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STRUCTURE OF THE SADCA MRA AND THE PROCEDURE FOR EXPANSION OF THE SCOPE OF THE MRA

SOUTHERN AFRICAN DEVELOPMENT COMMUNITY COOPERATION IN ACCREDITATION

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1. PURPOSE

This document describes the structure of the SADCA Mutual Recognition Arrangement (MRA) as well as the process used by SADCA to consider and approve new conformity assessment activities (Level 2) and normative documents (Levels 3 and 4) for inclusion into the SADCA MRA.

The structure of the SADCA MRA described in this document includes all areas currently covered by the SADCA MRA as well as those areas where the SADCA MRA Council has agreed to initiate the expansion of the SADCA MRA. The expansion of the SADCA MRA may not have been launched in all of the areas listed herein. Details of the areas currently covered by the SADCA MRA can be found in SADCA M002 "SADCA Mutual Recognition Arrangement".

2. DEFINITIONS

The definitions relating to the conformity assessment activities covered by this document are detailed in the following documents: ISO/IEC 17000, ISO/IEC 17011, ISO/IEC 17025, ISO 15189, ISO/IEC 17020, ISO/IEC 17043, ISO 17034, and ISO/IEC Guide 99 (VIM).

3. SADCA MRA STRUCTURE

3.1 There are five levels in the SADCA Arrangement structure as follows:

Level 1	***ISO/IEC 17011**, which specifies the criteria for the Accreditation Body (AB).*
Level 2	Conformity assessment activities performed by Conformity Assessment Bodies (CAB) for which the accreditation body grants accreditation according to the generic, normative documents listed in Level 3. The conformity assessment activities are: - Testing, including Medical Testing; - Calibration; - Inspection; and - Management Systems Certification.
Level 3	Generic, normative documents used by the AB to assess the competence of a CAB for each activity in Level 2 are: - For Testing: ISO/IEC 17025; - For Medical Testing: ISO 15189; - For Calibration: ISO/IEC 17025; - For Inspection: ISO/IEC 17020; - For Management Systems Certification: ISO/IEC 17021-1
Level 4	Sector-specific normative documents which specify recognised applications of a generic normative document listed in Level 3. The application documents are used by the AB, in combination with the generic normative documents listed in Level 3, to assess the CAB competence of a CAB in the relevant sector. The sector-specific normative documents are described as follows and in **Annex 1**: Internationally recognised documents currently are:

	a. Normative documents to be used in combination with ISO/IEC 17021-1: - For Environmental Management Systems (EMS) – ISO/IEC 17021-2 - For Quality Management System (QMS) –ISO/IEC 17021-3 b. Normative documents to be used in combination with ISO/IEC 17025: • The WADA International Standard for Laboratories (ISL) - ISO 15195: Laboratory medicine – Requirements for the competence of calibration laboratories using reference measurement procedures. c. Normative documents to be used in combination with ISO 15189: - ISO 22870: Point-of-care testing (POCT) – Requirements for quality and competence d. There are no endorsed documents to be used with the following normative documents: - ISO/IEC 17020
Level 5	The scope of accreditation of the CAB accredited by the SADCA Arrangement signatory. It includes the conformity assessment normative documents used by the CABs. Normative documents in this level are specified in **Annex 1** only for Management Systems Certification.

Note: the term "scope" is a generic term for all MRA levels; the term "sub-scope" is used for levels 4 and 5 of the SADCA MRA.

3.2 SADCA is responsible for ensuring that the MRA signatories comply with the Level 1 document. The MRA signatories for a particular Level 2 scope must ensure the compliance of their accredited CABs for specific conformity assessment activities in accordance with Level 3 and 4 documents as relevant.

The scope of accreditation as required by Level 5 is maintained by the SADCA MRA signatory for each of its accredited CABs.

4. PROCEDURE FOR EXPANSION OF THE SADCA MRA

The procedure for expansion of the SADCA MRA within Levels 2 and 3 has the following steps:

4.1 Proposal to expand the SADCA MRA
4.2 Review of the proposal to expand the SADCA MRA
4.3 Approval by the SADCA GA to expand the SADCA MRA
4.4 Development of the expansion of the SADCA MRA
4.5 Launching of the expansion of the SADCA MRA

Note: *Documents and activities in Level 4 (which would typically be of a sectorial specific nature) would not usually require a formal expansion of the SADCA MRA, however, the general principles could be applied on a case-by-case basis as appropriate to ensure that SADCA has the required competencies to evaluate Level 4 scopes.*

4.1 Proposal to expand the SADCA MRA

4.1.1 The proposal for expansion of the SADCA MRA could be received from various sources including, but not limited to:

- Organisations (e.g. CABs associations, industry or professional associations) which need independent recognitions of the competence of CABs for activities not currently addressed by SADCA;

- Regulators, specifiers, purchasers and other customers needing reassurance of the technical competence of organizations against commonly agreed criteria not currently addressed by SADCA;

- Recognised regions that have established an MRA/MLA for an activity not currently covered by the SADCA Arrangement; and

- Accreditation bodies themselves may need confirmation of competence in areas which are complementary to areas already covered by their accreditation schemes.

4.1.2 Proposals to expand the SADCA MRA shall be submitted to the SADCA MRA Council together with the relevant supporting documentation and detailing the rationale for the proposal taking into consideration the following needs:

i) A new Level 2 activity, not currently covered by an ISO Standard, but already subject to accreditation by a number of accreditation bodies and with potential for the development of a standard or normative document by ISO and/or ARSO (or, if necessary, by ILAC, IAF or SADCA itself).

ii) A new Level 3 standard or normative document, applicable to a conformity assessment body and the attestation of its competence; or

iii) A new Level 4 normative document which is a sector-specific application based on a Level 3 standard already used for accreditation by SADCA Members.

4.1.3 The MRA Council will, within at least 60 days, review the proposal initially, focusing on the appropriateness of expanding the SADCA MRA into the new area, and may determine not to proceed if there are insufficient grounds to warrant further consideration. As a minimum, the MRA Council shall consider:

i) The background on the need for the new area including the relevance of accreditation of CABs;

ii) The importance of the scope to the regional or member states national objectives;
iii) The implications of the lack of inclusion of the new area, e.g. impact on any existing standard currently under the SADCA MRA;
iv) If the proposal is based on an agreement between an accreditation scheme owner and SADCA:

- The scheme requirements shall not conflict with SADCA objectives; and
- The scheme shall not discriminate against any member of the SADCA MRA and does not impose unnecessary requirements on them.

The MRA Council may seek further information from the party making the proposal before making any determination to proceed to full review in accordance with 4.2.

4.2 Review of the proposal to expand the SADCA MRA

4.2.1 The MRA Council, following the determination to proceed will refer the specific proposal to the MRA Committee, who, in consultation with the Technical Committee shall consider the technical criteria issues and the Arrangement related issues, depending on the nature of the proposed expansion.

4.2.2 The MRA Committee and Technical Committee shall conduct a review of the proposal, within at least 3 months, which includes the following considerations:

- If the proposal involves a new activity (Level 2) or a new generic, normative document (Level 3);
- Views of affected parties, including any external bodies that may have proposed the need;
- Whether there is an established accreditation standard or normative document covering the conformity assessment activity, and whether the standard or document is credible and robust, for example, has it been produced by an international consensus process involving relevant interested parties. If not, is SADCA prepared to develop and publish such a document.
- Consideration of impartiality of the AB in relation to services that CABs perform, as required by ISO/IEC 17011.
- Current experience of SADCA members in the area of the proposed expansion and a determination of whether there are sufficient numbers of SADCA members with an interest in the new area to justify inclusion in the SADCA MRA.
- Consultation with interested parties for comments, as relevant.
- Ensuring that the new area does not jeopardize the existing obligations already undertaken by SADCA Members under the ILAC/IAF or SADCA Arrangement.
- The need to propose new or revised SADCA documents.

If the proposal involves a new Level 4 activity and/or is based on an agreement between an accreditation scheme owner and SADCA, it will be necessary to ensure that:

- The assessment process shall at least fulfil all the relevant requirements established in ISO/IEC 17011;
- Requirements established by the scheme owner are not in contradiction with ISO/IEC 17011 nor with the applicable generic normative document (Level 3);
- Decisions regarding the maintenance of an accreditation body in the SADCA MRA can only be taken by the SADCA MRA Council; and
- The information supplied to the market must always be transparent and not create barriers to competition amongst the affected bodies covered by the accreditation.

4.2.3 The MRA Committee shall prepare a report addressing the considerations in Clause 4.2.1 and 4.2.2 and including a recommendation for consideration by the MRA Council to proceed (or not) with the proposed expansion to the SADCA Arrangement.

4.3 Approval by the SADCA MRA Council to expand the SADCA MRA

The results of the review and recommendation of the MRA Committee on whether or not to proceed with the expansion of the SADCA MRA shall be submitted to the MRA Council for their approval.

Once approved, the new area will be included in the Structure of the SADCA Arrangement (Annex 1) and this document will be updated accordingly.

4.4 Development of the expansion of the SADCA MRA

4.4.1 Prior to acceptance of any applications to enter the expanded MRA, the MRA Council shall ensure that SADCA has the appropriate infrastructure to effectively administer the expanded MRA. It shall use the MRA Committee, who will work in conjunction with the Technical Committee, as relevant to oversee, coordinate and/or conduct the following activities to this end:

i) Review any related activities in other regions and include any learning in the development work to be undertaken to avoid duplication of efforts and ensure consistency.

ii) Analyse any potential problems in the new area associated with the application of existing requirement documents on SADCA's MRA signatories, e.g. but not necessarily limited to:

- ISO/IEC 17011
- IAF/ILAC-A2
- SADCA M001
- Relevant IAF / ILAC requirements
- Expressions of scopes of accreditation (for any ABs already accrediting in the new area), which are a common source of inconsistency and should also be considered.

Anticipated problems shall be brought to the MRA Council for resolution.

iii) Analyse any potential problems in the new area associated with the interpretation and application of the accreditation standard(s) or normative document(s) by ABs in the assessment and accreditation of applicant CABs. Anticipated problems shall be brought to the MRA Council, who typically will request resolution through the Technical Committee or appropriate sub-committee. Additional criteria and/or guidance documents may be required before the expanded MRA can be implemented.

iv) Identify the evaluator resources that will be required to evaluate AB's in the new area. In particular, what, if any, additional competencies will be required (from the current SADCA evaluators), and whether evaluator training / workshops will need to be undertaken.

v) Propose the inclusion of any additional criteria, competence requirements, peer evaluation processes, etc., in the relevant SADCA documents, needed to administer the new scope of the MRA.

vi) Recruit, train if necessary, and qualify sufficient evaluators to evaluate ABs applying for the new scope / sub-scope.

vii) Arrange for other SADCA documents to be reviewed to identify and implement changes needed to reflect the expanded MRA.

4.4.2 Once developments are sufficiently advanced (typically up to and including 4.4.1(vi) above) the MRA Council will decide when applications to enter the expanded MRA can be accepted. Applications will be processed in accordance with SADCA M001.

5 IMPLEMENTATION OF THE EXPANSION OF THE SADCA MRA

5.1 The peer evaluation process established for the new area shall ensure that:

5.1.1 ABs requesting signatory status for a new Level 2 activity will require an on-site evaluation, in which all requirements of ISO/IEC 17011 and compliance of the AB's accredited CABs with the relevant Level 3 normative document(s) are evaluated. The evaluation team shall be competent in that activity and witnessing shall be included.

5.1.2 Where a new Level 3 generic normative document is added for an existing Level 2 activity in the SADCA MRA, the evaluation procedures will be determined based on the following factors:

- Distinction or uniqueness of technical aspects;
- Risk associated with the activity under accreditation;
- Extent of difference of the new standard with the existing standard(s);
- Complexity of the standard; and
- Requests from the users of accreditation or other concerned parties in the marketplace;

The initial evaluation procedures may be:

a) A full on-site evaluation of that activity including the implementation of the normative document(s);
b) A partial on-site evaluation of selected requirements of ISO/IEC 17011 and evaluation of compliance of the ABs accredited CABs with the new Level 3 normative document;
c) Document review only.

Normally alternative (a) or (b) will be used, but there may be cases where the new Level 3 normative document is so similar to the existing ones that a document review may be adequate.

5.1.3 Where a new Level 4 sector-specific normative document is added to the SADCA MRA, the evaluation of an AB which is already a signatory for the relevant Level 2 activity and Level 3 normative document may be recognised following self-declaration.

5.2 For the extension to all sub-scopes of Management System Certification (Level 4 sector-specific normative documents), the following shall apply:

- For a signatory to the SADCA MRA with a main scope of ISO/IEC 17021-1:

Note: The first sub-scope for each main scope shall be evaluated in accordance with SADCA M001 “SADCA Policies and procedures for a MRA among Accreditation Bodies’.
For additional sub-scope extensions under the same main scope: The AB shall provide a self-declaration, that the sub-scope has been introduced and relevant requirements as defined by SADCA M001 “SADCA Policies and procedures for a MRA among Accreditation Bodies’ have been met.

The additional sub-scope will be evaluated at the next peer evaluation of the SADCA signatory.

- For a signatory to the SADCA MRA but not for the main scopes of ISO/IEC 17021-1:

  The AB shall undergo a full evaluation in accordance with SADCA M001 “SADCA Policies and procedures for a MRA among Accreditation Bodies’, where any sub-scopes granted through self-declaration will be evaluated.

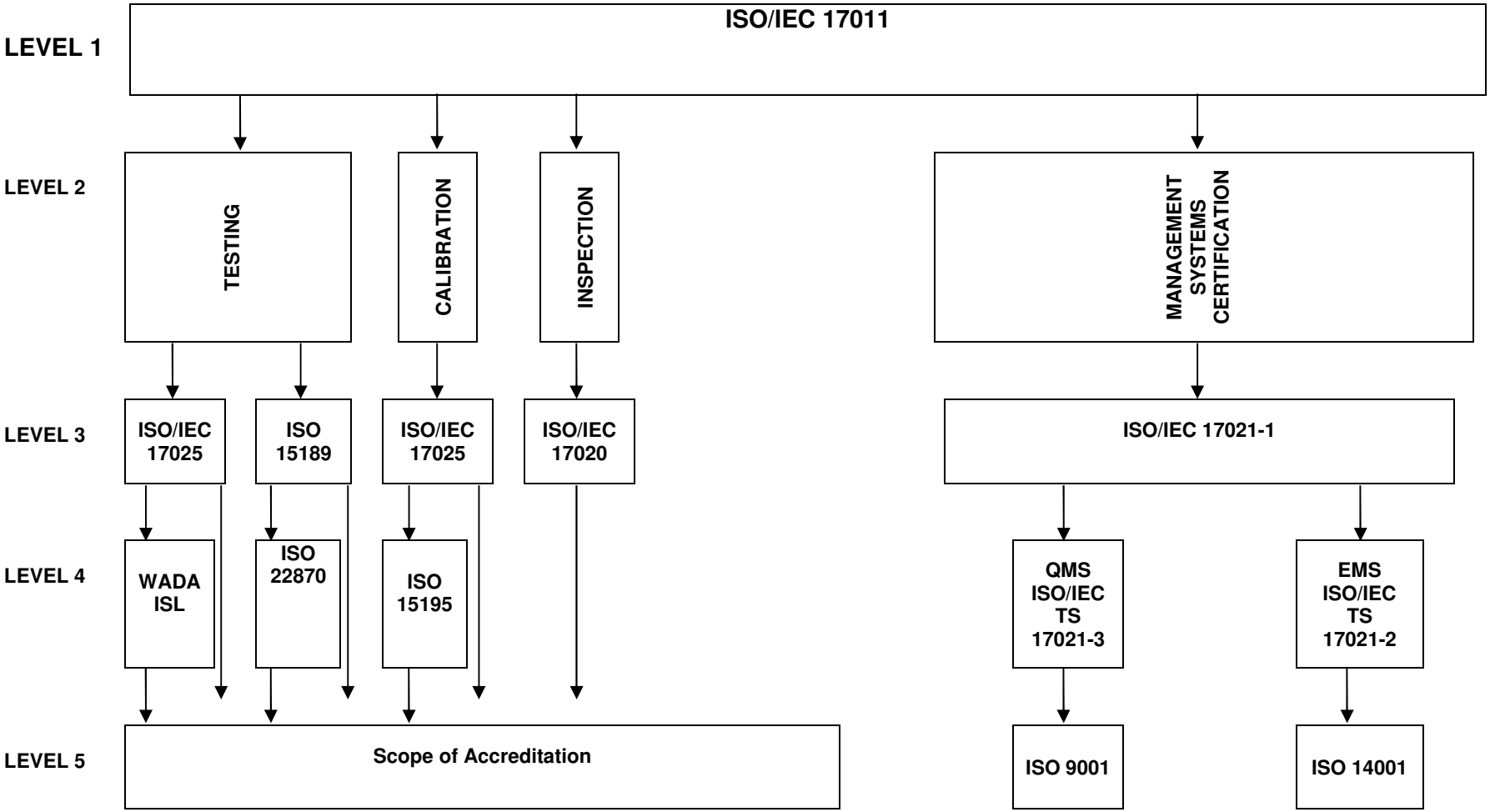
- Before an MRA signatory can apply for an extension for the second, third or fourth sub-scope, etc., the AB shall have at least one accredited CAB under that sub-scope.

5.3 The expansion of the SADCA MRA will become effective following:

- the formal adoption of any new or revised SADCA document, if applicable, and SADCA M001 procedure; and
- a positive vote on the evaluation of at least 3 AB’s by the MRA Council for that specific scope.

ANNEX 1: STRUCTURE OF THE SADCA ARRANGEMENT

The table below shows the different levels of the MRA structure and the corresponding applicable normative documents.



ANNEX 2: REFERENCES OF THE STANDARDS USED IN THE STRUCTURE OF THE SADCA MRA

Level 1:

- ISO/IEC 17011: Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies

Level 3:

- ISO 15189: Medical laboratories - Particular requirements for quality and competence
- ISO/IEC 17020: Conformity assessment - Requirements for the operation of various types of bodies performing inspection
- ISO/IEC 17021-1: Conformity assessment - Requirements for bodies providing audit and certification of management systems
- ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories

Level 4:

- ISO/IEC TS 17021-2: Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 2: Competence requirements for auditing and certification of environmental management systems.
- ISO/IEC TS 17021-3: Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 3: Competence requirements for auditing and certification of quality management systems
- ISO 15195: Laboratory medicine – Requirements for the competence of calibration laboratories using reference measurement procedures.
- ISO 22870: Point-of-care testing (POCT) – Requirements for quality and competence
- GLOBAL G.A.P Integrated Farm Assurance General Regulations

Level 5:

- ISO 14001: Environmental management systems - Requirements with guidance for use
- ISO 9001: Quality management systems – Requirements

APPENDIX A: AMENDMENT RECORD

Section	Change
	New document