

SADCAS Experiences- Medical Laboratories Accreditation Programme

Presented by

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Presentation Overview

- ❑ **Overview of SADCAS**
- ❑ **The SADCAS MLAP**
- ❑ **Accreditation process**
- ❑ **Trends from initial assessments**
- ❑ **Lessons learnt**
- ❑ **Conclusion**

Overview of SADCAS

- ❑ Accreditation bodies (ABs) are established in many countries with the primary purpose of ensuring that conformity assessment bodies (Laboratories, certification and inspection bodies) are subject to an oversight by an authoritative body.
- ❑ SADCAS is a multi - economy AB established to meet the accreditation needs of SADC Member States especially those without own national accreditation body.
- ❑ Within the SADC region of 15 countries only 2 countries namely South Africa and Mauritius have their own national ABs, SANAS of South Africa and MAURITAS of Mauritius.
- ❑ The remaining 13 countries namely: **Angola; Botswana; Democratic Republic of Congo (DRC); Lesotho, Madagascar; Malawi; Mozambique; Namibia; Seychelles; Swaziland; Tanzania; Zambia; and Zimbabwe** do not have national accreditation bodies hence serviced by SADCAS.

Overview of SADCAS



Overview of SADCAS

- ❑ Incorporated in December 2005 in Botswana.
- ❑ Office was set up in October 2008
- ❑ Launched in April 2009
- ❑ Started offering services in October 2009.
- ❑ The set up and operationalization of SADCAS was funded by the Norwegian Government
- ❑ Governments of Member States that are serviced by SADCAS now support SADCAS operations with some governments (**Zimbabwe, Mozambique, Namibia and Swaziland**) having already paid their contributions/part contributions towards SADCAS sustainability.

Overview of SADCAS

❑ Launch of SADCAS in April 2009



Overview of SADCAS

- ❑ **Accreditation services and training in accreditation associated activities**
- ❑ **SADCAS Accreditation programmes**
 - ↪ Calibration laboratories to ISO/IEC 17025
 - ↪ Testing laboratories to ISO/IEC 17025
 - ↪ **Medical laboratories to ISO 15189**
 - ↪ Management systems certification bodies to ISO/IEC 17021
 - ↪ Product certification bodies to ISO/IEC 17065
 - ↪ Personnel certification bodies to ISO/IEC 17024
 - ↪ Inspection bodies to ISO/IEC 17020
- ❑ **SADCAS will broaden scope of accreditation as needs arise**
- ❑ **Accreditation programmes comply with ISO/IEC 17011**

Overview of SADCAS

- **SADCAS is now in its 6th year of operation and has up to date**
 - Accredited 28 facilities in 7 SADC Member States.
 - Has 46 accreditation applications from 9 countries at various stages of processing.
 - Has cumulatively conducted 81 training courses in 11 SADC Member States in order to promote accreditation and an understanding of the accreditation requirements with over 1 100 participants benefiting from the SADCAS training courses.

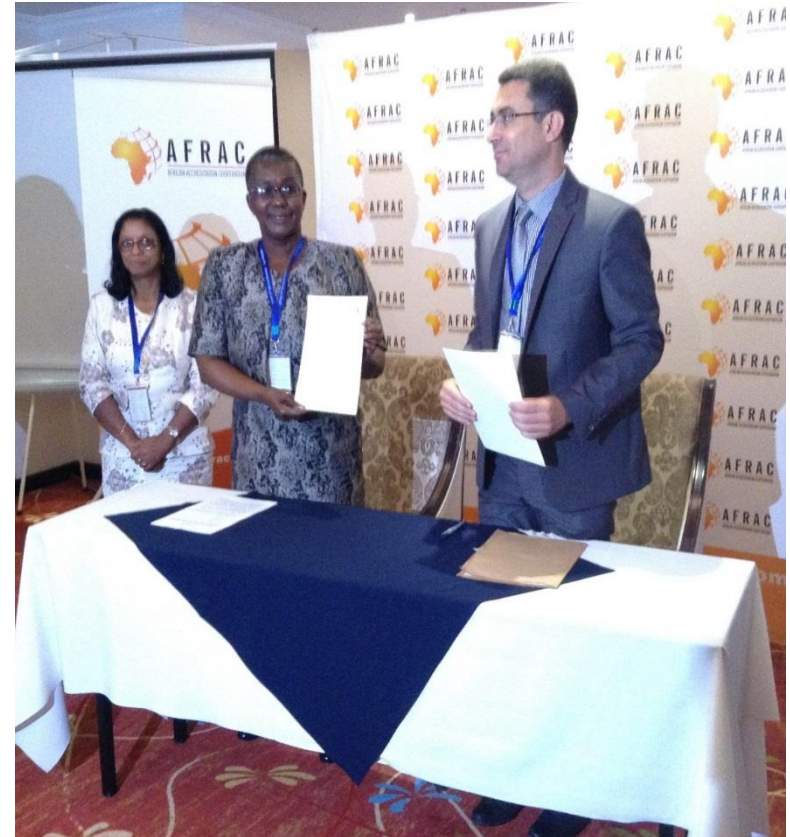
Overview of SADCAS

- ❑ **Accreditation services kick started through a twinning Partnership Arrangement (TPA) with the SANAS.**
- ❑ **In an effort to address the accreditation needs of French speaking SADC Member States, a TPA was signed in February 2014 with TUNAC.**
- ❑ **Both the SADCAS/SANAS and the SADCAS/TUNAC TPAs which involve joint assessments are in line with international best practice so as to facilitate SADCAS development and to give confidence on the market whilst SADCAS works towards signatory status in international accreditation arrangements.**

Overview of SADCAS

- ❑ **Efforts are now underway to enable SADCAS to service the accreditation needs of SADC countries where Portuguese is the official language.**
- ❑ **Great strides made towards international recognition, with SADCAS successfully undergoing a joint pre - peer evaluation by the ILAC and AFRAC in June 2014 and is due to undergo the peer evaluation in June 2015.**
- ❑ **SADCAS is therefore well on its way towards signatory status and aims to achieve the said status in the 2015/16 financial year.**

SADCAS/SANAS and SADCAS/TUNAC TPA Ceremonies



The SADCAS MLAP

The SADCAS Medical Laboratories Accreditation Programme (MLAP)

- ✦ Established in June 2010
- ✦ A multi-disciplinary accreditation programme operated in accordance with ISO/IEC 17011
- ✦ The fields of accreditation under the SADCAS MLAP include: **Biochemistry; Cytology; Hematology; Histopathology; Immunology; Microbiology; Pathology; Virology; Serology; and Andrology**

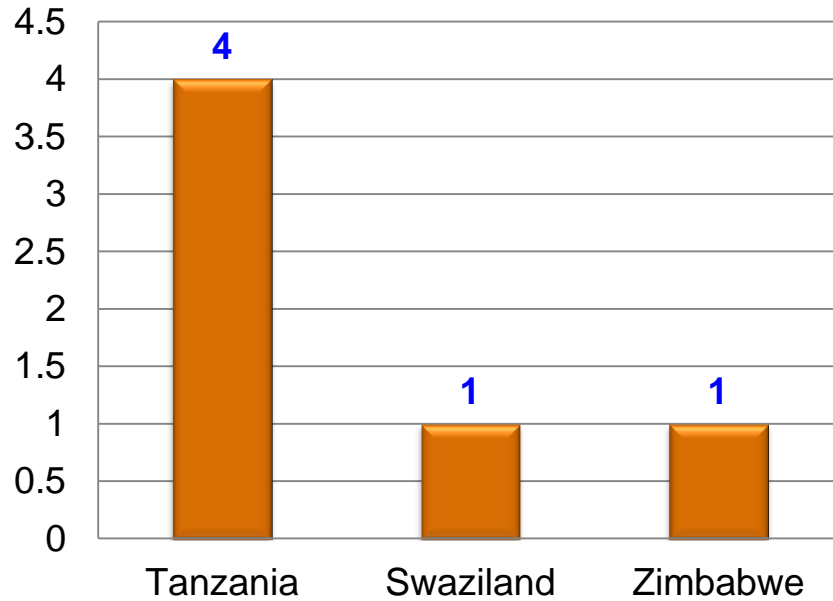
The SADCAS MLAP

Accreditations as at 24 November 2014

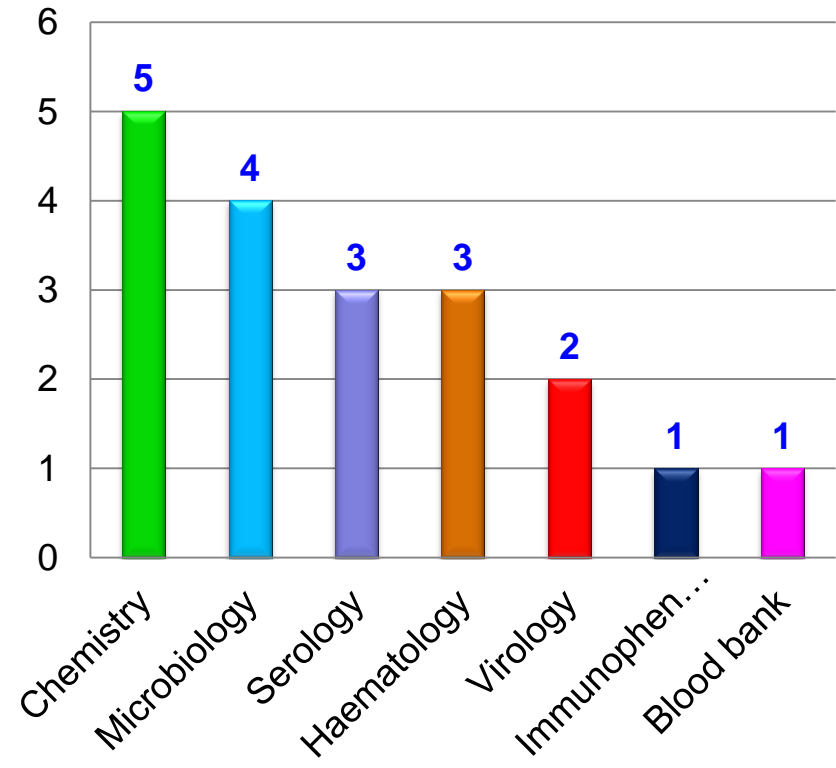
- ❑ **SADCAS has accredited 6 medical laboratories**
- ❑ **Breakdown of accredited laboratories by country**
 - ↪ Tanzania (4)
 - ↪ Swaziland (1)
 - ↪ Zimbabwe (1).
- ❑ **Medical laboratories constitute 21% of the accredited facilities**
- ❑ **Breakdown of accreditations by scope**
 - ↪ Chemistry (5)
 - ↪ Microbiology (4)
 - ↪ Serology (3)
 - ↪ Haematology (3)
 - ↪ Virology (2)
 - ↪ Immunophenotyping (1)
 - ↪ Blood Bank (1).

The SADCAS MLAP

Number of Accredited ML by Country



Accreditations by Scope



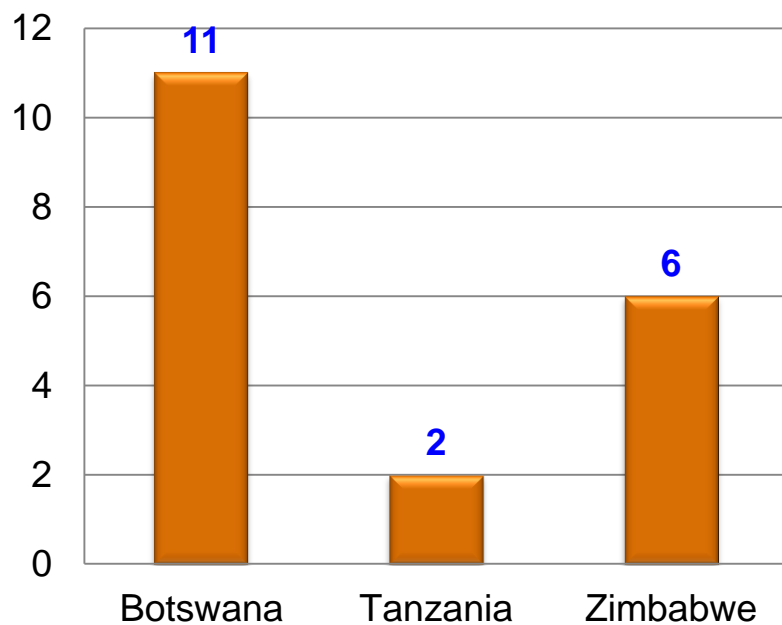
The SADCAS MLAP

Accreditations applications as at 24 November 2014

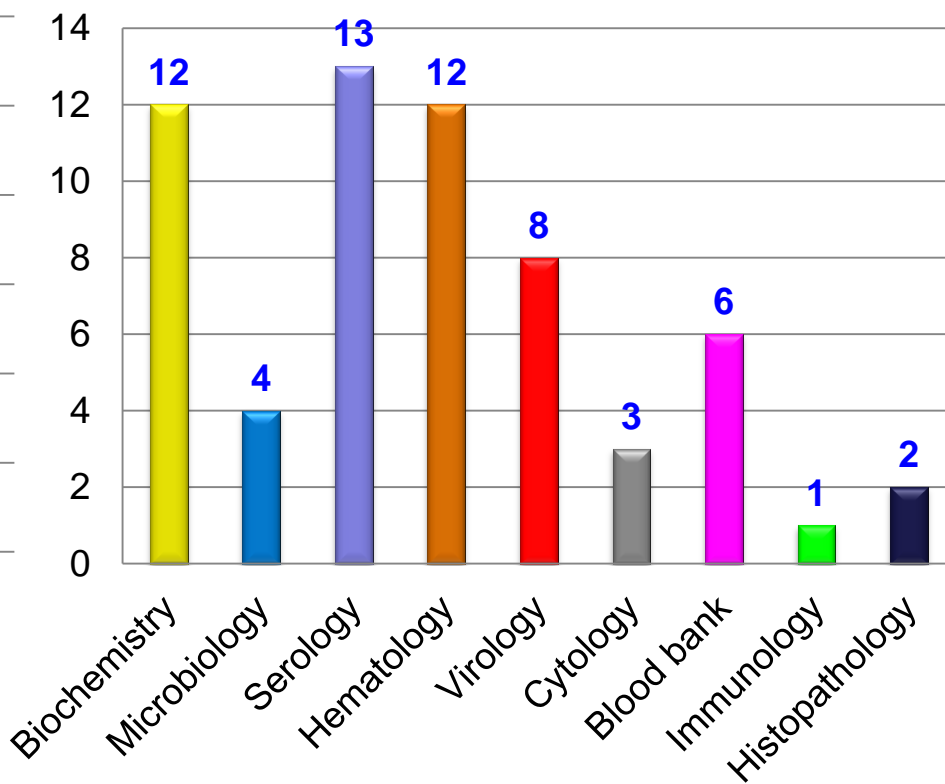
- ❑ **SADCAS has 19 applications from medical laboratories under process**
- ❑ **Medical laboratories constitute 41% of the applications under process**
- ❑ **Breakdown of applications by country**
 - ↪ Botswana (11)
 - ↪ Tanzania (2)
 - ↪ Zimbabwe (6).
- ❑ **Breakdown of applications by scope**
 - ↪ Microbiology (15)
 - ↪ Serology (13)
 - ↪ Hematology (12)
 - ↪ Biochemistry (12)
 - ↪ Virology (8)
 - ↪ Blood Bank (6)
 - ↪ Cytology (3)
 - ↪ Histopathology (2)
 - ↪ Immunology (1)

The SADCAS MLAP

Applications by Country



Applications by Scope



SADCAS Accreditation Process

- **The SADCAS accreditation process involves 5 main stages namely:**
 - ⇒ Application and documentation review
 - ⇒ Pre-assessment
 - ⇒ Initial assessment
 - ⇒ Surveillance
 - ⇒ Re-assessment
- **Assessments undertaken by a team of assessors**
 - ⇒ 11 SADCAS qualified and registered assessors
 - 3 Lead assessors
 - 8 Technical assessors
 - ⇒ 11 SANAS assessors
 - 4 Lead assessors
 - 8 Technical assessors

SADCAS Accreditation process

□ Accreditation applications by stage of processing

- ↪ Completeness check stage (4)
- ↪ Approval of quotation stage (5)
- ↪ Documentation review stage (1)
- ↪ Initial assessment stage (8)
- ↪ Accreditation approval stage (1)

□ Accreditation timelines

- ↪ Range of time taken to process from application to accreditation **12 to 30 months** with some facilities undergoing initial assessment twice
- ↪ Average time taken to process from application to accreditation approval **22 months**

Accreditation Costs

□ ML A (Zimbabwe) Scope: Serology, Haematology, Chemistry

↪ Application fees(Including DR)	USD	840
↪ Pre - assessment (optional)	USD	2,325
↪ Initial assessment	USD	7,040
↪ Total	USD	10,205

□ ML B (Tanzania) Scope: Chemistry, Microbiology, Parasitology, Molecular Biology

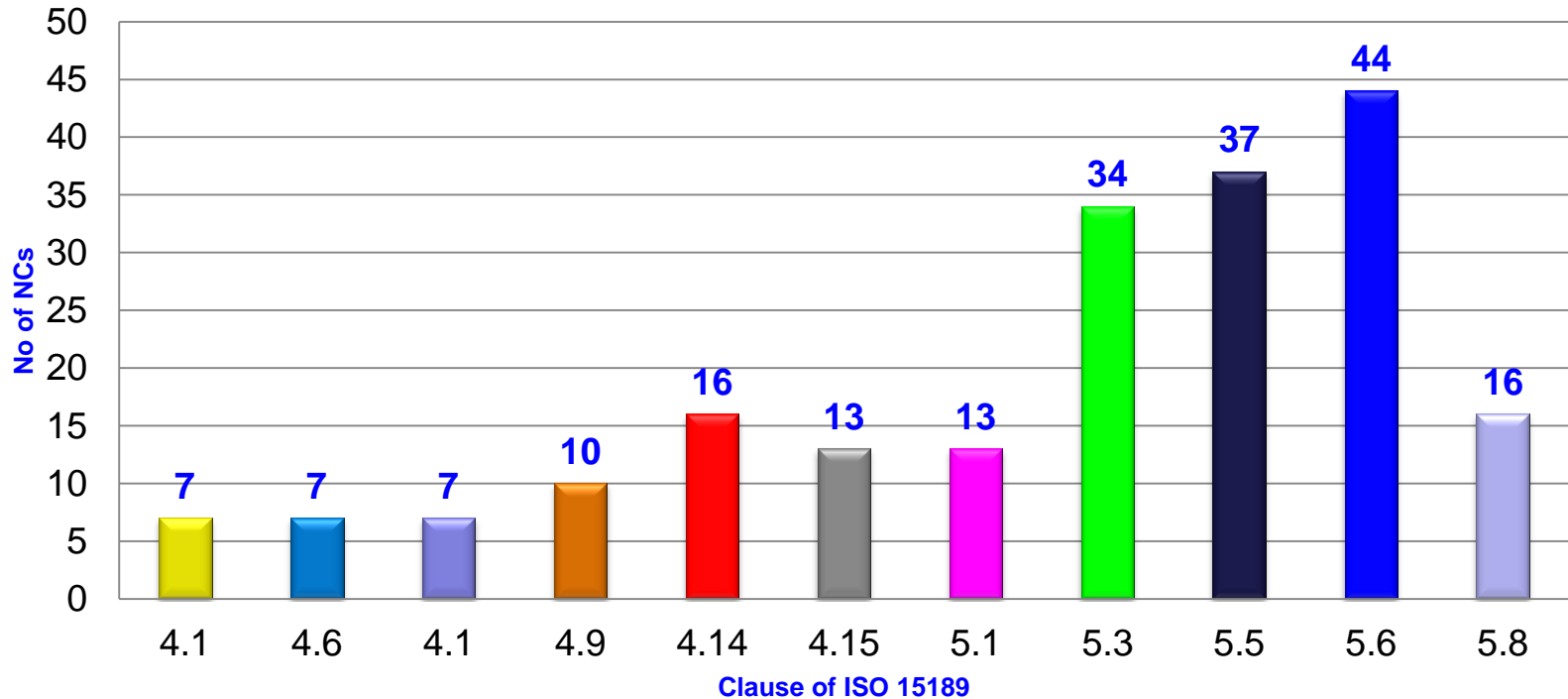
↪ Application fees(Including DR)	USD	870
↪ 1 st Initial assessment	USD	16,384
↪ 2 nd Initial assessment	USD	19,390
↪ Total	USD	36,664

Trends from Initial Assessments

- ❑ **Based on SADCAS experiences from 13 initial assessments undertaken, high numbers of nonconformities are recorded in the following areas and applicable clauses of ISO 15189:**
 - ↪ Clause 5.6: Ensuring quality of examination results (44);
 - ↪ Clause 5.5: Examination Procedures (37);
 - ↪ Clause 5.3: Laboratory Equipment (34);
 - ↪ Clause 4.14: Internal audits (16);
 - ↪ Clause 5.8: Reporting of results (16);
 - ↪ Clause 4.15: Management review (13); and
 - ↪ Clause 5.1: Personnel (13).
 - ↪ Clause 4.9: Identification and control of nonconformities (10)
 - ↪ Clause 4.1: Organization and management (7);
 - ↪ Clause 4.6: External services and supplies (7);
 - ↪ Clause 4.10: Corrective actions (7)

Trends from Initial Assessments

NCS vs Clause of ISO 15189



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.

Lessons Learnt for the benefit of ML

- ❑ **Internal audits** are conducted to determine whether all activities in the quality management system, including pre-examination, examination and post examination procedures conform to ISO 15189 and are implemented, effective and maintained (Clause 4.14.5).
- ❑ It is not uncommon to see laboratories conducting internal audits on just part of the system and neglecting the rest.
- ❑ It is also not uncommon to see laboratories conducting internal audits and then fail to
 - ↳ Undertake root cause analysis on nonconformities raised
 - ↳ Close the nonconformities within the stated time frame
 - ↳ Follow up on outstanding issues.

Lessons Learnt for the benefit of ML

ML seeking accreditation from SADCAS should be aware of the following

□ **SADCAS requirements**

- ✦ It is mandatory to understand SADCAS documents
- ✦ Downloadable on SADCAS website www.sadcas.org
- ✦ Documents detail accreditation process, technical requirements, technical guidance and SADCAS policy

□ **Validation/Verification of methods**

- ✦ Some laboratories could not distinguish between **verification** of examination procedures and **validation** of examination procedures
- ✦ Did not set acceptance criteria for approval of validation/ verification reports.
- ✦ Laboratories are required to **validate** nonstandard methods, laboratory designed and standard methods modified or used outside their intended use. If a laboratory uses standard methods (without modifications), such methods shall be subject to independent verification before being introduced into routine use

Lessons Learnt for the benefit of ML

□ Vertical Assessment

- ✦ Lack of understanding why assessors have to do a lot of writing and ask a lot of questions during the assessment.
- ✦ There is a general perception that assessors only record negative observations about the laboratories. Assessors are required to record every observation (positive or negative) in a way that can be understood by the SADCAS AAC. The AAC determines whether a thorough and complete assessment was performed based on the documents and forms submitted by the assessment team.
- ✦ This follows that assessors must ensure assessment forms/documents are comprehensive so that the AAC would arrive to the same conclusion as then. It is the AAC that grants accreditation. The assessment team can only give a recommendation.

Lessons Learnt for the benefit of ML

□ Nonconformities (NCs)

- ✦ Some laboratories view raising NCs negatively
- ✦ The purpose of raising NCs is continuous improvement.
- ✦ Laboratory staff perceive signing the corrective action and clearance report as admission of guilt. Signing the form is acknowledging that the finding has been recorded accurately and the wording is understood. It is not accepting the responsibility for the NC
- ✦ The finding recorded during the assessment is not necessarily an NC but a comment recorded by an assessor when noting a situation or action which may prejudice the organisation's ability to meet SADCAS accreditation requirements.
- ✦ The assessment team will convert the finding to an NC ONLY if the subject of the particular finding is deemed to cast doubt on the organisation's ongoing ability to meet SADCAS accreditation criteria.
- ✦ The NC will only be classified as Major if it indicates that the technical competence of the organization to continually perform work within the limits of its proposed/approved accreditation schedule/scope has either been or is in imminent danger of being seriously compromised.

Lessons Learnt for the benefit of ML

□ Management requirements

- ✚ There is a general perception in laboratories that technical requirements are more important than management requirements and that accreditation will be granted as long as technical requirements are met.
- ✚ The truth of the matter is accreditation cannot be granted if the organization cannot demonstrate that it has the ability to **consistently** produce results that meet the requirements of customers (patients and clinician).
- ✚ This ability can be demonstrated by developing and implementing a Quality Management System and continually improving its effectiveness.

Lessons Learnt for the benefit of ML

□ Transition to ISO 15189

- ✦ ISO 15189: 2007 was revised and the new edition of the standard was published on 1 November 2012.
- ✦ TR 10 outlines SADCAS Policy for ISO 15189 transition for those medical laboratories that had implemented a system based on ISO 15189: 2007.
- ✦ TR 10 is available and can be downloaded from the SADCAS website
- ✦ According to TR 10 applications for accreditation received after 30 June 2014 are assessed based on the new version of the standard.
- ✦ The agreed transition period to the new version of the standard is 3 years and is concluded on 1 March 2016.
- ✦ If by 1 November 2015 SADCAS cannot confirm compliance to the new version then accreditation to the 2007 version shall be suspended on 1 March 2016.
- ✦ Five of the accreditation certificates issued by SADCAS were to the 2007 version of the standard whilst CIMAS is the only one accredited to the 2012 version of the standard.

Conclusion

- ❑ Throughout the world many countries now rely on accreditation as a means of independently evaluating competence.
- ❑ Accreditation is the strategy for a medical laboratory to achieve this.
- ❑ SADCAS was established to meet the accreditation needs of 13 SADC Member States. A lot has been invested in SADCAS.
- ❑ In line with its value proposition, SADCAS is there to deliver confidence, assure competency and guarantee quality
- ❑ SADCAS is ready to meet your accreditation needs.



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