

## ACCREDITATION PROCESS FOR TESTING/ CALIBRATION/ MEDICAL LABORATORIES/PROFICIENCY TESTING PROVIDERS

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**Table of Contents**

|  | <b>Page</b> |
|--|-------------|
| 1. PURPOSE AND SCOPE .....                               | 3           |
| 2. GENERAL .....   | 3           |
| 3. APPLICATION AND RESOURCE REVIEW .....                 | 7           |
| 4. DOCUMENT REVIEW .....                                 | 8           |
| 5. PRE-ASSESSMENT.....                                   | 9           |
| 6. ASSESSMENTS .....                                     | 10          |
| 7. THE ACCREDITATION CYCLE.....                          | 17          |
| 8. PERIODIC ASSESSMENT.....                              | 18          |
| 9. REASSESSMENT.....                                     | 19          |
| 10. SCOPE EXTENSIONS.....                                | 20          |
| 11. SCOPE OF ACCREDITATION .....                         | 20          |
| 12. TIMESCALE FOR ACCREDITATION PROCESS.....             | 21          |
| 13. COMPLAINTS, APPEALS AND DISPUTES .....               | 21          |
| 14. OBLIGATIONS AND DUTIES OF ACCREDITED FACILITIES..... | 21          |
| 15. SUSPENSION OF ACCREDITATION.....                     | 21          |
| 16. WITHDRAWAL OF ACCREDITATION .....                    | 22          |
| 17. REDUCTION OF SCOPE OF ACCREDITATION .....            | 22          |
| 18. REFERENCES.....                                      | 23          |
| APPENDIX - AMENDMENT RECORD .....                        | 25          |

## 1. PURPOSE AND SCOPE

This document outlines the process and assessment techniques used in the accreditation of testing/calibration and medical laboratories in accordance with ISO/IEC 17025 and ISO 15189 respectively and accreditation of Proficiency Testing Providers in accordance with ISO/IEC 17043, SADCAS requirements as well as the International Laboratory Accreditation Cooperation (ILAC) requirements. Reference to calibration laboratories shall also apply to legal metrology bodies accredited to ISO/IEC 17025.

## 2. GENERAL

2.1 SADCAS function is to assess and recognize the competence of conformity assessment bodies and to ensure through monitoring that accreditation scheme requirements are maintained.

2.2 An authorized representative of each applicant laboratory provides basic information to SADCAS on its activities on SADCAS F 43 (a)/ SADCAS F 43 (b)/ SADCAS F 43 (c)/SADCAS F 43(j), personnel in SADCAS F 43 (f) i.e. nominated representative and technical signatory in the case of testing and calibration laboratories and only nominated representative in the case of medical laboratories together with the laboratory's quality manual. Assessment of the competence of a testing/calibration/medical laboratory/proficiency testing provider is carried out through a review of documentation, visits to the laboratory's central administrative office and other locations and witnessing of activities.

2.3 Relevant documents, procedures and application forms are available on the SADCAS website [www.sadcas.org](http://www.sadcas.org).

**Note:** Guidance for the implementation of a medical laboratory accreditation systems are available from the ILAC website [www.ilac.org](http://www.ilac.org).

2.4 Accreditation of a testing/calibration/medical laboratory/ proficiency testing provider is a voluntary activity. Testing/ calibration/medical laboratories/ proficiency testing providers from the public/private sector that want the competence of their organization to carry out specific tasks recognized can apply for accreditation to SADCAS.

2.5 SADCAS uses Assessors/Technical Experts with the relevant specialist knowledge to evaluate the competence of the laboratories to perform the tests/calibration for which accreditation is sought. The assessment team is required by SADCAS to maintain confidentiality, and to sign SADCAS F 45 (a): Nondisclosure/confidentiality statement specifying the need to declare any potential conflict of interest. Their activities will be confined to assess the testing/calibration/medical laboratory's activities for compliance with the respective requirements and reporting their findings to the laboratory and to SADCAS.

2.6 A five-year accreditation cycle is applicable to all testing/calibration/medical laboratories which have applied for accreditation to SADCAS.

2.7 Assessment of the competence of laboratories is carried out using various assessment techniques, which includes but are not limited to:

| Assessment techniques   | Purpose   | When is this done  |
|---|---|--|
| Document reviews  | To evaluate whether the laboratories' system conforms to the relevant standard(s) and other SADCAS accreditation requirements.  | On receipt of an initial application for accreditation   |
|   | At the discretion of the Scheme Coordinator, where an extension of an existing scope is applied for, however it does not change the technique, principle or technical signatory.  | At any time during the accreditation cycle   |
| On-site visits to the laboratories and other sites where the laboratory performs calibrations or tests. | To determine, through the gathering of objective evidence, whether the laboratory is competent and conforms to the relevant standard(s) and accreditation requirements, and where applicable regulatory and legal requirements.   | During the on-site assessments   |
| Remote assessment   | Assessment of the physical location or virtual site of a conformity assessment body, using electronic means this include assessments conducted via electronic means such as online access, video links, web conferencing, telephone interviews, desktop assessment of documents/records, etc.<br>Note 1: A virtual site is an online environment allowing persons to execute processes, e.g. in a cloud environment.<br>Refer to SADCAS AP 23 | During extraordinary events or circumstances;<br>- Travel to a CAB or specific location not permitted or possible (i.e. for safety reasons, travel restrictions, etc.);<br>- Periodic on-site assessments or reassessments;<br>- Extensions to a non-critical scope; |

| Assessment techniques  | Purpose   | When is this done  |
|--|---|--|
| Witnessing   | To determine whether: <ul style="list-style-type: none"> <li>• Documented procedures are being followed;</li> <li>• Personnel have the skills required to perform scope of accredited work or for which accreditation is sought;</li> <li>• The training and supervision provided is effective;</li> <li>• The resources available are adequate;</li> <li>• Any defects in the equipment have been detected and addressed; and</li> <li>• Answers to questions asked can be supported.</li> </ul> | As part of on-site assessment process  |
| Review of performance of proficiency testing or other inter laboratory comparisons or Measurement Audits | To confirm that the laboratory monitors the validity and reliability of test/ calibration results/reports through the review of results, detection of trends and implementation of appropriate corrective actions.  | 1) Prior to initial assessment and re-assessment, except when extra-ordinary events may delay the laboratory participation. In such cases, the Laboratory shall provide evidence of participation during the initial assessment or reassessment visit.<br><br>2) As a sampling exercise during the periodic on-site assessment |
| Interviewing   | <b>Laboratory personnel:</b><br>To confirm that personnel are knowledgeable and competent in performing their duties.   | As part of on-site assessment process  |
|  | <b>Technical Signatories (TS) or applicant TS:</b><br>To confirm the competence and suitability of the TS, and that the TS: <ul style="list-style-type: none"> <li>• understands significant issues in the calibration/test, etc. processes;</li> </ul>   | As part of on-site assessment process  |

| Assessment techniques | Purpose   | When is this done   |
|-----------------------|---|---|
|                       | <ul style="list-style-type: none"> <li>• is able to critically evaluate results;</li> <li>• takes responsibility for the adequacy of results;</li> <li>• understands the requirements for accreditation and the scope of accreditation held/sought; and</li> <li>• understands SADCAS, accreditation and standard requirements (Refer to SADCAS F 44 and SADCAS TR 03 for additional information)</li> </ul> <p><b>Nominated Representative (NR):</b><br/>To confirm that the NR:</p> <ul style="list-style-type: none"> <li>• is familiar with and fully understands the requirements of the relevant standard or principles applicable to the laboratory’s scope of accreditation;</li> <li>• Irrespective of other duties and responsibilities, has a defined responsibility and the authority to ensure that the management system is implemented and followed at all times to support their proposed/current accreditation scope;</li> <li>• has direct access to the highest level of management at which decisions regarding policy or resources are made;</li> <li>• has an in-depth knowledge of all SADCAS accreditation requirements applicable to the scope of accreditation; particularly as defined in the SADCAS F 44, the relevant SADCAS technical requirements documents; and</li> <li>• Keeps SADCAS informed of changes as required by SADCAS TR 03.</li> </ul> | <p>1) As part of on-site assessment process</p> <p>2) Can be a telephonic interview at any time during the accreditation process on application of a new NR</p> |

| Assessment techniques | Purpose   | When is this done     |
|-----------------------|---|-----------------------|
| Extraordinary visits  | <ul style="list-style-type: none"> <li>• To follow up on the investigation and resolution of a complaint against a laboratory;</li> <li>• To follow up on significant changes in relation to a laboratory which may have an effect on the laboratory's accreditation/ compliance status; or</li> <li>• For any other reason that SADCAS may deem necessary to confirm on-going compliance to accreditation requirements.</li> </ul> | Refer to SADCAS AP 18 |

### 3. APPLICATION AND RESOURCE REVIEW

An authorized representative of a testing/calibration/medical laboratory/ proficiency testing provider wishing to be accredited submits directly to SADCAS duly completed and signed SADCAS F 43 (a)/ SADCAS F 43 (b)/ SADCAS F 43 (c)/SADCAS F43(j) together with the laboratories' quality manual and duly completed relevant scheme checklists demonstrating that the accreditation requirements are addressed and in which policy and procedures they are addressed, duly completed SADCAS F 43 (f) i.e. for nominated representative and technical signatory in the case of testing/calibration laboratories and only nominated representative in the case of medical laboratories and duly signed SADCAS F 44.

3.1 Upon receipt of the above documents, SADCAS will undertake the following:

- (i) Review the application form for completeness and verify that the required information and documentation has been received;
- (ii) Review the acceptability of technical information provided such as but not limited to:
  - Validation information
  - Proficiency testing performance and results
  - Uncertainty of measurement
  - Any other technical aspects or procedures
- (iii) Determine the suitability of the application and verify whether SADCAS is able to carry out the assessment in the scope applied for, in terms of its competence and availability of personnel suitable for the assessment activities and decision making;
- (iv) Assign an assessment team and, before engagement, confirm that they possess the required competence in the scope applied for or area of accreditation and request the team to sign SADCAS F 45 (a) Nondisclosure/Confidentiality Statement – Assessors/ Technical Experts;

- (v) Verify whether SADCAS will be able to carry out the assessment within one year of receipt of application, and where this is not possible, the reason shall be communicated to the applicant;
- (vi) Verify that the accreditation agreement signed by the authorized representative of the laboratory has been received;
- (vii) Confirm the scope of activities for which the organization is seeking accreditation;
- (viii) In the case of multi-standard accreditation (refer to clause 6.4), confirm the multi-standard accreditation for which the organization is seeking accreditation;
- (ix) Confirm the different locations from which the testing/calibration service is managed and the activities which are carried out at each of these locations;
- (x) Seek agreement with the applicant to the appointment of a specified Team Leader (TL) and the Technical Assessors (TA)/Technical Experts (TE) required to cover the scope(s) of the application and assessment dates. SADCAS will send notification of the date(s) of the assessment and the names of the proposed assessment team members, including the organization they work for to the laboratory for acceptance.
- (xi) The laboratory may object to the appointment of the assessment team. Objection however will only be considered if there is a conflict of interest. In this case the laboratory shall provide SADCAS with clear and valid reasons of objection in writing within seven (7) working days of receipt of the notification, and proving that conflict of interests exists. The SADCAS Technical Manager will decide whether a change of assessor/TE is warranted or not.

If the laboratory has good reason to object to an assessor/TE and no other assessor/TE is available from the SADC region to carry out the assessment, SADCAS may opt to use competent assessors/TEs from other accreditation bodies outside the region that are signatories to the ILAC MRA. These assessors shall be classified as TE, therefore shall be accompanied by a SADCAS qualified assessor. In this case the laboratory will be liable for the full costs covering assessor fees, travel and subsistence (accommodation meals and incidental).

- (xii) If an application is received with scopes that the Scheme Coordinator has no technical competence to determine suitability and acceptability of technical information received, an Assessor/Technical Expert or other SADCAS personnel with the required competence in the scope shall be engaged to complement the Scheme Coordinator during the review.
- 3.2 If at any point in the application or initial assessment process there is evidence of fraudulent behaviour, if the laboratory intentionally provides false information or if the laboratory conceals information, SADCAS will reject the application or terminate the assessment process.
- 3.3 Prior to any work being carried out, SADCAS will provide the organization with a quotation detailing the cost of the application and/or pre-assessment and initial assessment. If acceptable, the applicant signs and returns duly signed quotation to SADCAS. Acceptance of the quotation is required in order to proceed to the next stage of the assessment process. Annual accreditation fees will also be quoted and invoiced on a pro-rata basis.
- 3.4 The SADCAS Policy Manual (SADCAS PM 01) and all other SADCAS accreditation documents applicable to the testing/calibration/medical laboratories are available on the SADCAS website [www.sadcas.org](http://www.sadcas.org).



#### 4. DOCUMENT REVIEW

4.1 The testing/calibration/medical laboratories' quality manual (policy and procedures, etc.) will be reviewed for compliance with the applicable standard(s), SADCAS technical requirements and ILAC/AFRAC/SADCA guidance documents as relevant.

4.2 Document reviews are conducted on initial application for accreditation.

4.3 The process to be followed for a document review is as follows:

4.3.1 The laboratory conducts a review of their documentation and completes the Management and Technical requirements checklists for the relevant accreditation standard, detailing where in their documents the accreditation requirements are addressed.

***Comments on HOW the requirements of the standard have been implemented, Clause no., sub-clause no., procedure numbers MUST be captured.***

4.3.2 The laboratory submits the completed application form, checklists, management system manual (policy and procedures, etc.) to SADCAS.

4.3.3 SADCAS records the date of receipt and forwards the information submitted to the appointed Team Leader.

4.3.4 The Team Leader will identify the relevant technical information to be reviewed by the technical assessor/technical expert prior to the assessment.

4.3.5 The Assessment Team confirms from the information submitted by the laboratory whether the requirements of the relevant standard, regulatory requirements and any other requirements for accreditation are addressed in the management system manual.

4.3.6 On completion of the document review by the assessment team, the Team Leader shall compile a report on the relevant document review report forms [SADCAS 60(a) and SADCAS 60(b) for Testing Laboratories or SADCAS F 61 (a-3) for Medical Laboratories]. The report will 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. The report will be issued to the laboratory and a maximum period of three (3) months is allowed for applicant organization to address the findings. Failure to address the findings within the 3-months' period may lead to a repeat of the entire process should the applicant decide to continue seeking accreditation.

4.4 The initial assessment of the laboratory shall be arranged within three (3) months after the facility has addressed the issues raised in the document review report and advised SADCAS of their readiness for initial assessment. The Assessment Team in collaboration with Scheme Coordinator

shall review additional information/documents submitted by the facility as part of addressing document review findings and confirm adequacy prior to arranging initial assessment.

- 4.5 In case of transition or migration to a new standard the CAB shall submit to SADCAS prior to the assessment, completed relevant revised SADCAS checklists and any revised CAB documented information. The duly completed checklists shall be submitted to the assessment team 2 weeks prior to the assessment.

## 5. PRE-ASSESSMENT

- 5.1 Pre-assessment is an optional stage. The laboratory that seeks accreditation may voluntarily request SADCAS to conduct a pre-assessment to assess their readiness for accreditation. Pre-assessment is carried out on-site by the Team Leader/Technical Assessor who shall complete the [SADCAS F 61 (d) – Pre-assessment Report .

- 5.1.1 The pre-assessment can be carried out at a specified location (generally the central office) of the testing/calibration/medical laboratories to:

- (i) discuss any findings related to the documentation;
- (ii) seek further information on the management system;
- (iii) briefly examine the systems which have been established and implemented;
- (iv) discuss any arrangements which have been made to include multiple locations, sub-contracted activities, etc. within the management system;
- (v) agree the proposed scope(s) of accreditation;
- (vi) determine whether any further assessors/technical experts will be required.

Note: Due care shall be exercised to avoid consultancy during a pre-assessment.

- 5.1.2 The pre-assessment visit will normally be completed within one (1) day.

**Note:** No technical assessment of the laboratory's technical capabilities of competencies will be conducted during the pre-assessment.

- 5.1.3 The laboratory may need to make changes to its policies, procedures and practices in order that the organizations documented system complies with the requirements of the relevant standard.

- 5.1.4 Once all the findings raised during the pre-assessment have been satisfactorily addressed by the facility, SADCAS will arrange the initial on-site assessment of the laboratory within 3 months.

## 6. ASSESSMENTS

### 6.1 Prior to Assessment

- 6.1.1 An assessment schedule and a quotation will be forwarded to the laboratory in advance of the assessment; written acceptance of the quotation will be required before a visit can be undertaken.
- 6.1.2 The time required for initial assessment, periodic assessment( on-site or remote assessment) and re-assessment will be dependent on the complexity of the laboratory, 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.
- 6.1.3 SADCAS shall ensure that the appointed assessment team as a whole has the appropriate knowledge of the specific scope(s) of the accreditation and understanding to make a reliable assessment of the competence of the laboratory to operate within the scope(s) of the accreditation sought.

## 6.2 Initial Assessment

- 6.2.1 The nature of the initial assessment will depend on the scope(s) of accreditation required by the laboratory and the complexity of the management system that is being operated. However, the following elements will be covered:
  - (i) Central office assessment and where applicable sample collection sites;
  - (ii) Assessment of multiple locations (however named and where applicable);
  - (iii) Assessments of laboratory's activities (onsite or remote).

Refer to SADCAS AP 20 which defines SADCAS procedures and specific requirements for sampling of locations, personnel and the scope(s) of accreditation within an accreditation cycle to determine the competence of the laboratory to perform the activities covered by the scope(s) of accreditation.

- 6.2.2 At least 2 weeks prior to an assessment the Team Leader shall develop and send to the laboratory an assessment plan indicating the date(s) of the assessment, assessment team members, activities to be assessed, assessment techniques to be utilized, locations at which activities will be assessed and personnel to be assessed where applicable. Assessment techniques utilized during initial assessment shall include witnessing of activities and vertical assessment, where appropriate or applicable.
- 6.2.3 If the laboratory is not able to accommodate any of the planned activities, this should be communicated to the Team Leader as soon as possible, in order for the assessment plan to be adjusted, as far as possible and within the constraints of the SADCAS AP 20
- 6.2.4 Prior to the assessment, the assessment team members will each be provided with an assessment pack containing the relevant assessment documents including the checklists completed by the laboratory and the document review report.

- 6.2.5 The SADCAS assessment team will start the assessment with an opening meeting with the laboratory at which the purpose of the assessment and accreditation requirements are clearly defined, and the assessment plan as well as the scope for the assessment are confirmed. Refer to SADCAS F 46(a).
- 6.2.6 The SADCAS assessment team shall conduct assessment based on the assessment plan, and shall analyse all relevant information and objective evidence gathered prior to and during the assessment to determine the competence of the laboratory as determined through its conformity with the requirements for accreditation.
- 6.2.7 Various assessment techniques will be used to establish whether
- (i) The management system support competence against their scope of accreditation, is appropriate to the laboratory's needs, organizational arrangements and methods of operation, including multiple location activities and number of personnel;
  - (ii) The laboratory conforms with all of the requirements for accreditation;
  - (iii) The laboratory has implemented all the requirements of the management system effectively;
  - (iv) The operational, administrative and technical procedures used to support the management system are complete, technically valid and appropriate.
- 6.2.8 The following techniques will be employed to establish that procedures are being correctly and fully implemented:
- (i) Questioning of management and personnel who have an involvement in or bearing upon the quality of tests/calibration activities;
  - (ii) Examination of records;
  - (iii) Examination of the suitability, maintenance, calibration, control and use of all equipment used for testing/calibration/medical laboratories activities; and
  - (iv) Examination of the arrangements for exercising control over sub-contractors and suppliers.
- 6.2.9 All fields and types of testing/calibration activities will be subject to an office assessment and technical review. The team will assess the technical competence of personnel related to the type of tests/calibration covered by the scope(s). This will be done through:
- (i) The examination of the records outlined above;
  - (ii) Discussions with personnel supervisors and manager;
  - (iii) Assessment of the performance of the personnel whilst conducting scheduled activities; and
  - (iv) Assessment of calibration certificates /test reports issued by the laboratory.
- 6.2.10 If the laboratory cannot provide at least one witnessing and/or sufficient supporting evidence in order for a vertical assessment to be conducted on the day of the assessment, the assessor has

the right to terminate the assessment, and reschedule for another day at full cost to the laboratory.

- 6.2.11 The Assessor shall record all the information gathered during the assessment on the relevant SADCAS forms provided for this purpose. The records shall be sufficiently comprehensive as to allow for an independent expert serving on the Accreditation Approvals Committee to reach the same conclusion.
- 6.2.12 The team will report the findings raised during the on-site assessment on the nonconformity, corrective action and clearance report form SADCAS F 61 (b) and will need to agree on the nature and classification of the nonconformity. Each form shall be signed by the Assessor and the organization's representative. If the team could not reach a decision about a finding, the matter shall be referred to SADCAS for clarification.
- 6.2.13 After each member of the assessment team has completed the respective assignment in accordance with the assessment plan, they shall hold a private meeting to summarize their conclusions and contribute to a coordinated view on the status of the applicant laboratory's system.
- 6.2.14 The team, together with the laboratory's representative will agree on the draft schedule of accreditation during the closing meeting.
- 6.2.15 At the end of an assessment, whether performed on-site or remotely, a closing meeting shall be held between the assessment team and the conformity assessment body. Refer to SADCAS F 46 (b). At this meeting, the assessment team shall report on the findings identified during the assessment and detail in writing any nonconformities. The Team Leader will provide the laboratory with an opportunity to seek clarification on the findings including any nonconformities and their basis.
- 6.2.16 A summary of the assessment report [SADCAS F 61 (c)] shall be provided to the laboratory in writing without undue delay. If the written report on the outcome of the assessment differs from the outcome delivered at the close of the assessment (see 6.2.15 above), SADCAS shall provide an explanation to the assessed conformity assessment body, in writing. Where corrective action by the laboratory is required [SADCAS F 61 (b)], the applicant organization shall be requested to analyse the extend and root cause of the nonconformities, and 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. In most cases evidence can be provided by post/fax/e-mail although there may be situations where additional visits to the laboratory will be required. If an additional visit for clearing of findings is recommended by the assessment team, it will be at cost to the organization. SADCAS will review the evidence provided and decide upon its acceptability.
- 6.2.17 The corrective actions provided by the laboratory will be reviewed by the relevant assessor, to determine whether the actions are appropriate and sufficiently address the nonconformities. Where the laboratory root cause analysis and/or corrective actions are found not to be sufficient,

further information will be requested from the laboratory, or a follow up assessment may be carried out to verify the effective implementation of corrective actions at the cost of the laboratory.

- 6.2.18 When all corrective actions have been approved by the assessment team, the SADCAS Accreditation Approvals Committee (AAC) will review the assessment documentation and decide whether to support the recommendation made by the team. If the AAC is satisfied, accreditation will be granted and a SADCAS certificate and schedule of accreditation will be issued. The AAC meetings shall be held as necessary without undue delay to the accreditation decision making process. The AAC should be held within two (2) weeks after the review of the file.

**Note:** The Certificate and schedule(s) of accreditation shall not be issued if there are any outstanding fees.

### 6.3 Multi-Location Laboratories

- 6.3.1 An applicant that operates from a central laboratory through a number of locations may seek a single accreditation provided that the conditions specified in the relevant standard are fulfilled.

Groups of medical laboratories operating under the same management system are allocated individual accreditation numbers, and each satellite laboratory shall be individually assessed.

- 6.3.2 Laboratories shall under no circumstances franchise their accredited activities to other laboratories/ organizations.

- 6.3.3 On application, the laboratory must indicate the number and range of locations being operated. All locations will be visited during the initial assessment, thereafter, SADCAS will visit selected locations taking into account:

- (i) The results of internal audits from central laboratory and locations;
- (ii) The results of management reviews;
- (iii) Variations in the size of locations;
- (iv) Complexity of the management system;
- (v) Complexity of the locations;
- (vi) Variations in working practices including, where applicable, equipment used;
- (vii) Variations in activities undertaken e.g. types of testing/calibration activities.

- 6.3.4 It will normally not be necessary to witness the full range of scopes for each selected location once accredited.

- 6.3.5 SADCAS will seek to establish through objective evidence and by using various techniques that:

- (i) All locations are operating under the same management system;
- (ii) All locations are included in the internal audit programme and central review process.

- 
- 6.3.6 All locations must be working to the same requirements and may be subject to assessment on a sampling basis as part of the accreditation process to provide evidence of the operation and effectiveness of the system.
- 6.3.7 During the central laboratory assessment SADCAS may need to see records of activities, which are being carried out at different locations.
- 6.3.8 If SADCAS observes non-compliance at the central laboratory or at any one of the locations of a laboratory with multiple locations, the corrective action procedure shall apply to all locations where applicable. In the event that the results of any of the assessments of 'sample locations' reveal that there is a significant weakness or inconsistency in the application of the management system, SADCAS will review the assessment programme and may increase the number of locations to be assessed.
- 6.3.9 Failure by one location to comply with SADCAS requirements may lead to removal of the location from the schedule of accreditation. If the cause of non-compliance is the lack of central control then the corporate accreditation will be subject to be reviewed by SADCAS and may lead to suspension or withdrawal of accreditation from all locations.
- 6.3.10 Generally, each location from which a laboratory is operating will be visited at least once during the assessment cycle.
- 6.3.11 SADCAS must be advised of any changes to location addresses and activities, see SADCAS F 44. The establishment of any new locations from which the laboratory proposes to offer an accredited service must be notified to SADCAS before these can be included in the schedule of accreditation. The need for assessment of the new location will be reviewed, the schedule of accreditation will be amended as appropriate and the location will be included in the programme of periodic on-site assessments and re-assessment.
- 6.4 **Multi-Standard Assessment**
- 6.4.5 A laboratory who wishes to be assessed to two (2) or more accreditation standards may be assessed to multiple standards at the same assessment, using one Team Leader knowledgeable in the multi-standards for which accreditation is sought, together with the required technical assessors/technical experts.
- 6.4.6 Where the scope applied for falls under different schemes (e.g. testing in accordance with ISO/IEC 17025 and ISO 15189 for medical laboratories), the accreditation application forms and approval of personnel forms of the different schemes must be completed in full, although only one copy of all the information required must be submitted to SADCAS. Each applicant organization also provides completed SADCAS checklists appropriate to its scope of application and Multi-Standard combination indicating where the requirements are addressed in their system.
- 6.4.7 The application forms are forwarded to the Scheme Coordinator who will process the application form as described in Clause 3 of this document.

6.4.8 It is important for the organization to ensure that the applicable Multi-Standards are fully addressed in their documented system to ensure that all the requirements are fully addressed. If the documented system does not address the applicable Multi-Standards fully additional time may be required for the document review and assessment. An integrated management system is preferred.

6.4.9 The normal application and assessment processes are followed, as described in Clauses 3 to 6, with a pre-assessment which may be mandatory for a multi-standard assessment.

### 6.5 **Witnessing of activities**

6.5.5 Witnessing of activities is an essential part of the SADCAS assessment of laboratory applicable to their field of operation. This is particularly important to determine the competency of the analysts/technician/metrologist when the laboratory is performing activities and where the personnel professional judgement is crucial to the outcome of tests/calibration results.

6.5.6 When deciding on the number of witnessing activities needed the following aspects will be considered by SADCAS:

- (i) The fields and types of tests/calibration on the accreditation schedule;
- (ii) The testing/calibration/medical laboratory's procedures for selecting, training, authorising and monitoring personnel, having regard to the qualifications and experience required for different fields and types of tests/calibration;
- (iii) The internal auditing arrangements of the testing/calibration/medical laboratory;
- (iv) The locations from which the personnel operate;
- (v) Any statutory requirements;
- (vi) The extent to which analysts/technician/metrologist are required to exercise professional judgement.

6.5.3 When deciding on the types of tests/calibration to be witnessed account will be taken of the following:

- (i) Types of tests/calibration covered by the testing/calibration activities;
- (ii) Skills needed by analysts/technician/metrologist;
- (iii) Any statutory requirements;
- (iv) The extent to which analysts/technician/metrologist are required to exercise professional judgement.

6.5.4 As a minimum, one analyst/technician/metrologist carrying out tests/calibration will be witnessed on-site for the fields and types of tests/calibration on the accreditation schedule.

6.5.5 When deciding on which analysts/technician/metrologist will be witnessed account will be taken of:



- (i) New recruits or new authorisations;
- (ii) Qualifications and experience;
- (iii) Location;
- (iv) Any statutory requirements;
- (v) The extent to which analysts/technician/metrologist are required to exercise professional judgement.

6.5.6 If none of the analysts/technician/metrologist can cover the entire scope of a specific field, then more than one analyst/metrologist will be witnessed for that field. Where there is any evidence, which casts doubt on the competence of laboratory's personnel, the sample size of analysts/technician/metrologist witnessed on-site may be increased.

6.5.7 It will be necessary to examine equipment and documentation, such as procedures and instructions, records, reports and planning arrangements. If an analyst/technician/metrologist operates in different locations, this examination will be arranged at a mutually acceptable location.

6.5.8 SADCAS assessors will ensure that their role during witnessing of activities is one of observer and they will not influence the activity being performed. The team will be looking to see that as a minimum:

- (i) The analyst/technician/metrologist has the competence for the test/calibration performed;
- (ii) The analyst/technician/metrologist's competence is consistent with the records;
- (iii) The analyst/technician/metrologist has been supplied with all necessary documented testing/calibration methods and procedures;
- (iv) The procedures are up-to-date;
- (v) the analyst/technician/metrologist implements the procedure in full and correctly i.e. no short-cuts, no personalised application where it is not permissible to do so;
- (vi) records of all observations are made while on-site as required by the procedure;
- (vii) Records clearly identify what has been inspected, using what method/procedure, and when;
- (viii) All records are signed/initialled, stamped, as applicable;
- (ix) All findings that indicate immediate or urgent action are reported as required to the customer whilst on site;
- (x) Reports comply with the laboratory requirements, the relevant standard [ISO/IEC 17025, ISO 15189] and/or as amplified by the relevant guidance documents;
- (xi) Facilities and equipment are fit for the analyst/technician/metrologist purpose.

## 7. THE ACCREDITATION CYCLE

7.1 The Accreditation Cycle begins on the day of the decision to grant the initial accreditation or decision after re-assessment, and is valid for a period of 5 years, subject to the Accreditation Requirements being met (Refer to F 44). The assessment programme shall ensure that the requirements of the international standard and other normative documents containing

requirements for laboratory and the scope of accreditation are assessed taking risks into consideration.

- 7.2 Once accreditation has been granted, the Scheme Coordinator shall apply an assessment programme in which the assessments of the laboratory's activities throughout the cycle are planned and conducted in accordance with SADCAS AP 20.
- 7.3 When establishing the assessment programme, the Scheme Coordinator shall cover the scope(s) of each laboratory and consider factors such as information about the laboratory's management system and activities, its performance, risks identified, relevant locations/sites, and number of personnel to be evaluated. Some of this information will normally be recorded by the Team Leader on the Assessment Matrix and/or on the Assessment Feedback (SADCAS F 57) forms, or will be contained in the Accreditation Approvals Committee decisions. The assessment programme needs to be periodically reviewed and updated.
- 7.4 The assessment programme consists of:
- Periodic on-site assessments; and
  - A re-assessment prior to the expiry of the Certificate of Accreditation.

## **8. PERIODIC ASSESSMENT**

### **8.1 General**

- 8.1.1 Following accreditation, SADCAS will check for continuing compliance with accreditation requirements by carrying out periodic on-site visits to a laboratory. The first periodic on-site assessment is undertaken not more than 12 months after accreditation thereafter annually throughout the accreditation cycle. The intervals between periodic on-site assessments can be extended depending on risks associated but must not exceed two years. 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.
- 8.1.2 The level of sampling of locations and analysts/technicians/metrologists will depend on performance over the assessment cycle, the extent of any changes, which have taken place, and the level of confidence, which can be placed in the performance measures, and control systems of the laboratory.

### **8.2 Periodic on-site assessment**

- 8.2.1 Periodic on-site visits will be planned to cover the whole of the schedule(s) of accreditation over the assessment cycle. SADCAS shall plan the periodic on-site visits of accredited laboratory taking into account other periodic on-site activities. Any revisions to the management system will be reviewed during these visits. Extensive changes may require additional assessment time.

8.2.2 A report will be provided to the facility at the time of the periodic on-site assessment. Where corrective action is required, the facility shall address the nonconformity and to have the corrective action cleared within two (2) months after the assessment.

8.2.3 In most cases evidence can be provided by email/fax/post although there may be situations where additional visits to the laboratory may be required. SADCAS will review the evidence provided and decide upon its acceptability.

### **8.3 Multi-Location Laboratories**

8.3.1 For multi-location laboratories the central quality system and technical requirements will be subject to periodic on-site assessments with the first periodic on-site visit being undertaken not more than 12 months after accreditation thereafter annually throughout the accreditation cycle. The intervals between periodic on-site visits can be extended depending on the risks associated but must not exceed two years. It is anticipated that, in addition to the central laboratory, at least one location will be visited each year, with a visit to each location generally taking place over the assessment cycle. However, the level of sampling of locations and analysts/technicians/metrologists will depend on performance over the assessment cycle, the extent of any changes which have taken place and the level of confidence which can be placed in the performance measures and control systems of the laboratory.

### **8.4 On-site Assessment of testing/calibration/medical laboratories**

8.4.1 On-site assessment of a laboratory will be carried out at **each** periodic on-site visit where practicable. The same criteria used for assessment will be considered when determining the number and type of tests/calibration, and the personnel to be witnessed. The laboratory shall inform SADCAS if a site is not available for the scheduled periodic on-site visit.

8.4.2 The applicant organization shall address the raised nonconformities and have corrective action cleared within two (2) months after the assessment.

## **9 REASSESSMENT**

9.1 The laboratory shall submit an application form for renewal of accreditation at least 9 months before the expiry of the accreditation, with at least the following:

- Fully completed management and technical checklists containing comments on how the requirements of the relevant standard are implemented and in which policy/procedures it is addressed.
- SADCAS may request other information as needed e.g. validation or proficiency testing reports for new scopes added.

**NOTE:** If an application and payment for reassessment is not received six months prior to the expiration of accreditation, the facility shall be required to undergo the initial accreditation process that includes payment of application fee and document review.

- 9.2** The application information will be submitted to the assessment team once they are appointed in order to allow the team to prepare for the assessment, and request any further information/clarification before the assessment. Feedback on this information need not be provided, unless they are any concern on information provided and where the laboratory is required to take actions.
- 9.3 A re-assessment is planned and conducted at least 6 months prior to the end of the accreditation cycle. Re-assessment visits will consider information gathered from assessments performed within the accreditation cycle. This information is normally obtained from the assessment matrix forms completed for the cycle. The Scheme Coordinator shall review and analyze the fully completed assessment matrix, document the analysis and consider the information from the review in planning the re-assessment. The same criteria used for assessment will be considered when determining the number and type of tests/calibration, and the personnel to be assessed. The reassessment shall confirm the competence of the laboratory and cover all the requirements of the standard(s) for which the laboratory is accredited.
- 9.4 The applicant organization shall address the raised nonconformities and have corrective action cleared within two (2) months after the assessment.

**Note:** Should the application for renewal of accreditation not be submitted before the expiry of the Certificate, a re-assessment may not be conducted prior to the end of the accreditation cycle, resulting in the expiry of the laboratory's accreditation and the laboratory having to re-apply for accreditation as a new applicant. All application fees and timeframes will be applied for the re-application.

## **10. SCOPE EXTENSIONS**

- 10.1 There are two types of extensions to the scope of accreditation:
- A whole new scope including the conformity assessment activities within that scope; and
  - Conformity assessment activities added to an existing accredited scope.
- 10.2 Following receipt of an application for extension of the scope of accreditation including supporting information to show that the requirements for accreditation are met, SADCAS will determine the application in accordance with clause 3 and determine whether or not there is a

need for an additional assessment or if an assessment of the requested scope can occur during the laboratory next planned assessment. SADCAS F 44 may be excluded from the documentation to be submitted by the CAB unless it has been revised since the last application. SADCAS F43(f) for the Nominated Representative may be excluded from documentation submitted by the CAB unless an alternate or new Nominated Representative is required for the scope extension.

10.3 The following factors will be taken into consideration:

- (i) Existing scope of accreditation;
- (ii) Risks associated with the activities or locations to be covered in the scope extension;
- (iii) Scopes applied for;
- (iv) The location at which the extension to scope is sought;
- (v) Whether or not different set of competencies required to perform the requested scopes; and
- (vi) Competence of personnel.

10.4 For an assessment of the extension of scope applied for to take place at the next scheduled assessment, the application must be submitted to SADCAS at least six (6) weeks prior to the next assessment date.

10.5 Where possible and desirable, any additional work will be carried out at the next periodic on-site assessment or re-assessment visit; where necessary, additional visits will be arranged. The assessment programme and planning for the subsequent assessments will be reviewed and may be revised and the laboratory fees may be revised accordingly.

## **11. SCOPE OF ACCREDITATION**

11.1 It is SADCAS' policy to define the scope(s) of a laboratory's accreditation as precisely as possible. Laboratories will therefore be asked to specify in detail the field, type and range of tests/calibration for which accreditation is sought and the locations at which these activities are to be carried out. The scope(s) will be agreed as far as possible before the assessment in order to determine the extent of the assessment activities. Following successful assessment, the scope, including standard specifications, methods and procedures relevant to the tests/calibration concerned will be identified on the accreditation Schedule.

11.2 Following accreditation, the Schedule is considered to be in the public domain unless otherwise requested by the laboratory for legitimate reasons and will form the basis of SADCAS publication Directory of Accredited Organizations.

## **12. TIMESCALE FOR ACCREDITATION PROCESS**

12.1 SADCAS makes every effort to ensure that all applications are processed as efficiently as possible. The time taken to process an application depends on a number of factors, some of which are outside the control of SADCAS. The timing is dependent on:

- (i) The quality of the applicant's documentation and the extent to which it complies with SADCAS requirements. A delay can occur due to insufficient documented procedures and submission of inadequate Quality Manuals;
- (ii) The availability of suitable assessors/technical experts;
- (iii) The level of implementation of the system and available evidence of technical competence
- (iv) How efficiently the applicant organization clears the nonconformities after the initial assessment;
- (v) The availability of the resources within SADCAS.

### **13. COMPLAINTS, APPEALS AND DISPUTES**

- 13.1 Complaints, appeals and disputes will be handled in accordance with the SADCAS AP 08.

### **14. OBLIGATIONS AND DUTIES OF ACCREDITED FACILITIES**

- 14.1 The obligations and duties of an accredited facility are captured in the SADCAS F 44: Accreditation agreement. All applicant organizations need to familiarize themselves with the content of this document.
- 14.2 Accredited facilities are obliged to pay fees specified in SADCAS AP 02. The current rates are published on the SADCAS website: [www.sadcas.org](http://www.sadcas.org)

### **15. SUSPENSION OF ACCREDITATION**

- 15.1 The procedure SADCAS TR 06 covers suspension and reinstatement of accreditation.
- 15.2 If the laboratory is to perform any activity in the suspended scope during the suspension period, they must inform SADCAS at their earliest opportunity for arrangements for a re-instatement assessment.

### **16. WITHDRAWAL OF ACCREDITATION**

- 16.1 The procedure SADCAS TR 06 covers withdrawal of accreditation.
- 16.2 If the laboratory accreditation is withdrawn, the laboratory shall submit a new application for accreditation to SADCAS should they want to continue.

### **17. REDUCTION OF SCOPE OF ACCREDITATION**

A laboratory may apply to SADCAS to have their scope of accreditation reduced at any time. An application for the reduction in scope may be for a number of reasons such as lack of access to the expertise needed for the scope, insufficient applications in the scope, etc.

If the laboratory fails to meet the requirements for accreditation for the tests methods already accredited including competence of personnel, SADCAS shall reduce the scope of accreditation to exclude those test methods.

SADCAS will update the certificate and schedule of accreditation accordingly and publish the amended version on the SADCAS website.

## 18. REFERENCES

- ILAC G19: Guidelines for forensic science laboratories
- ILAC G26: Guidance for the implementation of a medical laboratory
- SADCAS F 43(a) – Application for accreditation of calibration laboratories
- SADCAS F 43(b) – Application for accreditation of testing laboratories
- SADCAS F 43(c) – Application for accreditation of medical laboratories
- SADCAS F 43 (f) – Application for approval of personnel
- SADCAS F 43(j) - Application for Accreditation of Proficiency Testing
- SADCAS F 44 – Accreditation agreement
- SADCAS F 45 (a) – Nondisclosure/confidentiality statement – Assessors/Technical experts
- SADCAS F 46 (a) – On-site Assessment – Opening Meeting Agenda
- SADCAS F 46 (b) – On-site Assessment – Closing Meeting Agenda
- SADCAS F 57 – Feedback from assessment
- SADCAS F 60(a) - Management Requirements ISO IEC 17025
- SADCAS F 60(b) - Technical Requirements ISO IEC 17025
- SADCAS F 60(f) - Assessment Cycle Matrix – ISO/IEC 17025
- SADCAS F 61 (a-3) – Document review report for medical laboratories – ISO15189
- SADCAS F 61(b) - Conformity assessment body – Nonconformity, corrective and clearance report
- SADCAS F 61 (c) - Assessment recommendation report
- SADCAS F 91 (a) – Accreditation Approvals Committee – Assessment packs Testing/Calibration laboratories accreditation scheme
- SADCAS F 91 (b) – Accreditation Approvals Committee – Assessment packs Medical laboratory accreditation scheme
- SADCAS F 93 – Completeness check of application and Resource review
- SADCAS F134(a) Management Requirements for Medical laboratories ISO 15189
- SADCAS F 134 b - Vertical Assessment ISO 15189-2022 for Medical Laboratories
- SADCAS F 134(c) - Assessment Cycle Matrix for Medical Laboratories - ISO 15189
- SADCAS F 134 (e) - Proficiency Testing - ISO 15189-2022 Clause 7.3.7.3 & SADCAS Requirements

- SADCAS F 136(a) - Management Requirements ISO/IEC 17043
- SADCAS F 136(b) - Technical Requirements ISO/IEC 17043
- SADCAS F 136(c) - Vertical Assessment checklist for ISO/IEC 17043
- SADCAS F 136(d) - Witnessing of Activity for Proficiency Testing Scheme
- SADCAS F 136(c) - Assessment Cycle Matrix – ISO/IEC 17043
- SADCAS AP 08 - Customer feedback handling procedure
- SADCAS AP 18 – Criteria for extraordinary assessments
- SADCAS AP 20 – Sampling for assessment purposes
- SADCAS PM 01 - SADCAS Policy Manual
- SADCAS TR 06 - Suspension and Reinstatement of Accredited Organizations
- SADCAS SL 20 – Assessment Plan
- SADCAS AP 23- Remote Assessments- Management and Execution



**APPENDIX - AMENDMENT RECORD**

| Revision status | Change   |        |  | Approved by | Effective Date |
|-----------------|----------|--------|--|-------------|----------------|
|                 | Page No. | Clause | Description of change  |             |                |
| Issue 8         | 11       | 6.2.1  | <ul style="list-style-type: none"> <li>Item (iii): Deleted “on-site” and substituted with “onsite or remote”.</li> <li>Deleted note at end of paragraph which read “On-site assessment is a mandatory requirement for an initial assessment”.</li> </ul>   | CEO         | 2021-02-04     |
|                 | 13       | 6.2.15 | <p><u>New clause added:</u> “At the end of an assessment, whether performed on-site or remotely, a closing meeting shall be held between the assessment team and the conformity assessment body. Refer to SADCAS F 46 (b). At this meeting, the assessment team shall report on the findings identified during the assessment and detail in writing any nonconformities. The Team Leader will provide the laboratory with an opportunity to seek clarification on the findings including any nonconformities and their basis”.</p> <p>Renumbered subsequent clause</p> |             |                |
|                 | 13       | 6.2.16 | <p>Added: “without undue delay. If the written report on the outcome of the assessment differs from the outcome delivered at the close of the assessment (see 6.2.15 above), SADCAS shall provide an explanation to the assessed conformity assessment body, in writing” at the end of first sentence.</p>   |             |                |
| Issue 9         | 9        | 4.4    | <p>Added “The Assessment Team in collaboration with Scheme Coordinator shall review additional information/documents submitted by the facility as part of addressing document review findings and confirm adequacy prior to arranging initial assessment” at the end of the paragraph.</p>   | CEO         | 2023-02-28     |
|                 | 11       | 6.2.2  | <p>Added “Assessment techniques utilized during initial assessment shall include witnessing of activities and vertical assessment, where appropriate or applicable.”</p>   |             |                |
| Issue 10        | 5        | 2.7    | <p>Added provision for submission of proficiency testing(PT) results during initial assessment if an extraordinary event delays the facility’s participation in PT at time of application submission.</p>  | CEO         | 2023-09-22     |
|                 | 7        | 3.1    | <p>Added under (iv) “Assign an assessment team and, before engagement, confirm that they possess the required competence in the scope applied for or area of accreditation and request the team to sign SADCAS</p>   |             |                |

| Revision status | Change   |        |   | Approved by | Effective Date |
|-----------------|----------|--------|---|-------------|----------------|
|                 | Page No. | Clause | Description of change   |             |                |
|                 |          |        | F 45 (a) Nondisclosure/Confidentiality Statement – Assessors/ Technical Experts”  |             |                |
|                 | 8        |        | Added under (xii) : If an application is received with scopes that the Scheme Coordinator has no technical competence to determine suitability and acceptability of technical information received, an Assessor/Technical Expert or other SADCAS personnel with the required competence in the scope shall be engaged to complement the Scheme Coordinator during the review.   |             |                |
|                 | 20       | 9.1    | NOTE Added: If an application and payment for reassessment is not received six months prior to the expiration of accreditation, the facility shall be required to undergo the initial accreditation process that includes payment of application fee and document review.   |             |                |
|                 | 9        | 4.3.6  | Added - “ SADCAS 60(a) and SADCAS 60(b) for Testing Laboratories or SADCAS F 61 (a-3) for Medical Laboratories” .   |             |                |
| Issue 11        | 10       | 5.1    | Referenced SADCAS F 61 (d) – Pre-assessment Report  | CEO         | 2025-03-31     |
|                 | 11       | 6.1.1  | Deleted: “6.1.1 Prior to assessment, the laboratory will provide SADCAS with a list of current personnel, the fields and types of tests/calibration and the locations (however named) at which they are currently operating. The Scheme Coordinator (SC) will determine, in conjunction with the organization, when and which locations and personnel will be subject to on-site assessment (see 8.4) as part of the planning process.” |             |                |
|                 | 20       | 9.3    | Added “The Scheme Coordinator shall review and analyze the fully completed assessment matrix, document the analysis and consider the information from the review in planning the re-assessment” on first paragraph  |             |                |
|                 | 21       | 10.2   | Added “SADCAS F 44 may be excluded from the documentation to be submitted by the CAB unless it has been revised since the last application. SADCAS F43(f) for the Nominated Representative may be excluded from documentation submitted by the CAB unless an alternate or new Nominated Representative is required for the scope extension”   |             |                |
|                 | 23       | 18     | Referenced the new Proficiency Testing forms – SADCAS F136(a,b,c,d,e) and SADCAS F43(j)   |             |                |