European co-operation for Accreditation

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THE ROLE OF ACCREDITATION AND OF THE EUROPEAN ACCREDITATION INFRASTRUCTURE FOR THE PROGRESS OF THE EUROPEAN ECONOMY AND SOCIETY

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1. THE ACHIEVEMENTS OF ACCREDITATION

Accreditation – as independent and authoritative attestation of the competence, impartiality and integrity of conformity assessment bodies (CABs) 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) – has a long history.

It does, in fact, date back to the 70', as regarding the assessment of the technical competence of calibration laboratories providing metrological support to the industrial production and to the 80', as concerning the qualification of the main conformity assessment operators such as testing laboratories, certification bodies and inspection bodies.

In such history, accreditation has attained remarkable achievements. Its value has been spontaneously acknowledged by the economies and societies of the European countries (as well of many other major countries in the world) within which – in different forms and with different origins, but with substantial identity of roles and homogeneity of operation – the various national Accreditation Bodies (ABs), or systems, were established.

In Europe, in particular, the development of the accreditation practices has been promoted by the creation of the single European market, and, within this, by the development of the "third party quality approach", where all operations of quality assurance are carried out by specialized operators independent of the producers (first party) and users (second party) of the "object" of the assurance.

The success of this approach has been favoured, in turn, by the progress of standardization (with the issuance of normative references commonly acknowledged and accepted by the interested parties and no longer "owned" by the first or second parties) and by other factors, such as the increasing necessity of specialization and the tendency towards the outsourcing of the quality assurance activities.

Accreditation rules and procedures are, nowadays, harmonized at worldwide level 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 making reference to standards commonly accepted worldwide (for ABs, for CABs and for the "object" 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) cooperation entities.

Example of such entities are, at regional level:

- EA "European Cooperation for Accreditation";
- APLAC "Asia Pacific Laboratory Accreditation Cooperation";
- PAC "Pacific Accreditation Cooperation";
- IACC "Inter American Accreditation Co-operation";
- SADCA "South African Development Community Accreditation",

and, at worldwide level:

- ILAC "International Laboratory Accreditation Cooperation";
- IAF "International Accreditation Forum".

2. EA – EUROPEAN COOPERATION FOR ACCREDITATION

EA is the supra-national cooperation entity exerting the above mentioned coordination and control function at the European level.

European cooperation in the field of accreditation has developed in line with the advance of the accreditation principles and practices, outlined above. It started with the establishment of WECC – Western European Calibration Cooperation, in 1976 and of WELAC – Western European Laboratory Accreditation Cooperation, in 1987, and progressed with the merging of these two organizations into EAL – Laboratory Accreditation in 1994. Meanwhile, in 1991, EAC – Accreditation of Certification and Inspection Bodies was also established.

EA – European Cooperation for Accreditation was formed through the merging of EAL and EAC and became a legal entity, in form of a non-for-profit association registered in the Netherlands, in June 2000.

EA is the Association of the national European Accreditation Bodies (and systems) providing accreditation of all conformity assessment activities, such as calibration, testing, inspection, management system certification, product certification, personnel certification, EMAS declarations and others.

The EA organizational structure consists of an Advisory Board (gathering all major stakeholders such as conformity assessment bodies, industry, Regulators, consumers), a General Assembly, an Executive Committee, a number of Technical Committees (among which the EA MAC Committee ruling the EA MLA) and of a permanent Secretariat with three full time staff.

EA has, at present, 34 full members and 2 associate members. There are 26 signatories to the EA Multilateral Agreement (EA MLA, see below) out of which 19 have signed for all accreditation scopes. EA has entered into 16 contracts of cooperation, 9 of which have developed into bilateral agreements that convey the same benefits, in terms of mutual recognition, as the EA MLA.

EA operates under a Memorandum of Understanding with the European Commission and EFTA and its main purposes are:

- to develop – and enforce the application of – accreditation criteria and guidelines ensuring the effective and harmonized performance of national Accreditation Bodies in Europe and thus the equal reliability and usability of the corresponding accredited attestations of conformity which can therefore be trusted, as such, by the direct and indirect users of them (the "marketplace");

- to contribute to the pursuance of similar achievements worldwide, through its active membership in ILAC and IAF and collaboration with other regional organizations.

This mission is being accomplished by a number of activities and, chiefly, by the management of the EA Multilateral Agreement.

The creation of EA has represented a noticeable step forwards in the technical and political process of consolidation of the European accreditation infrastructure as an efficient and effective tool contributing to the progress of the European economy and society.

Putting together the two different types of accreditation:

- accreditation of testing and calibration laboratories providing experimental services at the basis of many processes of quality realization and assurance and

- accreditation of certification and inspection bodies delivering full attestations of conformity to the requirements of voluntary standards and mandatory regulations,

has meant, in particular:

- harmonization of the accreditation principles in two areas (the former more ancient and the latter more recent) historically characterized by different cultures and different accreditation standards (only recently unified into the new standard ISO/IEC 17011);

- synergic cross-fertilization between the technical and scientific aspects (typical of testing and metrological activities and, to an extent, of product certification and inspection activities) and the management aspects characteristic of management system certification;

- strengthening of the representation of the European accreditation community vis-à-vis the Public Authorities, the industry and all other stakeholders.

Note that this important result – achieved at the European level – has not yet been obtained at the world level where two distinct organizations (ILAC and IAF) still exist, with problems related, on the one hand, to overlapping and duplications and, on the other hand, to lack of technical and political synergies.

In spite of its relative young age, EA has achieved a remarkable success, as shown by the continuously increasing number of members, the quality and quantity of technical activities performed and the prestige acquired vis-à-vis its stakeholders and partners.

3. THE EA MULTILATERAL AGREEMENT (EA MLA)

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 accreditations": CABs accredited by signatories of 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 their perform their activities).

To ensure the effectiveness of the EA MLA – as an objective and credible attestation of the compliance of the signatories ABs with the applicable requirements and thus of their ability to proper exert their control function – each signatory is subject to rigorous routine evaluations by a 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 management of the EA MLA is ruled by well defined policies and procedures (document EA-2/02) describing the basic criteria for joining the MLA and 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 reports by ad-hoc task force groups, decision from the EA MAC Committee, and eventual appeal.

4. THE EUROPEAN ACCREDITATION MODEL

In 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 (market driven) and mandatory (law regulated) spheres.

As such, accreditation must be rendered, **at national level**, on suitable mandate of the Government, in conditions of independence and impartiality, with full accountability towards all the interested parties, with no single interest or group of interests predominating, as non-profit-distributing service activity and without competition.

Regarding "competition" **at international level** ("cross frontier accreditation"), the EA policy is that an Accreditation Body member of EA shall not promote or market its accreditation services to other countries or economies members of (or candidate to) EU (and EFTA) and shall only considering providing them to the former countries or economies where no Accreditation Body exists in the latter or such services cannot be provided by the local Accreditation Body and, in any case, in cooperation with the local Accreditation Body where one exists.

In the EA view, the concept of "cross frontier accreditation" should be replaced by that of "cross frontier cooperation".

5. THE DEVELOPMENT OF EA

5.1 The recognition of EA as the official European Accreditation Infrastructure

The principles inspiring the above mentioned "European Accreditation Model" will be formalized in a Regulation that the European Union is setting up as a major instrument for a new legislative approach to technical harmonization in Europe, ("revision" of the New Approach). Main goals of the instrument are:

- to redefine the overall legislative framework for safety (and other issues of public interest protection, e.g. environmental impact) of products made available on the European Union market (industrial and non industrial);

- to provide a legal basis for activities which do not yet have a Union legal base, such as accreditation and market surveillance;

- to set up all essential requirements relating to the common elements, including: essential requirements for the competence of conformity assessment bodies as well as for the designating and notifying authorities; requirements for the operation and organization of accreditation at the national level and the role of public authorities; requirements and rules of operation of accreditation at the European level and the role of public authorities.

This Regulation will confer to EA the official role of European Accreditation Infrastructure having the task to ensure that the accreditation activities are performed, in the Member States, in full compliance with the basic principles above cited.
In particular, EA MLA accreditation shall represent a solid base for granting the validity of conformity assessment services in both voluntary and regulated spheres, shall provide, specifically, 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), and shall support, in general, the function of National Public Authorities.

As official European Accreditation Infrastructure, EA will be considered as a Body pursuing an aim of general European interest, according to the applicable European legislation.
This role will 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.

5.2 The output focussed accreditation approach

To properly perform its function – generally important and even more critical when related to the protection of public general interests as per above – EA MLA accreditation must deliver the necessary "added value".
Namely, accreditation must be able to ascertain and confirm in depth – not only the generic compliance of the CABs with the generic requirements of the applicable normative documents – but also and chiefly their specialist knowledge and expertise regarding all technical and technological features and aspects involved in the conformity assessment activity.

Moreover, accreditation shall enable to assure – by means of appropriate procedures – that the above specialist knowledge and expertise are properly and consistently applied to the assess ments and that the "results" delivered by the accredited CABs are actually capable of fulfilling the associated needs.

For example, accreditation shall ensure that quality management systems certified by the accredited CABs are really able to deliver, consistently, products and services complying with the applicable requirements or that products certified by such CABs do really constantly meet the pertinent constructional and performance requisites.

In short, EA MLA accreditation shall be aiming at assuring the **quality of the final outputs** of the conformity assessment chain, namely of the results which are delivered to the marketplace.

In the end, in fact, the function of accreditation is to provide confidence in the value and credibility of such results.

Strengthening the accreditation rules (including a more rigorous policy in terms of sanction measures), conducting extensive surveillance activities (including extraordinary surveillance), enhancing the witness assessments and exploiting at best the opportunities offered by proficiency testing, comparisons and similar means, are the key features at the basis of an **"output focussed accreditation approach"**.

This "output focussed accreditation approach" – which is already being adopted and will be ever more implemented in the future – is of great significance for the conformity assessment activities in the voluntary sphere, having a major impact on the progress of the economy, and is of paramount importance in the mandatory and regulated areas, involving the protection of fundamental rights of the society.

5.3 The actions for improvement

To enhance the value and efficacy of European accreditation – with reference to all kinds of conformity assessment activities and with special regard to mandatory conformity assessments – various improvement actions are needed.

From the policy point of view, EA shall support and guide the establishment and maintenance of suitable relations between the Member States and the respective ABs or Systems.
These shall include the recognition and acceptance, by the national Authorities, of attestations of conformity issued under the EA MLA accreditation and the support to the national ABs to become and remain signatories of the EA MLA.

From the organizational and technical side, EA is called to:

- strengthen its corporate infrastructure and organization;
- reinforce the cooperation with the stakeholders (Regulators, industry, users/consumers, specialist technical and scientific fora, associations of CABs, etc..), searching for and valuing their feedbacks;
- improve the accreditation rules and procedures, by introducing more effective requirements and criteria for the initial assessments, reinforcing the surveillance activities (particularly extraordinary surveillance) and fostering the implementation of the related improvements by the accredited CABs. Enhancement of the accreditation rules shall also include specific and harmonized guidance for accreditation to be used as a basis for notification (definition and assessment of the scope, reporting and decision making, surveillance, cooperation with designating authorities and notified body fora);
- foster the adoption, by the ABs signatories to the EA MLA, of more rigorous sanction policies;

- strengthen the effectiveness of the peer evaluation process, by increasing the extent and frequency of the assessments, improving the qualification of the assessment teams and requiring periodic self-assessments by the signatories ABs. Improvement of the peer evaluation process shall also include the adoption of a more substantial and output focussed approach that would provide better evidence of the capability of the evaluated AB of ensuring the initial and continuous competence of the accredited CABs (both general and specialist) and their ability to consistently provide quality results.

Each of the above objectives encompasses a number of initiatives that have been outlined in a recent EA Position Paper and are being planned and implemented within a specific development project structured into 5 main lines of activity.
From the outputs of this project, a detailed “road map” will be defined and incorporated into a strategic plan being prepared, to adapt the EA structure and operation to its future institutional role of official European accreditation infrastructure.

The European accreditation and the related European conformity assessment system are looking towards a future of growing success and greater achievements – in their task of serving the progress of the European economy and the development of the prosperity of the European society – provided they will be capable to properly manage the outstanding challenges they are called to face.

One major key for winning such defiance, lays in the commitment to improvement of the EA members and in their willingness to work together, united in the pursuance of the common objectives. In the end, EA is as good as its members are and on them we should, chiefly, rely.