



European
co-operation for
Accreditation

Agreements among accreditation bodies

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Serving the European Economy and Society

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EA MLA ⁽¹⁾

- ❖ **The EA MLA is an agreement signed between the EA accreditation body members to recognise the equivalence, reliability and therefore acceptance of accredited certificates, inspection reports, calibration certificates and test reports across Europe.**
- ❖ **The MLA eliminates the need for suppliers of products or services to be certified in each country where they sell their products or services, and therefore provides a means for goods and services to cross boundaries in Europe and throughout the world.**

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EA MLA ⁽²⁾

- ❖ **It delivers confidence in the service supplied by accredited laboratories, inspection and certification bodies, thereby providing the framework for goods and services to cross borders in Europe and throughout the world, acting as a "passport for trade".**
- ❖ **The National Accreditation Body's mark on test reports and certificates is the assurance of the benefits of the MLA.**

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EA MLA ⁽³⁾

The EA Multilateral Agreement accepts:

- ❖ the equivalence of the operation of the accreditation systems administered by EA MLA signatory members;
- ❖ that the certificates and reports issued by organisations accredited by EA MLA signatory members are equally reliable.

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EA MLA ⁽⁴⁾

Benefits for governments and regulators ⁽¹⁾

- ❖ **Flexibility of approach:** accreditation delivers a multi-discipline solution that can be applied to support or act as an alternative to legislation (765/2008/EC Regulation; 768/2008/EC Decision); Increased confidence in data that is used to establish baselines for monitoring and enforcement;
- ❖ **Trade facilitation** due to internationally accepted testing and measurement practices, data generated by an accredited laboratory may lead to the more ready acceptance of exported goods in overseas markets. This reduces costs and eases exports and imports, as it reduces or eliminates the need for retesting in another country;

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EA MLA ⁽⁵⁾

Benefits for governments and regulators ⁽²⁾

- ❖ **Efficient Government:** Accreditation delivers a balance between risk and protection as it reduces the need for government and regulators to carry out additional audits, and so employ additional inspection staff;
- ❖ **Create a competitive environment:** businesses are able to differentiate their products and services, as well as being able to exploit overseas opportunities opened up through the mutual recognition arrangements.

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EA MLA ⁽⁶⁾

Benefits for industry and business community ⁽¹⁾

- ❖ Accreditation saves business time and money as it removes the need to re-test or re-certify a product in each and every country where it is sold.
- ❖ The EA MLA is a European network that supports industry and trade by removing barriers to trade: an accredited test performed in one country is recognised in all the other MLA signatory countries. For the manufacturer or the importer, it ensures greater access to new growth areas, and speed to market.

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EA MLA ⁽⁷⁾

Benefits for industry and business community ⁽²⁾

How to ensure that a certificate or test report is acceptable?

- ❖ check that there is an accreditation mark on the report or certificate;
- ❖ check that the accreditation mark is a mark of an accreditation body signatory to the EA MLA (ILAC MRA or IAF MLA);
- ❖ check that the supplier is accredited for the competence, the tests, the results you need;
- ❖ check that the tests have been carried out against international standards. Alternatively, check that the standards, methods used can be accepted in the country of destination;
- ❖ in case of problems, contact the national accreditation body.

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Benefits for European citizens ⁽¹⁾

- ❖ The EA MLA benefits all European citizens as accreditation underpins the quality of the air we breathe, the safety of the food we eat, the safety of our working environment.
- ❖ As an example, there is an ongoing project to develop accreditation for the certification of services performed by the breast cancer units (diagnosis, treatment) throughout Europe. It is a clear expectation of the European Parliament to make the same high quality services available to all women in Europe.

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EA MLA ⁽⁹⁾

Benefits for European citizens ⁽²⁾

Accreditation:

- **Delivers Public Confidence:** Despite a complex global marketplace, accreditation gives us confidence through ensuring consistently high standards in the quality of products or services purchased.
- **Minimises product failure or recalls:** Product testing carried out by a reliable independent organisation will minimise products failing or potential recalls.
- **Prevents dangerous outbreaks:** Tests conducted by accredited laboratories will prevent the risk of outbreaks (from food poisoning to water contamination) that can be hazardous to the public.

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EA MLA ⁽¹⁰⁾

Article 11 of 765/2008/EC Regulation

Presumption of conformity for national accreditation bodies

1. National accreditation bodies that demonstrate conformity with the criteria laid down in the relevant harmonised standard, the reference of which has been published in the Official Journal of the European Union, by having successfully undergone peer evaluation under Article 10 shall be presumed to fulfil the requirements laid down in Article 8.
2. National authorities shall recognise the equivalence of the services delivered by those accreditation bodies which have successfully undergone peer evaluation under Article 10, and thereby accept, on the basis of the presumption referred to in paragraph 1 of this Article, the accreditation certificates of those bodies and the attestations issued by the conformity assessment bodies accredited by them.

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Article 23 of 768/2008/EC Decision

Notification procedure

4. Where a notification is not based on an accreditation certificate, the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements.
5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

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EA-1/06

EA Multilateral Agreement

June 2007 Rev 5

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EA-1/06 ⁽¹⁾

- 1. The Agreement is based on the results of the evaluations carried out in accordance with the EA procedure.**
- 2. The parties entering the Agreement are the Accreditation Bodies in each country on behalf of which the Agreement was signed.**
- 3. EA MLA members shall not in any way market or promote their accreditation services in another EA Member country. This will not prevent an AB from providing accreditation services if requested by a CAB or AB, taking into account the principles of the Cross Frontier Policy.**

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EA-1/06 ⁽²⁾

- 4. On the basis of the equivalence of the operation of the Schemes operated by the Signatories and hereby declared, each Signatory to this Agreement will:**
 - i. accept the other Schemes operated by the other Signatories as equivalent to its own Scheme(s);**
 - ii. recognise as being equally reliable the certificates and/or reports from the organisations accredited by the Signatories under their equivalent Schemes;**
 - iii. recommend and promote the acceptance of certificates and/or reports from the organisations accredited by the Signatories under their Scheme(s) by all users in countries of the Signatories;**

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EA-1/06 ⁽³⁾

On the basis of the equivalence of the operation of the Schemes operated by the Signatories and hereby declared, each Signatory to this Agreement will:

- iv. investigate all complaints initiated by a Signatory resulting from certificates and/or reports issued by an accredited organisation of its own Scheme(s);**
- v. notify all other Signatories and the MLA secretariat as soon as possible of any significant changes that have occurred or will occur in its status or in the operational practices of its Scheme(s);**
- vi. nominate and commit itself to providing a number of peer evaluators in proportion to its size and to the needs of the MLA Council;**

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EA-1/06 ⁽⁴⁾

On the basis of the equivalence of the operation of the Schemes operated by the Signatories and hereby declared, each Signatory to this Agreement will:

- vii. operate according to the criteria specified in the relevant European Standards, published in the ISO/IEC 17000 and EN 45000 series of standards, or other internationally recognised normative documents, supplemented by EA application documents, if necessary;**
- viii. commit its evaluators to participate in training and retraining as appropriate.**

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- 5.** An EA member may refer at any time to its signatory status of the MLA. If the member is not a signatory to all MLA schemes, it shall specify to which MLA it is signatory.
- 6.** If, in accordance with the procedures set out in EA documentation, it is agreed that a further Accreditation Body will participate in the Agreement covering the scheme, a new signature sheet shall be signed by the new Accreditation Body and duly authorized by the Chairman of the MLA Council. The new Signatory shall be added to EA-1/08 and the list of MLA signatories available on the EA website. An analogous rule shall apply if it is agreed that a Signatory may extend its Scheme(s).

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EA-1/06 ⁽⁶⁾

- 7.** If a Signatory, for any reason whatsoever, has to withdraw from this Agreement or to reduce the extent of its Scheme(s), the other Signatories shall be notified in writing not later than three months in advance of withdrawing or reducing. Upon withdrawal of a Signatory or reducing the extent of its Scheme(s), EA-1/08 and the list available on the EA website shall be amended accordingly.
- 8.** This Agreement supersedes any previous Multilateral Agreement, which may exist between the Signatories.

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EA-1/06 ⁽⁷⁾

9. Any amendment of the text of this Agreement shall be made in accordance with the rules of procedure established by EA.
10. In the event of an appeal the matter shall be dealt with in accordance with EA-2/01-S3 EA Procedure for the Investigation and Resolution of Complaints & Appeals.
11. It is recognised and accepted by each of the Signatories that this Agreement does not create any rights, liabilities or obligations that would have binding effect in national, international or European Community law.

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Structure of EA MLA ⁽¹⁾

New structure  five tiers

Tier 1: ISO/IEC 17011

Tier 2: accreditation activity (scope) in which the AB has demonstrated competence (like testing; calibration; certification of products, management systems, persons; inspection)

Tier 3: generic standards or normative documents used by the AB to assess the CAB technical competence for each accreditation activity (like ISO/IEC 17025, 17020, 17021, 17024, ISO 15189, EN 45011)

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Structure of EA MLA ⁽²⁾

Tier 4: sector specific standards or normative documents used in combination with one of the generic standards of tier 3 (like ISO/TS 22003, ISO/IEC 27006 or schemes like WADA)

Tier 5: standards or normative documents used by the accredited CAB to deliver an accredited conformity assessment service, like test methods or standards at the laboratories, ISO 9001 or other management systems standards, product specification or standards, national or international schemes or normative documents issued by the regulators.

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Structure of EA MLA ⁽³⁾

New accreditation activities in the MLA

Whenever a new standard or normative document used for accreditation comes to the market, the EA General Assembly will decide whether it should be classified under the MLA and by what mechanism; a new accreditation activity (Tier 2) or a new normative document under one of the endorsed accreditation activities (Tier 3).

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Structure of EA MLA ⁽⁴⁾

New sector specific schemes in the MLA

The criteria and the process for accepting a new sector specific scheme into the list of endorsed EA sector specific schemes (Tier 4) are given in EA-2/11 EA Policy for Sector Schemes.

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Scopes of EA MLA

Accreditation of laboratories	Testing, calibration medical analysis	EN ISO/IEC 17025 ISO 15189
Accreditation of certification bodies	Certification of products	EN 45011 (ISO/IEC Guide 65)
	Certification of management systems	EN ISO/IEC 17021
	Certification of persons	EN ISO/IEC 17024
Accreditation of inspection bodies	Inspection	EN ISO/IEC 17020

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Other activities of the EA member ABs

❖ Accreditation not covered by EA MLA

- ✓ EMAS verifiers - FALB
- ✓ GHG verifiers
- ✓ PT providers
- ✓ RM producers
- ✓ Attestors for public procurement
- ✓ Good Laboratory Practise

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Management of the EA MLA

- ❖ The strength of the EA MLA is maintained through a **robust peer evaluation** process. The purpose of these rigorous on-site evaluations is to verify the Accreditation Body signatories' continuing conformity with the internationally accepted criteria.
- ❖ ABs are evaluated against the international standard ISO/IEC 17011, other related criteria such as application documents from EA, ILAC or IAF and applicable criteria on behalf of European or national regulators and industrial schemes.
- ❖ The MLA process is overseen by the European Commission, the EA Advisory Board and the national authorities.

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EA-2/02

EA Policy and Procedures for the Multilateral Agreement

November 2008 Rev 05

Effective from 18 January 2009

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EA-2/02 ⁽¹⁾

- ❖ The document describes the procedures that EA has adopted for the evaluation and re-evaluation of nationally recognised ABs, the operation of their accreditation systems and their accredited organisations when these ABs are or wish to be signatories to EA Multilateral Agreement or wish to enter into mutual recognition with an EA Multilateral Agreement as an individual AB.
- ❖ The procedure is fully based on the common ILAC/IAF document for the evaluation of single ABs.

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EA-2/02 ⁽²⁾

Criteria ⁽¹⁾

- ❖ **ISO/IEC 17000 series of standards and other ISO/IEC guides**
- ❖ **ILAC, IAF, EA guides mandatory for the EA MLA**

Applicant ABs and signatories shall bring these guidance documents to the attention of the accredited organisations for their use as accreditation criteria supporting the requirements in the accreditation standards.

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EA-2/02 ⁽³⁾

Criteria ⁽²⁾

❖ Supplementary requirements, the AB

- ✓ shall be fully operational;
- ✓ shall have sufficient experience in the assessment of its accredited organisations and have carried out at least one accreditation in each of the certification accreditation programs and inspection program for which it applies, for laboratory accreditation in the testing field at least four accreditations and for laboratory accreditation in the calibration field at least four accreditations;
- ✓ shall implement or fulfil other requirements of EA as described in the documents listed in EA-1/01 in accordance with the document categories described in EA-2/12.

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EA-2/02 ⁽⁴⁾

Criteria ⁽³⁾

❖ Proficiency Testing and other Laboratory Comparisons

- ✓ The AB shall demonstrate that it has an effective policy in place in accordance with ISO/IEC 17011 and ILAC/EA mandatory documents to ensure appropriate participation by its accredited bodies in PT and other laboratory comparison activities. The AB shall ensure that accredited bodies implement appropriate corrective action where necessary.
- ✓ Every applicant AB or Signatory to the MLA in the fields of calibration and testing shall ensure its laboratories participate in regional or national PTs and other laboratory comparisons where available and appropriate. ABs shall ensure that the results of the regional activities are reviewed and appropriate corrective action taken as necessary.

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EA-2/02 ⁽⁵⁾

Criteria ⁽⁴⁾

❖ Subcontracting

The Accreditation Body (AB) can only subcontract assessment activities to ABs having signed the MLA for that particular activity (IAF/ILAC or an MLA from a recognised region).

Types of peer evaluation

❖ Pre-evaluation

❖ Full (initial) evaluation

❖ Re-evaluation

2 years after the initial evaluation, 4 years between the re-evaluations, the duration of a re-evaluation is comparable to that of an initial evaluation.

❖ Extraordinary evaluations

The duration and the tasks of the extraordinary evaluations are basically determined by the EA MAC.

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EA MLA/BLA signatories ⁽¹⁾

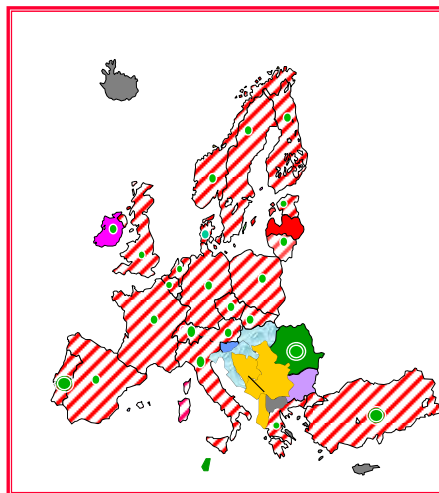
Scopes	MLA	BLA
Testing	28	7
Calibration	26	7
Inspection	27	4
Product certification	27	1
QMS certification	27	-
EMS certification	27	2
Persons certification	24	2

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EA & MLA Members April 2010

-  Calibration ; testing ; products, quality management systems and persons certification ; inspection
-  New signatories for full scope
-  Calibration ; testing ; products, quality management systems and persons certification
-  Calibration ; testing ; products and quality management systems certification; inspection
-  Calibration; testing; products and quality management systems certification
-  Persons and quality management system certification
-  Environmental management systems certification
-  Calibration ; testing
-  Full members non signatories
-  Contracts of Cooperation (European countries)



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EA MLA Signatories April 2010

 Austria	 France	 Malta	 Slovenia
 Belgium	 Germany	 Netherlands	 Spain
 Bulgaria	 Greece	 Norway	 Sweden
 Czech Rep.	 Ireland	 Poland	 Switzerland
 Denmark	 Italy	 Portugal	 Turkey
 Estonia	 Latvia	 Romania	 United Kingdom
 Finland	 Lithuania	 Slovakia	 Hungary
			 Croatia

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EA European co-operation for Accreditation

Signing the EA MLA Zürich, 20 May 2010

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EA BLA Signatories

- ❖ **Australia**
- ❖ **Israel**
- ❖ **New Zealand**
- ❖ **Russia**
- ❖ **South Africa**
- ❖ **Singapore**
- ❖ **Ukraine**
- ❖ **Tunisia**

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ILAC P5:04/2007

ILAC Mutual Recognition Arrangement

2007 Rev 4

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ILAC MRA signatories ⁽¹⁾

- ❖ **Testing**: EA, APLAC, IAAC & 63 ABs
- ❖ **Calibration**: EA, APLAC, IAAC & 55 ABs
- ❖ **Inspection**: in progress

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ILAC MRA signatories ⁽²⁾

- ❖ Argentina
- ❖ Australia
- ❖ Brazil
- ❖ Canada (2)
- ❖ China
- ❖ Costa Rica
- ❖ Cuba
- ❖ Egypt
- ❖ Guatemala
- ❖ Hong Kong
- ❖ India
- ❖ Indonesia
- ❖ Israel
- ❖ Japan (3)
- ❖ Korea
- ❖ Malaysia
- ❖ Mexico
- ❖ New Zealand
- ❖ Pakistan
- ❖ Papua New Guinea
- ❖ Philippines
- ❖ Russian Federation
- ❖ Singapore
- ❖ South Africa
- ❖ Sri Lanka
- ❖ Taiwan
- ❖ Thailand (3)
- ❖ Tunisia
- ❖ United Arab Emirates
- ❖ USA (7)
- ❖ Vietnam
- ❖ **EA MLA**

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IAF-ML-99-001

IAF Multilateral Recognition Agreement

22 January 1998

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IAF MLA signatories ⁽¹⁾

- ❖ QMS certification: EA, PAC, IAAC & 41 ABs
- ❖ EMS certification: EA, PAC & 37 ABs
- ❖ Product certification: EA, PAC & 33 ABs

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IAF MLA signatories (2)

- | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> ❖ Argentina ❖ Australia ❖ Brazil ❖ Canada ❖ China ❖ Egypt ❖ Guatemala ❖ Hong Kong ❖ India ❖ Indonesia ❖ Japan ❖ Korea (2) | <ul style="list-style-type: none"> ❖ Malaysia ❖ Mexico ❖ New Zealand ❖ Philippines ❖ Singapore ❖ South Africa ❖ Taiwan ❖ Thailand ❖ Tunisia ❖ USA (2) ❖ Vietnam ❖ EA MLA |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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International co-operations in the region

	DA	BATA	HAA	KAD	IARM	ATCG	ATS
EA	Associate	Associate	Full	Associate	Full	Associate	Associate
ILAC	Associate	Associate	Associate	Applied for Associate	Associate	Associate	Associate
IAF	AB	-	-	-	-	-	-
EA MLA	Applied for testing	Applied for testing, calibration inspection	Signatory for full scope 28 April 2010	-	Pre-evaluation for testing, inspection, product CB	-	Pre-evaluation for testing, calibration inspection

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Finally

- ❖ The international accreditation network is growing as more economies have set up competent national Accreditation Bodies. Since 2003, the number of new established Accreditation Bodies has grown by 42% globally. In Europe, all Member States and the candidate countries have established a national Accreditation Body.
- ❖ The number of accredited bodies in Europe has increased significantly in the last five years. Today, there are more than 20 500 bodies accredited by EA MLA signatories, compared to 14 000 in 2004, representing growth of 46%. At the international level, there are almost 30 000 laboratories accredited by ILAC MRA signatories, representing the same growth rate since 2004.

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**Thank you for your kind
attention!**

Questions?



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