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South African National
Accreditation System



WELCOME TO SANAS KNOWLEDGE TRANSFER



SANAS Laboratory Accreditation Process



WELCOME TO SANAS KNOWLEDGE TRANSFER



*10th Largest Accreditation
Body
Approximately 1350
Accredited Facilities*



WELCOME TO SANAS KNOWLEDGE TRANSFER

SANAS Main Scope of Accreditation

- **Laboratories**

Testing (medical), Calibration

- **Inspection Bodies**

X ray equipment (DoH)

- **Certification Bodies**

QMS, EMS, Prod. Cert.



284 Medical Laboratory Accreditations

Main Scopes of Accreditation

Chemistry

Microbiology

TB

Virology

Haematology

Serology

Immunology

Human genetics

Anatomical pathology (Histo. & Cyto.)



SANAS Accreditation

- The definition of an accreditation assessment of a laboratory is:

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



What is accreditation

Accreditation is the recognition that a laboratory can produce “accurate results” within acceptable limits on a consistent and sustainable basis.



Accreditation confirms

COMPETENCE



Competence concerning a laboratory

- **Personnel**
- **Methods**
- **Equipment**
- *Measurement traceability*
- *Environment*
 - *There has to be criteria for this competence e.g. Validation of Methods, known measurement relationship (standards, inter-comparisons).*



Accreditation is based on competence

Within the ISO 15189 there are system elements and technical elements.

Although both are important the system is secondary to the competency aspects.

An accreditation assessment team will *assess* back to the accreditation schedule

and

see that a system is implemented in accordance with ISO 15189 that can support the competency aspects. This is to give an assurance of the maintenance and sustainability of the laboratory's ability to continue to produce results in accordance with the accreditation schedule.



SCHEDULE OF ACCREDITATION

Testing Laboratory Number: M675

<p><u>Permanent Address of Laboratory:</u> Spear Laboratories Med. CentrePark Hotazel</p> <p><u>Postal Address</u> PO Box 232 Hotazel 2243</p> <p>Tel : (029) 642 4007 Fax : (019) 642 9965</p>	<p><u>Signatories:</u> Ms. D. Lawson de Wet : Contact Person Dr. M. Slimjan : Signatories as authorised by the Head of Laboratory</p> <p>Issue No : 4 Date of issue : August 2005 Expiry date : August 2009</p>	
Materials/Products Tested	Types of Tests/Properties Measured, Range of Measurement	Standard Specifications, Equipment/ Techniques Used
<u>HAEMATOLOGY</u>	Full Blood Count Reticulocytes ESR Differential count PI PTT D-Dimer Malaria smear – thick & thin smears ICT – Rapid for detection of Plasmodium (positive/ negative) falciparum & vivax	Cell-dyn 3500 Westergren Behring Fibrintimer/Manual D-Ditest Diagnostica Stago Manual



**Through ILAC the internationally
recognized requirements for
the accreditation of laboratories are:**

**That the laboratory is competent in
meeting their accreditation
*schedule/scope***

&

**has a system implemented that meets
the criteria of
*ISO 15189***





And

**Meets other Internationally
accepted accreditation body
requirements for that
laboratory's specific activities**

**(e.g. participation in PT / inter-comparison /
EQC schemes, test labs using accredited
calibration authorities)**

SANAS Assessment Process

Pre-opening meeting (assessors)

Opening meeting

ASSESSMENT

Pre-closing meeting (assessors)

Closing meeting



(SANAS Assessment process)

ASSESSMENT

Lead Assessor

Manages the assessment process

&

**Assesses – System and interface
with the**

Technical Aspects

**records the assessment on checklists
based on the requirements of ISO 15189**

Non Conformance forms



(SANAS Assessment process)

ASSESSMENT

Technical Assessor(s)

**Assesses the competency of the
Laboratory**

**Assesses –Technical Aspects against
the schedule of accreditation**

**records the assessment on Witnessing forms
and Vertical assessment forms based on
the requirements of ISO 15189**

Non Conformance forms



(SANAS Assessment process)

ASSESSMENT

Technical Assessor(s)

**Witnessing forms recording –
What is happening today.**

**Vertical assessment forms recording-
What happened in the past to assist in making
a judgment for the future.**



(SANAS Assessment process)

ASSESSMENT

Technical Assessor(s)

Vertical assessment cuts through the competency aspects.

Personnel

Methods

Equipment

Measurement traceability

Environment

- *There has to be criteria for this competence e.g. Method Validation known measurement relationship (standards, inter-comparisons).*



(SANAS Assessment process)

Pre-close out meeting

Feedback by all assessors on the
competency & support system of the
laboratory based on the evidence
recorded on the

System checklists,

Witnessing forms,

Vertical assessment forms

and the

Non conformance reports

RECOMMENDATION



(SANAS Assessment process)

Close out meeting

Feedback by the assessment team to Laboratory Management on the status of their system and competency to produce acceptable results.

&

Recommendation to be forwarded to the SANAS Approvals Advisory Committee



(SANAS Assessment process)

Clearance of Non Conformances

Either by documentation or on-site clearance in an agreed time period



(SANAS Assessment process)

*Final Decision by the
SANAS Approvals
Advisory
Committee*



- **For laboratories to maintain this recognition, conformity assessment bodies are re-evaluated periodically by the accreditation body to:**
 - ensure their **continued compliance with requirements;** and
 - check that their **standard of operation is being maintained.**
- **The conformity assessment body may also be required to participate in relevant proficiency testing programs between reassessments, as a further demonstration of technical competence.**



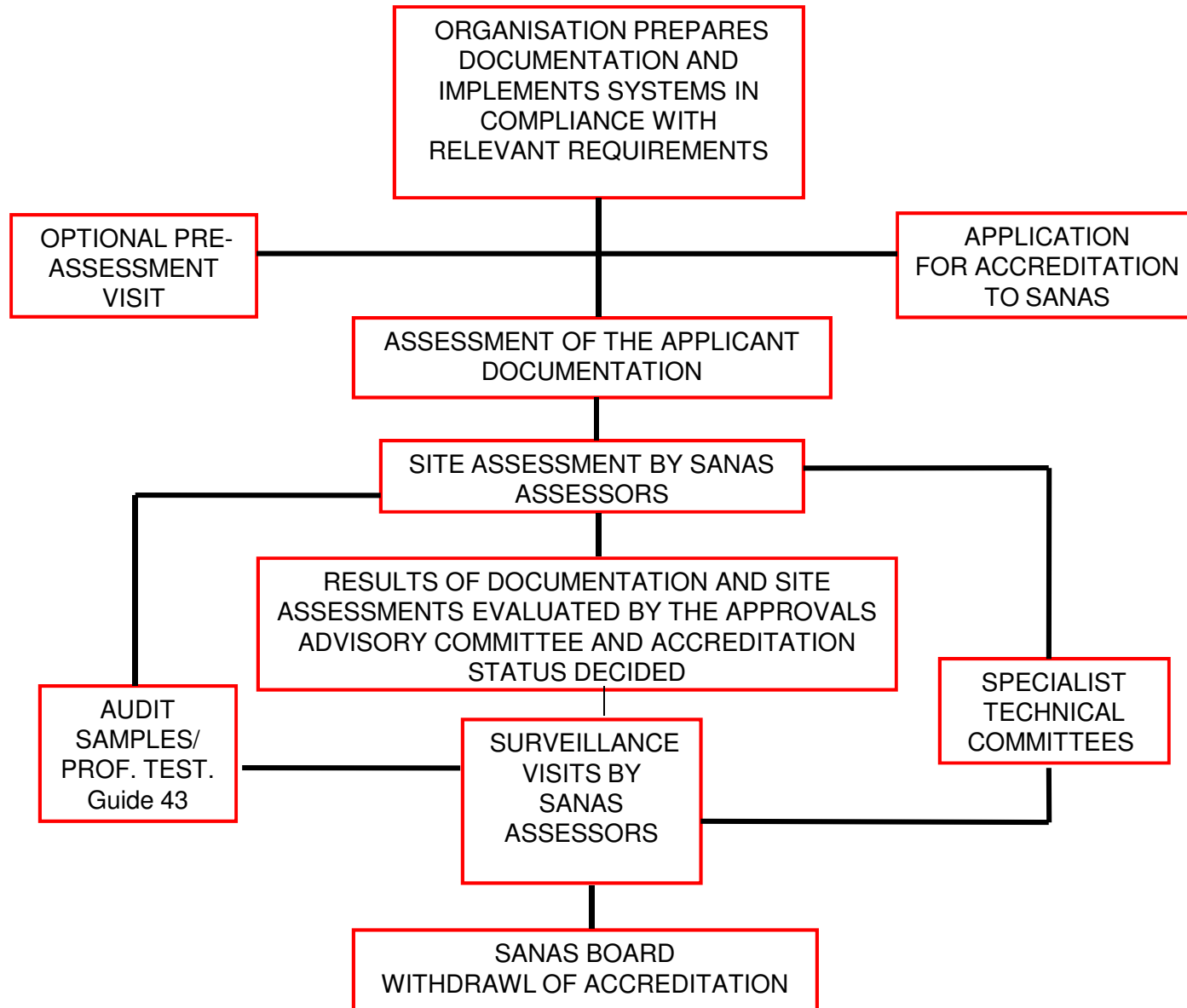
- **Within countries Government bodies and regulators are constantly called upon to make decisions related to:**
 - **Protecting the health and welfare of consumers and the public;**
 - **Protecting the environment;**
 - **Developing new regulations and requirements;**
 - **Assessing compliance;**
 - **Allocating resources.**

- **Government bodies and regulators must have confidence in data generated by laboratories and/or inspection bodies to help make these decisions.**

- **Therefore government departments are increasingly making use of accredited conformity assessment bodies to help establish and assure this confidence.**



ACCREDITATION PROCESS



Science finds

Industry applies

Man conforms (confirms)

