



NATIONAL HEALTH
LABORATORY SERVICE

SLMTA/SLIPTA SYMPOSIUM

EXPERT PANEL #2 – ACCREDITATION: GETTING
THERE AND STAYING THERE

Presenter : *Patience Dabula*
National Manager: Quality Assurance.
South African National Health Laboratory Service

Date: 08 DEC 2018

Is getting accredited easy?

Is getting accreditation possible?

Which ISO standards are applicable in medical laboratories?

How many accrediting bodies are in Africa?

What is key in accreditation?

- Management commitment
- Resources
- Accreditation plan
- Understanding of the standard? Training
- Staff commitment





ISO standards used in medical laboratories

- Different ISO standards for accreditation related to medical diagnosis
 - ✓ Medical Laboratories - [ISO 15189: 2012](#)
 - ✓ Proficiency Testing Schemes/ EQA - [ISO 17043: 2010](#)
 - ✓ POCT - [ISO 22870:2016](#)
 - ✓ Testing and Calibration – [ISO 17025:2017](#)
 - ✓ Manufactures of medical devices - [ISO 13485:2016](#)
 - ✓ Medical laboratory safety – [ISO15190:2003](#)
- Accreditation bodies are members of International Laboratory Accreditation Cooperation (ILAC)



10 Accreditation bodies in Africa:

Red- Full members **Blue** – Associate members

1. **ALGERAC** – Algerian Accreditation body
2. **EGAC** – Egyptian Accreditation Council
3. **ENAO** – Ethiopian National Accreditation Office
4. **KENAS** – Kenya Accreditation Service
5. **MAURITAS** – Mauritius Accreditation Service
6. **NINAS** – Nigeria National Accreditation Service
7. **SADCAS** – Southern African Development Community Accreditation Service
8. **SANAS** – South African National Accreditation System
9. **SEMAC** – Moroccan Accreditation Service
10. **TUNAC** – Tunisian Accreditation Council



Source: International laboratory Association Cooperation (homepage on the internet). cited (2018 Nov 29) Available from <https://ilac.org/>

Staying accredited

Is maintenance of accreditation easier than getting accreditation?

What is key in maintaining accreditation?

- Management commitment
- Resources
- **Internal audits?**
- **Continuous checks on maintaining status**
- **Management Review Meeting**
- **Reviewing and Improving the QMS**
- Staff commitment

Final word

The future and success of accreditation in the continent depends on the decision makers.

A proper QA plan is important for implementation

Accreditation succeeds or fails because of many reasons but management commitment is of key importance

Quality cannot be compromised.

Ignoring the requirements is more costly as patient lives are at stake.