



Medical Imaging Accreditation Scheme (MIAS)

Background

The SADCAS Medical Imaging Accreditation Scheme (MIAS) was established in April 2022. The MIAS is multi – disciplinary accreditation scheme operated in accordance with ISO/IEC 17011: Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.

The Need for Accreditation

Medical imaging is the technique and process of imaging the interior of a body for clinical analysis and medical intervention, as well as visual representation of the function of some organs or tissues. As a discipline and in its widest sense, medical imaging is part of biological imaging and incorporates radiology, which uses the imaging technologies of X-ray radiography, magnetic resonance imaging, ultrasound, endoscopy, elastography, tactile imaging, thermography, medical photography, and nuclear medicine functional imaging techniques. Medical imaging seeks to reveal internal structures hidden by the skin and bones, as well as to diagnose and treat disease. Medical imaging also establishes a database of normal anatomy and physiology to make it possible to identify abnormalities. Therefore, the competence and efficient operation of a medical imaging facility and timeous delivery of reliable and accurate medical imaging reports to the physician is critical in any health care delivery system and patient care. Accreditation is the strategy for a medical imaging facility to achieve this. The International Standard ISO 15189 specifies the requirements for quality and competence particular to medical laboratories including medical imaging facilities.

Accreditation of a medical imaging facility in accordance with ISO 15189 provides number of benefits:

- It is a means of demonstrating competence to clients both internal and external;
- It assures accurate and reliable medical imaging results;
- It improves patient care;
- It increases confidence in imaging reports issued;
- It provides continuous staff education and attracts professional reference due to accuracy and competence;

- It is a basis for the international recognition of medical imaging facility; and
- It is a credible and effective marketing tool.

Fields of Medical Imaging

The current fields of medical imaging offered on the SADCAS MIAS are:

1. Diagnostic Radiography
2. Ultrasonography

The fields of medical imaging are listed in SADCAS TG 03: Area of accreditation.

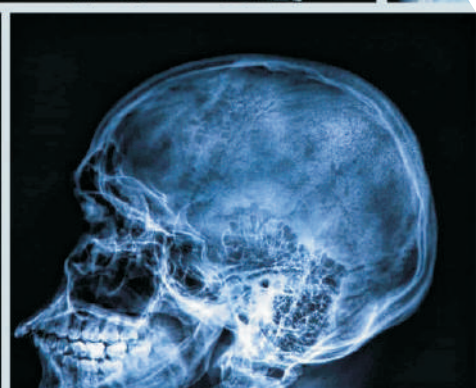
Accreditation Criteria

Medical Imaging service providers seeking to be accredited on the SADCAS MIAS need to comply with the International Standard ISO 15189: General requirements for the competence of medical laboratories.

The Accreditation Process

A medical imaging facility wishing to be accredited:

- Submits directly to SADCAS duly completed SADCAS F 43 (j): Application for accreditation of medical imaging service provider together with the quality manual, and duly completed SADCAS F 43 (f): Application for approval of personnel, i.e. nominated representatives in the case of medical imaging service provider and SADCAS F 44: SADCAS accreditation agreement.
- Upon receipt, SADCAS undertakes a **completeness check** of the application documents.
- SADCAS provides the applicant with a detailed quotation based on the scope of application. If acceptable, the applicant signs and returns duly signed quotation to SADCAS.





- SADCAS undertakes a **documentation review** of the applicant's quality manual and provides feedback to the applicant who, if there are nonconformities, institutes corrective action. If the quality manual addresses all the requirements of the standard, then the application proceeds to the assessment stage.
- **Pre- assessments** are optional but may be compulsory depending on the regulator's condition for acceptance where required. Pre-assessment is an on-site visit to check the readiness of applicant for accreditation.
- An **initial assessment** of the organization's competence is undertaken on-site and involves an opening meeting, assessment, witnessing of select technical activities and a closing meeting. Findings from the assessment are recorded as nonconformities where the laboratory needs to institute corrective action.

Assessors

Assessors are experts drawn from a pool of Medical Scientists, Technologists and Radiologists from the public and private sectors as well as from professional technical institutions/associations in the SADC region who have been trained, qualified and registered as assessors by SADCAS. Assessors trained and qualified by other accreditation bodies and evaluated for competence can also undertake assessments on behalf of SADCAS. An assessment is undertaken by an assessment team consisting of a Team Leader and at least one Technical Assessor/Technical Expert with expertise in the scope of assessment. The assessment team makes **recommendations for accreditation**.

Accreditation Certificate

Accreditation decision is made by the Accreditation Approvals Committee based mainly on the information gathered during an assessment. The accreditation certificate is valid for 5 years and

renewed subject to terms and conditions of the MIAS.

Periodic on-site Assessment and Re-assessment.

In order to maintain accreditation periodic assessments are conducted on-site. The first periodic assessment is undertaken not more than 12 months after accreditation thereafter annually throughout the accreditation cycle of 5 years. The intervals between periodic onsite assessments can be extended depending on the risks associated but must not exceed two years.

Re-assessments are conducted at least 6 months before the end of the assessment cycle of 5 years.

Appeals

Appeals from conformity assessment bodies on an accreditation decision shall be in writing and shall be forwarded to the Chief Executive Officer within 3 months of the cause of appeal. Appeals are handled in accordance with SADCAS AP 08: Customer feedback handling procedure which maintains independency and impartiality.

Accreditation Fees

SADCAS accreditation fees are contained in SADCAS AP 02: SADCAS Service Fees. The fees contained therein are estimates. Individual quotations are provided based on the fee estimates contained therein. SADCAS accreditation fees are reviewed annually.

Accreditation Documents

SADCAS accreditation documents are available from the SADCAS website www.sadcas.org



For further information, please contact:

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