Assuring Technical Competence - SADCAS Accreditation Process- MLAS

Presented by

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Presentation Overview

- Accreditation Process
- Accreditation Process Timelines
- Accreditation Costs
- Trends from Initial Assessments
- Lessons learnt
- Conclusion

SADCAS Accreditation

- Granted to organizations that fully meet requirements of the relevant international standards
- Standards Requirements for Medical laboratories is ISO 15189:2012

Accreditation Requirements

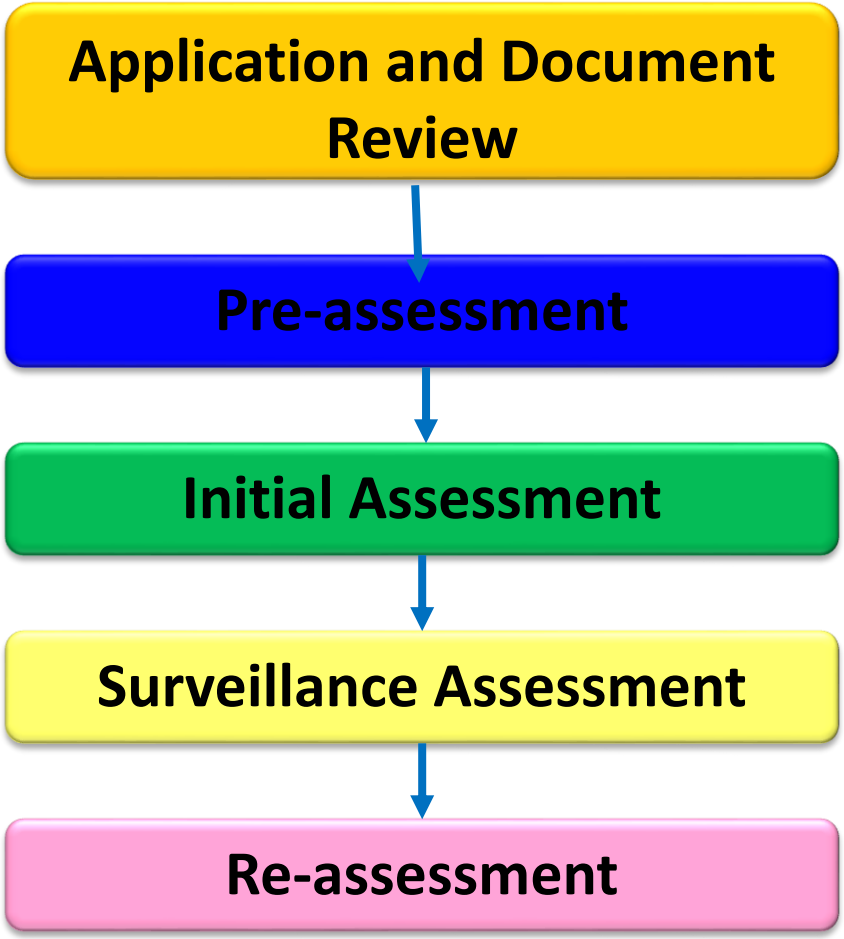
- **General Requirements**
  - SADCAS TR 01 Part 1 – Conditions for Use of SADCAS Accreditation Mark
  - SADCAS TR 01 Part 2 – Use of Combined Marks
  - SADCAS AP 02 – Accreditation Fees
- **Informative Document**
  - SADCAS TR 02 – Accreditation Requirements
  - SADCAS TG 01 - Information to Organizations Applying for Accreditation
  - SADCAS TG 03 – Area of Accreditation
  - SADCAS TG 04 – Guidance for addressing and Clearing Nonconformities
  - SADCAS F 111 – Accreditation Process Timelines

- **Documents available on SADCAS website: www.sadcas.org**

SADCAS Accreditation Process

- **The SADCAS accreditation process involves 5 main stages namely:**
  - Application and documentation review
  - Pre-assessment
  - Initial assessment
  - Periodic on site assessment
  - Re-assessment

Accreditation Process Flow Chart



Application

- **Applicant completes an application form available from SADCAS office and also from the SADCAS website: www.sadcas.org**
  - In the case of medical laboratories the applicable form is SADCAS F 43 (c)
- **Applicant also completes SADCAS F 43 (f) – Application for Approval of Personnel applicable to nominated representatives/management representative**
  - For clarity on NR/MR and TS refer to SADCAS TR 03: NR/TS responsibilities, qualifications and approval:

Application

- **Applicant signs SADCAS F 44 – SADCAS Accreditation Agreement**
- **All applications to be accompanied by a Quality Manual (policies, procedures/SOPs, etc)**
- **Applications to be submitted directly to SADCAS office in Gaborone, Botswana**

Document Review

- Upon receipt, SADCAS undertakes a completeness check of application documents
- SADCAS provides the applicant with a detailed quotation based on the scope of application. If acceptable applicant signs and returns signed quotation to SADCAS
- SADCAS Team Leader (TL) undertakes document review of the applicant's Quality Manual
- SADCAS provides feedback on document review to applicant. Report is made available within one month of receipt of complete documentation
- If there are NCs/ need for more information then applicant advised accordingly and institutes CA and submits additional documents. Corrective action timeline 6 months to address findings from DR

Pre-Assessment

- Pre - assessments are optional but may be compulsory depending on the regulator's condition for acceptance where required.
- Pre-assessment is an on site visit to check readiness of applicant for accreditation
- Undertaken by LA/Technical Assessor (TA)
- Findings recorded
- Recommendation report: ready or not for an initial assessment. Report is provided within 2 weeks after pre-assessment

Initial Assessment

- **Onsite assessment of organization's competence**
- **Covers all aspects of organization's scope of application**
- **Undertaken by an Assessment Team (AT)**
- **Assessment Team consists of**
  - Team Leader (TA) who is responsible for assessing the MS of the applicant
  - Technical Assessors responsible for advising the TL on specialist technical matters relating to applicant's scope
  - Organization given opportunity to object to proposed team on the basis of objective evidence of a conflict of interest
  - SADCAS evaluates reason and if acceptable proposes changes to the AT

Initial Assessment *(continued)*

- **Assessors Meeting**
  - Meeting of the Assessment Team
  - Consolidate findings
  - Agree on classification of findings
- **Closing Meeting**
  - Held at end of onsite assessment
  - Chaired by SADCAS LA
  - Attended by
    - AT members
    - Applicant organization's management
    - Nominated Representative
    - Personnel involved in areas assessed

Initial Assessment *(concluded)*

- **Findings recorded**
- **Organization will be advised of any improvement actions identified against the accreditation requirements by the AT**
- **Organization is given**
  - 1 month to identify and propose corrective action and to address them within 3 months from last date of assessment. Refer to TG 04 for Guidance for addressing and Clearing Nonconformities
- **Once improvement actions have been implemented to the satisfaction of SADCAS, accreditation will be granted**
- **Accreditation decision made by the Accreditation Approvals Committee based mainly on the information gathered during assessment**

Accreditation

- **Accreditation certificate and schedule of accreditation (SoA) issued**
- **Name of accredited organization together with certificate and SoA are published on the SADCAS website www.sadcas.org**
- **SADCAS F 44 covers all the aspects that a medical laboratory has to comply with in order to maintain accreditation**

Re-Assessments

- Will be conducted at end of accreditation cycle
- Assessment cycle 5 years
- A full assessment is undertaken on the management system and technical aspects including PT/ILC

Accreditation Timelines

- **SADCAS makes an effort to ensure that applications are processed as efficiently as possible**
- **Accreditation process timelines are outlined in F 111**
- **Accreditation timelines**
  - Range of time taken to process from application to accreditation 11 to 30 months with some facilities undergoing initial assessment twice
  - Average time taken to process from application to accreditation approval 20 months
- **The time taken to process an application depends on a number of factors, some of which are outside SADCAS control:**
  - A delay can occur due to insufficient documented procedures and submission of inadequate Quality Manual
  - Delays in submitting additional requested documents at DR stage
  - Availability of suitable assessors
  - Delays in identifying corrective action by conformity assessment body
  - Delays in submitting evidence of implementation of corrective action

Accreditation Costs

- **Outlined in AP 02. AP 02 Contains an estimate of fees**
- **Application Fee**
  - Includes one document review
  - Paid with submission of application documents
  - Non refundable if applicant withdraws
  - Approximately US $954
  - Resubmitted documentation review US $605
- **Pre-assessment Fees**
  - Charged at a rate of US $1,270 per assessor unit
  - One assessor unit is one assessor for one day or part thereof
  - Assessor travel and subsistence costs billed at cost to client

Accreditation Costs

- **Initial Assessment Fee**
  - Initial assessment fee based on two assessor units for 2 days approximately US $2,722
  - Additional assessor charged at a rate of US $877 per assessor unit
  - Assessor travel and subsistence costs also billed at cost to client
- **Annual Accreditation Fee**
  - Based on 2 assessor units
  - Estimated at US $2,722.00
  - Additional assessor units will be charged at US $877 per assessor unit
  - The annual accreditation fee excludes travel and subsistence costs which, at surveillance assessment stage, will be billed at cost

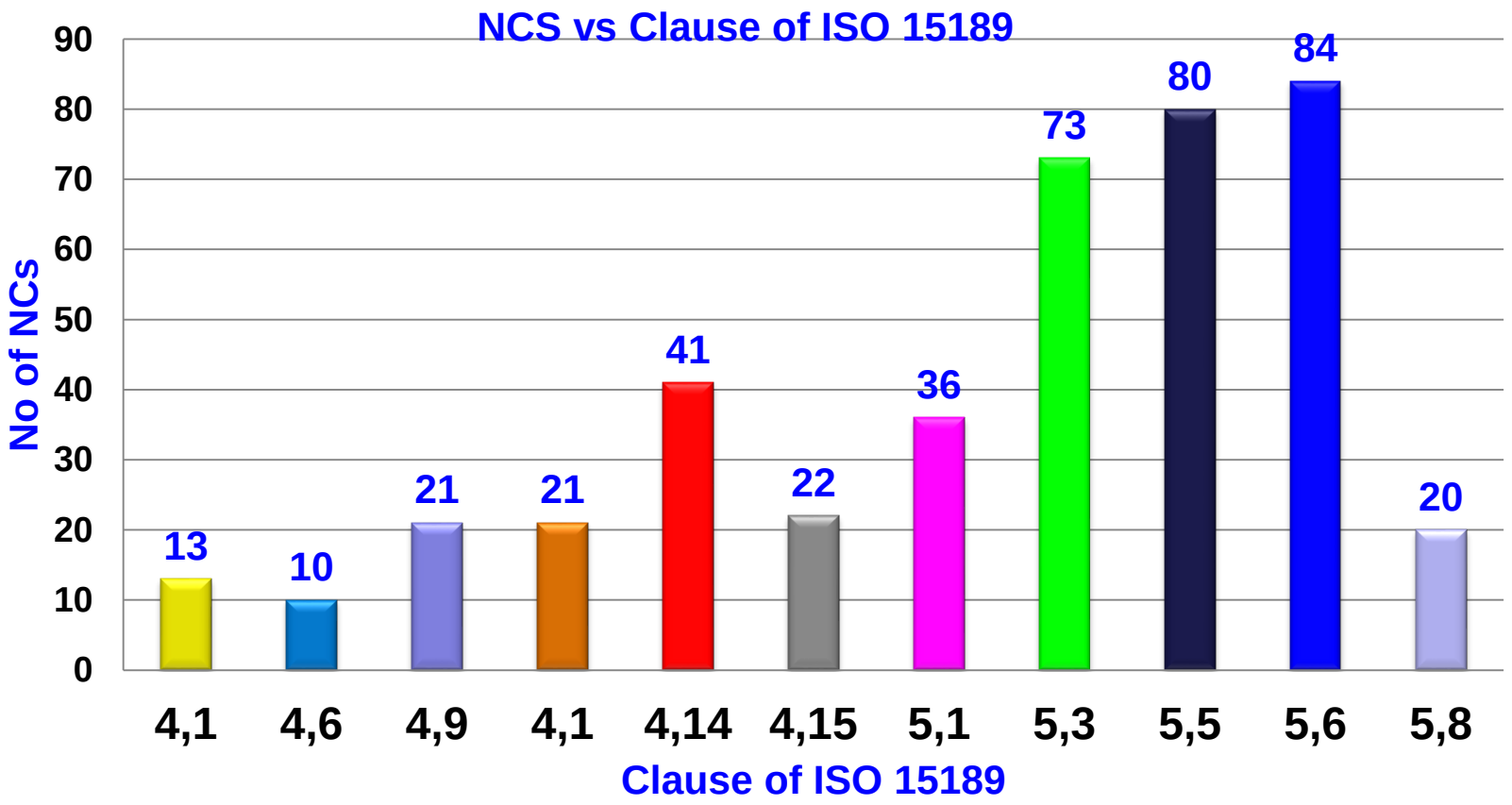
Accreditation Costs

- **ML A (Tanzania) Scope: Parasitology; TB (August 2018)**
  - Application fees(Including DR) USD 868
  - Initial assessment USD 8,709
  - **Total** **USD 9,575**
- **ML B (Zambia) Scope: Chemistry; Microbiology, Haematology, Immunology and Serology (July 2018)**
  - Application fees(Including DR) USD 868
  - 1st Initial assessment USD14,793
  - **Total** **USD15,660**

Trends from Initial Assessments

- **Based on SADCAS experiences from 29 initial assessments undertaken, high numbers of nonconformities are recorded in the following areas and applicable clauses of ISO 15189:2012**
  - Clause 5.6: Ensuring quality of examination results (84)
  - Clause 5.5: Examination Processes (80)
  - Clause 5.3: Laboratory Equipment (73)
  - Clause 4.14: Internal audits (41)
  - Clause 5.1: Personnel (36)
  - Clause 4.15: Management review (22)
  - Clause 4.9: Identification and control of nonconformities (21)
  - Clause 5.8: Reporting of results (20)
  - Clause 4.1: Organization and management (13)
  - Clause 4.6: External services and supplies (10)
  - Clause 4.10: Corrective actions (11)

Trends from Initial Assessments



Trends from Initial Assessments

Clause 5.6 of ISO 15189 : Ensuring quality of results covers the following areas:

- **Internal quality control analysis and review;**
- **Inter-Laboratory Comparison/EQA participation; and**
- **Analysis and review of performance.**

Trends from Initial Assessments

Clause 5.5 of ISO 15189: Examination procedures covers the following areas:

- **Selection, verification and validation of examination procedures;**
- **Measurement uncertainty; and**
- **Documentation of examination procedures.**

Trends from Initial Assessments

Clause 5.3 of ISO 15189: Laboratory Equipment, reagents and consumables is broad and it covers the following areas:

- **Equipment acceptance testing**
- **Equipment calibration and metrological traceability**
- **Equipment maintenance and repair**
- **Equipment records**
- **Reagents reception, acceptance testing,**
- **Reagents inventory management**
- **Reagents and consumables records**

Lessons Learnt for the Benefit of ML

Personnel

- **Some laboratories fail to provide exhaustive training in all areas stated in ISO 15189 for all personnel.**
  - Quality management systems
  - Health and safety
  - Applicable laboratory information systems
  - Ethics (5.1.5).
- **Laboratories seem to concentrate on equipment/analyser operator trainings only**
- **Some laboratories would only provide evidence of competence assessments without training records. The standard separates the two. Competence evaluation is done to check effectiveness of training.**

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