



SADCAS POLICY MANUAL

Prepared by: SADCAS CEO

Approved by: SADCAS Board of Directors

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ACRONYMS AND ABBREVIATIONS

AAC	Accreditation Approvals Committee
AC	Advisory Committee
AFRAC	African Accreditation Cooperation
APLAC	Asia Pacific Laboratory Accreditation Cooperation
BIPM	International Bureau of Weights and Measurements
BWP	Botswana Pula
CA	Conformity Assessment
САВ	Conformity Assessment Body
CABs	Conformity Assessment Bodies
CBAS	Certification Bodies Accreditation Scheme
CBAS – MS	Management Systems Certification Bodies Accreditation Scheme
CBAS-Prod	Products Certification Bodies Accreditation Scheme
CEO	Chief Executive Officer
CIPM	International Committee for Weights and Measures
CLAS	Calibration Laboratories Accreditation Scheme
СМС	Calibration and Measurement Capabilities
CPD	Continuous Professional Development
EA	European Accreditation
GCP	Good Clinical Practices
GLP	Good Laboratory Practice
HR	Human Resources
IBAS	Inspection Bodies Accreditation Scheme
IAAC	Inter – American Accreditation Cooperation
IAF	International Accreditation Forum
ICT	Information and Communications Technology
IEC	International Electro – technical Commission
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
IT	Information Technology
KCDB	BIPM Key Comparison Database
MLA	Multi – Lateral Arrangement
MLAS	Medical Laboratories Accreditation Scheme
MOU	Memorandum of Understanding
MRA	Mutual Recognition Arrangement
NAFP	National Accreditation Focal Point



NMI	National Metrology Institute
PA	Personal Assistant
PMS	Performance Management System
PR	Public Relations
РТ	Proficiency Testing
QMS	Quality Management Systems
RMP	Reference Materials Producers
SADC	Southern African Development Community
SADCA	Southern African Development Community Cooperation in Accreditation
SADCAS	Southern African Development Community Accreditation Service
SADCMET	SADC Cooperation in Metrology
SI	International System of Units
ТВТ	Technical Barriers to Trade
TLAS	Testing Laboratories Accreditation Scheme
VLAS	Veterinary Laboratories Accreditation Scheme



1. **PURPOSE AND SCOPE**

This document gives an overview of the organization of SADCAS and describes the key elements of SADCAS quality management system based on ISO/IEC 17011:2017: Conformity assessment – requirements for accreditation bodies accrediting conformity assessment bodies. All SADCAS personnel are required to be fully aware of the requirements of SADCAS quality management system and follow it at all times.



2. SADCAS POLICY STATEMENT

The Southern African Development Community Accreditation Service (SADCAS), a subsidiarity institution of the Southern African Development Community (SADC) is a multi-economy accreditation body established in terms of Article 15 B of the Technical Barriers to Trade (TBT) Annex to the SADC Protocol on Trade. It is a non-profit limited company incorporated under the Botswana Companies Act Ch. 42.01.

SADCAS objective is to provide accreditation services to calibration and testing laboratories, certification bodies (management systems /product/ personnel) and inspection bodies operating in those SADC Member States who do not have national accreditation bodies. The accreditation services are aimed at supporting regional and international trade, enhancing the protection of consumers and the environment and improving the competitiveness of SADC products and services.

SADCAS is committed to providing credible and cost-effective value-adding accreditation services.

In order to meet its objectives and commitments, SADCAS:

- Implements a quality management system in compliance with the requirements of ISO/IEC 17011 and of AFRAC, SADCA, ILAC and IAF for the purpose of Mutual Recognition Arrangements (MRA)/ Multilateral Arrangement (MLA). The system is appropriate to the type, range and volume of work performed.
- Shall ensure availability of competent staff, assessors and technical experts for confidence in accredited services.
- Uphold the following core values in service delivery:
 - > Excellence
 - Impartiality;
 - Transparency;
 - Non-discrimination;
 - Integrity;
 - Innovation; and
 - Diversity.
- Periodically reviews its management system for continual improvement.

Since quality is everyone's responsibility, SADCAS Top Management shall ensure that this policy is communicated, understood, implemented and maintained at all levels of the organization and by all concerned.

Signed:

Date: 2023-01-16

Eve Christine Gadzikwa SADCAS Chief Executive Officer



3. SADCAS IMPARTIALITY STATEMENT

Impartiality is one of the core values of SADCAS and the cornerstone of any accreditation service. SADCAS understands the importance of impartiality in carrying out its services and manages conflict of interest and any potential conflict of interest in order to safeguard objectivity and impartiality of accreditation services rendered. SADCAS adheres with the impartiality requirements as specified in ISO/IEC 17011:2017: Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies.

SADCAS is a non-profit limited company incorporated under the Botswana Companies Act Ch. 42.01 and is organized in such a manner as to ensure that impartiality requirements are met.

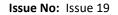
SADCAS offers accreditation services and training in accreditation associated matters. SADCAS does not provide consultancy services to any organization that it offers accreditation. SADCAS does not offer or provide any conformity assessment services that conformity assessment bodies perform.

SADCAS provides external training services in accreditation associated activities. In order not to compromise its impartiality and status in training service delivery, SADCAS offers generic training courses and does not give specific advice for the development of an organization's operations. Furthermore, the training courses delivered or facilitated by SADCAS are not a precondition of accreditation neither do they guarantee accreditation by SADCAS.

In general, SADCAS Committees shall have a balance of interest, be impartial and have no conflict of interest and shall be competent. SADCAS personnel and Committees shall declare all possible conflicts of interest. The SADCAS Board shall ensure that SADCAS company values are addressed in policies and procedures and upheld in operations and service delivery. Applicants and existing clients shall all be treated fairly and in an equitable manner.

In service delivery, SADCAS applies its policies and procedures in a non-discriminatory manner and its services are available to conformity assessment bodies (CABs) operating in those SADC Member States that do not have national accreditation bodies. Where services are offered to those countries outside SADCAS' operational boundaries SADCAS takes into account the ILAC/IAF cross frontier policies. Eligibility to SADCAS services does not depend on size, membership to association or groups and nature of the conformity assessment body (CAB) be it from the public sector or private sector.

SADCAS permanent staff, contracted assessors/technical experts are required to sign a contract with SADCAS that specifies their agreement to impartiality and non-conflict of interest in addition each assessor/expert, Board members, committee members and National Accreditation Focal Points (NAFPs) are required to declare any potential conflict of interest. Persons engaged in work for SADCAS are required to provide assurance that they are not under undesirable pressures of any kind (financial, commercial, personal etc.) that affect their judgment, quality or results of their work. Accreditation decisions are made by competent persons independent of the assessment. Any staff member who is found not to comply with policies and procedures shall be disciplined accordingly. Contract workers found not to uphold company values and contravene with policies and procedures in place to address





these issues shall cease to work for SADCAS immediately. Staff and contract workers are encouraged to advise the Chief Executive Officer of any individual or client who approaches them financially or otherwise to operate in a manner that contravenes SADCAS policies and procedures.

SADCAS has interactions with other organizations within and outside the SADC region.

SADCAS evaluates potential risks to impartiality on an ongoing basis through internal audits, management reviews, external financial audits, annual customer satisfaction surveys. SADCAS also operates an impartial complaints and appeals procedure which is open to all stakeholders. The SADCAS Board of Directors reviews the SADCAS risk profile which includes risk to impartiality and interactions with other organizations within and outside the SADC, annually and any residual risks to determine if it is within the level of acceptable risk.

The SADCAS Impartiality policy statement is publicly available on the SADCAS website www.sadcas.org

Signed:

Eve Christine Gadzikwa SADCAS Chief Executive Officer Date: 2023-01-16



4. **GENERAL REQUIREMENTS**

4.1. Legal Entity

4.1.1. Background

The Southern African Development Community Accreditation Service (SADCAS) is a multi-economy accreditation body incorporated in Botswana under the Botswana Companies Act Ch. 42:01 as a non-profit limited company. SADCAS is established in terms of Article 15 B of the Technical Barriers to Trade (TBT) Annex to the SADC Protocol on Trade. SADCAS is recognized by the SADC Council of Ministers as a subsidiarity organization of SADC. The relationship between SADCAS and SADC is formalized through a memorandum of understanding on general cooperation.

SADCAS is responsible for the accreditation of laboratories (calibration/testing/medical), certification bodies (management systems/product/personnel) and inspection bodies to relevant international standards and the respective International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF) interpretations thereof. The SADCAS Constitution allows SADCAS to expand its scope of work as required.

4.1.2. Authority and Legal Responsibility

The objects, powers and rules for the operation of SADCAS are set out in the Constitution lodged with The Registrar of Companies (Botswana). These documents also include the terms of appointment and terms of reference of the members and Board of Directors. The Company Secretary retains the current version of the Constitution of the SADCAS Ltd.

SADCAS is recognized by the SADC Council of Ministers as a subsidiarity organization of SADC hence an agency of SADC. SADCAS has signed a Memorandum of Understanding (MOU) with SADC. This MoU serves as the basis for recognition of SADCAS by SADC Member States as a multi-economy accreditation body. The MOU is reviewed from time to time to take into account any changes that may develop.

As a non-profit company incorporated in Botswana, SADCAS shall ensure compliance with the Botswana Companies Act (Companies Act 2003) and any other Act or Regulation that may be applicable to SADCAS and accreditation.

References:

- 1. Certificate of Incorporation
- 2. Record of SADC Council of Ministers meeting held in August 2007
- 3. TBT Annex to the SADC Protocol on Trade
- 4. Constitution of the SADCAS Ltd
- 5. SADCAS/SADC Memorandum of Understanding
- 6. Botswana Companies Act, 2003 Act No. 32 of 2004

Note: These documents are available from SADCAS upon request.



4.1.3. SADCAS Mission

SADCAS mission is to provide credible, cost effective, accreditation services for SADC Member States aimed at supporting trade, enhance the protection of consumers and the environment, and improve the competitiveness of SADC products and services in both the voluntary and regulatory areas.

4.1.4. SADCAS Objectives

SADCAS Objectives are to:

- a) Provide accreditation services to testing, medical and calibration laboratories, certification bodies for management systems, including but without limitation, quality, environmental, personnel certification and product certification, inspection bodies and in such other areas as identified from time to time;
- b) Accredit conformity assessment bodies in Member States without national accreditation bodies or whose accreditation bodies cover limited scopes or schedules;
- c) Promote and facilitate the use of accreditation services within Member States compliant with relevant international standards and best practices prevailing from time to time;
- d) Provide affordable and accessible accreditation services to Member States necessary to meet the requirements and objectives of the Protocol, including, but without limitation, the attainment of the removal of technical impediments or barriers to intra-SADC trade;
- e) Provide an authentication service with regional and international status and/or recognition to validate reports and certificates issued by Member States accredited organizations;
- f) Establish and maintain a register of all organizations accredited by the Company in the region;
- g) Promote the Company as a multi economy accreditation body:
- h) Arrange and participate in meetings, conferences and exhibitions that are related to and support accreditation;
- i) Establish, nurture and maintain appropriate relationships and cooperation with regional and international organizations, associations and persons that may assist the Company in obtaining and maintaining any or all of its objectives;
- j) Pursue each and every one of the objectives in a manner that promotes the Company as an internationally recognized accreditation body;
- k) Provide the necessary training in accreditation matters;
- I) Establish a pool of expertise in accreditation to serve Member State's needs; and
- m) Establish and acquire subsidiaries and other entities appropriate for the purpose of attaining the above objects.

SADCAS implements a quality management system in compliance with the requirements of ISO/IEC 17011 and of AFRAC, SADCA, ILAC and IAF for the purpose of Mutual Recognition Arrangements (MRA)/ Multilateral Arrangement (MLA).



4.1.5. SADCAS Vision

SADCAS vision is to be a sustainable accreditation body at the cutting edge of credible accreditation service delivery.

4.1.6. Company Values

In its service delivery, SADCAS upholds the following seven (7) core values:

Excellence	We strive for excellence in service delivery.
Impartiality	We are organized and operate so as to safeguard objectivity and impartiality of our services.
Transparency	We are dedicated to provide complete transparency in our work by communicating effectively with our clients.
Non-discrimination	We treat our clients fairly and in an equitable manner.
Integrity	We act with honesty and integrity.
Innovation	We generate new ideas and utilize creative approaches to problems for continuous improvement.
Diversity	We respect the diversity of our clients and ensure balance of interest in representation.

SADCAS value proposition is to delivering confidence and assuring competency.

4.1.7. SADCAS Services

SADCAS provides accreditation services and training in accreditation associated activities.

4.1.7.1. Accreditation services

The accreditation schemes offered by SADCAS are outlined in 4.6.1.

4.1.7.2. Training services

SADCAS offers training on accreditation related courses. Training can be conducted in-house or as open courses.

SADCAS offers the following training courses:

- One-day awareness training courses on the various key accreditation standards. The objective of the one-day awareness training courses is to create awareness on the benefits and importance of accreditation and the requirements of the respective accreditation standards.
- Five-day requirements, implementation and internal auditing on the key accreditation standards whose objective is to provide an insight into the respective system standards requirements,



implementation as well as to guide conformity assessment bodies' personnel on how to prepare and carry out an internal audit so as to monitor compliance with the system standard.

- Three-day training courses on the requirements and implementation of the key accreditation standards whose objective is to provide an insight into the respective system standards requirements and implementation thereof.
- Three-day internal auditing courses whose objective is to impart internal auditing knowledge and skills so that conformity assessment bodies are able to monitor compliance with the respective key accreditation standards.
- Five-day intensive course on Method Validation and Measurement Uncertainty covers statistical fundamentals and advanced concepts of statistical techniques that are used in both method validation/verification and in calculating measurement uncertainty of test results.
- Three-day course on Root Cause Analysis whose objective is to provide participants with knowledge and skills to manage nonconformities, with specific emphasis on the identification of root cause(s).

Besides the above courses, SADCAS can also offer other accreditation related courses depending on needs. The training courses are conducted on behalf of SADCAS by a pool of qualified and registered trainers who have hands on and up to date experience on accreditation matters. The training courses are designed to create awareness on the benefits and importance of accreditation and to promote an understanding of the requirements of the key accreditation standards. In order not to compromise its impartiality principles and status in training service delivery, SADCAS does not give specific advice for the development of an organization's operations. Furthermore, the training delivered or facilitated by SADCAS are not a pre-condition of accreditation neither do they guarantee accreditation by SADCAS.

4.1.8. Regional and International Connections

SADCAS is

- A full member of the International Laboratory Accreditation Cooperation (ILAC).
- An accreditation body and signatory member of the International Accreditation Forum (IAF).
- An arrangement member of the African Accreditation Cooperation (AFRAC).
- An arrangement member of SADC Cooperation in Accreditation (SADCA).

4.2. Accreditation Agreement

The conformity assessment bodies accredited by SADCAS shall sign a legally enforceable agreement which details the obligations of the accredited conformity assessment body and of SADCAS with regard to accreditation.

4.2.1. The agreement covers all aspects that the accredited conformity assessment body must comply with in order to maintain accreditation including:



- Commitment to fulfil continually the requirements for accreditation for the scope for which accreditation is sought or granted. This includes agreement to adapt to changes in the requirements for accreditation.
- Cooperation as is necessary to enable SADCAS to verify the fulfillment of the requirements for accreditation in all the premises where the conformity assessment body's activities take place.
- Provision of access to conformity assessment body personnel, locations, equipment, information, documents and records as necessary to verify fulfilment of requirements for accreditation.
- Arranging for witnessing of conformity assessment activities when requested by SADCAS.
- Having, where applicable, legally enforceable arrangement with their client that, on request gives SADCAS assessment teams access to assess the conformity assessment body's (CAB) performance when carrying out conformity assessment activities at the client's site.
- Provision of documents that provide insight into the level of independence and impartiality of the CAB from its related bodies where applicable.
- Claiming accreditation only with respect to the scope for which accreditation has been granted.
- Commit to follow SADCAS policy for the use of the accreditation symbol.
- Not to use its accreditation in a manner that will bring SADCAS into disrepute.
- Inform SADCAS, without delay of any significant changes relevant to its accreditation relating to:
 - its legal, commercial ownership or organization status
 - Organization, top management and key personnel
 - Resources and premises
 - Scope of accreditation
 - Other matters that can affect the ability of the conformity assessment body (CAB) to fulfil requirements for accreditation.
- Pay accreditation fees as determined by SADCAS.
- Assist in the investigation and resolution of any accreditation-related complaints about the conformity assessment body (CAB) referred to it by SADCAS.
- **4.2.2.** SADCAS undertakes to provide credible accreditation services. SADCAS:
 - Shall enter into twinning partnership with internationally recognized accreditation bodies for skills transfer.



- Shall participate in regional and continental accreditation cooperation such as the SADC Cooperation in Accreditation (SADCA) and the African Accreditation Cooperation (AFRAC) and their respective relevant committees.
- Shall participate in international accreditation bodies i.e. the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF) and their respective relevant committees.

Reference

- 1. SADCAS F 44 SADCAS Accreditation Agreement
- 2. SADCAS F 113 Sub-license agreement for the IAF Combined Symbols
- 3. SADCAS F 114 Sub-license agreement for the ILAC Combined Symbols

4.3. Use of Accreditation Symbols and Other Claims of Accreditation

SADCAS shall remain the sole proprietary owner of its trademark (name and logo) which has been registered and is therefore protected. The SADCAS trademark forms the main part of the accreditation symbol. The conditions for the use of the SADCAS accreditation symbol are documented. SADCAS also has documented requirements for use of combined symbols. The procedures also outline actions that SADCAS shall take in cases where the symbol is misused. SADCAS will not hesitate to take appropriate legal action in those instances where its trademark/accreditation symbol has been misused.

References:

- 1. SADCAS TR 01: Part 1 Conditions for the use of SADCAS Accreditation Symbols
- 2. SADCAS TR 01: Part 2 Use of Combined Accreditation Symbol and ILAC/IAF Mark
- 3. SADCAS F 113 Sub-license agreement for the IAF Combined Symbols
- 4. SADCAS F 114 Sub-license agreement for the ILAC Combined Symbols
- 5. IAF ML 2 General Principles on the Use of the IAF MLA Mark
- 6. ILAC/IAF A2: IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Requirements and Procedures for Evaluation of a single Accreditation Body
- 7. ILAC/IAF A3: IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Narrative Framework for Reporting on the Performance of an Accreditation Body
- 8. ILAC P 8: ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements and Guidelines for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories and Inspection Bodies
- 9. ILAC R 7: Rules for the use of the ILAC MRA Mark

4.4. Impartiality Requirements

4.4.1. Impartiality is one of the core values of SADCAS and the cornerstone of any accreditation service. SADCAS understands the importance of impartiality in carrying out its services and manages conflict of interest and any potential conflict of interest in order to safeguard objectivity and impartiality of accreditation services rendered. SADCAS adheres with the impartiality requirements as specified in



ISO/IEC 17011:2017: Conformity assessment – requirements for accreditation bodies accrediting conformity assessment bodies.

- **4.4.2.** SADCAS has documented its impartiality policy statement which is publicly available on the SADCAS website <u>www.sadcas.org</u>
- **4.4.3**. SADCAS is a non-profit limited company incorporated under the Botswana Companies Act Ch. 42.01 and is organized in such a manner as to ensure that impartiality requirements are met.

SADCAS offers accreditation services and training in accreditation associated matters. SADCAS does not provide consultancy services to any organization that it offers accreditation. SADCAS does not offer or provide any conformity assessment services that conformity assessment bodies perform.

SADCAS provides external training services in accreditation associated activities. In order not to compromise its impartiality and status in training service delivery, SADCAS offers generic training courses and does not give specific advice for the development of an organization's operations. Furthermore, the training courses delivered or facilitated by SADCAS are not a precondition of accreditation neither do they guarantee accreditation by SADCAS. Nothing shall be said or implied that would suggest that accreditation would be simpler, easier, faster or less expensive if any specified person (s), trainers or consultancy were used.

- **4.4.4.** All SADCAS personnel and Committees shall act objectively and be free from undue commercial, financial and other pressures that could compromise impartiality. All SADCAS personnel and Committees shall declare all possible conflicts of interest. The SADCAS Board shall ensure that SADCAS company values are addressed in policies and procedures and upheld in operations and service delivery. Applicants and existing clients shall all be treated fairly and in an equitable manner.
- **4.4.5.** SADCAS has documented and implements a process that provide the opportunity for the effective involvement by interested parties for safeguarding impartiality. In general, all SADCAS Committees shall have a balance of interest and shall be competent.

SADCAS permanent staff, contracted assessors/technical experts are required to sign a contract with SADCAS that specifies their agreement to impartiality and non-conflict of interest in addition each assessor/technical expert, Board members, committee members and National Accreditation Focal Points (NAFPs) are required to declare any potential conflict of interest. Persons engaged in work for SADCAS are required to provide assurance that they are not under undesirable pressures of any kind (financial, commercial, personal etc.) that affect their judgment, quality or results of their work. Accreditation decisions are made by competent persons independent of the assessment. Any staff member who is found not to comply with policies and procedures shall be disciplined accordingly. Contract workers found not to uphold company values and contravene with policies and procedures in place to address these issues shall cease to work for SADCAS immediately. Staff and contract workers are encouraged to advise the Chief Executive Officer (CEO) of any individual or client who approaches them financially or otherwise to operate in a manner that contravenes SADCAS policies and procedures



- **4.4.6.** SADCAS identifies, analyses, evaluates, treats and monitors potential risks to impartiality on an ongoing basis through internal audits, management reviews, external financial audits, annual customer satisfaction surveys. SADCAS also operates an impartial complaints and appeals procedure which is open to all stakeholders.
- **4.4.7.** Where risks to impartiality are identified, these are documented in the risk profile which also contains risk control measures which are monitored for effectiveness in reducing the risk. Any residual risks are also considered. SADCAS has interactions with other organizations within and outside the SADC region and these interactions are reviewed annually to ensure impartiality.
- **4.4.8.** The SADCAS Board of Directors reviews the SADCAS risk profile which includes risk to impartiality and interactions with other organizations within and outside the SADC, at every Board meeting to ensure effective implementation of risk control measures. Major reviews are conducted annually when risk profiles for the year are developed. Any residual risks is reviewed to determine if it is within the level of acceptable risk.
- **4.4.9.** In service delivery, SADCAS applies its policies and procedures in a non-discriminatory manner and its services are available to conformity assessment bodies (CABs) operating in those SADC Member States that do not have national accreditation bodies. Where services are offered to those countries outside SADCAS' operational boundaries SADCAS takes into account the ILAC/IAF cross frontier policies. Eligibility to SADCAS services does not depend on size, membership to association or groups and nature of the CAB be it from the public sector or private sector, nor is accreditation conditional based upon the number of CABs already accredited.

When an unacceptable level is identified and which cannot be mitigated to an acceptable level, then accreditation shall not be provided

References:

- 1. SADCAS AP 10: Contracting of Assessment Personnel
- 2. SADCAS AP 21: Management of Impartiality
- 3. SADCAS BP 06: SADCAS Risk Profile
- 4. SADCAS F 27: SADCAS Gift Register
- 5. SADCAS F 45 a: Nondisclosure/Confidentiality Statement Assessors/Technical Experts
- 6. SADCAS F 45 b: Nondisclosure/Confidentiality Statement Subcontractors (Other than Assessors/Technical Experts)
- 7. SADCAS F 45 c: Nondisclosure/Confidentiality Statement SADCAS Staff members
- 8. SADCAS F 45 d: Nondisclosure/Confidentiality Statement SADCAS Board/Committee members
- 9. SADCAS F 45 e: Nondisclosure/Confidentiality Statement National Accreditation Focal Points (NAFPs)
- 10. SADCAS F 49: Independent Contractor Agreement between SADCAS and Assessors/ Technical Experts
- 11. SADCAS F 50: Employment Agreement



- 12. SADCAS F 74: Independent Contractor Agreement Between SADCAS and Trainer
- 13. SADCAS BP 09: Risk Profile of Related Bodies
- 14. SADCAS APP 03: Staff Conditions of Service

4.5. Financing and Liability

4.5.1. Financing

SADCAS is a non-profit limited company. The establishment and operationalization of SADCAS was funded by the Norwegian Government through the Norwegian Agency for Development Cooperation (NORAD).

SADCAS generates its own income from accreditation services and training on accreditation associated activities. SADCAS operational budget deficit is funded by the Governments of SADC Member States that are serviced by SADCAS.

SADCAS accreditation services are priced fairly and equitably to recover all direct and indirect costs associated with the service. All costs are based on the financial rates of the Botswana Pula (BWP). SADCAS shall make publicly available and update regularly fees relating to its services. The SADCAS Strategic/Business Plan and Annual Implementation Plans/Budgets are approved by the Board and are set to cover costs and to enable SADCAS to secure a viable long-term future, meeting its future obligations. Financial reports are provided to the SADCAS Board at each Board meeting for monitoring purposes. SADCAS Strategic/Business Plan and Annual Implementation Plan and Annual Implementation Plans also set out SADCAS goals and objectives in service delivery.

4.5.2. Liability

SADCAS does not accept liability for possible errors made by accredited organizations. All accredited organizations are required to absolve SADCAS of any such liabilities by signing the appropriate section of SADCAS application form for accreditation and on the accreditation agreement. Liability is limited to SADCAS assets and staff (both permanent and contract), assessors/technical experts, trainers and Board of Directors for which SADCAS has an insurance for general liability and professional liability.

References:

- 1. SADCAS Strategic/Business Plan
- 2. SADCAS Annual Budgets
- 3. SADCAS Annual Implementation and Activity Plans
- 4. SADCAS AP 02: SADCAS Service Fees

4.6. Establishing Accreditation Schemes



4.6.1. SADCAS offers accreditation schemes for:

- Calibration laboratories in accordance with ISO/IEC 17025;
- Testing laboratories in accordance with ISO/IEC 17025;
- Legal Metrology in accordance with ISO/IEC 17025;
- Medical laboratories in accordance with ISO 15189;
- Management systems certification bodies in accordance with ISO/IEC 17021-1;
- Inspection bodies in accordance with ISO/IEC 17020;
- Product certification bodies in accordance with ISO/IEC 17065; and
- Personnel certification bodies in accordance with ISO/IEC 17024.

The accreditation schemes are established referring to the relevant international standard. SADCAS will broaden its scope of accreditation as needs arise.

- **4.6.2.** SADCAS uses the available international guidance documents and when needed SADCAS through its Advisory Committees develops guidance documents. These documents neither contradict nor exclude any of the requirements included in the relevant international standards.
- **4.6.3.** SADCAS has defined a policy and documented procedures to determine the suitability of conformity assessment schemes and standards for accreditation purposes.
- **4.6.4.** In broadening its scope of accreditation SADCAS has defined a process to be followed when developing a new accreditation scheme.

The process includes the following:

- Feasibility study;
- Approval of the feasibility study;
- Signing of a Memorandum of Understanding where deemed necessary;
- Establishment of Advisory Committee;
- Sourcing and training of assessors;
- Development and approval of technical requirements documents; and
- Implementation of new schemes.
- **4.6.5.** In discontinuing accreditation schemes SADCAS shall take into account the views of interested parties, contractual duties and transition arrangements. SADCAS shall also communicate with stakeholders concerning the discontinuation.

References:

1. SADCAS AP 16: Procedure for the Development of New Accreditation Schemes and Discontinuation of accreditation Schemes



5. STRUCTURAL REQUIREMENTS

5.1. SADCAS is structured and managed so as to safeguard impartiality.

5.2. SADCAS Structure

5.2.1. SADCAS governance

SADCAS is governed by the General Assembly. Drawn out of the General Assembly is the Board of Directors which oversees the running of SADCAS and fulfils any function that the SADCAS General Assembly may delegate to it. The Board is responsible for the appointment of a Chief Executive Officer who is responsible for the day-to-day functioning of SADCAS and is an ex-officio member of the Board of Directors.

References:

- 1. Constitution of the SADCAS Ltd
- 2. BP 01 Terms of Reference of the Finance, Risk and Audit Committee of the SADCAS Board of Directors
- 3. BP 02 Terms of Reference of the Human Resources and Remuneration Committee of the SADCAS Board of Directors
- 4. BP 07: Part 1: SADCAS Board of Directors Skills and Expertise Requirements
- 5. BP 07: Part 2: SADCAS Board of Directors Matrix

<u>Note</u>: These documents are available from SADCAS upon request

5.2.2. SADCAS staff structure

SADCAS is composed of three functional units. The **technical unit** is responsible for the overall management of the accreditation process. The **corporate services unit** provides support services to internal and external business interests and is responsible for ICT, marketing and public relations, business development and administration of training services. The **finance and administration unit** is responsible for financial management, human resources management and general administration of the Company. Refer to Figure 1.

5.2.3. National Accreditation Focal Points

National Accreditation Focal Points (NAFPs) are based in those SADC Member States using the services of SADCAS. Although NAFPs are appointed by and report to their respective governments, they are also accountable to the Chief Executive Officer (CEO) of SADCAS for all accreditation activities. Refer to Figure 1.

Reference: Register of NAFP Members



5.2.4. Committees

5.2.4.1. Accreditation Approvals Committee

The SADCAS Accreditation Approvals Committee is responsible for making decisions on granting, maintaining, extending, reducing, suspending and withdrawing accreditation. For decisions arising from initial assessments, reassessments and extensions to new scopes the Accreditation Approvals Committee (AAC) shall consist of not less than 2 competent members, one of whom shall be either the SADCAS Chief Executive Officer or Technical Manager. For decisions arising from periodic on-site assessments, extension to existing scopes and additional signatories, the AAC shall consist of at least one competent member. The AAC members shall in all cases be different from those who have undertaken the assessment. Any other specialized technical expert may be invited to serve on the AAC as deemed necessary.

References:

- 1. SADCAS AP 14: Accreditation Decision Making Process
- 2. List of SADCAS Accreditation Approvals Committee Members

5.2.4.2. Advisory Committees

SADCAS has Advisory Committees (ACs) to support the technical credibility of accreditation activities. These ACs cover the main disciplines and sectors within which SADCAS operates.

References:

- 1. SADCAS AP 11: Terms of Reference, Registration and Responsibilities of Advisory Committees
- 2. List of SADCAS Advisory Committee Members

5.2.4.3. Appeals Committee

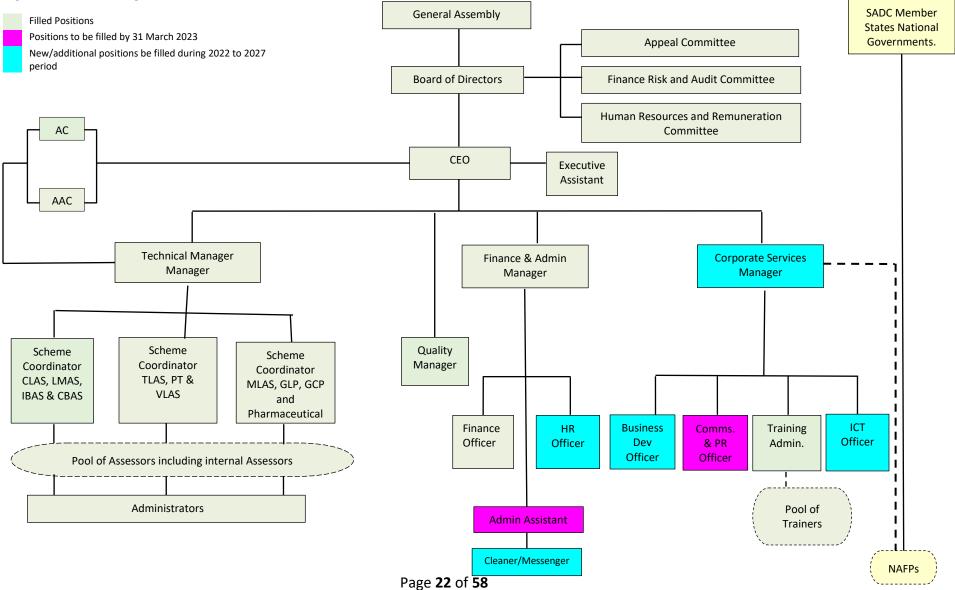
Appeals Committee shall be established by the Board to handle valid appeals on accreditation decisions.

References:

- 1. SADCAS AP 08: Customer Feedback
- 2. SADCAS BP 05: Terms of Reference of the Appeals Committee
- **5.3.** SADCAS is a body incorporated under the Botswana Companies Act [Chapter 42.01], as a non-profit limited company, and approved by the SADC Council of Ministers to be a Subsidiarity Organization of SADC.
- **5.4.** SADCAS is a non-profit company limited by guarantee, having members instead of shareholders. The members of the company consist of:
 - Subscribers to the memorandum and clauses of association;
 - Members of the Board of Directors;



Figure 1 – SADCAS Organizational Structure





- Appointed representatives of National Accreditation Focal Points in each SADC Member State using the services of SADCAS;
- Individuals or organizations who apply for admission as members of SADCAS.

References:

- 1. Register of SADCAS Members
- 2. Register of SADCAS Board Members
- *3. Register of NAFP Members*

<u>Note</u>: These documents are available from SADCAS upon request.

5.5. SADCAS draws its mandate from Article 15 B of the Technical Barriers to Trade (TBT) Annex to the SADC Protocol on Trade. SADCAS is recognized by the SADC Council of Ministers as a subsidiarity institution of SADC. The relationship between SADCAS and SADC is formalized through a Memorandum of Understanding (MOU) on general cooperation. The objects, powers and rules for the operation of SADCAS are set out in the Constitution of SADCAS Ltd lodged with the Registrar of Companies, Botswana.

5.6. Duties, Responsibilities and Authorities

5.6.1. The Chief Executive Officer

The Chief Executive Officer (CEO) is responsible to the Board of Directors for the development, direction and management of SADCAS in accordance with the Strategic/Business Plan and Annual Implementation Plans objectives. In his/her absence the CEO shall appoint an acting Chief Executive Officer. The appointment shall be formalized in a memo and distributed to relevant persons within SADCAS. Heads of units are responsible for SADCAS activities within their own units. The responsibilities and duties of the CEO are outlined in a job description duly signed by the CEO and the Chairman of the SADCAS Board of Directors.

Reference: Job description – Chief Executive Officer

5.6.2. Technical Manager

The Technical Manager is responsible for the overall management of the accreditation and assessment services. The responsibilities and duties of the Technical Manager are outlined in a job description duly signed by the Technical Manager and the Chief Executive Officer (CEO) as the immediate supervisor.

Reference: Job description – Technical Manager

5.6.3. Finance and Administration Manager

The Finance and Administration Manager is responsible for maintaining books of accounts and other records relating to accounting transactions of the company, budgeting and budgetary control and preparation of monthly and financial statements. The Finance and Administration Manager shall



ascertain that financial statements are true and fair and in accordance with International Financial Reporting Standards and in a manner required by the donor. The Finance and Administration Manager shall report to the Chief Executive Officer (CEO). The responsibilities and duties of the Finance and Administration Manager are outlined in a job description duly signed by the Finance and Administration Manager and the CEO as the immediate supervisor.

Reference: Job description - Finance and Administration Manager

5.6.4. Quality Manager

The SADCAS Quality Manager is responsible for ensuring amongst other duties that SADCAS complies with the requirements of ISO/IEC 17011 and other relevant criteria in order to achieve and maintain international recognition. The responsibilities and duties of the Quality Manager are outlined in a job description duly signed by the Quality Manager and the Chief Executive Officer as the immediate supervisor.

Reference: Job description - Quality Manager

Quality is everybody's business in SADCAS. Therefore, it is the responsibility of each SADCAS staff member to ensure that SADCAS policies and procedures as contained in the SADCAS quality management system are adhered to at all times. Each staff member shall read and understand the Quality Management System Manual which is made available to all staff at all times.

5.6.5. Scheme Coordinator

The Scheme Coordinator is responsible for ensuring that assessments for the assigned accreditation scheme are conducted in accordance with the relevant standards and SADCAS requirements and for implementing action plans from SADCAS Strategic and Annual Implementation plans in conjunction with the Technical Manager.

Reference: Job description – Accreditation Scheme Coordinator

5.6.6. Assessor

The Assessor is responsible for supporting the Scheme Coordinator to achieve accreditation targets.

Reference: Job description - Assessor

5.6.7. Training Administrator

The Training Administrator is responsible for ensuring that all external training on accreditation related matters are effectively undertaken. The responsibilities and duties of the Training Administrator are outlined in a job description duly signed by the Training Administrator and by the Chief Executive Officer as the immediate supervisor.



Reference: Job description- Training Administrator

5.6.8. Accreditation Administrator

The Accreditation Administrator is responsible for overseeing all administrative activities and assessment processes. The responsibilities and duties of the Accreditation Administrator are outlined in a job description duly signed by the Accreditation Administrator and the Accreditation Scheme Coordinator as immediate supervisor.

Reference: Job description - Accreditation Administrator

5.6.9. Finance Officer

The Finance Officer is responsible for providing financial and administrative support to internal and external clients. The responsibilities and duties of the Finance Officer are outlined in a job description duly signed by the Finance Officer and the Finance and Administration Manager as immediate supervisor.

Reference: Job description – Finance Officer

5.6.10. Communications and Public Relations (PR) Officer

The Communications and Public Relations (PR) Officer is responsible to render effective communications and marketing support services to SADCAS. The responsibilities and duties of the Communications and Public Relations (PR) Officer are outlined in a job description.

Reference: Job description – Communications and Public Relations (PR) Officer

5.6.11. Executive Assistant

The Executive Assistant is responsible to provide a full range of office management, secretarial services and personal assistance to the Chief Executive Officer and Technical Manager. The responsibilities and duties of the Executive Assistant are outlined in a job description duly signed by the Executive Assistant and the Chief Executive Officer and Technical Manager as immediate supervisors.

Reference: Job description – Executive Assistant

5.6.12. Administrative Assistant

The Administrative Assistant is responsible for providing administrative support to staff and assumes general office administration duties. The responsibilities and duties of the Administrative Assistant are outlined in a job description duly signed by the Administrative Assistant and the Finance and Administration Manager as immediate supervisor.



Reference: Job description – Administrative Assistant

5.6.13. National Accreditation Focal Points

The National Accreditation Focal Points (NAFPs) who are appointed by their respective SADC Member States' Governments are responsible for the administration, coordination, promotion and marketing of accreditation in their respective countries. National Accreditation Focal Points serve as the administrative link between SADCAS and clients/prospective clients in Member States. The responsibilities and duties of NAFPs are outlined in a job description duly signed by the National Accreditation Focal Points respective immediate supervisors and the SADCAS Chief Executive Officer and elaborated in the National Accreditation Focal Points (NAFP) handbook.

References:

- 1. Job descriptions National Accreditation Focal Points
- 2. National Accreditation Focal Points (NAFP) Handbook

5.6.14. Assessors/Technical experts

Assessors are experts from the public and private sectors as well as from technical institutions/associations in the SADC region who have been trained, qualified and registered as assessors by SADCAS. The SADCAS' assessors are responsible for undertaking accreditation assessments on behalf of SADCAS on a contracted basis. Assessors trained and qualified by other accreditation bodies and evaluated for competence can also undertake assessments on behalf of SADCAS. Assessment teams consist of a team leader and an appropriate number of assessors to cover the scope of accreditation. The team leader is responsible for organizing, directing and conducting Assessments, report findings and to evaluate corrective action.

During the assessment the team leader is also responsible for assessing the quality management system of the applicant as well as undertaking technical assessment within his/her field of expertise. The assessors are responsible for advising the team leader on specialist technical matters relating to the applicant's scope of accreditation. SADCAS may use technical experts on a subcontracted basis to assist in the assessment of an applicant or accredited facility. A SADCAS assessor always accompanies technical experts on assessment visits. Technical experts may also be contracted to provide expert opinion on any aspect of activities being assessed.

SADCAS keeps a register of assessors and database of technical experts.

Reference:

- 1. SADCAS AP 10: Contracting of Assessment Personnel
- 2. SADCAS F 49: Independent Contractor Agreement between SADCAS and Assessor/Technical Expert
- 3. SADCAS F 53: SADCAS Register of Assessors/Technical Experts
- **5.7.** SADCAS Top Management has the overall authority and responsibilities for the following as defied in the job descriptions referred in 5.6:



- Development of policies relating to the operation of SADCAS;
- Supervision in the implementation of the policies, processes and procedures;
- Supervision of the finances of SADCAS;
- Development or adoption of activities for the schemes offered by SADCAS;
- Decisions on accreditation;
- Performance of assessments and accreditation processes;
- Responding to complaints and appeals in a timely manner;
- Contractual arrangements;
- Provision of adequate resources;
- Delegation of authority to committees, or individuals as required to undertake defined activities on behalf of top management;
- Safeguarding of impartiality

Reference:

- 1. Job description- Chief Executive Officer
- 2. Job description Technical Manager
- 3. Job descriptions Finance and Administrative Manager
- 4. Job description Quality Manager
- **5.8.** SADCAS has formal rules for the appointment, terms of reference and operation of Committees that are involved in the accreditation process and identifies the interested parties participating thereon.

References:

1. SADCAS AP 11: Terms of Reference, Registration and Responsibilities of Advisory Committees

6. **RESOURCE REQUIREMENTS**

6.1. Competence of Personnel

6.1.1. General

SADCAS employs/contracts personnel who have the appropriate knowledge and skills relevant to the accreditation schemes and geographic areas in which it operates to enable them to competently undertake the work for which they are employed/ contracted for.

6.1.2. Determination of Competence Criteria

SADCAS ensures that all categories of personnel involved throughout the accreditation process demonstrate the following knowledge and skills as applicable to their areas of responsibility;

- Assessment principles, practices and techniques
- General management system principles and tools
- Accreditation body's rules and processes
- Accreditation and accreditation scheme requirements and relevant guidance and applicable documents.
- Conformity assessment scheme requirements, other procedures and methods used by the Conformity assessment Bodies.
- Risk-based assessment principles
- General regulatory requirements related to Conformity assessment activities.

SADCAS maintains a record of the knowledge and skills for each personnel involved in the management and performance of assessments.

SADCAS ensures that as a minimum, the assessment team demonstrates knowledge of practices and processes of the CAB business environment, communication skills with all levels of the CAB, note-taking and report writing skills, opening and closing meeting skills, interviewing skills and assessment management skills.

SADCAS ensures that personnel who review documents have note taking and report writing skills.

SADCAS ensures that personnel involved in accreditation decisions understand the applicable accreditation scheme requirements and are competent to evaluate outcomes of the assessment and the related recommendations of the assessment team.

Where additional specific competence criteria have been established for a specific accreditation scheme, SADCAS ensures that these are applied.

Reference:

- 1. SADCAS AP 22 Determination of Competence Criteria for Personnel Involved in the Management and Performance of SADCAS Accreditation Activities
- 2. SADCAS F 120 Knowledge and Skills Matrix



7.1.2. 6.1.3. Competence Management

SADCAS has a procedure for the nomination, selection and training of assessors and selection of SADCAS assessment team members. SADCAS keeps information records of assessors/technical experts and a register of all qualified assessors. SADCAS contracts on a needs basis, a number of qualified and registered assessors and technical experts.

In order to facilitate the monitoring of performance and competence of the personnel involved in the accreditation process, SADCAS has documented a procedure for monitoring of SADCAS assessors' performance which enables the regular review of performance and competence of assessors/technical experts. Monitoring shall be through on-site observation, review of assessment records feedback from conformity assessment bodies and peer monitoring.

The performance of the Accreditation Approvals Committee (AAC) members is also monitored. Whenever monitoring indicates a need for improvement, appropriate measures as agreed shall be effected.

SADCAS has a performance management system (PMS) in place for the review and appraisal of staff performance. Performance is reviewed on an ongoing basis with appraisals being undertaken twice a year.

SADCAS identifies training needs and provides access to specific training for all personnel involved in the accreditation processes to ensure competence for the accreditation activities that they perform.

References:

- 1. SADCAS AP 01: Nomination, Selection and Training of SADCAS Assessors; Selection of SADCAS Assessment Team Members; and Monitoring of SADCAS Assessors' Performance
- 2. SADCAS AP 10: Contracting of Assessment Personnel
- 3. SADCAS AP 14: Accreditation Decision Making Process
- 4. SADCAS APP 08: Balanced Score Card manual
- 5. SADCAS F 53: SADCAS Register of Assessors/ Technical Experts

6.2. Personnel Involved in the Accreditation Process

6.2.1. SADCAS only employs personnel who have the prerequisite qualifications and experience to enable them to undertake the work for which they are employed for. In all job advertisements, the prerequisite qualifications, experience and skills shall be included. All SADCAS staff shall sign an employment contract and a copy of a job description which outlines his/her responsibilities/ duties.

As part of its staff development, training is given to all staff in both technical and administrative areas as appropriate. All personnel are given the opportunity to undertake further training to advance their career. Training plans are discussed with all personnel.

References:

- 1. Job descriptions
- 2. SADCAS F 50: Employment Agreement



- 3. SADCAS AP 09: Training of SADCAS Personnel
- 4. SADCAS APP 05: Recruitment and Selection Policy and Procedures
- 5. SADCAS APP 08: Balanced Score Card manual
- **6.2.2**. SADCAS permanent staff contracted assessors/technical experts are required to sign a contract with SADCAS that specifies their agreement to confidentiality, impartiality and non conflict of interest. Copies of signed contracts shall be kept at the SADCAS office. In addition, each assessor/technical expert shall sign a non disclosure/confidentiality statement indicating any relationship they may have or have had with the organization/facility being assessed. SADCAS Board and Committee members shall sign a non disclosure/confidentiality statement upon appointment. Copies of confidentiality and conflict of interest are kept at SADCAS office.

References:

- 1. SADCAS F 27: SADCAS Gift Register
- 2. SADCAS F 45 a: Nondisclosure/Confidentiality Statement Assessors/ Technical Experts
- 3. SADCAS F 45 c: Nondisclosure/Confidentiality Statement SADCAS Staff members
- 4. SADCAS F 45 d: Nondisclosure/Confidentiality Statement SADCAS Board/Committee members
- 5. SADCAS F 49: Independent Contractor Agreement between SADCAS and Assessors/ Technical Experts
- 6. SADCAS F 50: Employment Agreement
- 6.2.3. SADCAS shall plan training/workshop/communication of assessors and ongoing Continuous Professional Development (CPD) attended by each assessor shall be recorded. All relevant and up to date and documented assessment procedures and information shall be provided to assessors.

References:

- 1. SADCAS AP 01: Nomination, Selection and Training of SADCAS Assessors; Selection of SADCAS Assessment Team Members; and Monitoring of SADCAS Assessors' Performance
- 2. SADCAS TG 02: Guidance for SADCAS Accreditation Assessors
- 3. SADCAS F 26 SADCAS Assessors/Technical Experts Information Records
- 4. SADCAS F 45 a: Nondisclosure/Confidentiality Statement Assessor/Technical Expert
- 5. SADCAS F 49: Independent Contractor Agreement between SADCAS and Assessor/ Technical Expert
- 6. SADCAS F 97: Assessor Training Program Record

6.3. Personnel Records

SADCAS maintains up to date records of each person (including assessors/technical experts) involved in the accreditation process. Records include:

a) Name and address;



- b) Position held and in the case of assessors/experts, position held in their own organizations;
- c) Educational qualifications and professional status;
- d) Work experience;
- e) Professional status and affiliations;
- f) Competence for specific assessment tasks; and
- g) Experience in assessment and result of their regular monitoring.

References:

- 1. SADCAS AP 04: Records Management
- 2. SADCAS F 26: SADCAS Assessors/ Technical Experts Information Records
- 3. SADCAS F 25: National Accreditation Focal Points Record

6.4. Outsourcing

SADCAS will normally carry out assessments itself. However, it may be necessary to subcontract parts of or whole of, an assessment of a specific organization. SADCAS will in such cases remain with the total responsibility for the assessment, decision making and periodic on-site and maintenance of the accreditation and all other decisions about accreditation. Accreditation assessments will only be subcontracted to Accreditation Bodies that are signatories to the relevant multilateral arrangements with IAF/ILAC. Where SADCAS plans to use a subcontractor, a written consent of the conformity assessment bodies shall be obtained prior to the assessment and SADCAS shall require the outsourced accreditation body personnel involved with the assignment to sign Nondisclosure/Confidentiality Statement from SADCAS and the Nondisclosure/Confidentiality statements are outsourced, SADCAS shall maintain a list of the accreditation bodies that provide the outsourced services.

SADCAS outsources various functions including IT and website maintenance, legal and litigation, human resources and marketing and communication. Subcontractors who may have access to confidential information and where deemed necessary shall sign confidentiality statements from SADCAS and the confidentiality statements shall be maintained in a file by the Accreditation Administrator.

Reference

- 1. SADCAS F 45 a: Nondisclosure/Confidentiality Statement Assessors/ Technical Experts
- 2. SADCAS F 49: Independent Contractor Agreement between SADCAS and Assessors/Technical Experts
- 3. SADCAS F 45 b: Nondisclosure/Confidentiality Statement Subcontractors (Other than Assessors/ Technical Experts)
- 4. SADCAS FPP 03: SADCAS Finance and Accounting Policies and Procedures Manual
- 5. SADCAS FPP 04: Tender Process



7. PROCESS REQUIREMENTS

7.1. Accreditation Requirements

7.1.1. General Requirements for Accreditation

SADCAS aims to achieve and maintain international recognition of all the accreditation schemes it operates. SADCAS policy is therefore to accredit conformity assessment bodies that fully meet the requirements of the relevant international standard and/or normative documents and the appropriate SADCA/AFRAC/ILAC/IAF guidance or interpretations thereof.

7.1.2. Accreditation Criteria

7.1.2.1. Testing/Calibration laboratories/Legal Metrology Bodies

The criteria which laboratories/legal metrology bodies must comply with to obtain accreditation are contained in ISO/IEC 17025 and the appropriate SADCAS requirement documents which include the appropriate ILAC criteria. Laboratories/ legal metrology bodies have to fully comply with all the requirements of the relevant standard for which accreditation is sought.

7.1.2.2. Medical laboratories

The criteria which laboratories must comply with to obtain accreditation are contained in ISO 15189 and the appropriate SADCAS requirement documents which include the appropriate ILAC criteria. Laboratories have to fully comply with all the requirements of the relevant standard for which accreditation is sought.

7.1.2.3. Certification bodies

SADCAS accredits management systems/product/personnel certification bodies.

a) Management systems certification bodies

SADCAS accredits quality/environmental/occupational health and safety/food safety management systems. The criteria which quality/environmental/food safety/occupational health and safety management systems certification body must comply with to obtain accreditation are contained in ISO/IEC 17021-1, the relevant sub-scope standard/technical specification and the IAF guidance or interpretations thereof.

The sub-scope standard applicable to quality management systems certification bodies is ISO/IEC 17021-3.

The sub-scope standard applicable to environmental management systems certification bodies is ISO/IEC 17021-2.



The sub-scope standard applicable to occupational health and safety management systems certification bodies is ISO/IEC 17021-10.

The sub-scope standard applicable to food safety management systems certification bodies is ISO/TS 22003.

b) Product certification bodies

The criteria which product certification bodies must comply with to obtain accreditation are contained in ISO/IEC 17065 and the IAF guidance or interpretations thereof.

c) Personnel Certification Bodies

The criteria which personnel certification bodies must comply with to obtain accreditation are contained in ISO/IEC 17024 and the relevant IAF guidance or interpretations thereof.

7.1.2.4. Inspection bodies

The criteria which inspection bodies must comply with to obtain accreditation are contained in ISO/IEC 17020 and the relevant ILAC guidance or interpretations thereof.

Fields and scopes of accreditation are available.

References:

- 1. ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories
- 2. ISO 15189 Medical laboratories Particular requirements for quality and competence
- 3. ISO/IEC 17021-1 Conformity assessment Requirements for bodies providing audit and certification of management systems
- 4. ISO/IEC 17024 Conformity assessment General requirements for bodies operating certification of persons
- 5. ISO/IEC 17020 General criteria for the operation of various types of bodies performing inspection
- 6. ISO/IEC 17065- General requirements for bodies operating product certification systems
- 7. ISO/TS 22003 Food safety management systems- Requirements for bodies providing audit and certification of food safety management systems
- 8. SADCAS TR 05 Criteria for the accreditation of Inspection Bodies Performing Inspection in terms of the Pressure vessels/boilers regulations in Zimbabwe.
- 9. SADCAS TR 11- Criteria for the accreditation of calibration satellite laboratories and branch offices
- 10. SADCAS TR 13 Criteria for the Accreditation of Inspection Bodies Performing Inspection of Metallic Tanks
- 11. SADCAS TG 03- Area of Accreditation
- 12. Applicable IAF MD Series Documents



7.2. Application for Accreditation

The applicant conformity assessment body submits directly to SADCAS duly completed and signed application form together with the conformity assessment body quality manual detailing the organization's ability to meet the requirements of the relevant international standard, and duly completed application for approval of personnel i.e. nominated representative and technical signatory as relevant and duly signed accreditation Agreement. The respective Scheme Coordinator shall undertake a completeness check or file review of the submitted applicant's documents to ensure completeness.

Prior to or after embarking on the formal accreditation process, organizations that seek accreditation may voluntarily request SADCAS to conduct a pre-assessment to assess their readiness for accreditation. Pre-assessments may however be compulsory for new organizations seeking accreditation depending on the regulator's condition of acceptance. Pre-assessments are carried on site by the Team Leader/Assessor and shall be undertaken after the document review.

At any point in the application, or assessment, if there is evidence of fraudulent behavior, if the conformity assessment body intentionally provides false information or if the conformity assessment body conceals information, SADCAS shall reject the application or terminate the assessment process.

References:

- 1. SADCAS F 43 (a) Application for Accreditation of Calibration Laboratory
- 2. SADCAS F 43 (b) Application for Accreditation of Testing Laboratory
- 3. SADCAS F 43 (c) Application for Accreditation of Medical Laboratory
- 4. SADCAS F 43 (d) Application for Accreditation of Certification Body Management Systems
- 5. SADCAS F 43 I Application for Accreditation of Certification Body Products
- 6. SADCAS F 43 (f) Application for Approval of Personnel
- 7. SADCAS F 43 (g) Application for Accreditation of Certification Body for Personnel
- 8. SADCAS F 43 (h) Application for Accreditation of Inspection Body
- 9. SADCAS F 43 (i) Application for Accreditation of Legal Metrology Body
- 10. SADCAS F 44 SADCAS Accreditation Agreement
- 11. SADCAS F 93 Completeness check/file review of application and Resource review

7.3. Resource Review

In undertaking a file review, SADCAS also undertakes resource review which takes into account the availability of personnel throughout the accreditation process including decision making. SADCAS also takes into account its ability its ability to carry out the assessment in a timely manner.

Where the initial assessment cannot be undertaken in a timely manner SADCAS shall communicate this to the conformity assessment body.

Reference: SADCAS F 93 – Completeness check/file review of application and Resource review



7.4. **Preparation for assessment**

- 7.4.1. A competent assessment team is identified to evaluate the applicant's documented system, and to conduct the assessment on behalf of SADCAS. Technical Experts, where required also form part of the assessment team.
- 7.4.2. An assessment team is set up and presented to the conformity assessment body sufficiently in advance, for approval. In case of objection raised by the applicant regarding impartiality, this shall be explained in writing within seven (7 days) of receipt of the notification and SADCAS shall evaluate if the reasons are acceptable, then changes are made to the assessment team.
- 7.4.3. The assignment given to the assessment team is clearly defined right from setting up the team when assurance is sought for the assessor/technical expert's ability to assess the assigned technical scope. Selection as a Technical Assessor/Technical Expert is in accordance with the specific expertise. The Technical Assessor/Technical Expert will still need to advise SADCAS should there be anything in the scope that have been assigned that Technical Assessor/Technical Expert are not able to or uncomfortable to assess.
- 7.4.4. SADCAS has documented procedures which outline the process and assessment techniques used in the accreditation of conformity assessment bodies in accordance with the relevant international standard, SADCAS requirements as well as the ILAC /IAF requirements.
- 7.4.5. All locations must be working to the same requirements and will be subject to an on-site assessment on a sampling basis as part of the accreditation process to provide evidence of the operation and effectiveness of the system.
- 7.4.6. Selection of activities to be assessed is on a sampling basis which takes into account the risk associated with the activities, locations and personnel covered by the scope of accreditation.
- 7.4.7. An assessment plan shall be prepared. The time required for assessment will be dependent on the complexity of the conformity assessment body, the geographical spread of its activities, the structure of the quality system, the proposed scope(s) of accreditation and where relevant, the combination of multi-standards for accreditation.
- 7.4.8. The assessment plan and a quotation will be forwarded to the laboratory in advance of the assessment for which a written acceptance of the quotation will be required before an onsite assessment can be undertaken.
- 7.4.9. The Team Leader shall provide the assessment team the assessment plan and information about the assessment and the conformity assessment body at least 2 weeks before an assessment.

Reference:

1. SADCAS AP 10 – Contracting of assessment personnel



2. SADCAS SL 20 – Assessment Plan and Agendas for Assessments.

7.5. Review of Documented Information

The appointed assessment team shall conduct a desk review of all relevant documented information provided by the applicant in order to evaluate its system for conformity with the relevant standard(s) and other requirements for accreditation. The assessment team shall use the appropriate checklist as a guide in reviewing the quality documentation.

On completion of the document review, a report on the relevant document review report shall be issued and the report shall contain comments on any nonconformity, areas which are not addressed, areas where actions are needed, areas where there are concerns or weaknesses and a recommendation on the way forward.

Once the applicant's documented quality management system has been confirmed to address all the requirements of the relevant standards, an assessment will be scheduled. SADCAS can decide not to proceed with the on-site assessment based on the review of the documented information.

References:

- 1. SADCAS F 61 (a-1) Document review report for laboratories ISO/IEC 17025
- 2. SADCAS F 61 (a-2) -Document Review for Inspection Bodies ISO-IEC 17020
- 3. SADCAS F 61 (a-3) Document review report for medical laboratories ISO/IEC 15189
- 4. SADCAS F 61 (a-4) Document Review Report for Management Systems Certification Bodies -ISO/IEC 17021-1
- 5. SADCAS F 61 (a-5)- Document Review Report for Product Certification Bodies- ISO/IEC 17065
- 6. SADCAS F 61 (a-6) Document Review Report for Personnel Certification Bodies-ISO/IEC 17024
- 7.6.1. SADCAS has documented procedures which describe the assessment techniques used, the timescales for the accreditation process and reporting to the conformity assessment body on the findings raised from the assessment.
- 7.6.2. Assessments are undertaken on-site at the applicant organization's premises or remotely and involve an opening meeting.
- 7.6.3. The assessment team conducts the assessment based on the assessment plan.
- 7.6.4. The assessment of the organization's competence to perform specific tasks for which accreditation is sought, witnessing of select technical activities are conducted. The initial assessment covers all aspects of the organization's scope of application.



- 7.6.5. The assessment team can ask for support from SADCAS when it cannot reach conclusion on a finding.
- 7.6.6. The assessment ends with a closing meeting during which a summary of the assessment report is presented to the conformity assessment body.
- 7.6.7. SADCAS is responsible for the content of the assessment reports.
- 7.6.8. The findings from the assessment are recorded as nonconformities where the conformity assessment body needs to institute corrective action. Where corrective action by the conformity assessment body is required the applicant organization shall be invited to identify and propose corrective actions to address the raised nonconformities within one (1) month after the assessment and have corrective action cleared within three (3) months after the assessment. For periodic on-site assessments and re-assessments conformity assessment bodies shall address the nonconformity and have the corrective action cleared within two (2) months after the assessment.

SADCAS requires the conformity assessment body to provide an analysis of the extent and cause (e.g., root cause analysis) of the nonconformities.

7.6.9. SADCAS reviews the responses of the conformity assessment body to determine if the actions are considered sufficient and appropriate. Where the conformity assessment body's response is found to be insufficient, further information shall be requested. Evidence of effective implementation may be requested or a follow up assessment may be carried out to verify effective implementation.

- 1. SADCAS TG 01 Information to Organizations Applying for Accreditation
- 2. SADCAS TG 02 Assessor Handbook
- 3. SADCAS AD 01 SADCAS Contact Details for Communicating with Clients
- 4. SADCAS AP 12: Part 1: Accreditation Process for Testing/ Calibration/ Medical Laboratories
- 5. SADCAS AP 12: Part 2: Accreditation of Inspection bodies Operating in the Regulatory/Voluntary Area
- 6. SADCAS AP 12: Part 3 Accreditation process for certification bodies
- 7. SADCAS AP 15: SADCAS Accreditation Administration Process
- 8. SADCAS AP 17: On-site Clearance of Findings
- 9. SADCAS AP 18: Criteria for Extraordinary Assessments
- 10. SADCAS AP 20: Sampling for assessment purposes
- 11. TPA J01: Guidelines for SADCAS/SANAS Joint assessments under the TPA
- 12. SADCAS F 111 Accreditation Process Timelines
- 13. SADCAS SL 20 Assessment Plan and Agendas for Assessments
- 14. AFRAC TP 001-01 Accreditation of National Metrology Institutes by AFRAC Accreditation Bodies
- 15. SADCAS AP 23: Remote Assessments- Management and Execution.



7.7. Accreditation Decision-making

Accreditation decisions relate to granting, maintaining, extending, reducing, suspending or withdrawing accreditation.

SADCAS maintains two (2) approaches to accreditation decision making process as follows:

- a) Decisions arising from initial assessments, reassessments and extensions to new scopes shall be made by the Accreditation Approvals Committee (AAC) consisting of not less than 2 competent members; and
- b) Decisions arising from periodic on-site assessments, extension of existing scopes and additional signatories to existing accredited facilities shall be made by the AAC consisting of at least one competent member.

Any other specialized technical expert shall be invited to serve on the AAC as deemed necessary. Personnel who have carried out the assessment shall not participate in the decision-making process.

SADCAS shall, without undue delay, make the decision on whether to grant, maintain, extend, reduce, suspend or withdraw accreditation and notify the conformity assessment body in writing of the decision including justification where relevant.

All accreditation decisions shall be made based on the information gathered and the recommendations made by the respective assessment team. The recommendation together with supporting documentation shall be forwarded to the Accreditation Approvals Committee for decision.

The supporting documentation shall include the following, as minimum:

- a) Unique identification of the conformity assessment body;
- b) Date(s) and type (s) of assessment;
- c) Name(s) of the assessor(s) and where applicable, technical experts involved in the assessment;
- d) Unique identification of all premises assessed;
- e) Scope of accreditation that was assessed;
- f) The assessment report(s);
- g) A statement on the adequacy of the internal organization and procedures adopted by Conformity Assessment Bodies to give confidence in its competence, as determined through its fulfillment on the requirements for accreditation;
- h) Sufficient information on the resolution of all nonconformities;
- i) Where relevant, any further information that may assist in determining the competence of the Conformity Assessment Bodies as determined through conformity with requirements; and
- j) Where appropriate, a recommendation as to the accreditation decision for the proposed scope.

Prior to making the decision SADCAS shall be satisfied that the information is adequate to decide that the requirements for accreditation have been fulfilled.



References: SADCAS AP 14 – Accreditation Decision Making Process

7.8. Accreditation Information

An accredited facility may only issue a SADCAS certificate for the type and range of activities for which accreditation has been granted and which is listed on the accompanying schedule of accreditation.

The certificate shall include the following information:

- a) The SADCAS name and logo;
- b) Name of accredited conformity assessment body and name of the legal entity if different;
- c) Details of the scope of accreditation:
 - ✓ For certification bodies to include:
 - Type of certification (e.g. management systems, products, processes, services or persons.
 - Certification scheme.
 - The standards, normative documents, and /or regulatory requirements to which management systems, products, processes and services, or persons are certified, as applicable.
 - Industry sectors where relevant.
 - Product, processes, service and persons categories where relevant.
 - ✓ For inspection bodies to include:
 - Type of inspection body as defined in ISO/IEC 17020.
 - Inspection schemes, where relevant.
 - Field and range for which accreditation has been granted.
 - Regulations, inspection methods, standards and/or specifications containing the requirements against which the inspection is to be performed, as applicable.
 - ✓ For calibration laboratories to include:
 - The calibration and measurement capability (CMC) expressed in terms of
 - Measurand or reference material
 - Calibration or measurement method or procedure and type of instrument or materials to be calibrated or measured
 - Measurement range and additional parameters where applicable e.g. frequency of applied voltage
 - Measurement uncertainty
 - ✓ For testing laboratories including medical laboratories to include:
 - Materials or products tested.
 - Component, parameter or characteristic tested.
 - Tests or types of tests performed and, where appropriate, the techniques, methods and/or equipment used.
- d) Locations from which key activities are performed and which are covered by the accreditation;
- e) Unique accreditation number;
- f) Effective date of granting accreditation i.e. the date of issue of certificate and date of expiry of certificate;



- g) Statement of conformity and reference to the standards/ other normative documents including issue or revision used for assessment of the conformity assessment body;
- h) Contact details of the accredited facility.
- i) Personnel approved.
- j) The certificate shall be signed by the SADCAS Chief Executive Officer (CEO) and the Schedule of accreditation shall be signed by the technical Manager.

SADCAS does not use flexible scopes of accreditation.

7.9. Accreditation Cycle

The SADCAS accreditation cycle shall be a period of 5 years for all the accreditation schemes. The accreditation cycle shall begin on the date of the decision to grant accreditation and shall be valid for five (5) years from that date.

During the accreditation cycle, SADCAS shall conduct periodic on-site assessments or remote assessments, where applicable to verify that the accredited conformity assessment body continues to comply with the accreditation requirements.

The first periodic on-site assessment shall be undertaken not more than twelve (12) months after the date of accreditation. Thereafter periodic on-site assessments are scheduled at a frequency such that the time between consecutive periodic on-site assessments does not exceed two years. However, if SADCAS determines that an on-site assessment is not possible or feasible, another assessment technique (e.g. remote assessment) shall be used to achieve the same objective as the on-site assessment being replaced.

In developing the assessment programme for assessing throughout the accreditation cycle, SADCAS shall take into account SADCAS' knowledge of the accredited organization's activities, management system and performance obtained from previous assessments and the possible risks thereof. The assessment programme shall ensure coverage of a representative sample of the organization's full scope of accreditation at the relevant locations.

Reassessments will be conducted at least six (6) months before the end of an assessment cycle. The reassessment shall be planned and performed taking into account the information gathered from the assessments performed over the accreditation cycle. The re-assessment shall be a complete assessment covering the organization's scope of accreditation and including all elements of the relevant standard. An accreditation decision shall be made after the reassessment.

SADCAS may decide that at any time extraordinary assessments be undertaken as a result of complaints or changes in the accredited conformity assessment body where such assessments are deemed necessary. SADCAS shall advice the conformity assessment body accordingly and of the scope and reasons for the extraordinary assessment.



7.10. Extending Accreditation

An accredited organization may extend its scope of accreditation by applying to SADCAS. After the scope extension has been assessed and approved, the organization's certificate and schedule of accreditation will be revised accordingly and issued to the organization. SADCAS shall take into account extensions granted when reviewing the assessment programme and planning the subsequent assessments.

References:

- 1. SADCAS TG 01 Information to Organizations Applying for Accreditation
- 2. SADCAS AP 12: Part 1: Accreditation Process for Testing/ Calibration/ Medical Laboratories
- 3. SADCAS AP 12: Part 2: Accreditation of Inspection bodies Operating in the Regulatory/ Voluntary Area
- 4. SADCAS AP 12: Part 3 Accreditation process for certification bodies
- 5. SADCAS AP 15: SADCAS Accreditation Administration Process
- 6. SADCAS AP 17: On-site Clearance of Findings
- 7. SADCAS AP 18: Criteria for Extraordinary Assessments
- 8. SADCAS AP 20: Sampling for assessment purposes
- 9. SADCAS AP 23- Remote Assessments- Management and Execution
- 10. TPA J01: Guidelines for SADCAS/SANAS Joint assessments under the TPA
- 11. SADCAS F 43 (a) Application for Accreditation of Calibration Laboratory
- 12. SADCAS F 43 (b) Application for Accreditation of Testing Laboratory
- *13.* SADCAS F 43 (c) Application for Accreditation of Medical Laboratory
- 14. SADCAS F 43 (d) Application for Accreditation of Certification Body Management Systems
- 15. SADCAS F 43 (e) Application for Accreditation of Certification Body Products
- 16. SADCAS F 43 (f) Application for Approval of Personnel
- 17. SADCAS F 43 (g) Application for Accreditation of Certification Body for Personnel
- 18. SADCAS F 43 (h) Application for Accreditation of Inspection Body
- 19. SADCAS F 43 (i) Application for Accreditation of Legal Metrology Body

7.11. Suspending, Withdrawing or Reducing Accreditation

An organization may have its accreditation suspended, withdrawn or the accreditation scope can be reduced when it fails to comply with the accreditation requirements. Suspension is normally the first step taken when serious non-compliance is noted. When an accreditation is suspended in part or as a whole, the accreditation is reinstated only when the necessary corrective actions have been instituted and after SADCAS has verified that the organization has fulfilled the requirements.

A suspended accreditation will be withdrawn if the organization is not able or willing to institute the necessary corrective actions within the timelines acceptable to SADCAS. In cases where there is evidence of fraudulent behavior, or the conformity assessment body intentionally provides false information, or conceals information, withdrawal may be effected without prior suspension. When an accreditation has been withdrawn, possible renewal shall be dealt with according to the procedure for dealing with new applications.



Reducing accreditation is the process of cancelling accreditation for part of the scope of accreditation.

Decisions to suspend/withdraw/reduce scope of accreditation shall be made by the Accreditation Approvals Committee.

References:

- 1. SADCAS TG 01: Information for Organizations Applying for Accreditation
- 2. SADCAS TR 01: Accreditation Requirements
- 3. TR 06: Suspension and Reinstatement of Accredited Organizations

7.12. Complaints

SADCAS shall actively encourage customer feedback, negative and positive. Negative feedback/complaints shall be used as a basis for the improvement and development of SADCAS services. SADCAS shall decide on the validity of complaints. Customer complaints shall be registered, investigated and resolved. Complaints shall be handled in a timely manner. The person investigating the complaint shall be independent to the complaint. All complaints relating to an organization accredited by SADCAS shall be first referred to the accredited organization. Only when the accredited organization has not been able to resolve the complaint shall the matter be referred to SADCAS. Complaints which have not been resolved through the SADCAS complaints handling system are classified as disputes and shall be brought to the attention of the Chief Executive Officer for resolution. The customer feedback procedure is publicly available.

SADCAS shall give formal notice to the complainant of the end of the complaint handling process.

The records pertaining to complaints, disputes shall be kept and maintained by the Quality Manager.

References:

- 1. SADCAS AP –8 Customer Feedback Handling Procedure
- 2. SADCAS AP -4 Records Management
- 3. SADCAS AD 01- SADCAS contact details for communicating with clients

7.13. Appeals

SADCAS accepts appeals from organizations on accreditation decisions. Appeals shall be in writing and validated before being registered, investigated and resolved. Appeals shall be handled by the Appeals Committee in a timely manner. Throughout the investigation of an appeal, all decisions made prior to the appeal, stand. The appeals procedure is publicly available

SADCAS provides the appellant with progress reports and the outcome after receiving the appeal. SADCAS shall give formal notice, to the appellant, of the end of the appeal handling process.

Records pertaining to appeals shall be kept by the Chief Executive Officer.



- 1. SADCAS AP 08: Customer Feedback Handling Procedure
- 2. SADCAS BP 05: Terms of Reference of the Appeals Committee
- 3. SADCAS AP 04: Records Management
- 4. SADCAS AD 01- SADCAS contact details for communicating with clients

7.14. Records on Conformity Assessment Bodies

SADCAS shall maintain records of all applicants and accredited organizations. The files shall contain at least the following information:

- a) Applicant forms;
- b) A copy of the accreditation certificate and schedule of accreditation;
- c) Correspondence including correspondence with assessors;
- d) Information on proficiency testing/inter-laboratory comparisons (where relevant);
- e) Assessment records and report; and
- f) Records of committee deliberations, if applicable, and accreditation decisions.

SADCAS ensures that all accredited/ applicant organization's records are held in a confidential manner and access is controlled. All records have to be signed out and back to the filing system. Access to files is controlled by the respective record keeper. Files may not be removed from SADCAS office under any circumstances. In the unlikely event that a file needs to be removed then a copy of the contents of the file has to be made in full. Assessors may be given photocopies of sections of the file as required. After use the assessor shall destroy copies of the records. System back-up for the server are kept by the IT hosted backup contractor.

Retention periods of CAB records are specified.

The accreditation scopes for all accredited organizations are kept in SADCAS database and are published in the Directory of accredited facilities on the SADCAS website.

- 1. SADCAS AP 04: Records Management
- 2. SADCAS TG 03: Area of Accreditation



8. **NFORMATION REQUIREMENTS**

8.1. Confidential Information

The agreement with conformity assessment body (CAB) includes commitment of SADCAS maintain as confidential and not to use or disclose to any third party, any information derived from the Body in connection with the services without written consent of the conformity assessment body. SADCAS shall inform the conformity assessment body, in advance, of the information it intends to place in the public domain.

When SADCAS is required by law or authorized by contractual arrangements to release confidential information, the CAB shall, unless prohibited by law, be notified of the information provided.

Information about the CAB obtained from sources other than the conformity assessment body (e.g. complainant, regulators) shall be confidential between the conformity assessment bodies and SADCAS.

All accreditation applicant CAB's names and information are confidential to SADCAS. Applicant files and accredited organizations files are securely kept at SADCAS office.

All SADCAS employees sign an Employment Agreement which covers among other contractual requirements for confidentiality. The Employee also agrees to cede and assign to SADCAS copyright in any material eligible for copyright. The Employee agrees to maintain as confidential and not to use or disclose to any third party, any information derived from any of SADCAS' customers in connection with their respective conformity assessment activities without written consent of the customer and SADCAS, except:

- to any person who of necessity requires it for the performance of her duties in terms of the Employment Agreement and relevant accreditation legislation;
- if such information is required in terms of any law or as evidence in any court of law;
- to any competent authority, which requires it for the institution, or an investigation with the view to the institution, of any criminal prosecution;
- by or on authority of the Chairperson of the SADCAS Board or the CEO of SADCAS; or
- any information which was in the possession of SADCAS prior to its disclosure by the customer.

Upon engagement, each Assessor/Technical Expert /Trainers shall sign an independent contractor agreement with SADCAS that specifies their agreement to confidentiality, impartiality and nonconflict of interest. All confidential information in relation to SADCAS and all general and confidential information in relation to a customer, whether it was gained by the Assessor/Technical Expert prior to, during or after an assignment, will be treated by the Assessor/Technical Expert as confidential and will not be reproduced or disclosed to any person or organization. The Assessor/Expert shall restrict the use of such information exclusively for purposes directed by SADCAS. Permission to disclose any such information about a customer or SADCAS may be deemed to have been granted once the Assessor/Expert has obtained unambiguous written permission from SADCAS' Chief Executive Officer to do so. In addition to this Agreement, the Assessor/Technical Expert agrees to sign a nondisclosure/confidentiality statement for purposes of each assignment involving accreditation assessment or related activities.



In addition, SADCAS maintains confidentiality in its operations by also requiring Board members, Committee members, National Accreditation Focal Points, subcontractors, assessors/technical experts and all staff to sign a declaration of confidentiality where they commit that no information gained while working for SADCAS shall be revealed to others than the relevant staff in SADCAS.

References:

- 1. SADCAS F 35-1, 35-2, 35-3- SADCAS Board and Committee Attendance Registers
- 2. SADCAS F 44 SADCAS Accreditation Agreement
- 3. SADCAS F 45 (a) Nondisclosure/Confidentiality Statements Assessor/Technical Expert
- 4. SADCAS F 45 (b) Nondisclosure/Confidentiality Statement Subcontractors (Other than Assessors/Technical Experts)
- 5. SADCAS F 45 (c)- Nondisclosure/Confidentiality Statement SADCAS Staff members
- 6. SADCAS F 45 (d) Nondisclosure/Confidentiality Statement SADCAS Board/ Committee members
- 7. SADCAS F 45 (e) Nondisclosure/Confidentiality Statement National Accreditation Focal Points (NAFPs)
- 8. SADCAS F 49 Independent Contractor Agreement between SADCAS and Assessor/ Technical Expert
- 9. SADCAS F 50 Employment Agreement
- 10. SADCAS F 74 Independent Contractor Agreement between SADCAS and Trainer

8.2 Publicly Available Information

8.2.1. SADCAS Policy Manual and relevant procedures are freely available to all assessors, SADCAS accredited organizations and all other interested parties to download from the SADCAS website: <u>www.sadcas.org.</u> It is the responsibility of users to ensure that they are using up to date documents by comparing with the contents list on the SADCAS website. The SADCAS Policy manual contains amongst others information about the authority under which SADCAS operates; description of SADCAS rights and duties; means by which SADCAS obtains financial support; SADCAS activities; and the Mutual Recognition Arrangements/Multilateral Arrangements that SADCIS is involved with. The relevant procedures contain information about the accreditation process.

SADCAS makes available the necessary requirements for obtaining and maintaining accreditation. Information on the assessment process is available on the websites well as from SADCAS office/ National Accreditation Focal Points offices in Member States.

SADCAS disseminates information through various publications including:

- SADCAS Directories of accredited organizations which is on the website.
- SADCAS Annual Report.
- SADCAS newsletter "The Pioneer".
- SADCAS corporate brochures/pamphlets.
- SADCAS reports and position papers.
- SADCAS Customer satisfaction surveys.

Copies of SADCAS publications are available from SADCAS office/ NAFP offices/website.



Some information such as Certificate of incorporation, Constitution, registers of the General Assembly, Board members and Advisory committees etc. are available upon request from SADCAS Office.

8.2.2. SADCAS makes publicly available on the website the current status of the accreditations it has granted to conformity assessment bodies and information on suspension or withdrawal of accreditation including dates and scopes.

The SADCAS customer feedback and appeals procedures are available on the website <u>www.sadcas.org</u>

- 8.2.3. Should there be changes to any of the accreditation requirements SADCAS shall, taking into account the views expressed by interested parties decide on the precise form and effective date of change, and within a reasonable period of time, notify all accredited conformity assessment bodies affected by any such changes. SADCAS shall give sufficient time for the accredited conformity assessment body to accommodate the changes. Such timelines shall be in line with IAF/ILAC stipulations.
- 8.2.4. SADCAS shall verify actions implemented to address the change(s). Verification can be done as an additional assessment or as part of the annual assessment. Where verification has been carried out as an additional assessment, then the accredited conformity assessment body shall be responsible for the additional charges incurred. Where verification has been carried out as a part of the annual assessment no additional charges shall be raised.

Following the publication of changed requirements for accreditation, SADCAS shall verify that each accredited body conforms to the changed requirements.

- 1. SADCAS AD 01- SADCAS contact details for communicating with clients
- 2. SADCAS AP 08: Customer Feedback Handling Procedure
- 3. SADCAS BP 05: Terms of Reference of the Appeals Committee



9. SADCAS QUALITY MANAGEMENT SYSTEM

9.1. General

SADCAS has established and is implementing and maintaining a Management System which ensures SADCAS' compliance with the requirements of ISO/IEC 17011 and of AFRAC, SADCA, ILAC and IAF. The Management System supports SADCAS staff, assessors and contractors in their work. It serves as information to other stakeholders on SADCAS Management System.

Within SADCAS quality is everyone's responsibility. Therefore, each person within SADCAS, assessors and contractors have to read and understand the policies and procedures and ensure that SADCAS complies with the requirements of the documented Management System. The Chief Executive Officer has the overall responsibility for SADCAS' Management System.

The work of establishing and maintaining SADCAS Management System documentation shall be delegated to the Quality Manager by the Chief Executive Officer (CEO).

SADCAS implements a management system in accordance with option **A** which shall address the following:

- management system;
- document control;
- records control;
- nonconformities and corrective actions;
- improvement;
- internal audits;
- management reviews

9.2. Management System

The Management System is documented and consists of a Policy Manual, procedures, forms and other documents.

The Quality Manager shall report to the SADCAS Quality Management Committee on the performance of the SADCAS Management System and shall make suggestions for improvement. The SADCAS Quality Management Committee shall comprise of CEO Technical Manager, Finance and Administration Manager, Quality Manager, Scheme Coordinators and Training Administrator. The Quality Manager shall arrange for internal audits. The results of internal audit shall be reviewed as part of the management review process. The Quality Manager arranges for the SADCAS Quality Management System (QMS) review meetings.

The hierarchy of SADCAS documents is given in Table 2.



Table 2 – Hierarchy of SADCAS Documents

Document Type	Prefix
SADCAS Policy Manual	PM
Strategic and Budget Documents	SD
Accreditation Procedural Documents	AP
Financial Policies and Procedures	FPP
Administrative and Human Resources Policies and Procedures	APP
SADCAS Board Policies and Procedures	BP
SADCAS Forms	F
Advisory Documents	AD
Technical Requirements Documents	TR
Technical Guidance Documents	TG
SADCAS Sample Letters	SL

9.3. Document Control

All SADCAS management system documents are assigned specific identification number and shall be legible and presented in prescribed format.

- **9.3.1.** Structure of the quality management system manual
- 9.3.1.1 Policy manual

The SADCAS Policy Manual describes the SADCAS Management System which is designed to ensure SADCAS' compliance with the requirements of ISO/IEC 17011 and of AFRAC, SADCA, ILAC and IAF, and to support SADCAS staff and contractors in their work as well as serve as information to other stakeholders on SADCAS quality management system. SADCAS staff and contractors shall read, understand, implement and abide with the SADCAS Quality Policy Manual.

9.3.1.2 Procedures manual

SADCAS has a number of procedures that detail the routines to be followed in undertaking SADCAS work. A list of procedures is found in the procedures manual.

9.3.1.3 SADCAS documents and forms

SADCAS documents and forms are published to provide information to applicants and other interested parties and to facilitate SADCAS daily work. List of forms and documents are available.

9.3.2 Authorization

Apart from SADCAS Board of Directors' documents and policy manuals which shall be authorized by the SADCAS Board, all other documents depending on their type shall be authorized by the Chief Executive Officer (CEO).



9.3.3 Implementation and maintenance

The Chief Executive Officer shall be responsible for ensuring the implementation of the SADCAS quality management system. The Quality Manager shall, amongst other duties, be responsible for managing the SADCAS Quality Management System and ensuring that it complies with the requirements of ISO/IEC 17011 and other relevant criteria in order to achieve and maintain international recognition.

9.3.4 Distribution

All staff in SADCAS and assessors/ experts shall, whenever amendments or new documents are issued, be informed by email and in turn they shall acknowledge receipt and confirm that they have familiarized and understand the document and further commit to implement the document. SADCAS quality management system documents shall be available to SADCAS staff on the network.

Accredited and applicant conformity assessment bodies shall access updated versions of relevant documents and of new documents from the SADCAS website <u>www.sadcas.org</u>.

9.3.5 Amendments

All amendments to the SADCAS Policy Manual, procedures manuals, documents and forms shall be authorized. Information about amendments is issued by the Quality Manager and distributed electronically. When a document or section of the Quality Policy Manual is amended the "issue number" effective date and approval date shall change accordingly.

Reference: SADCAS AP 03: Document Control

9.4. Record Control

SADCAS maintains all appropriate records as required by ISO/IEC 17011. Records maintained include amongst others, personnel and accredited organizations/applicant organizations, checklist and assessment reports, applications for accreditations and extensions, committee deliberations, accreditation decisions, accreditation fees invoices/receipts, SADCAS staff/assessor/experts records etc. These records shall be kept at the SADCAS Office. SADCAS ensures that all accredited/ applicant organization's records are held in a confidential manner and access is controlled. All records have to be signed out and back to the filing system. Access to files is controlled by the respective record keeper. Files may not be removed from SADCAS office under any circumstances. In the unlikely event that a file needs to be removed then a copy of the contents of the file has to be made in full. Assessors may be given photocopies of sections of the file as required. After use the assessor shall destroy copies of the records. System back-up for the server are kept by the IT hosted backup contractor.

The retention time of records is defined in the procedure for records control.

Reference: SADCAS AP 04: Records Management





9.5. Nonconformities and Corrective Actions

SADCAS has a documented procedure of nonconformities that arise in its entire operation. Nonconformities are regarded as opportunities for improvement and can be raised by anyone within and from outside SADCAS. Corrective actions are taken in order to address and eliminate the causes of nonconformities so as to prevent their recurrence. Corrective actions taken shall be appropriate to the impact of the problems environment and their effectiveness is reviewed.

Reference: SADCAS AP 05: Identification and Management of Nonconformities

9.6. Improvement

SADCAS has established mechanisms for the identification of opportunities for improvement and to take actions. Actions taken shall be appropriate to the impact of the potential problems. SADCAS has developed a risk profile which is reviewed annually by the Board with measures being put in place to militate against the identified risks. Progress on implementing the improvement measures shall be an input to the management review meetings and shall be reported upon by the Quality Manager.

Continual improvement in SADCAS is achieved through internal audits, management reviews, customer feedback, corrective action on nonconformities, training and continuous professional development and supervision and monitoring of assessors etc.

Reference: SADCAS BP 06: SADCAS Risk Profile

9.7. Internal Audits

SADCAS undertakes internal audits to:

- Determine compliance with its quality management system elements as specified in the Policy Manual, procedures manual, job descriptions and other documents.
- Determine the effectiveness and suitability of the quality management system; and
- Identify opportunities for improvement.

Internal audits are planned and initiated by the Quality Manager who may carry out the audit personally or may be assisted by other competent SADCAS personnel or may appoint an external auditor. Whoever is appointed to undertake the internal audit must be a competent person knowledgeable in accreditation, auditing and the requirements of ISO/IEC 17011. It is important that no member of staff audits his/her own work. The audit shall address elements of the quality system at least once a year. The results of the internal audit shall be reviewed as part of the management review process.

Reference: SADCAS AP 06: Internal Audits



9.8. Management reviews

Reviews of the SADCAS quality management system are performed by the Quality Management Committee. The reviews are arranged by the Quality Manager.

Inputs or agenda items for the management review meetings shall include:

- a) Results of audits;
- b) Results of peer evaluation;
- c) Participation in international activities;
- d) Safeguarding impartiality;
- e) Feedback from interested parties;
- f) New areas of accreditation;
- g) Trends in nonconformities;
- h) Status of corrective actions;
- i) Status of actions to address risks and opportunities;
- j) Follow up actions from earlier management reviews;
- k) Fulfillment of objectives;
- I) Changes that could affect the management system;
- m) Analysis of appeals; and
- n) Analyses of complaints.

The output of Management reviews shall include actions to:

- Improve the management system and its processes;
- Improve service delivery;
- Define and redefining policies, goals and objectives; and
- Address resource issues

The minutes of the management review meetings shall be filed for records.

Reference: SADCAS AP 07: Management Review



10. CROSS FRONTIER ACCREDITATION

SADCAS is a multi- economy accreditation body established to meet the accreditation needs of SADC Member States which do not have national accreditation bodies or where national accreditation body has a limited scope. Applications for accreditation received by SADCAS from conformity assessment bodies based in countries that are not part of the Southern African Development Community (SADC) shall be handled in accordance with the cross frontier procedure. SADCAS is committed to abide by the ILAC/IAF cross frontier accreditation principles of cooperation.

- 1. SADCAS AP 19: Cross frontier Accreditation
- 2. ILAC G 21: Cross Frontier Accreditation Principles for Cooperation



11. PROFICIENCY TESTING/INTER LABORATORY COMPARISONS FOR LABORATORIES

11.1. Testing laboratories

Applicant and accredited laboratories are required to participate in appropriate proficiency testing schemes/ inter laboratory comparisons and where such schemes are available in their technical field of work in order to demonstrate their capabilities and to assist in maintaining quality of laboratory performance. Laboratories are required to maintain complete records of participation in such schemes and to have procedures for evaluation of performance and implementation of corrective action. SADCAS assesses performance during assessments, periodic on-site and reassessments. If the results are outside the acceptable limits, corrective action shall be instituted. If causes for unacceptable results are not found within a reasonable time or if a laboratory is not undertaking suitable investigation to solve the problem, then the accreditation for the specific parameter/method/ analysis may be suspended or terminated.

SADCAS maintains links to PT service providers on the website <u>www.sadcas.org</u>

References:

- 1. SADCAS TR 08: Proficiency Testing and Other Comparison Programmes Requirements for Testing and Medical Laboratories
- 2. ILAC P9: ILAC Policy for Participation in Proficiency Testing Activities

11.2. Calibration laboratories

Applicant and accredited laboratories are required to participate in proficiency testing schemes/ inter laboratory comparisons before being accredited and thereafter in order to demonstrate their capabilities and to assist in maintaining quality of laboratory performance. The results of artifact measurement are communicated to the assessment team prior to the assessment. The assessment team shall ensure that corrective actions needed on the results of proficiency testing/inter laboratory comparison participation are actioned.

SADCAS maintains links to PT service providers on the website <u>www.sadcas.org</u>.

References:

1. SADCAS TR 04 – Proficiency Testing and other Comparison Programmes Requirements for Calibration Laboratories



12. METROLOGICAL TRACEABILITY

- 12.1. Accredited conformity assessment bodies are required to demonstrate that calibration of critical equipment and hence the measurement results generated by that equipment, relevant to their scope of accreditation, are traceable to the International System of Units (SI Units). The SADCAS policy on metrological traceability applies to conformity assessment activities where measurement is involved i.e., testing, calibration and medical laboratories, inspection and legal metrological traceability for its own activities, and which are not a part of the organization's scope of accreditation, the SADCAS policy in section 12.1.1 is also applicable. These internal calibrations are also known as "in-house" calibrations.
- **12.1.1. SADCAS Policy on Metrological Traceability of Measurement Results** When metrological traceability is required, the SADCAS policy is that the equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) shall be calibrated by:
 - a) A National Metrology Institute (NMI) whose service is suitable for the intended need and belongs to the CIPM and are signatories to its Mutual Recognition Agreement (MRA) amongst NMIs and who have approved CMC's within the BIPM Key Comparison Database (KCDB) which includes the range and uncertainty for each listed service.
 - b) A calibration laboratory accredited by an accreditation body covered by the ILAC Arrangement or by Regional Arrangements recognized by ILAC whose service is suitable for the appropriate calibration
 - c) An NMI whose service is suitable for the intended need but not covered by the CIPM MRA. The National Metrology Institute shall have participated in the SADC Cooperation in Metrology (SADCMET) or Intra-Africa Metrology System (AFRIMETS) through which SADC countries that are not yet signatory to the CIPM can get their traceability. Calibration certificates issued by the NMI shall provide sufficient information regarding the process of calibration
 - d) A calibration laboratory whose service is suitable for the intended need but not covered by the ILAC Arrangement or by regional arrangements recognized by ILAC.

For options c) and d) appropriate evidence for the technical competence of the laboratory and claimed metrological traceability shall include the following:

- Record of calibration method validation (7.2.2.4);
- Procedures for estimation of measurement uncertainty (7.6);
- Documentation and records for metrological traceability of measurements (7.5);
- Documentation and records for ensuring validity of results (7.7);
- Documentation and records for the competence of personnel (6.2);
- Records of equipment which can influence laboratory activities (6.4)
- Documentation and records for facilities and environmental conditions (6.3); and
- Audits of the calibration laboratory.



Numbers in brackets refer to clauses in ISO/IEC17025:2017 whose requirements are assessed for competence and compliance by SADCAS (6.6 and 8.8).

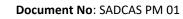
Options a) and b) above are the preferred SADCAS options for metrological traceability. Options c) and d) are only applicable when options a) and b) are not possible.

- 1. SADCAS TR 09: SADCAS Policy on Metrological Traceability of Measurement Results.
- 2. SADCAS TR 12: Estimation of the Uncertainty of Measurement by Calibration Laboratories and Specification of Calibration and Measurement Capability on Schedules of Accreditation



APPENDI-A - AMENDMENT RECORD

	Change				
Revision Status	Page	Clause/ Sub clause	Description of Change	Approved by	Effective Date
Issue 14			Aligned whole Policy Manual to ISO/IEC 17011:2017 and deleted cross referencing as the numbering of clauses is aligned to the revised standard Deleted Appendix A - Cross referencing ISO/IEC 17011 clauses, SADCAS policy manual and other SADCAS documents the cross table as the sections of PM 01 have been aligned to	SADCAS Board	2018-09-06
			ISO/IEC 17011:2017 and reference documents are listed under each Section.		
Issue 15	32	7.1.2.4	Deleted SADCAS TR 02 from list of References	SADCAS Board	2020-04-30
	35	7.6.8	Revised the period within which corrective action is undertaken for periodic on- site assessments and re-assessments from 3 months to 2 months.		
	36	7.6.9	Added SADCAS AP 23 Remote assessments Execution and Management to list of References		
	37	7.7 (b)	Added remote assessments as an assessment technique		
	39	7.10	Inserted the need to take into account extensions granted when reviewing assessment programme and planning subsequent assessments.		
			Added SADCAS AP 23 to list of References		
Issue 16	10, 21, 23, 45	4.1.2, 5.2.1, 5.5, 8.2.1	Deleted "Memorandum and Articles of Association" and substituted with "Constitution of the SADCAS Ltd"	SADCAS Board	2020-06-10
	11	4.1.4	Aligned the Objects of SADCAS to the Constitution		
	13	4.1.8	Updated membership in IAF and SADCA		
	22	5.4	Deleted "Memorandum and Articles of Association" and substituted with "memorandum and clauses of the association"		





			Change	Approved by	Effective Date
Revision Status	Page	Clause/ Sub clause	Description of Change		
	45	8.2.1	Added Certificate of incorporation to list of documents that can be availed upon request from SADCAS	SADCAS Board	2020-06-10
Issue 17	12	4.1.6	Line 1 – Deleted "six(6)" and substituted with "seven(7)" between "following" and "core". Added "Excellence" to list of core values.	SADCAS Board	2022-03-03
	22	Figure 1	Replaced with the approved organizational structure for the strategic period 2022 to 2027		
	31	7.1.2.3	1 st paragraph line 2 – inserted "food safety" between "environmental" and "occupational"		
			1 st paragraph line 4 – Inserted ", the relevant sub-scope standard/technical specification" between "ISO/IEC 17021-1" and "and"		
			2 nd paragraph - Deleted 2 nd paragraph of 7.1.2.3 (a) and substituted with : "The sub-scope standard applicable to quality management systems certification bodies is ISO/IEC 17021-3.		
			The sub-scope standard applicable to environmental management systems certification bodies is ISO/IEC 17021-2.		
			The sub-scope standard applicable to occupational health and safety management systems certification bodies is ISO/IEC 17021-10.		
			The sub-scope standard applicable to food safety management systems certification bodies is ISO/TS 22003".		
	46	9.2	2 nd paragraph line 3 – Deleted "all SADCAS staff" and substituted with "CEO, Technical Manager, Finance and Administration Manager, Quality Manager, Scheme Coordinators and Training Administrator".		
lssue 18	7	2	Added "Excellence" to the list of core values	SADCAS Board	2023-01-20



	Change				
Revision Status	Page	Clause/ Sub clause	Description of Change	Approved by	Effective Date
lssue 18	7	2	Deleted signature of retired CEO and substituted with signature of new CEO	SADCAS Board	2023-01-20
	9	3	Deleted signature of retired CEO and substituted with signature of new CEO		
	10	4.1.1	Last paragraph: Deleted "Memorandum of Association "and substituted with "SADCAS Constitution"	-	
	13	4.1.7.2	Added new training course: Root cause analysis.		
	16	4.4.3	Added: "Nothing shall be said or implied that would suggest that accreditation would be simpler, easier, faster or less expensive if any specified person(s), trainers or consultancy were used" at the end of third paragraph.	-	
	17	4.4.8	Added review of risk profile at every Board meeting		
	18	4.6.1	Added Legal Metrology to the list of established accreditation schemes.		
	22	Figure 1	Updated SADCAS Organisational Structure to reflect positions filled in the past year.		
	25	5.6	Added responsibilities of Finance Officer and Communications and Public Relations Officer and Executive Assistant		
	31	7.1.2.2	Updated accreditation criteria for Medical Laboratories		
	37	7.7	Bullet (a): Deleted "one of whom shall be either the SADCAS Chief Executive Officer (CEO) or Technical Manager"		
	53	12	Revised metrological traceability section to align with latest version of ILAC P10 and SADCAS TR 09.		