



**European  
co-operation for  
Accreditation**

**Third International Workshop on Conformity Assessment**

Rio de Janeiro (Brazil), 10-11 December 2007

**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 in favouring the elimination of technical barriers to trade and contributing to the protection of the fundamental rights of people.

# Accreditation

- Confidence provided by accreditation has been recognized and valued as equally needed for both purposes of protecting public general interests and supporting the economic progress and accreditation is having and will have, in Europe and elsewhere, an increasing impact on economical and social policies and related implementation.
- Any improvement in accreditation, both in Europe and worldwide, shall be brought to the advantage of both regulated and voluntary sectors.

# Accreditation

- Accreditation rules and procedures are harmonized at world wide level.
- Harmonization is achieved making reference to normative documents commonly accepted world wide – for accreditation bodies (ABs), for conformity assessment bodies (CABs) and for the objects of the conformity assessment (products, processes, systems, personnel) – and by proper control of the functioning of the accreditation bodies and related conformity assessment chains exerted by supra-national (regional/international) accreditation co-operation entities.

# Supra-national cooperation entities among ABs

- Supra-national cooperation entities 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 world wide level:

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

# The Multilateral Agreements

- Assuring that ABs are properly following the applicable rules and duly enforcing their observance by the accredited CABs is performed by means of “peer evaluations” managed by the above cited supra-national co-operations, leading to the establishment of Multilateral Recognition Agreements or Arrangements (MLA or MRA).
- These Agreements ensure that the signatories ABs operate accreditation systems that are equivalent, in terms of adequacy and effectiveness, and such to grant that the attestations of conformity, issued under the respective accreditation, are equally reliable and can be trusted by the direct and indirect users of them (the “marketplace” in its broader meaning).

# The Multilateral Agreements

- The Multilateral Agreements at world wide level (ILAC and IAF) are essentially based on the agreements managed by the regional organizations (so that ABs members of regional co-operations are, in turn, signatories to the ILAC and IAF agreements).
- The proper operation of the regional agreements is thus a must for the effectiveness and credibility of the world wide accreditation system and major efforts shall be placed on the improvement of the regional peer evaluation systems, concentrating the international agreements on their fundamental role of monitoring the functioning of the regional ones .

# **The European accreditation**

## **EA – European cooperation for accreditation**

- EA is the Association of the national European accreditation bodies providing accreditation of all conformity assessment activities in both voluntary and regulated spheres.
- EA was operationally formed in 1997, following the progressive merge of pre-existing European accreditation co-operations dating back to 1976 and was established as a legal entity in 2000.
- The organizational structure of EA consists of an Advisory Board (gathering all stakeholders categories), a General Assembly, an Executive Committee, 5 Technical Committees (among which the MAC Committee ruling the EA MLA) and of a permanent Secretariat.

# **The European accreditation**

## **EA – European cooperation for accreditation**

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

# The European accreditation

## The “EA accreditation model”

- 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, based on the vision of accreditation as “public authority activity” representing the last level of control of the conformity assessment services in both voluntary and mandatory areas.
- As such, EA accreditation must be performed on suitable mandate of the Governments, in compliance with the applicable technical requirements, in conditions of independence and impartiality, with accountability towards all the interested parties, as a non-profit-oriented activity, without competition at national level and with strict limitations to competition at the international level (“cross frontier” accreditation activity being essentially based on the principles of cooperation and subsidiarity, according to the policy recently established by EA).

# The European Accreditation

## The “EA accreditation model”

- EA accreditation is aiming at being, as much as possible, “output focussed”, namely at assuring the quality of the final output of the conformity assessment chain, i.e. the value and credibility of the results which are delivered to the “marketplace”.
- For example, accreditation shall ensure that organizations owning quality management systems certifications issued by accredited CABs are really able to deliver, consistently, products and services complying with the applicable requirements and that products certified by such CABs do really constantly meet the pertinent constructional and performance requisites.
- This “output focussed” accreditation approach – that has always inspired the EA’s policies and practices, as an essential part of the European accreditation model – is being continuously improved.

# The European accreditation

## The performance of the EA mission

- The EA mission is accomplished chiefly by:
  - developing accreditation criteria and guidelines favouring the effective and harmonized operation of national ABs;
  - operating a peer evaluation system of member ABs founded on solid and transparent criteria and procedures and managing the related Multilateral Agreement (MLA) and Bilateral Agreements (BLAs);
  - cooperating with the European Commission with which EA has signed a Memorandum of Understanding;
  - cooperating with the European CABs community, National Regulators and industry, and with all other European and international stakeholders;
  - performing all other activities (educational, communication, etc.) required for the effective pursuance of its purposes.

# The European accreditation

## The role of the EA MLA and BLAs

- The EA MLA (and BLAs) in particular:
  - At national level, confirm and enhance the confidence in the accredited conformity assessment services and in the corresponding results by the economies and societies of the countries whose ABs are signatories to the agreements.
  - At supra-national level, eliminate (or limit) the needs for:
    - \* “multiple accreditation”; CABs accredited by signatory ABs may operate in all respective countries based on one accreditation;
    - \* “multiple assessments”; organizations (and individuals) owning attestations of conformity issued under the accreditation of signatory ABs do not need to have their systems, products or services re-evaluated in each country where such products and services are marketed (or their competence re-qualified in each country where they perform their professional activity).

# The European accreditation

## The role of the EA MLA and BLAs

- The EA MLA and BLAs are thus the basis for:
  - reinforcing the credibility of accreditation vis-à-vis the interested parties, by ensuring the proper operation of signatories ABs subject to rigorous evaluations;
  - facilitating the free circulation of products and services, by ensuring the equal trustworthiness of the attestations of conformity issued in any country and under any of the signatory's accreditations, regarding the ability of such products and services of fulfilling the applicable requirements, either defined by voluntary norms and specifications or established by mandatory regulations.
- \* The new European legislative framework on accreditation is essentially founded on the above values and principles.

# **The European Accreditation**

## **The management of EA MLA and BLAs**

- To ensure the effectiveness of the EA MLA (and BLAs) – as an objective and credible attestation of the competency of the signatory ABs and of the reliability of the attestations of conformity issued under the respective accreditation – each signatory is subject to rigorous peer evaluation (first evaluation and surveillance) by a robust peer assessment process, in order to verify continuous conformity to the provisions of the international standards and guides and to ad-hoc EA application documents.

# **The European accreditation**

## **The management of the EA MLA and BLAs**

- The management of the EA MLA (and BLAs) is ruled by well defined policies and procedures establishing the 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 above ensures the necessary rigour and transparency of the process.

# The development of European Accreditation

## The main strengths of EA

Main strengths, on which the EA's development could be solidly founded, are:

- EA is internationally renowned (*Prestige*).
- EA has a peer evaluation system of tried experience and efficacy (*Credibility*).
- Members of EA have a broad and deep technical competence (*Know-how*).
- EA is working based on cooperative principles (*Democracy*).
- EA is trusted by the European Commission (*Recognition*).

# 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 chain and the uniformity and effectiveness of the operation of the ABs members of EA are to be continuously improved.
- Within this development strategy, consideration is also being given to how accreditation can fulfil at best the needs of the modern economy and society, either expanding into new spheres of application (particularly when protection of fundamental public rights is involved) or staying and consolidating within the traditional boundaries.

# 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 – although being engrafted on an accreditation structure already substantially complying with the related requirements, does introduce, indeed, a further thrust to the continuous EA's improvement process.

# **The development of European Accreditation**

## **The new legislative framework**

- 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 surveillance of the maintenance of their conformity to the applicable requirements.
- To this purpose, accreditation must be able to ascertain and confirm in depth that CABs have the specialist knowledge and expertise required to operate in the different technical sectors and that such know-how is properly and consistently applied to the assessments.
- This represents, on the one hand, a major challenge for EA, and, on the other hand, a unique opportunity that EA is not going to miss.

# The development of European accreditation

## The EA development strategy and actions

- EA is going to build on its strengths by a number of improvement actions being implemented in the frame of an EA Development Plan. These include:
  - reinforcing the corporate infrastructure and strengthening the organization, in order for EA to be able to timely and appropriately respond to the needs of the European economy and society, taking informed decisions in all respects and circumstances and ensuring their prompt and effective implementation;
  - ensuring the continuous improvement of the accreditation rules and practices and getting specifically prepared for the assumption of the new role in the mandatory area by developing and sharing among the members the necessary specialist knowledge and expertise, in strict cooperation with National Regulators and the CAB community (to this purpose an ad-hoc EA Development Project has been set up);

# The development of European Accreditation

## The EA development strategy and actions

- Development actions (cont.)
  - improving the effectiveness, consistency and transparency of the peer evaluation process, by enhancing its depth and continuity, including measures to provide confidence to National Regulators, by enabling them to participate in the operation and monitoring of the system;
  - fostering, in general the strengthening of the relations between national accreditation bodies and National Authorities, raising their awareness of accreditation and confidence in its value;
  - establishing a solid partnership with the European Commission (and EFTA), being fully responsive to them;

# The development of European accreditation

## The EA development strategy and actions

- Development actions (cont.)
  - strengthening the cooperation with the European conformity assessment community, enabling their effective contribution to the progress of the European accreditation and consolidating collaboration with and granting full answerability to all European stakeholders;
  - promoting cooperation with countries falling within the EU Neighbourhood Policy and countries in general connected to the EU through association and trade agreements, by providing, where needed, assistance to the development of the respective conformity assessment infrastructures, and establishing suitable relations with the respective accreditation bodies (to which appropriate EA membership status could be granted);

# The development of European accreditation

## The EA development strategy and actions

- Development actions (cont.)
  - Reinforcing the collaboration with other regional accreditation co-operations and enhancing the EA's influence within ILAC and IAF, promoting the strengthening of the relations between the two organizations and their possible unification into a single worldwide accreditation cooperation, in order to overcome the existing overlapping and duplications, value complementarities and exploit the related technical and political synergies;
  - organizing the financial resources needed for running EA in an appropriate professional way, as required to achieve and consolidate the above objectives.

# Concluding remarks

## The cooperation in Europe

- A robust and trustworthy 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.
- EA is committed to contribute to the development, consolidation and optimal exploitation of such infrastructure in strict cooperation with all other European actors involved, such as: the European legislator, the European Standardization Bodies, the conformity assessment bodies, the National Regulators, 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 interested parties.

## **Concluding remarks**

### **The cooperation with non European countries**

- Europe is not isolated in the world and, owing to increasing globalization, the prosperity of its economy and the well being of its citizens depend ever more on the relations with countries pertaining to other economical, political and cultural areas of the world, particularly if geographically, economically and culturally close to the Union.
- Quality of products and services exchanged between the Union and “third countries” is at the basis of successful and mutually rewarding relationships and this can be ensured thanks to the existence, in such countries, of adequate and trustworthy third party conformity assessment infrastructures operating under the aegis of competent and authoritative accreditation bodies.

# Closure

- EA is committed to contribute to the development of adequate conformity assessment infrastructures in non European countries and is willing to establish, with the respective Accreditation Bodies, suitable forms of cooperation and recognition – duly based on the “European accreditation model” reflecting, in turn, the provisions of the new European legislative framework, on which mutual confidence can be solidly founded and optimally exploited, for the benefit of the respective economies and societies.

**THANK YOU FOR YOUR ATTENTION**