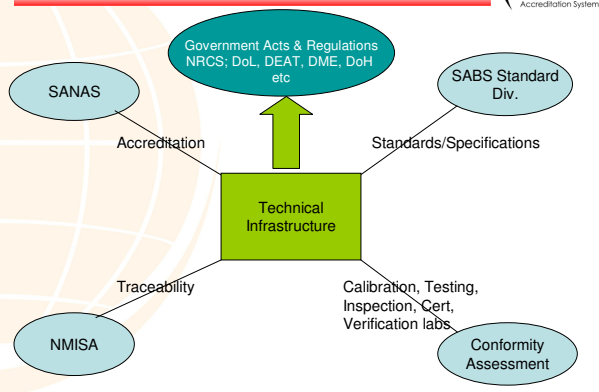
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## TECHNICAL INFRASTRUCTURE



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## 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.

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## 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

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## WTO / TBT & Accreditation



The WTO has specific requirements for the procedures for assessment conformity with technical regulations and standards by its members to prevent obstacles to trade.

The agreement on TBT set rules to make sure these regulations are fair, they must be:

**transparent, justifiable, non-discriminatory & wherever possible be based on international standards**

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## WTO / TBT & Accreditation

Although WTO desire that technical regulations, standards & procedures for conformity assessment do not create a TBT it is also recognised by the WTO that no country should be prevented from measures to ensure:

The quality of its exports, protection of human health or safety, protection of animal or plant life or health, the protection of the environment, prevention against deceptive practises & protection of its security interest.

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## WTO / TBT & Accreditation

In order to ensure *Conformity Assessment* activities are performed by competent service providers.

Governments are increasingly creating and employing National Accreditation Bodies

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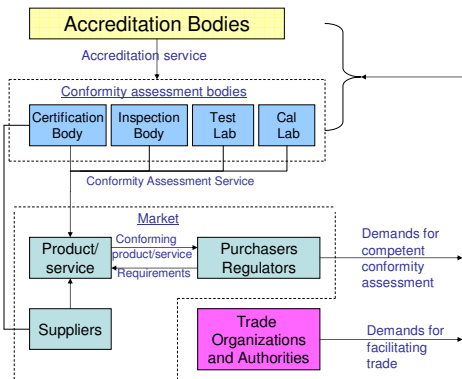
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### Supervision in the Market




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**Government / Regulatory Responsibility**



- **Government bodies and regulators are constantly called upon to make decisions related to:**
  - Protecting the health and welfare of consumers and the public;
  - Protecting the environment;
  - Developing new regulations and requirements;
  - Assessing compliance;
  - Allocating resources.
- **Government bodies and regulators must have confidence in data generated by laboratories and/or inspection bodies to help make these decisions.**
- Using an accredited conformity assessment body can help establish and assure this confidence.

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**Important Factors When Selecting a Conformity Assessment Body**



- **A conformity assessment body must be able to supply accurate and reliable testing, calibration or measurement results.**
- **Factors contributing to the technical competence of a conformity assessment body include:**
  - Qualifications, training and experience of the staff;
  - Correct equipment – properly calibrated and maintained;
  - Adequate quality assurance procedures;
  - Proper sampling practices;
  - Appropriate and valid testing procedures and methods;
  - Traceability of measurement to national standards;
  - Accurate recording and reporting procedures;
  - Suitable testing / inspection facilities.

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**MRAs 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)

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## 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

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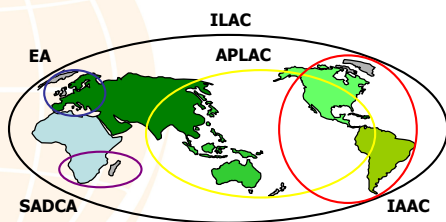
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## THE INTERNATIONAL PICTURE



- EA** European co-operation for Accreditation
- APLAC** Asia Pacific Laboratory Accreditation Cooperation
- IAAC** Inter-American Accreditation Cooperation
- SADCA** Southern African Accreditation Cooperation

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## 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 68 AB's in 56 economies



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## 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 54 economies



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## Conclusion



- Due to the strong technological component associated with competent conformity assessment, many developed countries have an **inherent suspicion** of products coming from developing countries and often insist on re-testing and/or inspection in their own country.
- **The risk to the importer of being found to be supplying non-conforming product can be very severe.**
- Globalisation **can therefore be expected to increase the need for local conformity assessment systems to be accepted internationally.**

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- Accreditation = Transparent and Impartial examination of the competence of a facility against a specific scope by an independent body.
- Without Accreditation ?
  - Risk based on assumption
  - How much risk ?



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