STRUCTURE OF THE ARAC MULTI-LATERAL RECOGNITION ARRANGEMENT AND PROCEDURE TO EXTEND THE ARRANGEMENT

CLASSIFICATION
This document is classified as an ARAC Procedures Document.

AUTHORIZATION

Issue Nº:	01
Prepared by:	MLA Committee
Date:	September 2013
Revision Nº:	01
Approved by:	General Assembly
Issue Date:	December 2013
Application Date:	Immediate
Document number:	ARAC PR 025
Inquiries:	ARAC Secretariat
E-mail:	secretariat@arabarac.org

AVAILABILITY
Copies of this document in Arabic and English, are available at the ARAC Secretariat and on the ARAC website.

Original: English

1. Purpose

This procedure describes the structure of the ARAC Multi-lateral Recognition Arrangement as well as the steps required to extend it.

2. ARAC MLA Structure

The Structure of the ARAC MLA has five levels which are described as follows:

Level 1	Includes the ISO/IEC 17011 standard which specifies the criteria for the accreditation bodies.
Level 2	Includes the accreditation activities for which the accreditation bodies have demonstrated competence to accredit against the requirements established in the normative documents listed in Level 3. The accreditation activities are: • Testing, includingClinical/Medical Testing • Calibration • Proficiency Testing • Reference Materials Production • Inspection • Product Certification • Management Systems Certification • Persons Certification
Level 3	Includes the normative documents used by the accreditation bodies to evaluate the Conformity Assessment Bodies (CABs) for each activity. The normative documents are: • Testing, including Clinical/Medical Testing: ISO/IEC 17025 and ISO 15189 • Calibration: ISO/IEC 17025 • Proficiency Testing , ISO/IEC 17043 • Reference Materials Production, ISO Guide 34. • Inspection: ISO/IEC 17020 • Product Certification : ISO/IEC 17065 • Management Systems Certification: ISO/IEC 17021 • Persons Certification: ISO/IEC 17024
Level 4	Includes the normative documents specific to the sector, which define the applications that are internationally recognized in the generic normative documents listed in Level 3. These applications are used by the accreditation bodies, in combination with the normative documents of Level 3, to assess the competence of the CABs in the relevant sector. The normative documents specific to the sector are described as follows and in Table 2: a. Normative documents to be used in combination with ISO/IEC 17025: – For Anti-doping Testing Laboratories, also accredited by the World Anti-Doping Agency (WADA), the WADA International Standards for Laboratories (ISL) – For medical or clinical reference laboratories, ISO 15195. b. Normative documents to be used in combination with ISO 15189: – For point of care testing, ISO 22870 c. Normative documents to be used in combination with ISO/IEC 17021 : – For certification of food safety management systems (FSMS) - ISO 22003;

	– For certification of information security management systems (ISMS) ISO/IEC 27006 d. There are no approved documents to be used with the following normative documents: a. ISO/IEC 17020 b. ISO/IEC 17065 c. ISO/IEC 17024 d. ISO/IEC 17043 e. ISO Guide 34
Level 5	Includes the conformity assessment normative documents used by CAB. Normative documents in this level are specified in Table 2 only for management systems certification. For other activities of the ARAC MLA this level includes the scope of accreditation of the CABs accredited by an ARAC signatory member.

Tables 1 and 2 present the different levels of the MLA structure described and the corresponding applicable normative documents. It must be considered that there are other ARAC, IAF and ILAC mandatory documents which are used in the peer evaluations for the ARAC MLA. These documents are not included in the ARAC structure, but may be found in the ARAC website, in the documents section, mandatory documents link.

Table 1: Structure of the ARAC MLA: Levels 1 to 3.

Level 1	ISO/ IEC 17011									
Level 2	Testing		Calibration	Proficiency Testing	Reference Materials Production	Inspection	Product Certification	Management Systems Certification	Persons Certification	Validation /verification
Level 3	ISO/IEC 17025	ISO 15189	ISO 17025	ISO/IEC 17043	ISO Guide 34*	ISO/IEC 17020	ISO/IEC 17065	ISO/IEC 17021	ISO/IEC 17024	ISO 14065

***It is assumed that Guide 34 already includes the necessary requirements of ISO/IEC 17025.**

Table 2: Structure of the ARAC MLA: Levels 3 to 5.

Level 3	ISO/IEC 17025 Testing	ISO 15189	ISO/IEC 17025 Calibration	ISO/IEC 17021				ISO 14065
Level 4	WADA (ISL)	ISO 22870	ISO 15195	FSMS ISO 22003	--	--	ISMS ISO 27006	--
Level 5	Accreditation scope			ISO 22000 ISO/TS 22002-1	ISO 9001	ISO 14001	ISO27001	ISO 14064-1 ISO 14064-2 ISO 14064-3 ISO 14066

3. Publication of the ARAC MLA scope.

For the accreditation activities: testing (included clinical / medical testing), calibration, proficiency testing, product certification, persons certification, reference materials production and inspection, levels 1, 2 and 3 of the ARAC MLA, are controlled by ARAC. Levels 4 and 5 are maintained for each ARAC MLA Signatory.

For the accreditation activities:, management systems certification and the control by ARAC is made until level 5.

The levels controlled by ARAC, are indicated in the mandatory document MD 001: ARAC Multi-lateral Recognition Arrangement (MLA). ARAC is responsible for the publication of the signatories accreditation bodies list, identifying the applicable normative documents for which the accreditation bodies are recognized.

4. ARAC MLA Extension

The following steps shall be followed:

4.1 Identification of a new need of international recognition through accreditation that is relevant for ARAC members. An extension application may be received from various sources including Stakeholders and ARAC Member Bodies and shall be delivered to the MLA Committee Chair.

4.2 Once a potential need of a new area for international recognition is identified, the MLA Committee Chair carries out a survey among MLA Committee members to consider:

- The ARAC members accreditation service experience in the new area,
- Confirm the interest and preparation of the ARAC members for an MLA.
- Have information on the number of ARAC members that are interested in order to justify the extension of the MLA.

4.3 Once the extension is approved by the MLA Committee, the MLA Committee shall submit a request for an extension of the ARAC MLA to the General Assembly. The model for the approval resolution by the General Assembly is the following:

The General Assembly agrees to extend the ARAC MLA 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 General Assembly requests the Technical Committee and the MLA Committee to follow the requirements and procedures of the PR 025 to extend the arrangement. The ARAC Secretary will update structure of the MLA defined in the procedure PR 025 , according to this approved extension.

Note: May be necessary before updating the MLA structure, additional information, by the MLA Committee or the Technical Committee on the specific standards of each level.

4.4 Once there is approval by the General Assembly, the MLA Committee and the Technical Committee shall create one or more working groups responsible for:

a) Conduct an analysis, considering the activities already developed by ILAC, IAF or other regions.

b) Determine the existence of harmonized general normative documents (Level 3) and/or the documents specific to the sector (Level 4).
c) Determine the processes, standards, and other documents of potential interest for the ARAC Arrangement, in addition to the ISO/IEC 17011 standard and the mandatory ARAC documents for the MLA.
d) Develop and approve the technical criteria within the Technical Committee, for example; application of the accreditation standard, application of the ISO/IEC 17011, among others.
e) Define the evaluation methodology which shall include a summary of general parameters that will serve as a guide to plan and conduct the evaluation, and update MD 002 procedure, as well as the applicable forms.
f) Review and update, if applicable, decision making and MLA text, peer evaluator qualification and other relevant topics regarding the new area.
g) Develop new documents that are required for the MLA.
h) Consider the need to make changes or adapt the structure of ARAC that is responsible for the technical topics.
i) Consider the impact on the ARAC fees.

During the process of developing the analysis it shall be ensured that the new program is not discriminating to any of the ARAC members, that no unnecessary requirements are imposed to the potential signatories, and that it does not contradict the ISO/IEC 17011 standard.

iForm FM 025: Review of the existing ARAC documents to extend the MLA may be used to facilitate
Form FM 025: Review of the existing ARAC documents to extend the MLA may be used to facilitate this work.

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

4.6 Once the document drafting or review by the MLAC and the Technical Committee has taken place, the document shall undergo the ARAC documents approval process.

4.7 In parallel to the activities defined in 4.4, 4.5 and 4.6, the MLA Committee Secretary shall collect information from 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 MLA committee. It is necessary that the MLA Committee develop a Work Plan for these activities.

4.8 Launch of the MLA: Once the above requirements have been achieved, the MLAC shall inform all of the ARAC members on the launch of the new ARAC MLA.

Annex I

List of the standards used in the different levels of the structure of the ARAC MLA

Level 1:

− ISO/IEC 17011:2004: Conformity assessment -- General requirements for accreditation bodies accrediting conformity assessment bodies

Level 3:

−ISO 15189: Medical laboratories -- Particular requirements for quality and competence
−ISO Guide 34: General requirements for the competence of reference material producers
−ISO/IEC 17020: Conformity assessment -- Requirements for the operation of various types of bodies performing inspection
−ISO/IEC 17021: Conformity assessment -- Requirements for bodies providing audit and certification of management systems
−ISO/IEC 17024: Conformity assessment -- General requirements for bodies operating certification of persons
−ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories
−ISO/IEC 17043: Conformity assessment -- General requirements for proficiency testing
−ISO/IEC 17065: Conformity assessment -- Requirements for bodies certifying products, processes and services

Level 4:

−ISO 15195: Laboratory medicine -- Requirements for reference measurement laboratories
−ISO 22870: Point-of-care testing (POCT) -- Requirements for quality and competence
− ISO/IEC 27006: Information technology -- Security techniques -- Requirements for bodies providing audit and certification of information security management systems
−ISO/TS 22003: Food safety management systems -- Requirements for bodies providing audit and certification of food safety management systems
−The WADA International Standard for Laboratories (ISL)

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
−ISO/IEC 27001: Information technology -- Security techniques -- Information security management systems -- Requirements
−ISO 13485 Medical Devices Management Systems – Requirements