

ACCREDITATION DECISION MAKING PROCESS

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1. PURPOSE AND SCOPE

This document outlines the SADCAS accreditation decision making process and defines the responsibilities thereof.

2. GENERAL

- 2.1 In order to mitigate against the high risk associated with granting, maintaining, extending, reducing, suspending or withdrawing accreditation in part or as a whole, SADCAS maintains two approaches to accreditation decision making as follows:

Option 1

- a) Decisions arising from initial assessments, reassessments, reducing, suspending or withdrawing accreditation in part or as a whole and extensions to new scopes shall be made by the Accreditation Approvals Committee (AAC) consisting of not less than 2 competent members, one of whom shall be a full-time employee of SADCAS; and

Option 2

- b) Decisions arising from periodic assessments with extension within existing scopes or voluntary reduction of existing scopes, additional signatories and equipment changes to existing accredited scopes shall be made by the relevant Scheme Coordinator or any competent member of the AAC.

- 2.2 All accreditation decisions shall be made based on the information gathered and the recommendations made by the respective assessment team and shall not be subject to approval by any other organization or person.

3. DECISIONS ARISING FROM INITIAL ASSESSMENTS, REASSESSMENTS AND EXTENSIONS TO NEW SCOPES

3.1 Role of the Accreditation Approvals Committee

- 3.1.1 The AAC shall make decisions on the granting, maintaining, extending, reducing, suspending and withdrawal of accreditation.

The conditions for Suspension re-instatement and withdrawal of accreditation are as defined in SADCAS TR 06.

- 3.1.2 The AAC shall also provide feedback on the performance of the assessment team and give advice on additional training needs of assessment teams, where applicable.

3.2 Composition of the Accreditation Approvals Committee

For decisions arising from initial assessments, reassessments reducing, suspending or withdrawing accreditation in part or as a whole and extensions to new scopes, the AAC shall consist of not less than 2 competent members, one of whom shall be a full-time employee of SADCAS.

Decisions arising from periodic assessments with extension within existing scopes or voluntary reduction of existing scopes, additional signatories and equipment changes to existing accredited scopes shall be made by the relevant Scheme Coordinator or any competent member of the AAC.

- 3.2.1 Where required SADCAS may request the attendance of specialized technical experts onto the AAC.
- 3.2.2 In order to ensure impartiality, for option 1, AAC members shall not evaluate an assessment of which the member was part of the assessment team or where he/she may have any other conflict of interest with the matter under review.
- 3.2.3 For option 2, a full-time AAC member may evaluate an assessment of which he/she was part of the assessment team.
- 3.2.4 Names of the approved AAC members shall be published on the SADCAS network and maintained by the Technical Manager. Any objections against the approved AAC members shall be notified to SADCAS in writing with reasons of objection.

3.3 Accreditation Membership Competence Criteria

- 3.3.1 Accreditation Approvals Committee members competence criteria shall meet the following competence criteria specified in SADCAS AP 22:
 - Have knowledge of SADCAS rules and accreditation process;
 - Have knowledge of assessment principles, practices and techniques;
 - Have knowledge of general management system principles and tools
 - Have general knowledge of accreditation and accreditation scheme requirements and relevant guidance and application documents;
 - Have knowledge of the conformity assessment scheme requirements, other procedures and methods used by the conformity assessment body;
 - Have knowledge of risk-based assessment principles; and
 - Have knowledge of the relevant regulatory requirements related to the conformity assessment activities, where applicable

3.4 Induction and Monitoring of Accreditation Approvals Committee Members

- 3.4.1 Potential AAC members shall undergo an induction program consisting of the following:

- Understanding of the SADCAS accreditation decision making process as outlined in this document SADCAS AP 14: Accreditation Decision Making Process
- Mentoring during at least one formal AAC meeting; and
- Monitoring whilst conducting an evaluation. The competence of a new AAC member shall be confirmed by an approved AAC member by evaluating a pack reviewed by that member at their first AAC meeting.

3.4.2 A record of such induction shall be maintained by the Technical Manager in the AAC member's file.

3.5 Monitoring Performance of AAC Member

3.5.1 The performance of AAC members shall be monitored at least once in three (3) years. If, however the AAC member needs further guidance then an additional monitoring shall be arranged.

3.5.2 A schedule of AAC members to be monitored in any financial year shall be prepared by the Technical Manager at the beginning of each financial year. Monitoring will be ongoing during the financial year as per the schedule and as and when AAC meetings are held and subject to the attendance of the AAC member to be monitored.

3.5.3 The AAC member as well as the peer member being monitored shall evaluate the same assessment report and complete SADCAS F 75 or SADCAS F 77.

3.5.4 The AAC Member conducting the monitoring shall complete SADCAS F 92: Report Template – Monitoring the Performance of AAC Members, with feedback being provided to the evaluated member who in turn shall note the feedback by signing the form.

3.5.5 Corrective action shall be taken as necessary to address any shortcomings raised in the AAC member's evaluation report.

3.5.6 Records of monitoring shall be kept in the respective AAC member's file.

3.6 Frequency of Accreditation Approvals Committee Meetings

3.6.1 AAC meetings shall be held as necessary without undue delay to the accreditation decision making process. The AAC meetings should be held within two (2) weeks after review of the file.

3.7 Quorum

3.7.1 A quorum shall consist of a majority of AAC members present throughout the meeting.

3.7.2 The AAC shall strive for consensus in the decision-making process. However, should this not be achieved then, decisions shall be taken by a simple majority of the members present throughout the meeting.

3.8 Accreditation Approvals Committee Meeting Proceedings

- 3.8.1 The Technical Manager in collaboration with relevant Scheme Coordinators shall ensure that AAC meetings are held without undue delay and shall invite members/experts to the meeting.
- 3.8.2 Accreditation Approvals Committee meetings are allocated assessment information relevant to the area of evaluations. The supporting documentation shall include the following, as minimum:
- a) Unique identification of the conformity assessment body;
 - b) Date(s) and type (s) of assessment;
 - c) Name(s) of the assessor(s) and where applicable, technical experts, observers, monitors involved in the assessment;
 - d) Unique identification of all premises assessed;
 - e) Scope of accreditation that was assessed;
 - f) The assessment report(s);
 - g) A statement on the adequacy of the internal organization and procedures adopted by Conformity Assessment Bodies to give confidence in its competence, as determined through its fulfillment on the requirements for accreditation;
 - h) Sufficient information on the resolution of all nonconformities;
 - i) Where relevant, any further information that may assist in determining the competence of the Conformity Assessment Bodies as determined through conformity with requirements; and
 - j) Where appropriate, a recommendation as to the accreditation decision for the proposed scope.

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

- 3.8.3 Accreditation Approvals Committee meetings shall ensure definite outcome in terms of decision and way forward on matter(s) considered.
- 3.8.4 The AAC members must evaluate whether a thorough assessment was carried out and appropriately recorded bearing in mind that assessments are undertaken by competent assessors and that the objective is not to try and undertake a re-assessment of the organization/facility through the submitted information.
- 3.8.5 The AAC's review shall therefore be limited to:
- a) Reviewing the completeness of the documentation;
 - b) Evaluating the completeness of supporting evidence for clearance of corrective actions;
 - c) The coverage of the scope of the assessment;

- d) Evaluating whether the information submitted is adequate to support that the technical and administrative requirements for accreditation or extension of scopes have been fulfilled and that these conclusions had been reflected in the final recommendation;
- e) Evaluating whether the comments made were sufficiently detailed and allowed for intelligent interpretation;
- f) Where relevant, evidence that validation, verification of results and proficiency testing data had been assessed;
- g) Reviewing the evidence submitted in support of granting signatory status to conformity assessment body personnel;
- h) Reviewing the proposed schedule of accreditation recommended;
- i) Identifying further training required for the assessment team member(s); and
- j) Making a decision of either:
 - For initial assessments:
 - Unconditional accreditation – where all requirements for accreditation have been fulfilled.
 - Deferral of decision – where additional information is required before a decision can be made.
 - Rejection of accreditation – where the requirements of accreditation have not been met.
 - For re-assessments:
 - Unconditional accreditation – where all requirements for accreditation have been fulfilled.
 - Conditional accreditation – where additional information is required before a decision can be made.
 - Suspension of accreditation (or part thereof) – where the issues raised are of such a nature as to impact on the results produced by the conformity assessment body, and where the conformity assessment body has failed to satisfactorily address the non-conformities raised.
 - Withdrawal of accreditation – where the requirements of accreditation have not been met.

3.8.6 All reviews shall be recorded by the AAC on SADCAS F 75 – Accreditation Approvals Committee Evaluation of Assessment Packs and a register [SADCAS F 46 (d)] of members' attendance to AAC meetings shall be kept.

3.8.7 The decisions of the AAC shall be formalized as relevant by:

- Signing of the accreditation certificate by the Chief Executive Officer and the accreditation schedule by the Technical Manager or;
- Signing of the Accreditation schedule by Technical Manager or any other competent persons as authorized.
- Signing of Notification letter by the Chief Executive Officer.
- Signing of letter of withdrawal by the Chief Executive Officer.
- Signing of the suspension letter by the Technical Manager.

3.8.8 The effective date of granting, maintaining, extending, suspending, withdrawal of accreditation, as relevant, shall be the date when the decision was made.

3.8.9 Where technical issues arising from AAC meetings are not satisfactorily addressed after discussion with the assessment team, the Technical Manager shall be responsible for determining if the matter needs to be referred to a SADCAS Advisory Committee.

3.8.10 Where the AAC's decision is different from the recommendation made by the assessment team, the Technical Manager shall investigate further the reasons for the difference and notify the affected facility of the situation.

3.8.11 The Technical Manager/AAC member shall instruct the Scheme Coordinator through the use of SADCAS F 75 the decisions including justification where relevant to be communicated to the conformity assessment body. The decisions shall be communicated to the facility in writing without undue delay in accordance with the administration procedure.

4. DECISIONS ARISING FROM PERIODIC ASSESSMENTS, VOLUNTARY REDUCTION OF SCOPE, EXTENSION OF EXISTING SCOPES AND ADDITIONAL SIGNATORIES TO ACCREDITED FACILITIES

4.1 The Scheme Coordinator or any competent AAC member shall undertake a review of all the information arising from periodic assessments and where existing facilities have applied for reduction or extension of existing scope and additional signatories.

4.2 The information to be reviewed is the same as outlined in Clause 3.8.

4.3 The assessment pack review shall be recorded on SADCAS F 77.

4.4 Outcome of the assessment pack review shall include what needs to be communicated to the facility e.g., accreditation continued, Technical Signatory approved, extension of existing scopes approved or changes required to the accreditation certificates or schedule of accreditation.

4.5 If the reviewer is not satisfied with the periodic assessment process, he/she shall take the necessary actions to address the identified problems. This may require additional information

from the assessors or require services of an expert to advise on the matter, whichever is deemed necessary.

4.6. The decisions of the reviewer shall be formalized as relevant by:

- Signing of Notification letter by the Technical Manager
- Signing of the schedule of accreditation by the Technical Manager.

5. **CONFIDENTIALITY AND IMPARTIALITY**

5.1 All members involved in the accreditation decision making process are required to maintain confidentiality on SADCAS and organization/facility matters discussed during the accreditation decision making process and not to use the information for commercial gain.

5.2 Members shall declare any relationship or potential conflict of interest they have or have had (within the last 2 years) with any organization/facility under review. SADCAS F 75 includes a statement which members shall sign at the beginning of each AAC meeting.

6. **RECORDS**

The Technical Manager shall maintain the following AAC member records in member files:

- CV which is required to be updated every 3 years;
- Proof of qualifications;
- AAC Member competence and where the AAC member is an assessor the assessor competence;
- Assessor contract where the AAC member is a registered assessor;
- Evidence of induction and approval as a member of the AAC; and
- Monitoring of AAC members.

7. REFERENCES

- SADCAS AP 22 - Determination of Competence Criteria for Personnel Involved in the Management and Performance of SADCAS Accreditation Activities
- SADCAS TR 06 - Suspension and Re-instatement of Accredited Organizations
- SADCAS F 46 (d) – Attendance Register – Accreditation Approvals Committee Meetings
- SADCAS F 75 – Accreditation Approvals Committee Evaluation of Assessment Packs - Initial Assessments, Reassessments and Extensions to New Scopes
- SADCAS F 77 –Review of Assessment Packs – Periodic Assessments, Extension and Reduction of Existing Scopes and Additional Signatories to Existing Accredited Facilities
- SADCAS F 91 (a) - Accreditation Approvals Committee – Assessment Packs Testing/Calibration Laboratories Accreditation Scheme
- SADCAS F 91 (b) - Accreditation Approvals Committee – Assessment Packs Medical Laboratories Accreditation Scheme
- SADCAS F 91 (c) - Accreditation Approvals Committee – Assessment Packs Inspection Bodies Accreditation Scheme
- SADCAS F 92 – Report template – Monitoring the Performance of AAC Members
- Schedule for the Monitoring of AAC Members.

APPENDIX – AMENDMENT RECORD

Revision Status	Change		Approved by	Effective Date
	Page	Clause		
Issue 5	3	2.1	<p>Deleted (a) and (b) and substituted with</p> <p>a) Decisions arising from initial assessments, reassessments and extensions to new scopes shall be made by the Accreditation Approvals Committee (AAC) consisting of not less than 2 competent members, one of whom shall be either the SADCAS Chief Executive Officer (CEO) or the Technical Manager; and</p> <p>b) Decisions arising from surveillance assessments, extension and reduction of existing scopes and additional signatories to existing accredited scopes shall be made by at least one competent member of the AAC</p>	SADCAS Board
	3	2.2	Added at end of sentence “and shall not be subject to approval by any other organization or person.”	
	3	3.1.1	<ul style="list-style-type: none"> Added “maintaining” between “granting” and “extending” Deleted “when the conformity assessment body fails to comply with the accreditation requirements” and substituted with new paragraph “The conditions for Suspension reinstatement and withdrawal of accreditation are as defined in SADCAS TR 06”. 	
	3	3.1.2	Deleted 3.1.2 and substituted with “The AAC shall also provide feedback on the performance of the assessment team and give advice on additional training needs of assessment teams, where applicable”	
	3	3.2.1	<ul style="list-style-type: none"> Line 2 – Inserted “competent” between “2” and “members” Line 2 – Inserted “either” between “shall be” and “the SADCAS”. Line 3 – Added at end of sentence “or Technical Manager”. Line 5 – Inserted “competent” between “one” and “member”. 	
	4	3.3	Title of Subclause 3.3 - Inserted “Competence” between “Membership” and “Criteria”	

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	Page	Clause		
	4	3.3.1	<p>Deleted 3.3.1 and substituted with “Accreditation Approvals Committee members competence criteria shall meet the following competence criteria specified in SADCAS AP 22:</p> <ul style="list-style-type: none"> ▪ Have knowledge of SADCAS rules and accreditation process; ▪ Have knowledge of assessment principles, practices and techniques; ▪ Have knowledge of general management system principles and tools ▪ Have general knowledge of accreditation and accreditation scheme requirements and relevant guidance and application documents; ▪ Have knowledge of the conformity assessment scheme requirements, other procedures and methods used by the conformity assessment body; ▪ Have knowledge of risk-based assessment principles; and ▪ Have knowledge of the relevant regulatory requirements related to the conformity assessment activities, where applicable 	SADCAS Board 2018-10-12

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	Page	Clause			
	5	3.8.2	<p>After 1st sentence added “The supporting documentation shall include the following, as minimum:</p> <ul style="list-style-type: none"> a) Unique identification of the conformity assessment body; b) Date(s) and type (s) of assessment; c) Name(s) of the assessor(s) and where applicable, technical experts involved in the assessment; d) Unique identification of all premises assessed; e) Scope of accreditation that was assessed; f) The assessment report(s); g) A statement on the adequacy of the internal organization and procedures adopted by Conformity Assessment Bodies to give confidence in its competence, as determined through its fulfilment on the requirements for accreditation; h) Sufficient information on the resolution of all nonconformities; i) Where relevant, any further information that may assist in determining the competence of the Conformity Assessment Bodies as determined through conformity with requirements; and j) Where appropriate, a recommendation as to the accreditation decision for the proposed scope. <p>Prior to making the decision SADCAS shall be satisfied that the information is adequate to decide that the requirements for accreditation have been fulfilled”</p> <ul style="list-style-type: none"> ▪ Signing of Notification letter by the Technical Manager ▪ Signing of the schedule of accreditation by the Technical Manager. ▪ Signing of the suspension letter by the Technical Manager. 	SADCAS Board	2018-10-12
	8	3.8.11	<ul style="list-style-type: none"> • Inserted “/AAC member” between “The Technical Manager” and “shall” • Deleted the title of F 75. • Inserted “which is including justification where relevant’ between “decisions” and “to be communicated” • Inserted “in writing without undue delay” between “facility” and “in accordance” 		
	8	4.2	Inserted “assigned AAC member” between “the and “is the same”		
	8	4.3	Deleted “Technical Manager” and substituted with “assigned AAC member”		

Revision Status	Change		Approved by	Effective Date	
	Page	Clause			
	8	4.4	Deleted “The Technical Manager shall instruct the Accreditation Administrator” and substituted with “The assigned AAC member shall instruct the Scheme Coordinator”	SADCAS Board	2018-10-12
	8	4.6	<p>Added new 4.6 which reads” The decisions of the AAC shall be formalized as relevant by:</p> <ul style="list-style-type: none"> ▪ Signing of Notification letter by the Technical Manager ▪ Signing of the schedule of accreditation by the Technical Manager. ▪ Signing of the suspension letter by the Technical Manager. 		
	9	6	<p>Reworded bullets 3 and 4 as follows:</p> <ul style="list-style-type: none"> ▪ AAC Member competence and where the AAC member is an assessor the assessor competence; ▪ Assessor contract where the AAC member is a registered assessor. 		
	9	7	<ul style="list-style-type: none"> ▪ Added “SADCAS TR 06 - Suspension and Reinstatement of Accredited Organizations” to list of referenced documents. ▪ Deleted the title of SADCAS F 75 and substituted with “Accreditation Approvals Committee Evaluation of Assessment Packs - Initial Assessments, Reassessments and Extensions to New Scopes ▪ Deleted the title of SADCAS F 77 and substituted with “AAC Member’s Review of Assessment Packs – Periodic On-site Assessments, Extension and Reduction of Existing Scopes and Additional Signatories to Existing Accredited Facilities ▪ SADCAS F 91 (a), (b) and (c)- Deleted “Programme and substituted with “Scheme” 		
Issue 6			<ul style="list-style-type: none"> ▪ Revised whole procedure to align with developments at SADCAS. 	SADCAS CEO	2022-09-01