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

CLASSIFICATION
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Inquiries:	ARAC Secretariat
E-mail:	secretariat@arabarac.org

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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, including Medical Testing ▪ Calibration ▪ Inspection ▪ Proficiency Testing ▪ Reference Material Production ▪ Biobanking ▪ Product Certification ▪ Management Systems Certification ▪ Certification of Persons
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, ISO/IEC 17025 ▪ Medical Testing ISO 15189 ▪ Calibration: ISO/IEC 17025 ▪ Inspection: ISO/IEC 17020 ▪ Proficiency Testing: ISO/IEC 17043 ▪ Reference Material Producers: ISO 17034 ▪ Biobanking: ISO 20387 ▪ Product Certification : ISO/IEC 17065 ▪ Management Systems Certification: ISO/IEC 17021-1 ▪ 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 to be considered equally reliable. 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 such as: - For Anti-doping Testing Laboratories, also accredited by the World Anti- Doping Agency (WADA), the WADA International Standards for Laboratories (ISL) - For Laboratory medicine - Requirements for the competence of calibration laboratories using reference measurement procedures, ISO 15195. b) Normative documents to be used in combination with ISO 15189: - For point of care testing (POCT), ISO 22870 c) Normative documents to be used in combination with ISO/IEC 17021-1 : - For certification of food safety management systems (FSMS) – ISO/TS 22003; - For certification of Quality Management System (QMS) ISO/IEC TS 17021-3 - For Certification of Environmental Management System (EMS) ISO/IEC TS 17021-2 - For certification of occupational health and safety management systems (OH&SMS) - ISO/IEC TS 17021-10 - For certification of information security management systems (ISMS) -ISO/IEC 27006 - For certification of Anti-bribery management systems- ABMS: ISO/IEC TC 17021-9 - For certification of Business continuity management systems- BCMS ISO/IEC 17021-6: - For certification of Energy management systems- EnMS: ISO 50003 d) Normative documents to be used in combination with ISO/IEC 17065: – GLOBAL G.A.P Integrated Farm Assurance General Regulations e) Normative documents to be used in combination with ISO/IEC 17024: – International Personnel Certification Association (IPC)
Level 5	Includes the conformity assessment normative documents used by CABs. Normative documents in this level are specified in Table 2. For other activities of the ARAC MLA this level includes the scope of accreditation of the CABs accredited by an ARAC MLA 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	Inspection	Proficiency Testing	Reference Material Producers	Biobanking	Product Certification	Management Systems Certification	Certification of persons
Level 3	ISO/IEC 17025	ISO 15189	ISO/IEC 17025	ISO/IEC 17020	ISO/IEC 17043	ISO 17034	ISO 20387	ISO/IEC 17065	ISO/IEC 17021-1	ISO/IEC 17024

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

Level 3	ISO/IEC 17025 Testing	ISO 15189 Medical Testing	ISO/IEC 17025 Calibration	ISO/IEC 17021-1 Management System									ISO/IEC 17065	ISO/IEC 17024
Level 4	WADA (ISL)	ISO 22870	ISO 15195	FSMS ISO/TS 22003	QMS ISO/IEC TS 17021-3	EMS ISO/IEC TS 17021-2	MDMS --	OH&S MS ISO/IE C TS 17021-10	ISMS ISO/IEC 27006	Anti-bribery management systems-ABMS ISO/IEC TC 17021-9	Business continuity management systems-BCMS ISO/IEC 17021-6	Energy management systems-EnMS ISO 50003	EOMS --	GLOBALG.A.P. IFA General Regulations	
Level 5	Accreditation scope			ISO 22000	ISO 9001	ISO 14001	ISO 13485	ISO 45001	ISO/IEC 27001	ISO 37001	ISO 22301	ISO 50001	ISO 21001	GLOBALG.A.P. IFA Control Points and Compliance Criteria (GG IFA)	IPC-PL-11-006 (IPC)

3. Publication of the ARAC MLA scope.

For the accreditation activities: testing (included clinical / medical testing), calibration, product certification, persons certification 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 to level 5.
With regard to recognition of accreditation of sub-scopes (Level 4 & 5) for certification of management systems, the AB shall present to the MLA Secretary a self- declaration using IAF MLA MC 28 "MLA Declaration for sub-scope extensions (ABs)". The MLA Group will decide on the acceptance of the self-declaration by resolution taking into consideration the Peer evaluators' necessary competence resources that ARAC has for the requested sub scopes.

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 Group Chair.

4.2 Once a potential need of a new area for international recognition is identified, the MLA Group Chair carries out a survey among MLA Group 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 Group, the MLA Group shall submit a request for an extension of the ARAC MLA to the General Assembly, except for the levels 4 & 5. 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 Group to follow the requirements and procedures of the PR 025 item 04 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 Group or the Technical Committee on the specific standards of each level.
4.4 Once there is approval by the General Assembly, the MLA Group 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 and reports.

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, if applicable

h) Consider the need to make changes or adapt the structure of ARAC in order to assign responsible parties for the technical topics regarding the extension of the ARAC MLA scope.

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.

Form FM 033: 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 Group 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 Group. It is necessary that the MLA Group 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: Requirements for accreditation bodies accrediting conformity assessment bodies

Level 2:

Conformity assessment activities performed by conformity assessment bodies for which the accreditation body grants accreditation according to the generic, normative documents listed in Level 3.

- Testing, including Medical Testing
- Calibration
- Inspection
- Proficiency Testing
- Reference Material Production
- Biobanking
- Product Certification
- Management Systems Certification
- Certification of Persons

Level 3:

- ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories
- ISO 15189: Medical laboratories -- Requirements for quality and competence
- ISO/IEC 17020: Conformity assessment -- Requirements for the operation of various types of bodies performing inspection
- ISO/IEC 17043 Conformity assessment - General requirements for proficiency testing
- ISO 17034 General requirements for the competence of reference material producers
- ISO 20387 Biotechnology — Biobanking — General requirements for biobanking
- ISO/IEC 17021-1: 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 17065: Conformity assessment -- Requirements for bodies certifying products, processes and services

Level 4:

- 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
- 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
- ISO/IEC TS 17021-10 Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 10: Competence requirements for auditing and certification of occupational health and safety management systems
- ISO/IEC 27006 Information technology -- Security techniques -- Requirements for bodies providing audit and certification of information security management systems
- ISO/IEC TC 17021-9: Anti-bribery management systems- ABMS
- ISO/IEC 17021-6: Business continuity management systems- BCMS
- ISO 50003: Energy management systems- EnMS
- GLOBALG.A.P. IFA General Regulations V4

Level 5:

Examples of normative documents used by Certifications bodies:

- 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 for regulatory purposes.
- ISO 13485 Medical Devices Management Systems – Requirements
- ISO 45001 Occupational health and safety management systems — Requirements with guidance for use
- ISO 21001: Educational organizations — Management systems for educational organizations — Requirements with guidance for use
- ISO 37001: Anti-bribery management systems
- ISO 22301: Security and resilience — Business continuity management systems — Requirements
- ISO 50001: Energy Management
- GLOBALG.A.P. IFA Control Points and Compliance Criteria (GG IFA),
- IPC-PL-11-006 (IPC).