

Facilitating cross border trade with reliable goods and services



The importance of accreditation of conformity assessment bodies has substantially increased over the last decades. Consumers, businesses, regulators and other organisations all over the world want to be able to trust and have confidence in the goods and services they buy and use.

Consequently, there has been a growth in specified national and international requirements for products, processes and services.

# THE BENEFITS OF ACCREDITATION

#### Facilitates cross border trade

Accreditation is of major importance for the development of Europe's internal market, as this facilitates cross border trade, eliminates barriers to trade and ensure a better regulation between EU Member States

#### Minimises product failure or recalls

Product testing carried out by a reliable independent organisation will minimise products failing, potential recalls and help organizations to save money

#### **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

The importance of accreditation has been further strengthened following the implementation of the Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008, setting out the requirements for accreditation and market surveillance relating to the marketing of products, and repealing Regulation (EEC) No 339/93 (hereinafter Regulation 765/2008) which, for the first time, provides a legal framework for the provision of accreditation services across Europe. This legal framework identifies European co-operation for Accreditation (EA) as an important association and defines its responsibilities and obligations.

EA is an association of national accreditation bodies in Europe, set up in 1997, that are officially recognised by their national Governments to assess and accredit - against international standards - organisations that carry out conformity assessment services.

For 20 years, EA has provided a framework for the mutual recognition of accredited conformity assessment results, to promote development and transfer of knowledge, improve accreditation and conformity assessment activities in Europe and together with the International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC) at a global level.

#### **OUR MISSION**

Ensure confidence in accredited conformity assessments results through harmonized operation of accreditation activities in support of European and global economies.

The role of EA is defined by three dimensions:

- Strategic by developing accreditation to facilitate the market for conformity assessment services in close cooperation with European regulators, stakeholders and other interested parties;
- Operational in cooperating with regulators, stakeholders and other interested parties, including its members the national accreditation bodies in managing accreditation in specific sectors or areas to ensure that the parties have a common understanding and approach to the accreditation criteria in order to arrive at trustworthy attestations of conformity;
- Supportive for its members to all issues regarding accreditation and conformity assessment.

The EA MLA is an agreement signed between national accreditation bodies – Full and Associate Members of EA – to recognise the equivalence, reliability and therefore acceptance by the European market, of certification, verification, inspection and calibration certificates and test reports issued by accredited conformity assessment bodies.

Voluntary and mandatory technical regulations, standards, testing and certification procedures can all serve legitimate public policy goals but they can also vary from country to country, or can be costly and burdensome in their effect. As a result they can be detrimental to businesses, hindering access to markets and export opportunities. Acknowledging this, the World Trade Organisation (WTO) Agreement on Technical Barriers to Trade strongly encourages countries to recognise the results of other countries' conformity assessments.

This EA MLA is providing the European market with a network of conformity assessment bodies that are competent within their scope of accreditation to issue reliable and credible statements of conformity for products and services, thereby reducing costs and adding value to business and consumers. This contributes to the freedom of trade by eliminating technical barriers.

For National Accreditation Bodies (NABs) located outside the EU or EFTA, signing a bilateral agreement with EA under the conditions applicable to EA MLA signatories gives access to the European market to products tested by conformity assessment bodies accredited by AB Associate members of EA. It enables recognition of test, certification and inspection results on the European market thus facilitating export and trade between Europe and non-European countries.

Accreditation of Activity	Standards
Laboratories Testing and Medical examinations	EN ISO/IEC 17025 EN ISO 15189
Laboratories Calibration	EN ISO/IEC 17025
Certification Bodies Products certification	EN ISO/IEC 17065
Certification Bodies Certification of persons	EN ISO/IEC 17024
Certification Bodies Management systems certification	EN ISO/IEC 17021
Inspection Inspection	EN ISO/IEC 17020
Validation and verification Validation and verification	EN ISO 14065
Proficiency Testing Providers Proficiency Testing Providers	EN ISO/IEC 17043

# 2017 EA MLA KEY FIGURES

members signatories to the MLA
(34 Full Members and 7 Associate Members through a bilateral agreement with EA out of a total of 36 Full Members and 14 Associate Members)

**146** evaluators authorised to perform peer evaluations on behalf of EA

18 peer evaluations (PE) performed for a total of 1,080 man-days provided by EA NABs

56 MAC Members appointed in the Task Force Groups for the review of PE reports,

9 MAC Management Group members in addition to the MAC Chair and Vice Chair

More than 35,150 accreditations delivered by EA MLA signatories

According to article 14 of Regulation (EC) No 765/2008 'Setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) 339/93', EA has been recognized by the European Commission to operate the peer evaluation system of national accreditation bodies.

# **EA MLA PROCESS**

# 1- APPLICATION

The National Accreditation Bodies applies for MLA signatory status for specific scopes. The MLA Council Secretariat reviews the application and appoints an evaluation team.

# 2- PEER EVALUATION

The team performs the document review (quality management system documents, procedures of the national accreditation body etc.) and a pre-evaluation is conducted where applicable. Then, the team carries out the on-site evaluation. The evaluation combines evaluation of the management system at the office with observation of assessments carried out by the NAB.

# **3- REPORT & DECISION**

The team drafts the evaluation report. Findings are approved with the NAB at the closing meeting. Atask force group (TFG) appointed by the EAMLACouncil management group looks at the evaluation report to issue a recommendation for consideration by EA MLA Council. The EA MAC takes a decision and the EA publications and website are updated accordingly.

The peer evaluation (PE) process is currently being further strengthened to accommodate the specific needs of regulatory fields to raise the reassurance of sector based stakeholders and regulators that the accreditation bodies' technical competence is thoroughly assessed.

The purpose of on-site evaluations is to verify the accreditation body signatories' continuing compliance with the internationally agreed criteria for accreditation bodies. The EA MLA provides a framework to realise the objective 'Accredited once, accepted everywhere'.

EA and its member accreditation bodies invest significant efforts and resources to maintain the integrity and robustness of the EA MLA through a rigorous PE process.

#### A new IT to digitize the peer evaluation system

The development of the specific IT tool for an improved management of peer evaluations and peer evaluators has been progressing according to the plan in 2017.

The aim of the new tool is to manage peer evaluations and evaluators in a more efficient way.

After tests had been carried out by MAC Members, Team Leaders, Deputy Team Leaders and Team Members, the tool was demonstrated at the two refresher training sessions held in December 2017.

The brand-new IT tool should be launched in 2018 to be used by all the persons involved in the peer-evaluation system, i.e. the MAC Secretariat, the MAC Management Group Members, Team Members, Team Leaders and Deputy Team Leaders, NABs under evaluation, trainers, all with dedicated access rights. The new tool will offer functionalities that will lead to stop using a certain number of forms and templates, while giving users dedicated access to peer-evaluation records and documents in a more friendly and convenient way. Data on peer evaluations will also be stored to facilitate sharing and consultation by those involved in the process.



# A long term project for the re-engineering of the peer evaluation system

The project will involve all EA members and stakeholders and develop based on 3 major objectives:

- Re-think the PE model and methods for instance by implementing a new sampling approach for the proper coverage of the NAB range of activities
- 2. Re-think the decision-making process to enhance transparence, smoothness and consistency of decisions
- Streamline the reporting process to ensure harmonization and consistency for a better decisionmaking

#### Training and knowledge-sharing

In order to support the necessary development of the EA pool of evaluators to serve an increasingly busy PE program, EA organises regularly newcomer trainings. These workshops intend to give the participants the specifics of a peer evaluation and a common level of understanding of the procedures, requirements and their application. It aims also to provide the potential team members with insight in the management processes supporting the peer evaluation system. The objective is to qualify as many participants as possible as trainees or team members directly, to be assigned quickly and be able to confirm their qualification thus reinforcing the EA resources.

NAB assessors are trained during 3 days through presentations and discussions in work groups about how an EA evaluator should assess the effective implementation of the requirements (review of documents or records, interviews, observation/witness, etc.), looking for evidence and identifying specific risks and causes of non-compliance. Case studies and role play exercises are used extensively.

At the end of the workshop, the trainers review the performance of each participant and come up with a recommendation about qualification as an EA evaluator, based on:

- Demonstration by the participants of their understanding and awareness of the evaluation process and the evaluation requirements.
- Demonstrated ability to work as evaluator (open minded, team worker, communication skills, in particular, communication in English).
- Demonstration of dedication to the work as evaluator.

Qualification and performance are then continuously monitored by EA in close cooperation with the EA accreditation body members.



Newcomer training, hosted by RvA, the Dutch NAB, in June 2017 in Utrecht, Netherlands.

The well-established, harmonised and transparent assessment procedures involved in the accreditation processes carried out by EA MLA signatories are applicable to all forms of conformity assessment and deliver benefits across the full range of economic activities.

#### National governments and regulators

- Accreditation can be used to support implementation of European or national legislation. It provides a 'stamp of approval' to demonstrate compliance against agreed standards and requirements.
- Accreditation minimizes risk as decisions can be based on reliable certificates or reports and there can be greater confidence in the data being used to establish baselines for monitoring and enforcement.
- The EA MLA provides a framework that allows Governments to rely on data from accredited organizations in other countries

#### Consumers

 Accreditation can impact positively on all aspects of our daily life from the safety of the products we buy to the quality of the environment we live in. The accreditation of testing, inspection and certification ensures that these activities are carried out by competent organisations. The influence of accreditation may not always be recognised or understood by the consumer but it plays an important role in ensuring that he or she has access to goods and services of consistent and reliable quality and safety



#### Industry and the business community

- Exporting and access to new markets is made easier and less expensive because having once been tested or certified by an EA MLA-accredited body, there should be no need to re-test or re-certify a product for foreign markets.
- Importing goods and services with an EA MLAaccredited report or certificate can be both less risky and cheaper because accreditation confirms conformity to recognised standards of consistency and quality and can therefore also avoid the costs of re-testing.
- Being recognised internationally, the EA MLA opens new opportunities on the global market.
- Buying conformity assessment services from an organisation accredited by an EA MLA signatory can also help businesses differentiate their services by providing evidence of technical competence, impartiality and compliance with international requirements within their supply chain.

#### **The European Commission**

- The importance of accreditation to the EU's and EFTA's economic infrastructure is recognised in Regulation (EC) No 765/2008 which provides a legal framework for the provision of accreditation services across Europe
- Regulation (EC) No 765/2008 covers the operation
  of accreditation in support of voluntary conformity
  assessment as well as conformity assessment required
  by European legislation. It provides Commission
  Directorates with the legal basis to ensure confidence
  in the consistent and harmonised implementation of
  legislation across Europe based on accreditation.
- The existence of the EA MLA means that national authorities in Member States can recognise - in accordance with article 11 (2) of Regulation (EC) No 765/2008—the equivalence of accreditation services provided by peer evaluated national accreditation bodies and therefore the equivalence of reports and certificates issued by the conformity assessment bodies they have accredited. This supports a harmonised implementation of Community legislation.

Acceptance in the marketplace of the EA MLA - and therefore of the conformity assessment results provided by conformity assessment bodies accredited by EA MLA signatories - is of major importance for the development of industry and business opportunities by removing the need to re-test or certify a product in each and every country.

# AN EXAMPLE OF BENEFIT OF THE EA MLA

# How an EU manufacturer can sell hot-water boilers in Canada

#### 1/ Recognized Accreditation Bodies

To allow EU manufacturers to sell their products on the Canadian market, EU Recognized Accreditation Bodies will accredit EU Conformity Assessment Bodies (CABs). That means that they will assess and confirm the technical competence of CABs offering, for example, testing services in compliance with the Canadian legislation, in the fields mentioned listed in the Conformity Assessment Protocol.

### 2/ Conformity Assessment Bodies

Then, the EU Conformity Assessment Bodies will deliver conformity assessment services to confirm that products –hot water boilers in our example- comply with the Canadian requirements (legislation, standard and other relevant specifications).

#### 3/ Canadian government

The Canadian government will authorize the EU manufacturer due to the certificate issued by the Conformity Assessment Body to export its hot-water boilers on the Canadian market and apply the relevant marking.

#### 4/ EU manufacturer

Once the hot-water boilers have been marked, the manufacturer will be able to sell them on the Canadian market and benefit from a competitive advantage in terms of reputation and credibility for future consumers.

#### 5/ Consumers

The Canadian consumers will buy, in full confidence, the hot-water boiler, produced by the EU manufacturer.

#### What does this mean at the end?

Thanks to the EA MLA, whatever the technical field and the market, industry can save time and money by making the informed choice to procure conformity assessment services from an organisation accredited by an EA MLA signatory.

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.

# WHY THE EA MLA INSPIRES MARKET CONFIDENCE?

NABs are admitted to the MLA only after meticulous peer evaluation of their operations to check their compliance with the internationally agreed standard for accreditation bodies. These evaluations are repeated at least every 4 years.

Evaluations are carried out by experienced senior staff from other NABs and the process is observed by personnel from the European Commission, national authorities, and representatives of the EA Advisory Board consisting of stakeholders and other interested parties in the business and regulatory community.

Evaluations include office-based scrutiny as well as the observation of assessor visits in order to determine that, before being accredited, conformity assessment bodies are examined in sufficient depth to establish their competence, impartiality, performance capability and their sustainability.

To ensure consistency, transparency and acceptability to all, the peer-evaluation process is itself continuously updated to take into account the changing needs of business, regulators and national authorities.

EA regularly reviews market feedback through complaints and benchmarking processes from organisations represented on the EA Advisory Board, including the European Commission, and from other stakeholders and interested parties.

The EA MLA is recognized at international level by IAF (International Accreditation Forum) and ILAC (International Laboratory Accreditation Cooperation). This means that a test report or certificate accredited by an EA MLA signatory is also recognized by the signatories to the IAF and ILAC multilateral agreements. IAF and ILAC have developed MLA marks which can be used by their member accreditation bodies and their conformity assessment bodies under specific conditions set out in a license agreement.

Thanks to this recognition, international markets have confidence in the EA MLA and the conformity assessment results provided by organisations accredited by EA MLA signatories. Because of this, there is no need for products and services to be re-tested, re-calibrated, re-inspected or re-certified in each country into which they are imported and sold. This helps the free movement of goods and services in Europe and the rest of the world.

EA and its members are working actively in both associations with the purpose of ensuring that the European accreditation system is recognized at the global level and that the development of the international accreditation system as far as possible is in line with the accreditation policy adopted and implemented in Europe.

Moreover, as a Recognized Regional Accreditation Group, EA is peer evaluated every four years to confirm that its membership and MLA peer evaluation criteria and processes meet IAF and ILAC requirements. As a result of the peer review of EA, IAF and ILAC renewed their confidence in EA and its members in October 2016 by deciding to maintain EA in their MLA/MRA respectively for testing, medical testing, calibration, inspection, management systems, products certification, and certification of persons.

To get more information about EA MLA <a href="https://www.european-accreditation.org">www.european-accreditation.org</a> - <a href="mailto:secretariat@european-accreditation.org">secretariat@european-accreditation.org</a>







