

**THE ROLE OF ACCREDITATION AND OF THE  
EUROPEAN ACCREDITATION INFRASTRUCTURE  
VIS-À-VIS THE NEW EUROPEAN LEGISLATIVE FRAMEWORK  
ON ACCREDITATION AND MARKET SURVEILLANCE AND ON  
A COMMON FRAMEWORK FOR THE MARKETING OF  
PRODUCTS**

**Lorenzo Thione**  
Chairman

EA – European co-operation for Accreditation

## **Accreditation**

- Accreditation – as independent and authoritative attestation of the competence, impartiality and integrity of conformity assessment bodies (CABs) and bodies performing related activities and thus of the value and credibility of the corresponding attestations of conformity (calibration certificates, test reports, inspection reports, certifications of management systems, products and personnel, other attestations) – has, in the last two decades, definitely affirmed its major role and attained remarkable achievements.

## **Accreditation**

- The unique value of accreditation has been spontaneously acknowledged by the economies and societies of the European countries (as well of the majority of countries in the world) and accreditation, performed by authoritative and recognized Accreditation Bodies (ABs), has been successfully applied as the last level of control of the quality of the conformity assessment services delivered in both voluntary (market driven) and mandatory (law regulated spheres).
- Confidence provided by accreditation has been recognized and valued as equally needed for both purposes of supporting the economic progress and protecting public general interests and any improvement in accreditation, both in Europe and worldwide, shall be brought to the advantage of both voluntary and regulated sectors.

## **Accreditation**

- Accreditation rules and procedures are harmonized at international level (both regionally and worldwide) to underpin free global trade of products and services conforming to customer's requirements and to legal requirements regarding health and safety and protection of public interests in general.
- Harmonization is achieved with reference to normative documents commonly accepted and recognized (for ABs, for CABs and for the "objects" of conformity assessment) and by means of proper control of the functioning of the Accreditation Bodies and related conformity assessment chains exerted by supra-national (regional and international) organizations.

## Accreditation

- The supra-national cooperation entities – exerting the above mentioned control and granting uniform and effective operation of accreditation and related conformity assessment activities – include:

At regional level (just to mention the main ones):

- **EA “European co-operation for Accreditation”**;
- APLAC “Asia Pacific Laboratory Accreditation Co-operation”
- PAC “Pacific Accreditation Co-operation”
- IAAC “Inter American Accreditation Co-operation”
- SADCA “South African Development Community Accreditation”

At worldwide level:

- ILAC “International Laboratory Accreditation Co-operation”
- IAF “International Accreditation Forum”

## The Multilateral Agreements

- Assuring the effective and uniform operation of accreditation and related conformity assessment activities is achieved by means of “peer evaluations” managed by the above cited supra-national organizations, leading to the establishment of Multilateral Recognition Agreements (or Arrangements) (MLA or MRA).
- Such Agreements ensure that the signatories ABs operate an accreditation system complying with the requirements of the applicable normative and guidance documents and such to grant that the attestations of conformity, issued under the respective accreditation, are equally reliable (or, in some cases, truly equivalent) and can be trusted by the direct and indirect users of them (the “marketplace” in its broadest meaning).
- The Multilateral Agreements at worldwide level (ILAC and IAF) are essentially based on the agreements managed by the regional organizations who are, in turn, signatories to the ILAC and or IAF agreements.

## **The European accreditation**

### **EA – European co-operation for Accreditation**

- EA was operationally formed in 1997, following the gradual merge of pre-existing European accreditation co-operations dating back to 1976 and was established as legal entity in 2000
- EA is the Association of the national European Accreditation Bodies (and systems) providing accreditation of all conformity assessment activities and related activities, such a calibration, testing, inspection, system/product/personnel certification, EMAS declarations and others, being performed in both voluntary and regulated spheres.
- The EA organizational structure consists of an Advisory Board (gathering all stakeholders such as conformity assessment bodies, industry, regulators, consumers), a General Assembly, an Executive Committee, 5 Technical Committees (among which the EA MAC Committee ruling the EA MLA) and of a permanent Secretariat with 3 full time staff.

## **The European Accreditation**

### **EA – European co-operation for accreditation**

- EA has, at present, 34 full members, these being Accreditation Bodies (or systems) of countries members of EU and EFTA or candidate to join the European Union. Among these, there are 26 signatories to the EA MLA out which 19 have signed for all accreditation activities currently covered by the MLA.
- EA has entered into 18 contracts of cooperation with Accreditation Bodies of European Countries not yet fulfilling the requirements for full membership and of non European countries.
- 9 of those partnerships have developed into Bilateral Agreements that convey the same benefits, in terms of mutual recognition, as the EA MLA.

## **The European accreditation EA – European co-operation for accreditation**

- The main purpose of EA is to provide Europe with an effective and reliable accreditation infrastructure serving at best the needs of the economy and society. This mission is accomplished, chiefly, by:
  - developing accreditation criteria and guidelines favouring the effective and harmonized operation of national accreditation bodies;
  - operating a peer evaluation system, based on sound and transparent criteria and procedures;
  - managing the related Multilateral Agreement (MLA) and Bilateral Agreements (BLAs), ensuring that the signatory status to the Agreements is an effective attestation of the validity and equivalence of the operation of the signatories and of the reliability of the conformity assessment chains referring to them.
  - cooperating with European and international stakeholders and performing all other activities required for the proper accomplishment of its purposes.

## **The EA Multilateral Agreement and peer review system**

- At the level of single national economies and societies, accreditation creates confidence in the accredited conformity assessment services and in the corresponding results.
- At the European level, the EA MLA confirms and enhances such confidence and eliminates (or limits):
  - “multiple accreditation”: CABs accredited by signatories to the EA MLA may operate in different European countries based on one single accreditation;
  - “multiple assessments”: organizations owning EA MLA accredited attestations of conformity do not need to have their systems or products or services re-evaluated in each country where such products and services are marketed (as well as persons certified under EA MLA accreditation do not need to be re-qualified in each country where they perform their activities).

## The EA Multilateral Agreement and peer review system

- To ensure the effectiveness of the EA MLA – as an objective and credible attestation of the “competence” at large of the signatories ABs – each signatory is subject to rigorous evaluations (first evaluation and surveillance) by a peer assessment process, in order to verify continuous conformity to provisions of the international standards and guides and to ad-hoc EA application documents.
- The management of the EA MLA is ruled by well defined policies and procedures defining the basic criteria for achieving and maintaining the signatory status and ruling the different phases of the evaluation process: application, review and acceptance of the application, formation of the evaluation team, document review, pre-evaluation stage (if applicable), on site evaluation, evaluation report, interactive study of the evaluation report by an ad-hoc task force group, decision by the EA MAC Committee, and eventual appeal.

## The European Accreditation Model

- Within the above context, EA endeavours to promote the proper recognition of the role of accreditation and the adequate exploitation of its function, as a **service of general interest**, with definite characteristics of public authority, representing the last authoritative level of control of the conformity assessment services delivered in both voluntary and mandatory spheres.
- As such, accreditation must be performed on suitable mandate of the Government, in full compliance with the applicable technical requirements, in conditions of independence and impartiality, with accountability towards all the interested parties, with no single interest or group of interests predominating, as non-profit-distributing service activity, without competition at national level and with strict limitations to competition at the international level (principle of subsidiarity).

## **The development of European Accreditation Generals**

- Improving its capability of properly performing its function of ensuring the added value of accreditation and its effective use throughout Europe is a permanent target of EA.
- To this purpose, accreditation is to be ever more focused on the quality of the final outputs of the conformity assessment chains referring to it (e.g. value and credibility of accredited management system certifications) and the uniformity and effectiveness of the operation of the member Accreditation Bodies members of EA are to be continuously improved.
- Within this development strategy, consideration is also being given to how can accreditation fulfil at best the needs of the modern economy and society, either expanding into new spheres of application (particularly where protection of fundamental public rights is involved) or staying and consolidating within the traditional fields.

## **The development of European Accreditation The new legislative framework**

- The new European legislation on accreditation and market surveillance and on a common framework for the marketing of products – establishing a legal base for accreditation, strengthening its use in the mandatory area and providing for the recognition of EA as the official European Accreditation Infrastructure – is going to introduce a further impellent push to the continuous EA's improvement process.
- The use of EA MLA accreditation as a basis for notification will provide effective and harmonized criteria for the initial qualification of CABs and for the continuous surveillance of the maintenance of their conformity to the applicable requirements, provided accreditation delivers the necessary added value. This represents a major challenge for EA.

## **The development of European Accreditation The recognition of EA**

- The new European legislation will confer to EA the role of official **European Accreditation Infrastructure** having the task to ensure that the accreditation activities are performed, in the Member States, in full compliance with the provisions of the said legislation (fully in line with the principles of the above cited “European accreditation model”), being such to:
  - represent a solid base for granting the validity of the conformity assessment services in both voluntary and regulated spheres;
  - provide a uniform, reliable and robust criterion for the recognition of CABs attesting conformity to the requirements of the European Directives and Regulations (Notified Bodies and similar);
  - support, in general, the function of National Public Authorities.

## **The development of European Accreditation The recognition of EA**

- As official European Accreditation Infrastructure, EA will be considered as a Body pursuing an aim of general European interest, pursuant to the applicable European legislation.
- It is expected this role be legally recognized and empowered through a Framework Partnership Agreement to be stipulated between EA and the European Commission (and EFTA), within the meaning of Article 163 of European Regulation N. 2342/2002.

## **The development of European accreditation The development strategy and actions**

- To strengthen the EA capability of properly performing its function of ensuring the added value of accreditation and its effective use throughout Europe – with particular although not exclusive reference to the new forthcoming role – various improvement actions are needed.
- These are being considered in the frame of an EA Development Plan under preparation and include:
  - strengthening the corporate infrastructure and the organization of the Association, in order for EA to be able to take informed decisions in all respects and circumstances and ensure their prompt and effective implementation;
  - get specifically prepared for the assumption of the new role in the mandatory area by developing and sharing among the members the necessary knowledge and expertise;
  - improving the effectiveness, consistency and transparency of the peer evaluation process, including measures to provide direct confidence to National Regulators and enable proper oversight of the system;

## **The development of European accreditation The development strategy and actions**

- Development actions (cont.)
  - improving the operation of the technical structure of EA (Committees and WGS);
  - enhancing the educational role of EA and its services to the members;
  - strengthening the relations with the European stakeholders, enhancing in particular the cooperation with CABs and National Regulators operating in the mandatory area;
  - reinforcing the international relations by: promoting cooperation with countries falling within the EU Neighbourhood Policy; strengthening the partnership with other regional accreditation co-operations and enhancing the EA's influence within ILAC and IAF;
  - making available the financial resources needed for running EA in an appropriate professional and effective way, as required to achieve and consolidate the improvement targets, including finding an appropriate balance between the various sources of financing of the EA activities (voluntary performances of members, membership fees, possible financial contribution from the EC).

## Conclusions

- A strong, effective and trustable third party conformity assessment infrastructure is needed to support the progress of the European economy and the growth of the prosperity of the European society.
- Many actors are involved in the development, consolidation and optimal exploitation of such infrastructure: the European legislator, the European Standardization Bodies, the European accreditation community, the conformity assessment bodies, the National Regulators and Authorities, the economical operators using accredited conformity assessment services to assess and ensure the quality of their products, the final users and consumers relying upon such assurances and all other stakeholders. These actors must be capable to properly manage the outstanding challenges they are called to face.
- The key for winning such defiance lays in the commitment of all such parties to work together, united in the pursuance of the common objectives. We know it is not easy but let's try to do our best. Be sure that EA will make its part.