



# **SANAS's Role**

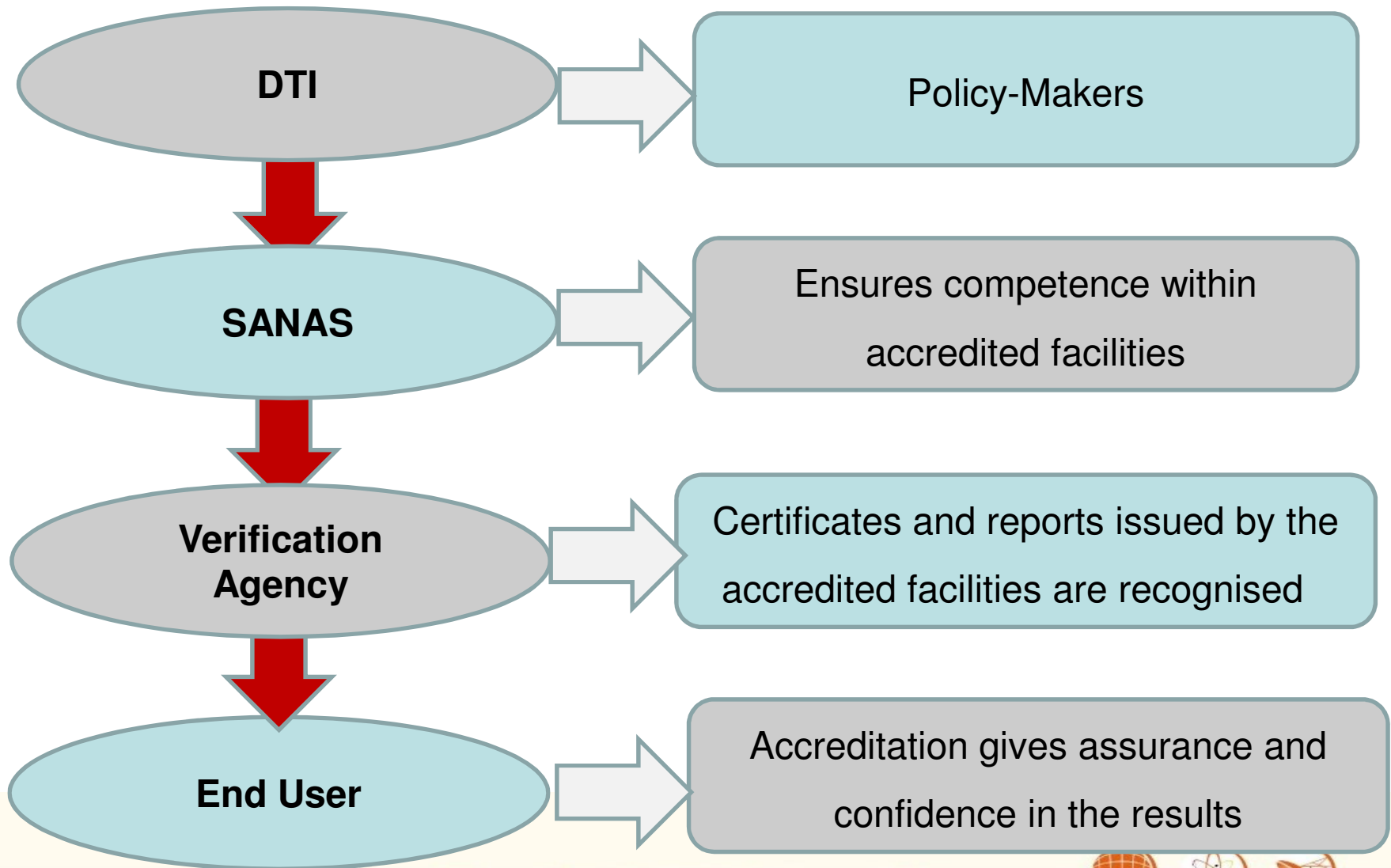


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# Relationships



# Accreditation Act.

- Act No. 19 of 2006: Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act.
- To provide for an internationally recognised and effective accreditation and monitoring system for the Republic by establishing SANAS as a juristic person;
- To recognise SANAS as the only accreditation body in the Republic for the accreditation of conformity assessment and calibration and monitoring of good laboratory practice; and to provide for matters connected therewith.



# What is Accreditation?

- ❑ Accreditation assessment of a facility

“An **independent assessment** (by experts) on the competence of an organisation and/or individual to perform tests against a schedule of accreditation”

- ❑ Accreditation **confirms** technical competence



# Government Bodies and Regulators

- In order to make informed decisions, Government must have confidence in the data generated by laboratories carrying out testing, measurement or calibration in these fields.

i.e Verification laboratories of petrol pump (protection of consumers)

- Accurate results after the assessment
- Using an accredited laboratory can help establish and assurance this confidence



# Accreditation Programs

1. **Blood Transfusion Services**
2. **Calibration Laboratories**
3. **Forensic Laboratories**
4. **Legal Metrology**
5. **Medical Laboratories**
6. **Pharmaceutical**
7. **Testing Laboratories**
8. **Veterinary**
9. **B-BBEE Verification Agencies**
10. **Certification Bodies**
11. **Inspection Bodies**
12. **Proficiency Testing**
13. **GLP and GCP**



# Accreditation Program for BBBEE VA's



Accreditation of BEE verification agencies is conducted by SANAS on behalf of the **dti** in terms of the accreditation criteria, and is maintained and enforced by SANAS

- ☐ Broad-Based Black Economic Empowerment Amendment Act, 2013.
- ☐ B-BBEE Codes of Good Practice
- ☐ Verification manual (Government Gazette 31255)
- ☐ Sector Codes
- ☐ R47 Accreditation standards



# What makes SANAS Acceptable?



SANAS has to comply with international criteria (including Quality Management criteria) and demonstrate our technical competence with regards to the various sectors that is accredited

- Peer evaluation by international teams with relevant expertise, every 4 years to ensure continued compliance with requirements
- Over the years SANAS has been commended for its technical competence. SANAS established SADCAS a regional accreditation body. SANAS assisted in set up a continental body know as AFRAC.



# Impact of accreditation

1. Promotes removal of technical barriers to trade  
i.e if electrical cables are tested here in the South Africa by an accredited facility and exported overseas , re-testing is not required
2. It boast revenue because we are able to access internationally markets.
3. It gives South African competitive edge on the international market (Motor industry quality assurance )



# Eligibility as an Exempted Micro Enterprise (EME)



**EME** – Annual Total Revenue up to R10 million

## Enhanced Recognition status

- 100% Black Owned Entities receive automatic Level 1 (One) recognition of 135%
- 51% and more Black Owned Entities receive automatic Level 2 (Two) recognition of 125%
- All other EME's receive automatic Level 4 (Four) recognition of 100%



# Eligibility as an Exempted Micro Enterprise (EME)



An EME is required to obtain a sworn affidavit or Certificate issued by Companies and Intellectual property Commission (CIPC) on an annual basis, confirming

- Annual Total Revenue of R10 million or less;
- Level of Black Ownership;

**An EME is allowed to be measured in terms of the QSE scorecard should they wish to maximise their points and move to a highest B-BBEE recognition.**

**Any misrepresentation of the above constitutes a criminal offence as set out in the Amended B-BBEE Act No. 53 of 2013.**



# Eligibility as a Qualifying Small Enterprise (QSE)



**QSE** – Annual Total Revenue R10 million – R50 million

## Enhanced Recognition status

- 100% Black Owned Entities receive automatic Level 1 (One) recognition of 135%
- 51% and more Black Owned Entities receive automatic Level 2 (Two) recognition of 125%
- All other QSE's must be verified in terms of Code 600



# Eligibility as a Qualifying Small Enterprise (QSE)



A 100% and 51% or more QSE is only required to obtain a sworn affidavit on an annual basis, confirming

- Annual Total Revenue of R10 million – R50 Million;
- Level of Black Ownership;

Any misrepresentation of the above constitutes a criminal offence as set out in the Amended B-BBEE Act No. 53 of 2013.



# Start – Up Enterprise

- A Start-up enterprise is recognised as an EME in the first year following their formation and incorporation.
- A Start-up Enterprise will have a deemed recognition level in terms of the provisions for EME's
- Start-up enterprises are automatically recognised as Empowering Suppliers under Statement 400 for the first year following their formation or incorporation.
- Any Start-up enterprise that does not meet the enhanced recognition criteria for EME's and QSE's must obtain a QSE scorecard when tendering for any contract or seeking any other economic activity covered by Section 10 of the Act with a value of R10 Million – R50 Million.
- If the contract exceeds R50 million the Generic Scorecard must be applied.

# Accreditation application Process



- 1) Application and Submission of the Quality Manual
- 2) Document Review
- 3) Initial assessment
- 4) Clearance of non-conformance
- 5) Approvals Committee
- 6) Accreditation
- 7) Six Month visit
- 8) Annual assessment
- 9) Re-assessment



# Application and Submission of the Quality Manual

- ☐ Review of the application by SANAS to determine the scope and the expertise that will be required
- ☐ SANAS sending out the acknowledgement letter which also spells out the processes that will follow.
- ☐ Application and Document Review payment (Invoice valid for 30 days)
- ☐ The application and Document Review fee (fee structure is on P14)

# Document Review

- ☐ Document Review carried out against the ISO/IEC 17025 by a SANAS Lead Assessor
- ☐ Document Review report to be given to the VA after 4 weeks.
- ☐ VA is given 6 months to work on non-conformances identified during the document review process.
- ☐ If there are major gaps identified, the laboratory might be required to re-submit its Quality Manual for a second review.



## Initial Assessment

## Process Non-conformances

- ❑ Initial Assessment is carried out by a full strength team i.e. a team comprised of a Lead Assessor and Technical Assessors/Experts.
- ❑ The time frame for initial assessment depends on many factors such as:
  - i. Availability of the assessment team
  - ii. SANAS receiving payment from the VA
  - iii. Readiness of the VA
- ❑ VA is given a total of 6 months to work on non-conformances identified during the initial assessment.
- ❑ After submitting the corrective actions, the assessment team has 5 working days to evaluate corrective actions.



Process Non-conformances

Approval process



- ☐ When all the corrective actions have been accepted by the assessment team, the assessment pack will be reviewed by the Approval Advisory Committee (AAC) within a month.
- ☐ Within two days of the AAC meeting, laboratory will be advised of the accreditation outcome.
- ☐ If the assessment team's recommendation has been approved, the laboratory will receive the Certificate and Schedule of Accreditation within 15 working days of the AAC meeting.



Six Month  
visit

Annual  
Assessment

Re-  
assessment



- ☐ The purpose of the visit is to follow-up on any non-conformances raised at the initial assessment and to ensure that the management system is still implemented and functioning properly.
- ☐ SANAS will check for continuing compliance with accreditation requirements by carrying out surveillance visits at periods not exceeding 24 months
- ☐ Re-assessment visits will involve a comprehensive re-examination of the VA's accredited activities



# Important information

- ❑ The accreditation process takes at least minimum of 3 months from application to granting of accreditation. Thus, if an application has been submitted in April 2015, the entire process could be concluded by July 2015.
- ❑ Each stage is preceded by payment by the laboratory
- ❑ Initial Assessment depends of various factors, namely: Availability of the assessment team; type of expertise required; readiness of the laboratory and payment of the assessment fee.
- ❑ An application that has not proceeded to the initial assessment stage within 1 year from the date of application will lapse





**Questions**

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**Thank You**

