

SADCAS

SOUTHERN AFRICAN DEVELOPMENT COMMUNITY



THE PIONEER

SADCAS NEWSLETTER

MARCH 2023 EDITION ISSUE 44

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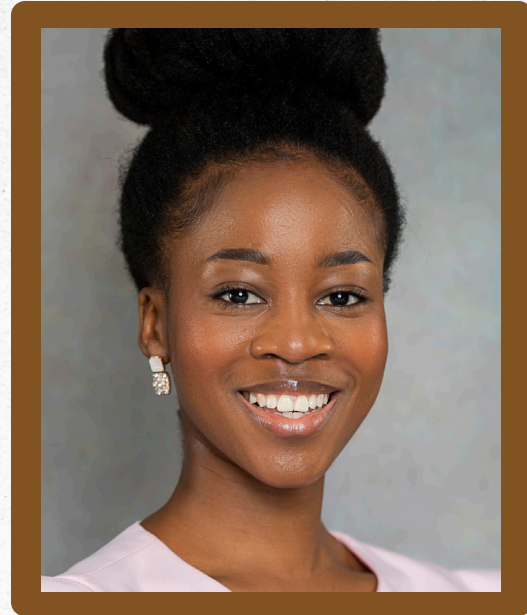
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Mr Xavier Mugari



Ms Nicole Sekgoma

We are pleased to present Issue 44 of the SADCAS Newsletter (March 2023 Edition) to keep our readers updated on accreditation activities in the region and beyond. Inside you will find news on accreditation activities undertaken by SADCAS and developments in the field of accreditation.

Following the publication of ISO 15189:2022 - Medical Laboratories – Requirements for quality and competence, SADCAS developed transition policy in line with International Laboratory Accreditation Cooperation (ILAC) that provides a 3-year transition period. The transition policy is available on the website: <https://www.sadcas.org/sadcas-policy-iso-151892022-transition>

At the end of the transition period, accreditation of a medical laboratory to the old standard - ISO 15189:2012 will not be recognised under the ILAC Arrangement and all organisations accredited to ISO 15189:2012 must have been assessed and accredited to the new standard. Training on ISO 15189:2022 will be launched in May 2023. Medical Laboratories

are strongly encouraged to familiarise with the transition policy to ensure smooth changeover to the new standard within the transition period.

June 9th 2023 marks World Accreditation Day (#WAD2023), a global initiative established by ILAC and IAF to promote the value of accreditation. This year's theme, **Accreditation: Supporting the Future of Global Trade** focuses on how accreditation supports the United Nations Sustainable Development Goals (SDGs) 1, 2, 3, 5, 8, 9, 10, 14, and 17. As in previous years, SADCAS will join the rest of the world in celebrating this global initiative.

Enjoy the reading!

ZAMBIA BUREAU OF STANDARDS - CERTIFICATION SERVICES HAS ATTAINED ACCREDITATION

ZABS-Certification Services (ZABS-CS) is now a SADCAS accredited certification body. To celebrate, an Accreditation Certificate Handover Ceremony was held at a local hotel in Lusaka, Zambia on 2 March 2023. The accreditation certificates were received by the Permanent Secretary in the Ministry of Commerce, Trade and Industry - Mr John Mulongoti, on behalf of ZABS.



SADCAS Chief Executive Officer delivering her speech at the official Accreditation Certificate Handover Ceremony held at a local hotel in Lusaka, Zambia on 02 March 2023.

The ZABS-CS, situated at Lechwe House South End, Freedom Way, Lusaka, Zambia was granted accreditation to the following scopes:

- Product Certification to ISO/IEC 17065:2012 and ISO/IEC 17067:2013 Type 5, IAF Codes 3, 12 and 16; accreditation number **PROD-CERT 001. (Flour, Beverages, Detergents and Cement)**
- Quality Management Systems to ISO/IEC 17021-1:2015 and ISO/IEC 17021-3:2017 (Certification to ISO 9001:2015), IAF Codes 2, 16, 17 and 34; accreditation number **QMS-CERT 006;**
- Occupational Health and Safety Management Systems to ISO/IEC 17021-1:2015 and ISO/IEC TS 17021-10:2018 (Certification to ISO 45001:2018), IAF Codes 2 and 17; accreditation number **OHS-CERT 002**

The certificates which were issued for each sub-scope on 28th December 2022, are valid for 5 years and will expire on 27th December 2027, prior to which the CB will be expected to apply for renewal of accreditation.

ZABS-CS becomes the first Certification Body (CB) to be accredited by SADCAS in Zambia. In fact, ZABS-CS is the first CB in the region to be accredited by SADCAS under the **SADCAS Product Certification Scheme**. ZABS-CS is the sixth Certification Body among the 14 SADC Member States serviced by SADCAS to be accredited by SADCAS under the sub-scope of Quality Management Systems Certification and the second to be accredited under the sub-scope of Occupational Health and Safety Management Systems.

ZABS' vision of being **"A Credible and Proactive Institution in providing Standardization and Quality Assurance Services"** is now underpinned by internationally recognized accreditation provided by SADCAS. This accreditation is a guarantee for reliable certification of management systems and products implemented by ZABS clients which serves as assurance of the quality of products from Zambia.



Permanent Secretary in the Ministry of Commerce Trade & Industry, Zambia Mr John Mulongoti receiving ZABS-Certification Service Accreditation Certificate from SADCAS Chief Executive Officer Ms Eve Christine Gadzikwa

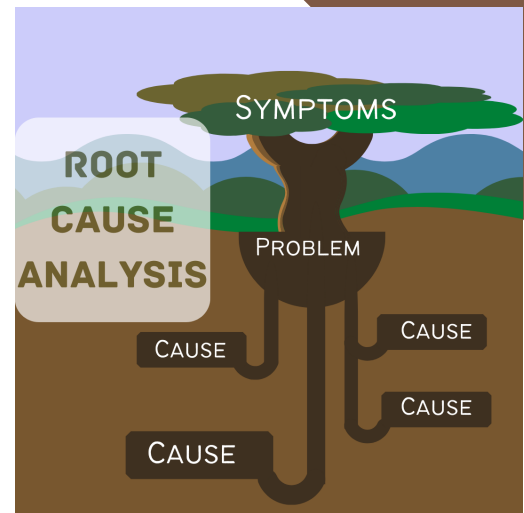


Permanent Secretary, ZABS Senior Management, together with SADCAS Chief Executive Officer pose for photos at the end of the event.

CONGRATULATIONS ZAMBIA BUREAU OF STANDARDS CERTIFICATION SERVICES FOR THIS NOTABLE ACHIEVEMENT

NEW TRAINING COURSE ALERT: ROOT CAUSE ANALYSIS

- The Southern African Development Community Accreditation Service (SADCAS) is pleased to announce the launch of a new training course on Root Cause Analysis (RCA). Understanding RCA and the corrective action process is a requirement of key accreditation standards such as ISO/IEC 17025, ISO 15189, ISO/IEC 17020, ISO/IEC 17021-1, ISO/IEC 17065 and ISO/IEC 17043.
- Consisting of presentations, exercises, group work, scenarios and role-playing, this 3-day course is designed to provide participants with an in-depth understanding of how to analyze a system and identify the root causes of nonconformities. This course will significantly improve the approach to effective management of corrective actions leading to continuous improvement.
- The objective of the RCA course is to provide participants with knowledge and skills to manage incidents/nonconformities, with specific emphasis on the identification of the root cause and applying RCA methodologies. This course will enable participants to understand root cause analysis as a technique for ascertaining and analyzing the causes of nonconformities and determine appropriate corrective actions to be undertaken and prevent recurrences. Participants will also acquire skills for continuously improving the effectiveness of quality management systems through implementing effective corrective actions. The course will provide and familiarize participants with a systematic, structured and evidence-based RCA process that can be embedded into their organizations.



Format of the Course: Face to face or Virtual via Zoom Video Conferencing

For any further information, please contact: The SADCAS Training Administrator, **Mr. Mogae Molaoa**

Tel: +267 313 2909/ 313 2910; Mobile: +267 77 833 409; Email: mmolaoa@sadcas.org; Website: www.sadcas.org



SADCAS CHIEF EXECUTIVE OFFICER PAYS A COURTESY CALL TO THE OFFICE OF THE PERMANENT SECRETARY AT THE MINISTRY OF COMMERCE TRADE AND INDUSTRY, LUSAKA, ZAMBIA



Permanent Secretary in the Ministry of Commerce Trade & Industry, Zambia Mr John Mulongoti receiving token of appreciation from SADCAS Chief Executive Officer Ms Eve Christine Gadzikwa

From 1 - 3 March 2023, the SADCAS CEO – Eve Christine Gadzikwa, visited the Republic of Zambia and paid a courtesy call to the office of the Permanent Secretary in the Ministry of Commerce Trade and Industry, Mr John Mulongoti. This was her first visit to Zambia since her appointment as SADCAS CEO and it coincided with ZABS-Certification Services (ZABS-CS) Accreditation Certificate Handover Ceremony.

The visit was an opportunity to update the Permanent Secretary on accreditation developments in Zambia, to reaffirm SADCAS commitment to support Zambia in terms of its accreditation needs and to underscore the importance of accreditation in terms of national authorities and regulators, businesses and consumers.

In terms of national authorities and regulators the SADCAS CEO reiterated that:

- Accreditation moderates the need for additional legislation as well as reduces the risk of unintended consequences.
- Internationally recognized certification provides regulators with a robust and credible framework to accept accredited certifications from overseas accredited certification bodies with an equivalent level of confidence as if carried out in the local economy.

In relation to businesses, she highlighted that:

- Internationally recognized certifications allow certificates to be recognized around the world thus reduces the risk of products being rejected by international trading partners, and the need to have products re-evaluated on entry into each country.
- Supports businesses in the supply chain against potential liability claims.
- Accreditation serves as a credible and effective marketing tool that enhances market access by providing confidence through assuring competence and impartiality confirmed by authoritative body such as SADCAS.
- In terms of consumers, she emphasised that;
- Consumer confidence can be gained from products that are accompanied by an accredited certificate of conformity.
- Provides assurance that products placed on the market from whichever country of origin meet quality and safety standards.

In a nutshell, the CEO reinforced that accreditation makes good business sense, enhances confidence in locally produced products and services in a country, supports regulators and also at a national level, contributes to economic development.

SADCAS HOLDS 16TH ANNUAL NATIONAL ACCREDITATION FOCAL POINT (NAFP) MEETING

National Accreditation Focal Points (NAFPs) were established in SADC Member States using SADCAS services between 2003 and 2009 except for NAFP-Comoros which was established in October 2019 following the admission of the Union of Comoros as a SADC Member State. In the case of SADCAS, NAFPs are primarily responsible for the promotion of accreditation and marketing of SADCAS services within their respective countries and serve as a channel of information to and from SADCAS.

The NAFPs who are officially appointed by their respective governments, are housed in the national standards bodies or the ministries responsible for trade and/or industry. NAFP offices are manned by one or two officers as follows: Angola (1); Botswana (2); Comoros (1); DR Congo (1); Eswatini (2); Lesotho (2); Madagascar (2); Malawi (2); Mozambique (1); Namibia (2); Seychelles (2); Tanzania (1); Zambia (2) and Zimbabwe (2). This brings the total number of NAFPs to (23). The NAFPs meet once a year to review the NAFP model, to evaluate their performance, to hear first-hand the challenges that NAFPs face in executing their roles and responsibilities, to find ways of enhancing their effectiveness, as well as to develop a Marketing Plan.

The meeting was held on 21-22 November 2022 and was attended by eleven (11) NAFPs and three (3) SADCAS staff, namely, Dr Christine Gadzikwa – SADCAS CEO, Mr Mogae Molaoa - SADCAS Training Administrator and Mr Xavier Mugari- SADCAS Quality Manager. National Accreditation

Focal Points from Botswana (2), Eswatini (2), Lesotho (1), Malawi (1), Seychelles (1), Comoros (1), Namibia (1) and Zimbabwe (2) attended the meeting

The meeting developed the Framework for the 2023/24 Marketing Plan, reviewed Government Contributions for the periods 2012 – 2017 and 2017 – 2022, reviewed a summary of quarterly reports for the period 1 April 2022 to 30 September 2022, conducted an ISO/IEC 17011:2017 training as well as training on the SADCAS Quality Management System. This meeting was also used as an opportunity to consider the 2023/24 training needs as well as other submissions from the NAFPs that can improve the delivery of SADCAS training services in their respective member states.



NAFPs posing for a group photo with SADCAS CEO Dr Eve C. Gadzikwa (far right)

The meeting was very interactive with NAFPs committing to step up their promotion and marketing efforts so as to realize the objectives set in the SADCAS 2023/24 Marketing Plan.

The NAFPs thanked SADCAS for arranging the annual meeting and have urged their colleagues who did not attend the meeting to avail themselves in 2023 as this is an important opportunity to provide feedback, to network and share ideas.



Most Improved NAFP for 2022 – NAFP Botswana Represented by Ms Boikhutso Pheto (2nd NAFP)



Most Effective NAFP for 2022 – NAFP Seychelles Represented by Ms Corina Chang Ty-Sing (2nd NAFP)

INVITATION TO REGISTER TECHNICAL EXPERTS - PRIORITIZED SCOPES

SADCAS invites experts with specific technical expertise in the newly introduced Medical Imaging Accreditation Scheme (MIAS) and any of the accreditation schemes currently offered by SADCAS to be registered as Technical Experts. A Technical Expert is a person assigned by SADCAS to an assessment team to provide specific knowledge or expertise within the scope of assessment. A Technical Expert works under the supervision of an experienced Team Leader or Technical Assessor.

Technical Experts with experience in the following;

- General Radiography
- Computerised Tomography (CT)
- Magnetic Resonance Imaging (MRI)
- Ultrasound (US)
- Interventional Radiography (IR)
- Nuclear Medicine and Molecular Imaging (NM)
- Mammography



Testing Laboratory Accreditation Scheme (TLAS)

Forensic analysis
DNA Testing
Civil Engineering
Mechanical Engineering
Electrical Engineering
Radiation Dosimetry
Non-destructive Testing
Textile Testing



Medical Laboratories accreditation Scheme (MLAS)

Histopathology
Cytology
Parasitology
Endocrinology
Immunophenotyping
Blood Banking



Veterinary Laboratory Accreditation Scheme (VLAS)

Mycology
Parasitology
Helminthology
Protozoology
Histology
Cytology
Toxicology
Pathology



Pharmaceutical Laboratory Accreditation Scheme (Under TLAS)

Microbiology
Chemical
Toxicity
Medical Devices Testing



Calibration Laboratory Accreditation Scheme (CLAS)

Viscosity
Electrical – DC low frequency
Electrical RF
Fibre Optics
Force/ Hardness/ Torque
Flow
Humidity
Radio Activity
Photometry
Radio frequency
Time and frequency
Wind speed
Acoustics and Vibration
Radiation Dosimetry Metrology



Legal Metrology Accreditation Scheme (LMAS)

Verification
Repair and Maintenance
Inspection of Products for Sale
Quantity Control
Type Testing
OIML Certification Scheme
Certification of Verifiers
Certification of Repairers

Technical experts from private and public sectors as well as from technical institutions are invited to apply by completing SADCAS F 26: SADCAS Assessor/Technical Expert Information Record which can be downloaded from the SADCAS website link [http://Microsoft Word - SADCAS F 26 - SADCAS Assessors-Technical Experts Information Record \[Issue 5\] SADCAS](http://Microsoft Word - SADCAS F 26 - SADCAS Assessors-Technical Experts Information Record [Issue 5] SADCAS) will review and evaluate all applications received to ensure that the experts have the requisite qualifications, technical knowledge and experience required by SADCAS.

Applications shall be addressed to:
Mrs Pinkie Malebe SADCAS - Technical Manager
Email: pmalebe@sadcas.org

MALAWI APPOINTS 2ND NATIONAL ACCREDITATION FOCAL POINT

The government of Malawi appointed Ms Gladys Chimpokosera as 2nd National Accreditation Focal Point (NAFP) for Malawi. The appointment was confirmed in February 2023. Ms Chimpokosera replaces Mrs Margaret Sauzande, who was NAFP2 for Malawi until she retired in June 2022. She will therefore join Masautso Ngamwane, who is currently NAFP1 for Malawi.

Ms Chimpokosera is currently working in the Ministry of Trade and Industry as Deputy Director of Industry. She has worked in the ministry for 18 years, rising through the position of Assistant Director of Industry to her current post, to which she has just been promoted in March 2023.

As Deputy Director of Industry, her section is responsible for setting of product standards and quality management, exploring TBT and devising appropriate measures, advising on fiscal and non-fiscal incentives of enhancing production and reducing cost of production hence creating an enabling environment for private sector effectively operate. The section is also responsible for the provision of incentives and monitoring the implementation incentive policies and strategies with relevant institutions.

In addition to other duties as spelled out in the NAFP annual work plan, as NAFP2, Ms Chimpokosera will be responsible for ensuring that government contribution to SADCAS is timely made.

Ms Chimpokosera is a holder of International Masters in Business Administration degree with a major in International Business Management obtained from National Chengchi University, Taiwan, Republic of China (RoC) in 2004 and a Bachelor of Arts (Public Administration) degree with a major in Public Administration and minor in Economics obtained from University of Malawi, Chancellor College in 1993.

With the vast experience that Ms Chimpokosera has in the fields of trade, industry, standardization and quality management, she will be instrumental in the office of NAFP.

Let us welcome Ms Chimpokosera to the family.



Ms Gladys Chimpokosera

SADCAS HOLDS 5TH ASSESSOR CONCLAVE

The SADCAS 5th assessor conclave was held remotely on 25 January 2023. The assessor conclave was attended by over 100 assessors and Technical Experts.

HSADCAS registered assessors and Technical Experts carry out assessments across the SADC member states and beyond on behalf of SADCAS. The assessment team makes recommendations to the Accreditation Approvals committee for accreditation decision. As at 31 December 2022 SADCAS had registered 129 Technical Assessors 50 Team Leaders and 26 Technical Experts.

The assessor conclave started with the opening and welcome remarks from the SADCAS CEO Ms Eve Gadzikwa. The objective of the assessor conclave was to update assessors:

- On developments at SADCAS;
- Revised SADCAS QMS Documents
- Revised ISO 15189
- SADCAS Transition plans
- Findings from the Internal Audit IA.09 relating to assessors/ assessments;
- SADCAS digitalisation Project
- Electronic Filing and submission of assessment packs
- Assessments
- Assessor issues which included; Travel and logistics, Feedback from assessors

Ms Gadzikwa reported that the Inaugural CEO Mrs Maureen Mutasa had retired on 30 June 2022 and that she had joined SADCAS on the 1st of August 2022. Currently SADCAS had a staff compliment of 17 staff members (14 Full time and 3 Graduate interns).

Mr Mugari the Quality Manager gave a report on the revised ISO 15189:2022 – Medical Laboratories – Requirements for Quality and Competence which was published on 6 December 2022. The standard was updated to align with the structure of ISO/IEC 17025:2017 which was aligned to ISO 9001:2015. The revised standard is patient-focused and risk-based as this is a clinical standard for a service that is key to the patient pathway.

He reported that ILAC had set a 3-year transition period for medical laboratories to transition to ISO 15189:2022. SADCAS was going to publish the ISO 15189:2022 Transition policy by end of January 2023. The assessors will be required to monitor the implementation plans of medical Laboratories during the assessments. It is important that all Medical Laboratories transition by 5 December 2025

Mrs Eva Muronda; SADCAS Scheme coordinator – Medical Laboratories Accreditation Scheme gave feedback on the findings of the SADCAS internal Audit conducted from 21 September to 16 November 2022. The audit was conducted by 8 members assessing all SADCAS schemes including the

network and website.

The audit team concluded that SADCAS has established and maintained its management system in line with the requirements of the ISO/IEC 17011:2017, ILAC & IAF requirements and has demonstrated to the audit team that it has the ability to systematically achieve the requirements for the services within the scope of its activities and in accordance with its policy, objectives and procedures.

The Management System of SADCAS and the accreditation schemes are well managed, with procedures and records generally easily retrievable and available. SADCAS staff demonstrated the required knowledge, skills and competencies in their respective areas of responsibility. A total of 8 Comments (CM), and 19 non-conformances (NC) were raised.

Mr Victor Mudembe SADCAS Scheme Coordinator CBAS/IBAS/CLAS/LMAS gave an update on the SADCAS digital transformation project aimed at Increasing efficiency and process optimization with the aim of improving the customer experience. SADCAS is embarking on making greater use of new technologies and digitization to deliver accreditation and training services in a more efficient and effective manner expanding the use of digital services by its personnel, registered assessors, technical experts and accredited conformity assessment bodies. This will result in the digitalization and automation of repetitive processes and procedures.

Mrs Pinkie Malebe gave an update on the resumption of onsite assessments; Group assessments and selection of assessment teams, Responsibilities of assessment teams; assessor conduct; Clearance of nonconformities and conducting document reviews as teams.

The conclave gave refresher trainings on Metrological Traceability and Statement of Conformity and Decision rules. Mr Mundembe trained on Metrological Traceability and Mr Mikhail Sakharov – A metrology specialist, Research and Development Manager at LMC Solutions South Africa trained on Decision rules.

The conclave had breakaway sessions for specific schemes. The breakaway sessions discussed the following areas:

- Update on developments at regional and International Level
- Feedback from advisory Committee meetings
- Scheme specific issues

The assessor conclave was fruitful and a success. The conclave gave a platform for continued communication with the assessors and Technical Experts ensuring the integrity and consistency of SADCAS assessments and continual improvement of SADCAS services.

UNDER THE EYES OF AN ASSESSOR: MARIAM TEFFO

Miriam Teffo is a medical technologist based in South Africa. She has a Bachelor in Biomedical technology specializing in Immunology as well as more than 25 years of service working in both government and private laboratories where she gained extensive knowledge and experience.



Miriam Teffo

In 2013, she completed training through SANAS on ISO 15189:2012 as a technical assessor. She qualified in 2014 and was incorporated as an independent contractor to perform assessments for SANAS throughout South Africa.

Miriam transitioned to SADCAS in 2022 and has since then performed assessments in various SADC countries.

Performing SADCAS assessment involves extensive travelling - presenting assessors with the privilege of experiencing different cultures. It is pleasant to witness the different approaches countries are taking towards implementation of ISO 15189 standard.

The effort that medical facilities are putting towards implementing quality management system is quite commendable, it is observed that many of the new accredited laboratories are maturing in the maintenance of quality management system

STAFF NEWS

NICOLE SEKGOMA PROMOTED TO ACCREDITATION ADMINISTRATOR POSITION UNDER TLAS

Nicole Sekgoma, a University of Cape Town BSc (Biochemistry) degree holder, joined SADCAS as Intern, Marketing and Communication in January 2022. She was promoted to Accreditation Administrator for IBAS, CBAS, LMAS and CLAS from 1 October 2022. As of 1 April 2023, she commenced her position as Accreditation Administrator for TLAS – where she can better apply herself as a STEM graduate.

“The SADCAS office culture inspires me to produce my best work through the guidance of my colleagues and supervisors. I attribute my growth in this organization to the guidance and support of my colleagues and supervisors. I am committed to and excited about continuing to contribute to the SADCAS objectives.” she said.



Nicole Sekgoma

VIKASH RAMESSUR JOINS SADCAS AS ASSESSOR FRENCH.



Vikash Ramessur

SADCAS - being a multi economy organisation, unites people with different cultures and languages on one platform so as to facilitate trade. One of the objectives of SADCAS is effective and efficient communication with SADC member states for service delivery.

To strengthen the existing team, Mr Vikash Ramessur was recruited as Assessor French as from March 2023. Being bilingual in both spoken and written French and English, he will be vested with the responsibility of assisting in the accreditation process of French speaking member states. He holds a Master degree in Forensic Science and holds 22 years of experience in the Forensic Human DNA Analysis field. He also assumed the responsibility of Quality Manager of the Mauritius Forensic Science Laboratory. He is also a registered Technical Assessor for SADCAS and the Mauritius Accreditation Service where he assisted in the accreditation process of a few facilities.

SÉRGIO MACHAVA JOINS SADCAS AS ASSESSOR PORTUGUESE

SADCAS plays a key role towards the achievement of SADC goals in trade facilitation and in the protection of health, safety and the environment, by assuring technical competence through accreditation.

Sérgio Machava is from Mozambique and was recruited to join SADCAS as of March 2023, and he will be entrusted with the responsibility of marketing SADCAS services and assisting with the accreditation process in Portuguese speaking SADC member states such as Angola and Mozambique.

Prior to Joining SADCAS, he worked as Temperature Metrologist at INNOQ- a National Institute for Standardization and Quality in Mozambique for 15 years. He also worked as a researcher at the Water Research Institute-Ministry of Science, Technology and High Education.

He holds a Master's degree in Environmental Management, a Bachelor degree in Environmental Sciences and a Vocational Certificate in Electronics.

He has been trained as SADCAS Technical Assessor, for assessment of the calibration and testing laboratories, according ISO/IEC 17025:2017.

He is very excited to start his new journey with SADCAS family.



Sérgio Machava Junta

SADCAS PUBLISHES ISO 15189:2022 TRANSITION POLICY

This serves to announce the publication of SADCAS TR 29 - SADCAS Policy on ISO 15189:2022 Transition, Issue 1 by the Southern African Development Community Accreditation Service (SADCAS).

ISO 15189:2022. The document applies to ISO 15189:2012 accredited Medical Laboratories and new applicants under the Medical Laboratories Accreditation Scheme (MLAS). The published document is available on the SADCAS website: <https://www.sadcas.org/sadcas-policy-iso-151892022-transition>. Medical Laboratories are encouraged to familiarise themselves with the SADCAS Transition Policy and note the important dates below:

The purpose of this document is to define the SADCAS policy on ISO 15189:2022 and the process to be followed by Medical Laboratories to ensure successful transition to

Date Accredited	Scheme
6 December 2022	ISO 15189:2022 - Medical laboratories — Requirements for quality and competence published.
1 July 2023 onwards	New applications for accreditation shall be based on ISO 15189:2022. Applications based on ISO 15189:2012 shall not be accepted.
Up to 31 March 2024	Laboratories that have their annual periodic assessment/reassessment within this period can choose to be assessed to the 2022 version or remain with the 2012 version.
31 December 2023	Deadline for submission of Transition Plans by all ISO 15189:2012 accredited facilities.
1 April 2024 onwards	All Assessments shall be conducted in accordance with ISO 15189:2022.
6 December 2025	ISO 15189:2012: Medical Laboratories – Requirements for Quality and Competence ceases to be valid. Medical Laboratories that have not transitioned to the 2022 version by this date will no longer be able to claim accreditation for their laboratory activities.

MEDICAL LABORATORIES CRITERIA DOCUMENTS PUBLISHED

This serves to announce the publication of SADCAS TR 29 - SADCAS Policy on ISO 15189:2022 Transition, Issue 1 by the Southern African Development Community Accreditation Service (SADCAS).

SADCAS published the following two documents in February 2023 for Medical Laboratories:

SADCAS TR 27- Criteria for Accreditation of Microbiology in Medical Laboratories

[hyperlink](#)

SADCAS TR 28 – Criteria for Accreditation of Blood Transfusion Services

[hyperlink](#)

The purpose of the documents is to define the general, technical and specific requirements to be met by laboratories in the field of Microbiology and Blood Transfusion Science requiring accreditation to ISO 15189.

The documents elaborate on the following aspects of the fields of Microbiology and Blood Transfusion; namely:

- Examination procedures
- Reporting of results
- Laboratory Equipment and reagents
- Laboratory Safety and Environmental conditions

Both documents are publicly available on the SADCAS website www.sadcas.org.

SADCAS AT THE FOREFRONT OF TRANSITION TO ISO 15189:2022 REVISED STANDARD

“After 3 years of work under ISO TC 212 Workgroup 1, Quality and Competence in the Medical Laboratories, input from over 30 countries and contribution of 60 plus global experts, the ISO 15189:2022 was finally published on 06 December 2022. This 4th edition replaces ISO 15189:2012 which was technically revised taking into account changing needs of patients and laboratory users. As at 31 December 2022 only 680 Medical Laboratories in SADC were accredited to the 2012 version. This was hardly enough to meet the quality and competence requirements to assure confidence in the test results.”

The purpose and scope of ISO 15189 is therefore to promote the welfare of patients and satisfaction of laboratory users through confidence in quality & competence in medical laboratories.

In appreciating the extent of the change in the new standard, one needs to compare with the 2012 version. A bird's eye view of the new revised standard reveals that, the structure of the new standard is a departure from the 3rd edition that only had two auditable clauses compared to the new standard that has 5 auditable clauses. Another point of departure from ISO 15189:2012 is that, point of care testing (POCT) is now totally integrated to the new revised standard, which means ISO 22870:2016 has been withdrawn by ISO.

The main emphasis of the new version is in terms of risk and how risks impact the patient. ISO 22367:2020 is a companion standard which covers the application of risk. Overall emphasis of ISO 15189:2022 is on the standard being risk based, patient focused and encourages continuous improvement within medical laboratories. The Standard is aligned to the revised ISO 9001:2015 which in turn led to a revision of ISO 17025:2017 and now follows a similar structure in how it is organised.

The new standard is organised into 8 parts, 5 of which are auditable clauses;

- Clause 4. General Requirements
- Clause 5. Structural and Governance Requirements
- Clause 6. Resource Requirements
- Clause 7. Process Requirements
- Clause 8. Management System Requirements

In addition, ISO 15189 is now also aligned with ISO 22367:2020 Medical laboratories — Application of risk management to medical laboratories, ISO 15190- Laboratory Safety, ISO 20658 Sample Collection and Transport.

One of the other notable changes from the 2012 standard is that, 2022 version is far less prescriptive, which means there is more flexibility as to how to meet and evidence the requirements set out in the document. For instance, the new revised standard does not prescribe the use of a quality policy.

The implications of all these changes place a significant burden on national policy makers and regulators of medical facilities in terms of providing the needed resources to implement the quality and risk management requirements for accreditation which need to be defined in the National Quality Infrastructure Policies.

There are also implications at operational level where, medical laboratory leadership is now required to properly train laboratory directors and technical personal in terms of risk management approach. Competence requirements are also needed on the concept of how clinical decision making can be used as a factor when performing risk assessments. Risk also incorporates 'equipment risk' and how medical laboratories will safeguard the health and safety of patients and laboratory personnel. In addition, Point of Care Testing (POCT) now falls under the 15189: 2022 standard, meaning that requirements to operate POCT now falls under the ambit of medical laboratory oversight.

The new revised standard also has accreditation implications. SADCAS has taken note of all these exciting developments and decided to be in the forefront of getting ready for the transition. The first step was to understand the accreditation requirements by participating in a 15189:2022 Transition Training. The entire team of SADCAS experts and medical laboratory assessors allocated time to be trained and understand what it takes to get SADCAS and its clients ready for the transition to ISO 15189:2022 over the next 3 year period.



SADCAS Staff and Assessors pose for a photo after successfully completing ISO 15189:2022 Training

In line with SADCAS core values of excellence and innovation, our clients are at the heart of everything we do. It is for this reason that, SADCAS having announced the publication of 15189:2022 Medical Laboratories-Requirements for Quality & Competence on our official website on 14th December 2022, proceeded to initiate the development and publication of SADCAS TR 29 - SADCAS Policy on ISO 15189:2022 Transition, Issue 1 by the Southern African Development Community Accreditation Service (SADCAS) on 24th February 2023.

The purpose of the policy is to define the SADCAS-policy on ISO 15189:2022 and the process to be followed by Medical Laboratories to ensure successful transition to ISO 15189:2022. The document applies to ISO 15189:2012 accredited Medical Laboratories and new applicants under the Medical Laboratories Accreditation Scheme (MLAS). The published document is available on the SADCAS website: <https://www.sadcas.org/sadcas-policy-iso-151892022-transition>.

Date Accredited	Scheme
6 December 2022	ISO 15189:2022 - Medical laboratories — Requirements for quality and competence published.
1 July 2023 onwards	New applications for accreditation shall be based on ISO 15189:2022. Applications based on ISO 15189:2012 shall not be accepted.
Up to 31 March 2024	Laboratories that have their annual periodic assessment/reassessment within this period can choose to be assessed to the 2022 version or remain with the 2012 version.
31 December 2023	Deadline for submission of Transition Plans by all ISO 15189:2012 accredited facilities.
1 April 2024 onwards	All Assessments shall be conducted in accordance with ISO 15189:2022.
6 December 2025	ISO 15189:2012: Medical Laboratories – Requirements for Quality and Competence ceases to be valid. Medical Laboratories that have not transitioned to the 2022 version by this date will no longer be able to claim accreditation for their laboratory activities.

SADCAS TR 29 was prepared by the SADCAS Technical Manager and approved by the SADCAS Chief Executive Officer on 21 February 2023.

NEW ACCREDITATIONS, SCOPE EXTENSIONS, SUSPENSIONS AND WITHDRAWALS FROM 1 NOVEMBER TO 31 MARCH 2023

	Organization and Location	Date Accredited	Scheme	Accreditation Number	New Accreditations	Renewal of Accreditation	Scope Extensions	Scope Reduction	Withdrawal of Accreditation
1	Zambia Bureau of Standards QMS	2022.12.28	Certification ISO/IEC 17021-1: 2015	QMS-CERT 006 OHS-CERT 002	IAF Codes 2,16,17,34 IAF Codes 2,17				
2	Zambia Bureau of Standards Product Certification	2022.12.28	Certification ISO/IEC 17065: 2012	PROD-CERT 001	IAF Codes 3, 12, 16				
3	TBS Metrology	2022-12-13	Calibration to ISO/IEC 17025:2017	CAL-12 002	Pressure				
4	Lancet Laboratories - Eswatini	2023/01/31	Medical to ISO 15189:2012	MED 006			Molecular Biology		
5	National Tuberculosis Reference Laboratory, Zimbabwe	2023/02/17	Medical to ISO 15189:2012	MED 113					
6	Nyamagana District Hospital Laboratory, Tanzania	2023/02/20	Medical to ISO 15189:2012	MED 114					
7	Seko- Toure Regional Referral Hospital Laboratory, Tanzania	2023/03/02	Medical to ISO 15189:2012	MED 115					
8	Zomba Central Hospital Laboratory, Malawi	2023/03/06	Medical to ISO 15189:2012	MED 116					
9	Mzuzu Central Hospital Laboratory, Malawi	2023/03/08	Medical to ISO 15189:2012	MED 117					
10	Rumphi District Hospital Laboratory, Malawi	2023/03/14	Medical to ISO 15189:2012	MED 118					
11	National Tuberculosis Reference Laboratory, Lesotho	2023/03/16	Medical to ISO 15189:2012	MED 119					
12	Lewanika General Hospital Laboratory, Zambia	2023/03/17	Medical to ISO 15189:2012	MED 120					
13	Simiyu Regional Referral Hospital Laboratory, Tanzania	2023/03/22	Medical to ISO 15189:2012	MED 121					
14	Motebang Regional Referral Hospital Laboratory, Lesotho	2023/03-/27	Medical to ISO 15189:2012	MED 122					
15	Pathcare - Roman Catholic, Namibia	2023/03/27	Medical to ISO 15189:2012	MED 123					
16	Pathcare - Lady Pohamba, Namibia	2023/03/27	Medical to ISO 15189:2012	MED 124					
17	Korogwe Town Hospital Laboratory, Tanzania	2023/03/28	Medical to ISO 15189:2012	MED 125					
18	National Microbiology Reference Laboratory, Malawi	2023/03/28	Medical to ISO 15189:2012	MED 126					
19	Patchcare - Otjiwarongo	2023/03/28	Medical to ISO 15189:2012	MED 127					

NEWS ON SERVICES

	Organization and Location	Date Accredited	Scheme	Accreditation Number	New Accreditations	Renewal of Accreditation	Scope Extensions	Scope Reduction	Withdrawal of Accreditation
20	Pathcare - Walvis Bay	2023/03/29	Medical to ISO 15189:2012	MED 128					
21	Patchcare - Windhoek Main Lab	2023/03/29	Medical to ISO 15189:2012	MED 129					
22	Pathcare Ongwediva	2023/03/30	Medical to ISO 15189:2012	MED 130					
23	Haydom Lutheran Hospital Clinical Laboratory	2023/03/30	Medical to ISO 15189:2012	MED 131					
24	NIMRC - Tanga Research Centre	2023/03/31	Medical to ISO 15189:2012	MED 132					
25	Kamuzu Central Hospital Laboratory	2023/03/31	Medical to ISO 15189:2012	MED 133					
26	Vivo Energy, Botswana	2022.12.20	Testing to ISO/IEC 17025:2017	TEST-5 0075	Chemical Testing (Fuel)				
27	Government Analyst Laboratories, Zimbabwe	2023.03.28	Testing to ISO/IEC 17025:2017	TEST-5 0076 & TEST-1 0026	Microbiological and Chemical (Water)				
28	Government Chemist Laboratory Agency - Lake Zone, Tanzania	2023.03.28	Testing to ISO/IEC 17025:2017	TEST-5 0077	Chemical Testing (Water)				
29	BITRI Botswana	2023.03.31	Testing to ISO/IEC 17025:2017	TEST-5 0078	Chemical Testing (Water)				
SCOPE REDUCTIONS/ WITHDRAWAL OF ACCREDITATION									
25	Lancet Laboratories - Eswatini	2023/03/06	Medical to ISO 15189:2012	MED 006					Clinical Chemistry Haematology
RENEWAL OF ACCREDITATION									
26	Zimplats Selous, Zimbabwe	TEST-5 0025	2022-11-01	TEST-5 0025			Chemical - Mineral testing		
27	Gaborone Laboratory Services	2023.03.16	Testing to ISO/IEC 17025:2017	TEST-1 0014 TEST-5 0064			Chemical and Microbiological Testing		
28	National Dosimetry Laboratory, Botswana	2023.03.21	Testing to ISO/IEC 17025:2017	TEST-7 0001			Radiation Dosimetry		
29	Omamanya Laboratory, Namibia	2023.03.15	Testing to ISO/IEC 17025:2017	TEST-3 0002			Civil Engineering		
30	Environmental Management Agency	2023.03.31	Testing to ISO/IEC 17025:2017	TEST-5 0005 TEST-1 0002			Chemical and Microbiological Testing		

THE BUSINESS BENEFITS OF STANDARDS AND ACCREDITATION

There are many cases where standards and accredited conformity assessment help businesses of any size and sector reduce costs, increase productivity and access new markets. They can help to:

- **Build customer confidence that your products are safe and reliable;**
- **Meet regulation requirements, at a lower cost;**
- **Reduce costs across all aspects of your business; and**
- **Gain market access across the world.**

Business Benefits www.business-benefits.org is a website jointly developed by the International Accreditation Forum (IAF), ILAC, International Organization for Standards (ISO), Independent International Organisation for Certification (IIOC), and International Certification Network (IQNet), that showcases these benefits through case studies, research papers, and supporting materials. The examples published on the site cite tangible financial data to evidence the cost savings achieved whether through resource efficiency or meeting regulation at lower cost, the value of accessing new markets, or savings achieved through recognition from organisations such as insurers, regulators or purchasers. The site contains case studies from multinationals such as IBM, Chrysler, and Hitachi to national companies such as Aberdare Cables and Pretoria Portland Cement Company.



**BUSINESS
BENEFITS**
Evidence. Impact. Value.



ENVIRONMENTAL PERFORMANCE



MARKETING MESSAGE



COST SAVINGS



MARKET OPPORTUNITIES



QUALITY IMPROVEMENT



COMPANY PERFORMANCE

The site was launched in October 2017 at the ILAC and IAF conference in Vancouver. Additional case studies will be added in due course to ensure that the site can be a valuable resource to promote the use of standards and accreditation to the business community. The site aims to mirror the success of **Public Sector Assurance**, a similar site that promotes the value of accreditation to policy makers.



SADCAS 
SOUTHERN AFRICAN DEVELOPMENT COMMUNITY ACCREDITATION SERVICE