2017

AFRAC STRUCTURE OF THE MRA AND THE PROCEDURE FOR EXTENDING THE MRA SCOPES

AFRICAN ACCREDITATION COOPERATION

This document describes the procedures for the adoption of international documents.

Publication reference: M003-01

This document has been prepared by the AFRAC MRA Documents Working Group.

Classification

This document is classified as an AFRAC MRA Publication.

Authorisation

Issue Number:	01
Prepared by:	AFRAC MRA Documents Working Group
Date:	26 September 2016
Approved by:	General Assembly
Issue and application date:	17 February 2017

Official language

The text may be translated into other languages as required. The English language version remains the definitive version.

Copyright

Further information

For further information about this publication, contact the AFRAC Secretariat on:

AFRAC Secretariat
Private Bag X23
Sunnyside
Pretoria
0132
South Africa
Tel: +27 12 394 3793
Fax: +27 12 394 4793
Email: yolandav@sanas.co.za

CONTENTS

1. PURPOSE 3
2. AFRAC MRA STRUCTURE 4
3. PUBLICATION OF THE SIGNATORIES OF THE AFRAC MRA 6
4. EXPANDING THE AFRAC MRA 6

ANNEX 1: Structure of the AFRAC Arrangement 5
ANNEX 2: List of the Standards used in the different levels of the structure of the AFRAC MRA 11

1. PURPOSE

This procedure describes the structure of the AFRAC Mutual Recognition Arrangement (MRA) as well as the steps to be taken by AFRAC to include new accreditation programs under the AFRAC MRA.

2. AFRAC MRA STRUCTURE

The structure of the AFRAC MRA has five levels which are described as follows:

Level 1	***ISO/IEC 17011, which specifies the criteria for Accreditation Bodies (ABs).***
Level 2	Conformity assessment activities of the Conformity Assessment Bodies (CAB) to which the accreditation body grants accreditation to the generic, normative documents listed in Level 3. The conformity assessment activities are: - Testing, including Medical Testing; - Calibration; - Inspection; and - Management Systems Certification (QMS, EMS, FSMS)
Level 3	Generic, normative documents used by the ABs to assess the CABs for each activity are: - Testing: ISO/IEC 17025; - Medical: ISO 15189; - Calibration: ISO/IEC 17025; - Inspection: ISO/IEC 17020; and - Management Systems Certification: ISO/IEC 17021-1
Level 4	Sector specific normative documents which specify internationally recognised applications of the generic, normative documents listed in Level 3. The application documents are used by the ABs, in combination with the normative documents listed in Level 3, to assess the CAB competence in the relevant sector. The sector-specific normative documents are described as follows and in **Annex 1**: a. Normative documents to be used in combination with ISO/IEC 17021-1: - For Certification of Food Safety Management Systems (FSMS) – ISO 22003; - For Certification of Environmental Management System (EMS) – ISO/IEC TS 17021-2 - For Certification of Quality Management System (QMS) – ISO/IEC TS 17021-3 b. There are currently no endorsed documents to be used with the following normative documents: - ISO/IEC 17025 - ISO 15189 - ISO/IEC 17020
Level 5	The scope of accreditation of the CAB accredited by the AFRAC MRA. 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 AFRAC MRA.

ANNEX 1: Structure of the AFRAC Arrangement

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

It must be taken into consideration that there are other AFRAC, IAF and ILAC mandatory documents which are used in the peer evaluations for the AFRAC MRA. These documents are not included in the table, but may be found on the AFRAC website, in the documents section, mandatory documents page.

Level 1	**ISO/IEC 17011**						
Level 2	Testing		Calibration	Inspection	Management Systems Certification		
Level 3	ISO/IEC 17025	ISO 15189	ISO/IEC 17025	ISO/IEC 17020	ISO/IEC 17021-1		
Level 4	-	-	-	-	FSMS ISO/TS 22003	QMS ISO/IEC TS 17021-3	EMS ISO/IEC TS 17021-2
Level 5	Scope of Accreditation				ISO 22000	ISO 9001	ISO 14001

3. PUBLICATION OF THE SIGNATORIES OF THE AFRAC MRA

Levels 1, 2 and 3 of the AFRAC MRA are controlled by AFRAC.

Levels 4 and 5 are maintained by each AFRAC MRA Signatory. Before re-evaluations, each signatory shall provide AFRAC with information on the Level 4 normative document for which it provides accreditation under the AFRAC MRA.

For the accreditation activities of Management Systems Certification, AFRAC controls levels 1 to 5.

The levels controlled by AFRAC, are indicated in the **AFRAC M002-01: AFRAC Mutual Recognition Arrangement (MRA).** AFRAC is responsible for publishing the MRA Signatories' list, identifying the applicable normative documents for which they are recognised.

4. EXPANDING THE AFRAC MRA

The following steps shall be followed to expand the AFRAC MRA:

4.1 Proposal to expand the AFRAC MRA

A new need for international recognition through accreditation that is relevant to AFRAC members may be identified. A proposal for an expansion may be received from various sources such as AFRAC Member Bodies, stakeholders such as regulators, trade bodies, industry or professional associations, groups of affected conformity assessment bodies, etc. The proposal shall be submitted to the MRA Council Chair.

There may be three different situations:

4.1.1 A new accreditation program uses a Level 4 normative document which is a sector specific application based on the internationally recognized Level 3 standards already used for accreditation by AFRAC Members;

4.1.2 The program is for a completely new Level 3 standard or normative document, covering a conformity assessment body or attestation of competence of a body; or

4.1.3 The need may be for a Level 2 activity, not currently covered by an ISO Standard, but already in general use by a number of accreditation bodies and with potential for future development by ISO.

Proposals for AFRAC to consider new areas for accreditation and their potential relevance to the AFRAC MRA shall first be presented to the MRA Council Chair together with relevant supporting documentation.

4.2 Review of the proposal to expand the AFRAC MRA

Once a potential need of a new area for international recognition is identified, the MRA Council Chair shall undertake a survey among MRA Council Members to inquire the following:

4.2.1 The background on the need for the new area;
4.2.2 The current experience of the AFRAC Members in the new area;
4.2.3 The views of affected parties including any external bodies that may have proposed the need;
4.2.4 The availability of initial criteria;
4.2.5 The interest and preparation of the AFRAC Members for an MRA in the new area; and
4.2.6 The number of AFRAC Members that are interested in order to justify the extension of the MRA.

As part of its review of the new proposal, the MRA Council Members shall consider whether the standard or other normative documents proposed for the new area, meet the following criteria:

4.2.7 Significant relevance to accreditation of CABs involved in related activities;
4.2.8 Sufficient substance to enhance the recognition of competence;
4.2.9 Fulfils appropriate needs on an international basis;
4.2.10 Lack of inclusion poses threats to AFRAC leadership in accreditation;
4.2.11 Complementary to or supportive of any other standard being currently used;
4.2.12 Does not dilute the substance of any existing standard under the AFRAC MRA; and
4.2.13 Document must be produced by a regional consensus process (including all relevant interested parties).

If the proposal involves operation in a new activity (Level 2) or a new generic, normative document (Level 3) for AFRAC, the review shall include consideration of impartiality of the AB in relation to services that CABs perform, as required by ISO/IEC 17011. This is of the utmost importance if the new activity is outside those mentioned in ISO/IEC 17011.

The MRA Council Members shall undertake a survey among AFRAC Members and, if relevant, other parties to establish their existing experience or interest in the proposed new area. The results of such surveys shall be used to determine if there are sufficient numbers of AFRAC members with an interest in the new area to justify its further development and consideration for inclusion in an expanded AFRAC MRA.

AFRAC will also consult ILAC, IAF, ISO and other interested parties for comments, as relevant.

The MRA Council Members will also ensure that the new area does not jeopardize the existing obligations already undertaken by AFRAC Members under the AFRAC Arrangement. If the proposed program is based on an agreement between a program owner and AFRAC, it will be necessary to ensure that:

4.2.14 The program does not discriminate against any member of the AFRAC MRA and does not impose unnecessary requirements on them.

4.2.15 The assessment process shall at least fulfil all the relevant requirements established in ISO/IEC 17011.

4.2.16 Requirements established by the program owner are not in contradiction with ISO/IEC 17011 nor with the applicable generic, normative document (Level 3).

4.2.17 The accreditation body is the only body responsible for the decisions taken with respect of accreditation.

4.2.18 Decisions regarding the maintenance of an accreditation body in the AFRAC MRA can only be taken within AFRAC where the accreditation body is a Member.

4.2.19 The information supplied to the market must always be transparent and not create barriers to competition amongst the affected bodies covered by the accreditation.

4.3 Approval by the AFRAC GA to initiate development of the expansion of the Arrangement

The results of the review should be distributed to the members at least 30 days before the AFRAC General Assembly (GA) for a decision on whether or not to proceed with the development.

Once the expansion is accepted by the MRA Council, the MRA Council Chair shall submit a request to the GA for an expansion of the AFRAC MRA.

If the AFRAC GA agrees to initiate the development of the expansion, the new area will be included in the Structure of the AFRAC Arrangement (Annex 1) and this document will be updated accordingly.
The process will continue as specified in 4.4.

The model for the resolution to be approved by the GA is as follows:

The GA agrees to extend the AFRAC MRA to include the following scopes:

- (Name of the Level of the structure to be extended), according to (specify the specific and applicable normative documents)

The GA requests the Technical Committee and the MRA Committee to follow the requirements and procedures to extend the arrangement.

The AFRAC MRA Secretary shall update the structure of the MRA defined in the relevant AFRAC Procedure.
Note: It may be necessary before updating the MRA structure, to include additional information provided by the MRA Council or the Technical Committee on the specific standards for each level.

4.4 Development of the expansion of the AFRAC MRA

The MRA Council and the Technical Committee shall create one or more working groups in order to:

4.4.1 Determine whether the existing criteria for Arrangement Signatory, i.e. ISO/IEC 17011 and the relevant AFRAC documents can be used, or need to be amended for an expansion of the AFRAC MRA, and draft any additional criteria or peer evaluation processes that are needed to address the new area;

4.4.2 Conduct an analysis, considering the activities already developed by ILAC, IAF or other regions;

4.4.3 Determine the existence of harmonised generic normative documents (Level 3) and/or when applicable, the sector specific documents (Level 4 and/or Level 5);

4.4.4 Determine the processes, standards, and other documents of potential interest for the AFRAC Arrangement, in addition to the ISO/IEC 17011 Standard and the AFRAC Mandatory documents for the MRA;

4.4.5 Develop and approve the technical criteria within the Technical Committee, for example, the application of an accreditation standard, the application of ISO/IEC 17011, or applications of the normative documents at Level 3, among others;

4.4.6 Define the evaluation methodology which shall include a summary of general parameters that will serve as a guide to plan and conduct the evaluation. Include this evaluation methodology in the M001, as well as in the applicable forms and reports;

4.4.7 Review and update, if applicable, the decision making and the MRA text, peer evaluator qualifications and other relevant topics regarding the new area;

4.4.8 Develop new documents as required by the MRA, if applicable;

4.4.9 Consider the need to make changes or adapt the AFRAC structure in order to assign responsible parties to the technical issues regarding the extension of the MRA Scope; and

4.4.10 Consider the impact on the AFRAC fees.

The F022 Document Review Status for the Extension of the AFRAC MRA Form may be used to facilitate this work.

4.5 The Working Group shall draft and maintain a development plan which includes all of the issues described in 4.4.

4.6 Once the MRA Council and the Technical Committee have completed drafting or reviewing the documents, the documents shall undergo the AFRAC document approval process.

4.7 In parallel to the activities defined in 4.4, 4.5 and 4.6, the Evaluators Working Group (EWG) and the MRA Secretary shall collect information on the existing peer evaluators, with the purpose of determining the need to incorporate new evaluators or the existence of peer evaluators already qualified for the new scope, and plan the necessary training in cooperation with the relevant AFRAC Committee dealing with training. It is necessary that the Evaluators Working Group develop a Work Plan for these activities.

4.8 Evaluation of the Expansion of the AFRAC MRA

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

4.8.1 Any Level 2 activity that is added to the AFRAC MRA, together with the first corresponding Level 3 generic, normative document will require an on-site full initial evaluation and regular re-evaluation, in which all requirements of ISO/IEC 17011 are evaluated. The evaluation team shall be competent in that activity and witnessing will be included.

4.8.2 For any additional Level 3 generic, normative document that is added for an existing Level 2 activity in the AFRAC MRA, the AFRAC GA will need to decide on the application and initial evaluation and re-evaluation procedures to be followed, based on a recommendation by the MRA Council.

4.8.3 When determining the initial evaluation and re-evaluation procedures to be followed AFRAC shall consider the following factors:

- Requests from the users of accreditation or other concerned parties in the marketplace;
- 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.

4.8.4 The initial evaluation procedures may include:

- An on-site full evaluation for that activity / normative document, including witnessing;
- A partial on-site evaluation (selected requirements of ISO/IEC 17011), including witnessing;
- Document review only;
- Self-declaration by the AB.

Normally bullet 1 or bullet 2 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 or self-declaration may be adequate.

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

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

- The AB shall provide a self-declaration, that the sub-scope has been introduced and relevant requirements as defined by AFRAC M001 “AFRAC Policies and procedures for a MRA among Accreditation Bodies’ have been met.

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

- The AB shall undergo a full evaluation in accordance with AFRAC M001 “AFRAC Policies and procedures for a MRA among Accreditation Bodies’.

4.9 Launching the expansion of the MRA

After completion of 4.4 including any balloting on criteria, AFRAC procedures and documents, the AFRAC MRA Committee shall make a formal draft resolution to the AFRAC GA for launching the expansion of the AFRAC MRA, including details of the standards or other normative documents for criteria, and invite AFRAC members to present applications for the Arrangement.

Annex 2: List of the Standards used in the different levels of the structure of the AFRAC 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/TS 22003: Food safety management systems - Requirements for bodies providing audit and certification of food safety management systems
- 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

Level 5:

- ISO 14001: Environmental management systems - Requirements with guidance for use
- ISO 22000: Food safety management systems - Requirements for any organization in the food chain
- ISO 9001: Quality management systems – Requirements