European Co-operation for Accreditation - MLA aspects

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Abstract:

EA's history dates back as far as 1975. At present it has full stakeholder representation and it has strong ties with the European Commission. The EA-MLA covers all fields of accreditation. MLAs are increasingly important to trade. Stakeholders are pushing accreditors in Europe to not only recognize accredited conformity assessment from other countries but to accept it as well. This necessitates further deepening of MLA evaluation procedures. This is achieved through enhanced training, through harmonizing of evaluators and through the introduction of key issues to be addressed during evaluations. An international logo will demonstrate the acceptance to the market.

1. EA's roots

The European co-operation for Accreditation (EA) was created in November 1997 through a merger of the European Accreditation of Certification (EAC), which was created in 1991, and European Co-operation for Accreditation of Laboratories (EAL). EAL, itself was the result of the 1994 merger of the Western European Laboratory Accreditation Co-operation (WELAC), which was created in 1989, and the Western European Calibration Co-operation (WECC), which was created in 1975.

EA now covers the accreditation of all fields of conformity assessment, i.e. calibration, testing, inspection, certification of quality management systems, environmental management systems, products and personnel.

During 1998 and 2000 major changes took place in EA's organization. The changes involved the introduction of an Advisory board (EAAB) in November 1998 and the incorporation of EA in June 2000 in the Netherlands.

In the same period the committee structure was modified to reflect the main areas for accreditation. A Laboratory Committee was created for testing and calibration issues, a Certification Committee was created for all certification activities and an Inspection Committee was established to cover all technical issues around the accreditation of inspection bodies. The tasks of the supportive committee on Publication and Promotion did not change and cover

management of EA publications and development of promotion materials. The EA-MLA[1] Committee (EA-MAC) got delegated decision-making authority with respect to the signatory status.

2. Stakeholders

The creation of the EAAB in 1998 was of paramount importance. It formalized the stakeholder representation in EA. It improved communication with the European Commission and with national authorities as well. Although in the past stakeholders could participate in the work of the technical committees, the transparency of EA increased through the EAAB.

Presently the EAAB is composed of 20 members: 5 representing conformity assessment bodies, 5 representing industry, 5 representing national authorities, 1 for consumer representation and 1 for the European Commission, 1 for European Free Trade Association, 1 for European Standards Organizations and 1 for the European Organization for Conformity Assessment (EOTC).

The EAAB formulated a number of issues that needed priority attention of EA. One of the issues directly involves MLA aspects through pushing for acceptance rather than recognition of accredited conformity assessment by the MLA signatories. This would then optimally support the European Community's conformity assessment policy in relation to the free movement of goods.

3. Interaction with regulators

EA's members come from the entire European Economic Area, thereby giving EA a key role as an interface between the European Community Policy and conformity assessment. Because accreditation in Europe is performed without competition, in an impartial and in an independent manner, it can play an increasingly important role in the notification process of conformity assessment bodies under the New Approach directives.

Effectively it results in an amalgamation of voluntary and regulatory spheres with respect to accreditation. The European Commission considers the establishment of the MLA for testing, calibration and certification as the most important result of EA.

Accreditation under the MLA plays an important role in the negotiations between the European Union and other countries concerning the free movement of goods and the New Approach directives.

To underline the EA's importance a Memorandum of Understanding was signed in June 1999 between the European Commission and EA. The main objective of the Commission was to ensure that EA "operates in line with and in support of the Community Policy, in particular with regard to the Single Market, the common commercial policy and the technical assistance to third

[1] While in many regions MRA is used to abbreviate mutual recognition arrangements, MLA is the common abbreviation used in Europe. MLA originates from MultiLateral Agreement. In Europe MRA is reserved for government-to-government agreements. In this paper the abbreviation MLA is used to identify agreements between accreditation bodies.

countries". The Memorandum commits the Commission to seek advice from EA on technical matters relating to accreditation and it commits EA to take on board advice from the Commission on policy matters related to accreditation. An equivalent MoU was signed with EFTA (European Free Trade Association).

4. MOU and MLA

Like EA, all regional and international accreditation co-operations started with establishing a memorandum of understanding (MoU). For an accreditation body to become member of a MoU it self declares its commitment to observe the rules of the co-operation, including the use of international standards and guidance documents.

For a MLA signatory it is formally established that it works according to specific standards and that it correctly uses guidance documents, leading to harmonized accreditation procedures. Only signatories to the MLA can recognize and promote acceptance of conformity assessment declarations issued under accreditation by other signatories.

For the stakeholders it is important to realize this difference between a MOU member and a MLA signatory especially when international trade is at stake. It would therefore be appropriate for the hierarchically highest MLAs, those of the International Laboratory Accreditation Co-operation (ILAC) and of the International Accreditation Forum (IAF), to facilitate the identification of the signatories through the permission to use a specific MLA-logo.

This is why ILAC and IAF have initiated reflections about promotion of their MRAs and use of a unique international logo.

5. EA-MLA history

The first MLA dates back to 1989 and was concluded amongst the WECC accreditors for calibration laboratories of eight countries. The WELAC accreditors for testing laboratories of five countries followed it in 1992. In 1994 the EAC accreditors for certification of seven countries concluded their MLA.

Soon accreditation bodies from outside Europe wanted to join the EA-MLAs because it was beneficial for trade with Europe and for the MRA negotiations of their economies with the European Union. The first two bilateral agreement signatories joined the calibration and testing MLAs in 1996. Table 1 provides data on the EA-MLAs.

Since both ILAC and IAF have now created MLAs, there should be less need in the future for non European countries to become a bilateral signatory. Especially when the earlier mentioned international logo comes into effect the need will diminish completely. Such a development would not only be more cost effective but it would also enhance the ultimate purpose of the MLAs to create one-stop conformity assessment and one-stop accreditation.

Table 1 Number of participating accreditation bodies in various EA-MLAs

MLA field	EA member signatories	Bilateral signatories
Calibration	18	8
Testing	22	8
Certification of Products	17	1
Certification of QMS	15	0
Certification of Personnel	13	0
Certification of EMS	14	2

6. EA-MLA present practice

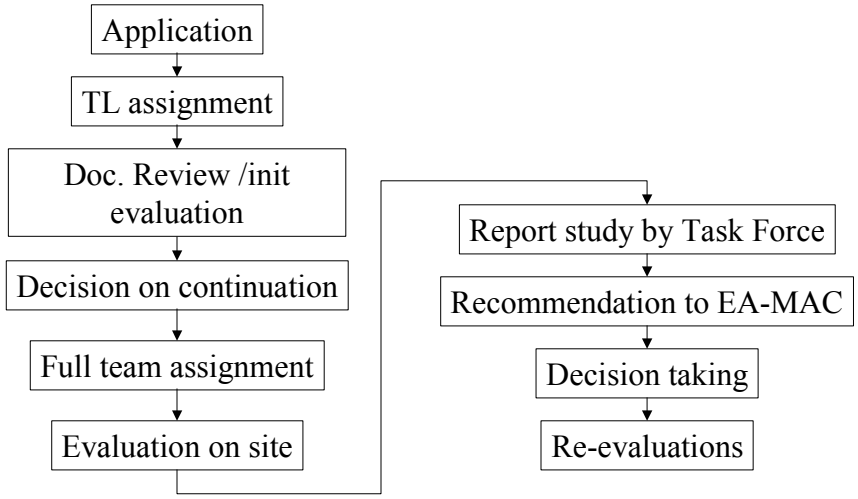
From the text above it is obvious that MLAs are important. It is obvious that the number of participants in any particular MLA is increasing. It is also obvious that regional MLAs have an increasingly international dimension. Since accreditors are pushed to "accept rather than recognize" it becomes urgent to further deepen the MLA.

Basically to become signatory of a MLA the applicant accreditation body has to follow a well-defined process, which ultimately consists of a thorough evaluation based on a peer review mechanism. Although the regions, as well as ILAC and IAF, have their own MLA procedures which only differ in detail, it does not mean that our practices are equivalent (Figure 2 provides the major steps in the EA-MAC evaluation procedure).

When we have to accept conformity assessment results we need to know that the evaluation practices are equivalent and ultimately that the accredited conformity assessment bodies are equally competent.

To achieve this is not easy. The first step is a close co-operation on a worldwide level of all MLA committees. This co-operation should lead to one single procedure, very similar practices, well trained evaluators, cross regional participation in evaluations, adequate control mechanisms and last but not least competent decision takers.

Figure 2 Main steps in the EA evaluation procedure



To improve the process of decision taking, EA-MAC introduced the study of evaluation reports by specifically assigned Task Force Groups. These TFGs study in detail the reports and interact with the evaluation team and the evaluated accreditation body. In addition a specific training was conducted for the decision takers on how to read and interpret evaluation reports.

7. Key Performance Indicators

As a first step for improvement of the MLA evaluation process EA developed key performance indicators (KPIs). The immediate cause for the KPIs was the perceived differences in the many evaluations in Europe. Some evaluations were aiming at details others were aiming at the major operational and policy issues while all evaluations followed the respective ISO and EN standards.

The KPIs (see table 2) identify those issues that will contribute most to determining if the accreditation body is able to do a trustworthy assessment of the conformity assessment bodies' competence.

Training courses have been and are being conducted to educate the evaluation team members in a harmonized KPI-use. The first course took place in March 2000 with participation of evaluators of other regions as well. Since then 5 trainings have been conducted internationally and as a result slight modifications to the KPIs were introduced. ILAC and IAF have adopted the KPIs in the mean time and thus this is a major step to worldwide-harmonized evaluations which has been taken.

Table 2 Key Performance Indicators summary. (KPI 10 + 11 are specific for laboratory accreditation bodies)

KPI	Subject	Brief description
1	Access to Expertise	Determining the (technical) competence of conformity assessment bodies is of paramount importance. The AB therefore must have access to numerous types of highly qualified experts.
2	Scope of the AB and extension of scope	The AB must be conversant with the specific conformity assessment branch. Effective procedures must be in place to move to new fields.
3	AB's staff, assessors and experts	Recruitment procedures, training and monitoring processes must be in place as well as job descriptions.
4	Assessor support	Training in assessment techniques, access to administrative and technical support/information. Feedback mechanisms.
5	Assessment team	Composing of teams, which cover the scope of the CAB. Ability of teams to collect evidence of the CAB's competence. Ability to determine the criticality of findings.
6	Impartiality	Impartiality, independence and integrity of all persons involved in the accreditation process must be established.
7	Monitoring of staff, assessors and experts	Various techniques of monitoring must be available and must be utilized.
8	Non conformities, Corrective actions and decision making	The AB must have procedures for dealing with NCs and corrections by the CAB. Decisions must be based on adequate reports and records. Decision and assessment must be separated.
9	Internal audits and reviews	The AB must have an effective internal audit and review mechanism. Improvement mechanisms must be in place.
10	Proficiency testing	The AB must have policies on selection, frequency and appropriateness of PT in relation to the laboratories scope.
11	Calibration, traceability and reference materials	The AB must have clear policies on calibration, traceability and the use of reference materials. Training on these issues must be in place. Policies on requiring method validation and estimating measurement uncertainty.
12	Surveillance activities	The AB must have an effective surveillance system in place to ensure continued competence of the CAB.
13	Value adding services	The AB should provide stakeholders and CABs services and information beyond the assessment service such as seminars, relations with government and client groups etcetera.

8. Further improvements

The KPIs and the associated training are obviously the basic elements for harmonized evaluations. The KPIs are still not perfect, but since their philosophy is correct, improvements will be made through their use and continued feedback from evaluators in follow-up training.

Increased monitoring of the evaluation teams is the next important step. Monitoring is presently done through feedback forms from the evaluated accreditation bodies and through in-depth study of the evaluation report.

Discussions on the duration of an evaluation are taking place including on the amount of witnessing of the accreditation body's performance in the field.

Discussions on sanctions, such as suspension and withdrawal of the signatory status are progressing in EA and on an international level.

Because of a growing number of evaluations, operating an MLA is in need of further professionalism. In essence there is no difference between operating an MLA and operating an accreditation body. A cost effective possibility could be to create a single MLA-operation that services all regional and international co-operations.

9. Unnecessary developments

Some regulators are requiring extensive technical evaluations of the accreditation body's competence. Experts in specific technical fields should then be part of an evaluation team. MLA-scopes will become similar to the scopes of for instance laboratories. Such developments will lead to not only very large teams and prolonged evaluations but it will also lead to huge costs without actually providing the regulator with enhanced assurance of the conformity assessment bodies' competence.

Such a development is unnecessary because the detailed technical expertise must be available in the assessment teams of the accreditation body and not in the evaluation teams. At the level of an evaluation it is sufficient to look at how an accreditation body composes its teams, so that the technical competence of the conformity assessment body can be correctly established.

10. Conclusions

Regional and international accreditation co-operations are putting much effort in creating solid evaluation processes that will give the required confidence to the stakeholders. They are introducing more control mechanisms. They are harmonizing their procedures. Therefore regulators are more and more inclined to use accreditation.

But accreditor co-operations still have to educate the market of the essence and the advantages of MLAs. They must continue to closely interact with the regulators and convince them of the large benefits of MLAs for trade. The creation and wide use of an international MLA logo will facilitate this.

Ultimately the worldwide MLA will be able to contribute to the free movement of goods through minimizing conformity assessment and accreditation to 'once only activities'.