

ACCREDITATION OF INSPECTION BODIES OPERATING IN THE REGULATORY/VOLUNTARY AREA

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1. PURPOSE AND SCOPE

This document outlines the process and assessment techniques used in the accreditation of inspection bodies (IBs) in accordance with ISO/IEC 17020, SADCAS requirements, relevant regulations as well as the International Laboratory Accreditation Cooperation (ILAC) requirements.

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 IB provides basic information to SADCAS on its activities on SADCAS F 43(h); Application for accreditation of inspection bodies, staff in SADCAS F 43 (f): Application for approval of personnel i.e. nominated representative and technical signatory in the case of inspection bodies together with the inspection body's quality manual. Assessment of the competence of an IB is carried out through a review of documentation, visits to the IB's central administrative office and other locations and witnessing of inspections.
- 2.3 Guidelines on the application of ISO/IEC 17020 are provided in ILAC P15 and available from www.ilac.org. Inspection documents, procedures and application forms are available on the SADCAS website www.sadcas.org.
- 2.4 Accreditation of inspection bodies is offered in both the Regulatory and the Voluntary areas. In the Regulatory area the various Regulators require accreditation as a pre-requisite prior to granting approval to operate as an Approved Independent Inspection Authority.
- 2.5 SADCAS uses Technical Assessors (TAs) and/or Technical Experts (TEs) with the relevant specialist knowledge to evaluate the competence of the IB to perform the inspections 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 assessing the IB's activities for compliance with the requirements and reporting their findings to the IB and to SADCAS.
- 2.6 A five year accreditation cycle is applicable to all inspection bodies whether they are operating within the voluntary or regulatory area.
- 2.7 Assessment of the competence of IBs 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 IBs' 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 IBs and other sites where the IB performs inspections	To determine, through the gathering of objective evidence, whether the IB is competent and conforms to the relevant standard(s) and accreditation requirements, and where applicable regulatory and legal requirements.	during on-site assessments
Remote Assessments	<p>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.</p> <p>Note 1: A virtual site is an online environment allowing persons to execute processes, e.g. in a cloud environment.</p>	<p>During extraordinary events or circumstances;</p> <ul style="list-style-type: none"> - Travel to a CAB or specific location not permitted or possible (i.e. for safety reasons, travel restrictions, etc.); - Periodic on-site assessments or reassessments; - Extensions to a non-critical scope;

Assessment techniques	Purpose	When is this done
Witnessing	To determine whether: <ul style="list-style-type: none"> • Documented procedures are being followed; • Staff have the skills required to perform scope of accredited work or for which accreditation is sought; • The training and supervision provided is effective; • The resources available are adequate; • Any defects in the equipment have been detected and addressed; and • Answers to questions asked can be supported. 	As part of on-site assessment process
Review of performance of inspections undertaken	To confirm that the IB monitors the validity and reliability of inspections/reports through the review of results, detection of trends and implementation of appropriate corrective actions.	1) As part of an on-site initial assessment and re-assessment 2) As a sampling exercise during the Periodic on-site assessment
Interviewing	IB personnel: To confirm that personnel are knowledgeable and competent in performing their duties.	As part of on-site assessment process
	Technical Signatories (TS) or applicant TS: To confirm the competence and suitability of the TS, and that the TS: <ul style="list-style-type: none"> • understands significant issues in the inspections, processes, etc. ; • is able to critically evaluate results; • takes responsibility for the adequacy of results; • understands the requirements for accreditation and the scope of accreditation held/sought; and • understands SADCAS, accreditation and standard requirements (Refer to SADCAS F 44 –SADCAS Accreditation Agreement and SADCAS TR 03 - Nominated Representative and Signatories: 	As part of on-site assessment process

Assessment techniques	Purpose	When is this done
	<p><i>Responsibilities, Qualifications and Approval for additional information)</i></p> <p>Nominated Representative (NR): To confirm that the NR:</p> <ul style="list-style-type: none"> • is familiar with and fully understands the requirements of the relevant standard or principles applicable to the IB’s scope of accreditation; • 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; • has direct access to the highest level of management at which decisions regarding policy or resources are made; • 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 • keeps SADCAS informed of changes as required by SADCAS TR 03. 	<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>
Extraordinary visits	<ul style="list-style-type: none"> • To follow up on the investigation and resolution of a complaint against an IB; • To follow up on significant changes in relation to an IB which may have an effect on the IB’s accreditation/compliance status; or • For any other reason that SADCAS may deem necessary to confirm on-going compliance to accreditation requirements. 	Refer to SADCAS AP 18

3. APPLICATION AND RESOURCE REVIEW

An authorized representative of an inspection body wishing to be accredited submits directly to SADCAS duly completed SADCAS F 43(h); Application for accreditation of inspection bodies together with the inspection body's quality manual and duly completed scheme checklist SADCAS F 40 (d) demonstrating that the accreditation requirements are addressed and in which policy and procedures are addressed, duly completed SADCAS F 43 (f): Application for approval of personnel i.e. nominated representative and technical signatory and duly signed SADCAS F 44: SADCAS accreditation agreement.

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:
 - Procedures
 - Any specific technical aspects
- (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) 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;
- (v) Verify that the accreditation agreement signed by the authorized representative of the IB has been received;
- (vi) Confirm the detailed list of fields and type of inspection for which the organization is seeking accreditation;
- (vii) In the case of multi-standard accreditation (refer to clause 6.4), confirm the multi-standard accreditation for which the organization is seeking accreditation;
- (viii) Confirm the different locations from which the inspection service is managed and the activities, which are carried out at each of these locations.
- (ix) Seek agreement with the applicant on 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 date(s) of the assessment and the names of the proposed assessment team members to the inspection body, including the organization they work for to the CAB for acceptance.
- (x) The IB may object to the appointment of the assessment team. Objection will only be considered if there is a conflict of interest. In this case the inspection body 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 exist. The SADCAS Technical Manager will decide whether a change of assessor/TE is warranted or not.

If the Inspection Body has good reason to reject an assessor/TE and if 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 Inspection Body will be liable for the full costs covering assessor fees, travel and subsistence (accommodation meals and incidental).

- 3.2 If at any point in the application or initial assessment process, there is evidence of fraudulent behaviour, if the IB intentionally provides false information or if the IB 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 IB are available on the SADCAS website www.sadcas.org.

4. DOCUMENT REVIEW

- 4.1 The organization's quality manual and procedures will be reviewed for compliance with the applicable standard(s), SADCAS technical requirements and guidance documents and/or the relevant national regulation(s) for their field of operation.
- 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 IB conducts a review of their documentation and completes the 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 IB submits the completed application form, checklists, management system manual and where required, procedures 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 IB 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 document review report SADCAS 61 (a-2). The report will contain comments on any non-conformities, 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 IB and a maximum period of three (3) months is allowed for applicant organization to address the findings. Failure to submit 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 inspection body 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.
- 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 Inspection Bodies operating in the Regulatory area (Approved Independent Inspection Authorities)
- 5.2 A pre-assessment may be **compulsory** for IBs that cannot demonstrate their competence due to the fact that they need to be approved by the relevant Government Departments or Regulator prior to starting any work. The pre-assessment is conducted to assess the readiness for accreditation and can be carried out on-site by the Team Leader/Technical Assessor at a specified location (generally the central office) of the IB 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, inspectors, sub-contracted activities etc. within the management system;
 - (v) agree the proposed scope of accreditation; and
 - (vi) determine whether any further technical assessors / technical experts will be required.

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

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

Note: No technical assessment of the IBs technical capabilities of competencies will be conducted during the pre-assessment.

- 5.2.2 The IB may need to make changes to its policies, procedures and practices prior to SADCAS acknowledgement that the organizations documented system complies with the requirements of the relevant standard.
- 5.2.3 Once all the findings raised during the pre-assessment have been satisfactorily addressed by the facility, SADCAS will issue an Indicative Letter (IL) (SADCAS SL 13) to the IB.
- 5.2.4 Once an IL has been issued by SADCAS, the IB must apply for provisional approval to the relevant regulator. The organization is responsible to inform SADCAS of the date of approval by the regulator. The regulator's approval will be subject to the organization undergoing an initial assessment by SADCAS within 6 months.
- 5.2.5 The applicant IB will be subjected to an on-site assessment within 6 months, where the organization will be required to demonstrate its technical competence by performing inspection functions as detailed on their application for accreditation. Failure to demonstrate technical competence within the defined period will result in the withdrawal of the SADCAS IL and subsequently the organization's approval status. A repeat of the entire process would be required, should the organization decide to continue seeking accreditation.
- 5.2.6 During the 6 months' probation period the organization must keep a detailed record of all technical work performed in the regulatory area under their accreditation application. In the event that the organization fails to demonstrate their technical competence within the defined period, resulting in the withdrawal of the SADCAS IL and subsequently the organization's approval status by the regulator, all work performed in the regulatory area within the probation period will be deemed as un-accredited work. The organization will be responsible to ensure that all work performed in the regulatory area in the probation period is redone by an appropriately accredited facility, at their cost, to ensure that the health and safety of the public is not compromised.

5.3 Voluntary Inspection Bodies

- 5.3.1 Although not mandatory, a pre-assessment may be conducted with the agreement of the IBs. The pre-assessment is conducted to assess the readiness for accreditation and carried out on-site by the Team Leader/Technical Assessor at a specified location (generally the central office) of the IB 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, inspectors, subcontracted activities etc. within the management system;
 - (v) Agree the proposed scope of accreditation;
 - (iv) Determine whether any further technical assessors/technical experts will be required.

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

- 5.3.2 The pre-assessment visit will normally be completed within one (1) day.
- 5.3.3 The IB may need to make changes to its policies, procedures and practices prior to SADCAS undertaking the assessment.
- 5.3.4 If necessary, further TAs/TEs will be identified and the agreement of the IB to their appointment will be sought.
- 5.3.5 Once all the findings raised during the pre-assessment have been effectively cleared, SADCAS will arrange the initial on-site assessment of the IB within 3 months.
- 5.4 **Multi-Standard Inspection Bodies**
 - 5.4.1 A pre-assessment is mandatory for multi-standard inspection bodies at a specified location (generally the central office).

6. ASSESSMENTS

6.1 Prior to Assessment

- 6.1.1 Prior to assessment, the organization will provide SADCAS with a list of current personnel, the fields and types of activity 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.
- 6.1.2 An assessment schedule and a quotation will be forwarded to the IB in advance of the assessment; written acceptance of the quotation will be required before a visit can be undertaken.
- 6.1.3 The time required for initial assessment, periodic assessment (on-site or remote assessment) and re-assessment will be dependent on the complexity of the organization, the geographical spread of its activities, the structure of the quality system, the proposed scope of accreditation and where relevant, the combination of multi-standards for accreditation.
- 6.1.4 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 IB 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 IB and the complexity of the management system that is being operated. However, the following elements will be covered:

- (i) Central office assessment;
- (ii) Assessment of multiple locations (however named and where applicable);
- (iii) Assessments (on-site or remote) of inspections for different fields and types of inspection and inspectors.

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 IB 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 IB an assessment plan indicating the date(s) of the assessment, assessment team members, activities to be assessed, locations at which activities will be assessed and personnel to be assessed where applicable.

6.2.3 If the IB should not be 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 IB and the document review report.

6.2.5 The SADCAS assessment team will start the assessment with an opening meeting with the IB 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).

6.3 **Central Office Assessment**

6.3.1 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 IB as determined through its conformity with the requirements for accreditation.

6.3.2 Various assessment techniques will be used to establish whether:

- (i) The management system support competence against their scope of accreditation, is appropriate to the IB's needs, organizational arrangements and methods of operation, including multiple location operations and number of personnel;
- (ii) The IB conforms with all the requirements of the standard and/or the relevant technical regulation applicable to their field of operation have been satisfactorily addressed;

- (iii) The IB 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.
- 6.3.3 The following techniques will be employed to establish that procedures are being correctly and fully implemented:
- (i) Questioning of management and staff who have an involvement in or bearing upon the quality of inspection work;
 - (ii) Examination of records;
 - (iii) Examination of the suitability, maintenance, calibration, control and use of all equipment used for inspection work;
 - (iv) Examination of the arrangements for exercising control over sub-contractors and suppliers.
- 6.3.4 All fields and types of inspection will be subject to an office assessment and technical review. The team will assess the technical competence of inspectors in each field or type of inspection covered by the schedule. This will be done through:
- (i) The examination of the records outlined above;
 - (ii) Discussions with staff, supervisors and managers;
 - (iii) Assessment of the performance of the staff whilst conducting scheduled inspections.
 - (iv) Assessment of the inspection reports issued by the Inspection Body.
- 6.3.5 If the IB 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 IB.
- 6.3.6 The assessors 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. 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.
- 6.3.7 After each member of the assessment team has completed their assignment in accordance with the assessment plan, they shall hold a private meeting to summarize their conclusion and contribute to a coordinated view on the status of the applicant Inspection Body's system.
- 6.3.8 The team, together with the organization's representative will agree on the draft scope of accreditation during the closing meeting.
- 6.3.9 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 Inspection Body with an opportunity to seek clarification on the findings including any nonconformities and their basis.

- 6.3.10 A summary of the assessment report [SADCAS F 61 (c)] shall be provided to the Inspection Body 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 6.3.9 above), SADCAS shall provide an explanation to the assessed conformity assessment body, in writing. Where corrective action by the Inspection Body is required [SADCAS F 61(b)], the applicant organization shall be requested to analyse the extent and root cause of the nonconformities, and identify and propose corrective actions to address the raised non conformities 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 IB 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.
- 6.3.11 The corrective actions provided by the IB will be reviewed by the relevant assessor, to determine whether the actions are appropriate and sufficiently address the nonconformities. Where the IB root cause analysis and/or corrective actions are found not to be sufficient, further information will be requested from the IB, or a follow up assessment may be carried out to verify the effective implementation of corrective actions at the cost of the IB.
- 6.3.12 When all corrective actions have been completed and 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 of accreditation shall not be issued if there are any outstanding fees.

6.4 Multi-Location Organizations

- 6.4.1 An applicant that operates from a central office through a number of locations may seek a single accreditation provided that the conditions specified in ISO/IEC 17020 are fulfilled.
- 6.4.2 On application, the IB 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 office and locations;
 - (ii) The results of management reviews;
 - (iii) Variations in the size of locations;
 - (iv) Complexity of the quality system;

- (v) Complexity of the locations;
 - (vi) Variations in working practices including, where applicable, equipment used;
 - (vii) Variations in activities undertaken e.g. fields of inspection, types of inspection.
- 6.4.3 It will normally not be necessary to witness the full range of scopes for each selected location once accredited.
- 6.4.4 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.
- 6.4.5 Temporary 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.
- 6.4.6 During the central office assessment SADCAS may need to see records of activities, which are being carried out at different locations.
- 6.4.7 If SADCAS observes non-compliance's at the central office or at any one of the locations of an organisation 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.
- 6.4.8 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 review by SADCAS and may lead to suspension or withdrawal of accreditation from all locations.
- 6.4.9 Generally, each location from which an organization is operating will be visited at least once during the assessment cycle.
- 6.4.10 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 IB proposes to offer an accredited service must be notified to SADCAS before these can be included in the scope 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 assessment and re-assessment.

6.5 Multi-Standard Assessment

- 6.5.1 Organizations who wish 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 or technical experts.

- 6.5.2 Where the scope applied for falls under different schemes (e.g. Inspection and Certification), 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.
- 6.5.3 The application forms are forwarded to the Scheme Coordinator, who will process the application form as described in Clause 3 of this document.
- 6.5.4 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.
- 6.5.5 The normal application and assessment process is followed, as described in Clauses 3 to 6, with a pre-assessment being mandatory for a multi-standard assessment.

Note 1: Each Multi-Standard accreditation application will be processed by SADCAS on its merit for accreditation taking into account the ILAC MRA's in place at the time of application.

6.6 Witnessing of Inspections

- 6.6.1 Witnessing of inspections is an essential part of the SADCAS assessment of IBs to ISO/IEC 17020 and/or the relevant regulation applicable to their field of operation. This is particularly important when the IB is performing inspections of such nature where the inspector's professional judgement is crucial to the outcome of inspection.
- 6.6.2 When deciding on the number of witnessing inspections needed the following aspects will be considered by SADCAS:
- (i) The fields and types of inspection on the accreditation schedule;
 - (ii) The IB's procedures for selecting, training, authorising and monitoring inspectors, having regard to the qualifications and experience required for different fields and types of inspection;
 - (iii) The internal auditing arrangements of the IB;
 - (iv) The locations from which inspectors operate;
 - (v) Any statutory requirements;
 - (vi) The extent to which inspectors are required to exercise professional judgement.
- 6.6.3 When deciding on the types of inspection to be witnessed account will be taken of the following:

- (i) Variety of products, services, processes and plant covered by the inspection activities;
 - (ii) Skills needed by inspector;
 - (iii) Any statutory requirements;
 - (iv) The extent to which inspectors are required to exercise professional judgement.
- 6.6.4 As a minimum, one inspector carrying out inspections will be witnessed on-site for the fields and types of inspection on the accreditation schedule.
- 6.6.5 When deciding on which inspectors 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 inspectors are required to exercise professional judgement.
- 6.6.6 If none of the inspectors can cover the entire scope of a specific field, then more than one inspector will be witnessed for that field. Where there is any evidence, which casts doubt on the competence of inspection staff, the sample size of inspectors witnessed on-site may be increased.
- 6.6.7 It will be necessary to examine equipment and documentation, such as procedures and instructions, records, reports and planning arrangements. If an inspector operates from home, this examination will be arranged at a mutually acceptable location.
- 6.6.8 SADCAS assessors will ensure that their role during witnessing of inspections is one of observer and they will not influence the inspection being performed. The team will be looking to see that as a minimum:
- (i) The inspector has the competence for the inspection performed;
 - (ii) The inspector's competence is consistent with the records;
 - (iii) the inspector has been supplied with all necessary documented inspection methods and procedures;
 - (iv) The procedures are up-to-date;
 - (v) the inspector 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 IB requirements and ISO/IEC 17020 and/or as amplified by the relevant guidance document, relevant regulations;
 - (xi) Facilities and equipment are fit for the inspection 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 IB 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 IB'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 IB and consider factors such as information about the IB'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 IBs. Then 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 inspectors 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 IB.

8.2 Periodic on-site assessment

- 8.2.1 Periodic on-site visits will be planned to cover the whole of the schedule of accreditation over assessment cycle. 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 IB may be required. SADCAS will review the evidence provided and decide upon its acceptability.

8.3 Multi-Location Organizations

- 8.3.1 For multi-location organizations the central quality system and technical control 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. It is anticipated that, in addition to the central office, at least one location will be visited each year, with a visit to each location generally taking place over the assessment cycle. The intervals between periodic on-site visits can be extended depending on the risks associated but must not exceed two years. However, the level of sampling of locations and inspectors 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 IB.

8.4 On-site Assessment of Inspections

- 8.4.1 On-site assessment of inspections 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 inspections, and the inspectors to be witnessed. The IB 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 IB 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 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. inspection reports for new scopes added.

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 IB is required to take actions.

9.3 A re-assessment is conducted at least 6 months prior to the start of each new 5-year accreditation cycle. Re-assessment visits will involve a comprehensive re-examination of the IB's management system and inspection activities and will be similar in format and content to the initial assessment. 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 same criteria used for assessment will be considered when determining the number and type of inspections, and the inspectors to be assessed. The reassessment shall confirm the competence of the IB and cover all the requirements of the standard(s) for which the IB 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 IB's accreditation and the IB 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 to 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 central office and/or location assessment and/or on-site assessments of inspection to take place or if an assessment of the requested scope can occur during the IB next planned assessment.

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) Inspector competencies within scopes;
 - (v) The range of scopes;
 - (vi) The location at which the extension to scope is sought.
 - (vii) Whether or not different set of competencies required to perform the requested scopes; and
 - (viii) Competency 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 IB fees may be revised accordingly.

11. SCOPE OF ACCREDITATION

- 11.1 It is SADCAS' policy to define the scope of an IB's accreditation as precisely as possible. IBs will therefore be asked to specify in detail the field, type and range of inspections for which accreditation is sought and the locations at which these activities are to be carried out. The scope 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 inspections 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 IB for legitimate reasons and will form the basis of SADCAS publication Directory of Accredited Inspection Bodies.

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 non-conformities 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: Customer Feedback handling procedure.

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

15. SUSPENSION OF ACCREDITATION

- 15.1 The procedure SADCAS TR 06 covers suspension and reinstatement of accreditation.

16. WITHDRAWAL OF ACCREDITATION

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

17. REDUCTION OF ACCREDITATION

An inspection body 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 Inspection body fails to meet the requirements for accreditation or for the scope already accredited including competence of personnel, SADCAS shall reduce the scope of accreditation to exclude those scopes.

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

18. NO WORK CARRIED OUT BY FACILITY IN THE REGULATORY AREA

- 18.1 If an accredited Inspection Body operating in the regulatory area does not have any proof of technical work performed for two (2) consecutive assessments in any particular scope, that scope is to be suspended in accordance with SADCAS TR 06.
- 18.2 If the Inspection Body is to perform any work in the suspended scope during the suspension period, they must inform SADCAS at their earliest opportunity for arrangements for a re-instatement assessment.
- 18.3 If the Inspection Body does not perform any technical work in the suspended scope within the suspension period, the suspension process will be followed and withdrawal will be recommended.

19. REFERENCES

- ILAC P15 – Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies
- SADCAS F 43(h) – Application for accreditation of inspection bodies
- SADCAS F 43 (f) – Application for approval of personnel
- SADCAS F 44 – SADCAS 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 61(b) – Conformity assessment body – Nonconformity, corrective and clearance report
- SADCAS F 61 (c) – Assessment recommendation report
- SADCAS F 91 (c) – Accreditation Approvals Committee – Assessment packs Inspection Bodies Accreditation Scheme
- SADCAS F 93 – Completeness check of application and resource review
- 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
- SL 13 – Indicative Letter
- 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 7	4	2.7	Added remote assessments as an assessment technique.	CEO	2020-04-24
	6		Deleted “unannounced visits” and substituted with “extraordinary visits”		
	18	8.1.1	Added “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” at the end of first paragraph.		
	22	19	Added SADCAS AP 23- Remote Assessments-Management and Execution to list of References.		
Issue 8	12	6.2.1	<ul style="list-style-type: none"> Item (iii): Deleted “on-site” and substituted with “onsite or remote”. Deleted note at end of paragraph which read “On-site assessment is a mandatory requirement for an initial assessment”. 	CEO	2021-02-04
	13	6.3.9	<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 Inspection Body with an opportunity to seek clarification on the findings including any nonconformities and their basis”.</p> <p>Renumbered subsequent clauses.</p>		
		6.3.10	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 6.3.9 above), SADCAS shall provide an explanation to the assessed conformity assessment body, in writing” at the end of first sentence.		