**EUROPEAN ACCREDITATION**

*Publication Reference*

# EA-INF/11: 2022

# Scope of the EA MLA and the application of an EA MLA signatory to join the IAF MLA for a specific main scope/sub-scope and/or the ILAC MRA for a specific activity

## PURPOSE

This document gives information on the process to be followed by an EA MLA signatory, when applying for ILAC/IAF MRA/MLA signatory status for a specific scope, sub-scope or activity.

*Authorship*

This document has been written by the Technical Management Board.

*Official language*

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

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*Further information*

For further information about this document, contact the EA Secretariat. Please check the EA website for up-to-date information (http://www.european-accreditation.org).

**Category:** Information document

**Date of Publication**: 27th September 2022

**Implementation:** Immediate

**Transitional period**: None

# *CONTENTS*

## 1.    GENERAL

The EA MLA refers to the level 2 and 3 areas only i.e.:

Testing laboratories including medical laboratories EN ISO/IEC 17025, EN ISO 15189
Calibration laboratories                              EN ISO/IEC 17025
Certification bodies for Products                     EN ISO/IEC 17065
Certification bodies for Persons                      EN ISO/IEC 17024
Certification bodies for Management systems           EN ISO/IEC 17021-1
Inspection bodies                                     EN ISO/IEC 17020
Validation and Verification bodies                    EN ISO/IEC 17029
Validation and Verification bodies (GHG)              EN ISO 14065[1]
Proficiency Testing Providers                         EN ISO/IEC 17043
Reference Material Producers                          EN ISO 17034
Biobanking                                            EN ISO 20387

[1] It relates to EN ISO 14065:2013


## 2.    LEVELS 4 AND 5 COVERAGE OF THE EA MLA

The National Accreditation Bodies (NABs) are peer evaluated based on the statistical information provided including all accreditation activities. The peer evaluation program covers (in addition to the requirements from the levels 1 and 3 standards, the EA additional requirements documents, the relevant IAF/ILAC mandatory documents, Regulation 765/2008 EU, Regulation 600/2012 EU, all scheme requirements for the schemes covered by the NAB) all level 4 and 5 activities based on a statistical based sampling, hence all activities are covered by the peer evaluation and are included in the EA MLA. Furthermore, regulatory or international sector schemes have increased focus in the peer evaluation process.

An accreditation body can extend its level 4 and 5 activities following the extension procedure foreseen in EN ISO/IEC 17011 § 4.6, i.e. these areas are covered under the EA MLA immediately after completion of the corresponding process by the NAB – including an evaluation of the scheme according to EA-1/22 (if applicable) – and publication e.g. on its webpage. The extension process (including the demonstration of competence) will be checked at the next regular peer evaluation as part of the normal peer evaluation process as described above.


## 3.    IAF MLA SCOPING

IAF covers the following activities:

Certification of management systems (ISO/IEC 17021-1), Certification of Products, Processes and Services (ISO/IEC 17065), Certification of Persons (ISO/IEC 17024), Validation and Verification (ISO/IEC 17029, ISO 14065) on the IAF MLA main-scope level.

An IAF MLA extension to Certification of Management system will only be granted, if at least one IAF MLA sub-scope is covered.

As a supplement IAF endorses AB members to specific IAF MLA sub-scopes.

IAF accepts an accreditation body for IAF MLA sub-scope extension only if that sub-scope is covered by the peer evaluation in the way described by IAF only.


## 4.    ILAC MRA SCOPING

The ILAC MRA covers the following activities: calibration (ISO/IEC 17025), testing (ISO/IEC 17025) and medical examinations (ISO 15189), inspection (ISO/IEC 17020), proficiency testing providers (ISO/IEC 17043), reference material producers (ISO 17034) and biobanking (ISO 20387). ILAC accepts an accreditation body if it has been peer evaluated according to IAF/ILAC A2 for the specific activity.


## 5.    APPLICATION TO THE IAF MLA OR THE ILAC MRA OF AN EA MLA SIGNATORY

As EA is an IAF and ILAC recognized region EA MLA signatories could be accepted into the respective IAF MLA or ILAC MRA, provided that the EA peer evaluation covered the relevant activity.

### 5.1    ILAC

See ILAC- R6 and ILAC-P4.

### 5.2    IAF

See IAF PR 4 and IAF ML 4.

If an EA MLA signatory has expanded its area of activity for IAF MLA sub-scopes after the last EA peer evaluation based on a self-declaration that all requirements are fulfilled, an application to IAF can be submitted. The application shall be supported by EA and the new sub-scope shall be covered in the next regular EA peer evaluation of the NAB.