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**What conformity
assessment
operators
expect from
accreditation**

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EUROLAB POSITION PAPER

WHAT CONFORMITY ASSESSMENT OPERATORS AND LABORATORIES EXPECT FROM ACCREDITATION

1 – Background and evolution of accreditation

Historically, accreditation has developed in five distinct and successive phases, with different motivations having a direct impact on its contents and procedures, as well as on the appreciation of its added value by the accredited operators and the stakeholders of measurement, testing, inspection and certification:

- in the fifties, some countries, such as Australia, set up accreditation schemes for laboratories for purely internal reasons, as a means of making the best use of available national testing and analytical resources, assisting in their development and upgrading the quality of their services,
- in the seventies, the focus was on the accreditation of calibration laboratories, as a means of ensuring the coherence and availability of traceability of measurements to national and international reference standards,
- in the eighties, the adoption of the GATT agreements aiming, i.a., at the reduction of technical barriers to trade, stimulated the development of the accreditation of testing laboratories as a means to gain international acceptance of test data and thus facilitate "one-stop-testing", in particular through mutual recognition agreements between accreditation bodies. From then on, laboratory accreditation has developed as the specific mechanism for laboratories to obtain third party recognition of their competence and ability to perform calibration and testing services
- in parallel to the development of laboratory accreditation, and in distinct organisations, the emergence of the certification of compliance of quality systems to the ISO 9000 standards induced the emergence of accreditation of certification bodies (known also as "registrars" in the North America), as a means both for international acceptance of certificates and of qualification of the offer of certification services which was proliferating,
- finally, in the nineties, a general tendency has been particularly in Europe, to concentrate accreditation in multifunction accreditation bodies and to generalise accreditation to all forms of activities related to measurements and conformity assessment

Today, these successive layers underline most of the national accreditation schemes which have developed world-wide. This evolution, however, has resulted in a shift from an essentially technical approach to accreditation with higher focus on its economic and commercial consequences. Governments and economic partners have become more involved and accreditation bodies have had to be more aware to their needs and expectations, in addition to, and sometimes to the detriment of, a strong relationship with the operators.

Discussing added value of accreditation requires therefore to identify the different levels of the interests involved:

- the laboratories and conformity assessment operators,
- their direct customers,
- the national interest,
- international trade and co-operation.

This position paper presents an analysis of the expected added value of accreditation at these various levels, together with an identification of key conditions to obtain it effectively.

2 – Expected added value of accreditation for the laboratories and conformity assessment operators

Accreditation has a cost for the accredited, both internal, for the implementation of accreditation requirements, and external. Indeed, fees charged by the accreditation bodies tend to be closer to actual costs of assessment and surveillance, as public funding becomes scarce. Differences in the fee structure and the fees exist. It should be noted that the external costs vary from one country to the other, depending on the content of the assessment and surveillance process, the cost of assessors and the amount of public funding. As it may reach several percent of the turnover of the accredited activity and adds to the internal cost, the decision for an organisation to seek and maintain an accreditation is a strategic and economic decision that requires a clear perception of its added value. Too often, operators see accreditation as an unquestionable must and they have a rather defensive approach to the process which may generate frustrations. These have been enhanced in the past decade with the difficulty to have customers admit, in the voluntary sector and especially for laboratories, that accreditation ensures compliance of their quality system with the requirements of the ISO 9002 standard.

Important elements that operators expect from accreditation are:

- an occasion and a stimulation to improve and formalise their quality system, as well as the evaluation and maintenance of their technical competence,
- an assurance for the management that these are documented and assessed regularly, hence facilitating the continuity of the desired level of the quality of the services they offer,
- the recognition of the value of accreditation by the market and, where relevant, by public authorities which prescribe measurements, testing and conformity assessment in the context of regulations, thus effectively reducing multiple assessment and creating a "level playing field" for the competition amongst operators,
- effective and harmonised procedures and mechanisms for reference to accreditation for commercial purposes,
- an optimised procedure for accreditation, in terms of time schedules, prices and rationalisation of the assessment when several fields of calibration and testing or several functions are concerned in the accredited organisation.

Some conditions to meet these objectives in a cost effective way are that:

- the description of the scope of accreditation fits as much as possible with the offer of services of the operator, maximising the issuance of accredited documents,
- the credibility of the assessment for the staff of the operator is ensured: insufficient technical competence, too much focus on documentary aspects and possible prejudice and arbitrary of the assessors must be avoided by adequate selection, qualification and instructions by the accreditation body,
- clear and harmonised reporting and decision making mechanisms are implemented: accreditation is supposed to provide a level playing field for conformity assessment services; it should therefore make sure that its requirements are interpreted and applied in a homogeneous way, which means that some form of "expert system" must be put in place so that the grading and inference of non-compliances be harmonised, nationally and across borders, in the context of mutual recognition agreements,
- the fees charged for accreditation are linked to the direct costs of assessment and surveillance, and not to the volume of accredited services,
- the assessment process mutualises the evaluation of the quality system, when it covers the whole organisation and provides for effective mechanisms for the extension of the scope of accreditation
- accreditation is actively promoted to the other stakeholders,
- the accreditation body itself does not confuse the message by being itself involved in activities that compete with its accredited organisations (such as certification of quality systems or of competence of staff or accreditation of the accreditation body's own activities i.a. providing proficiency testing schemes or reference materials), and therefore contributes to the clarification of the offer of conformity assessment services,
- when accreditation is required as a prerequisite for designation to operate in the context of regulations, clarification is needed as to what competence and means should be assessed in order to satisfy the regulatory authority: today, the link between accreditation and notification (or designation in the context of the MRAs between the EU and third countries) is not clarified and varies considerably from one country to the other,
- the commercial use of accreditation is encouraged but also codified and surveyed: nothing is more disturbing for an operator to see a competitor abuse its customers without sanction on its scope of accreditation or by proposing, without adequate warning, unaccredited services on stationary bearing the accreditation logo,
- the accreditation bodies take into account assessments made by other organisations or peers, arrange their assessments in an effective way and try to avoid multiple assessments.

Some current criticisms should be underlined:

- there is a tendency of accreditors to develop interpretation documents in order to refine the requirements laid out in the referentials (EN 45000 or ISO guides). This leads to a confused situation where these standards are supplemented by documents which have an unclear status and to which the accredited operators have often been insufficiently associated: ILAC and IAF guidelines, EA guidelines, national documents. The ILAC laboratory liaison committee, the EA-EUROLAB permanent liaison group offer mechanisms to improve this situation, but, basically, the development of refined (and sometimes additional or even conflicting) requirements should be absolutely avoided,
- the national monopolies that most European accreditation bodies have is a source of perplexity for the operators. It can only be justified if harmonised procedures and fees are applied, which is far from being the case. For example, the fee structures vary by a factor 1 to 4 or 5 (and even 10 for Eastern European countries),
- the relation between accreditation and certification of the quality system of operators has yet to be uniformly clarified: can an accreditor use the assessments of the quality system made by a certification body (which it may itself have accredited!) to simplify its own assessment? The subject is particularly relevant for laboratories, confronted to a request from the market for both forms of assessments. There are also other areas, in which the accreditation body has put itself into a position that might give raise to a conflict of interest situation,
- accreditation is widely referred to in the context of designation of bodies to operate in relation with Mutual Recognition Agreements between the EU and third countries. Yet, the implication of this has not really been explored, which is not surprising since the subject of accreditation and notification still needs clarification within the EU itself. How will this impact on the fairness of competition between European and overseas operators and their respective customers?

3 – Expected added value for the direct customers of the operators

The supposed advantages of accreditation for the direct customers of conformity assessment operators are well known and publicised by the accreditation bodies themselves:

- clarification and qualification of the offer of conformity assessment services,
- third party assessment and surveillance of accredited operators,
- higher national and international acceptance of accredited calibration and test results, as well as certificates and accredited reports, be it for regulatory, voluntary certification or contractual purposes,

For laboratories, two aspects which customers often seek and that accreditation does not clearly provide today are a measure of the independence and impartiality of the laboratory and its ability to conclude on compliance of a tested item to specific requirements when such compliance may be directly deducted from the test results. Accreditation bodies should clarify and harmonise their positions on these key points: the development of the new ISO/IEC 17025 standard is the occasion, all the more as it will have to fit in a series of ISO standards relating to conformity

assessment alongside a standard for inspection bodies where these issues will be clearly addressed if, as foreseen, it derives from the current EN45004 standard.

To profit from the advantages listed above, customers of conformity assessment services wish to:

- have access to a clear and regularly updated source of information on the offer of accredited services,
- be precisely informed on the scopes of accreditation (and, for laboratories, associated uncertainties, when relevant ...) in such a way that they might compare offers,
- have confidence in the accreditation process, e.g. by the involvement of their peers as assessors or in committees contributing to this process, or the surveillance mechanisms including proficiency testing,
- be able to document, through mutual recognition agreements or legislation, the recognition of accredited test reports and calibration certificates,
- have access to appeal procedures when difficulties are encountered with accredited laboratories or with the recognition of accredited results.

It should be underlined that there exists little documented evidence that accredited operators perform better than non-accredited, i.a. in inter-comparisons. Accreditation bodies could collectively endeavour to generate such information and exchange experience on the enquiries they conduct with the customers of accredited operators to measure their satisfaction.

4 – Expected added value for a nation

The development of accreditation should also be considered for its contribution to the technical infrastructure of a nation, to support the achievement and control of the quality and safety of products, health services or environmental protection. It facilitates the access to qualified measurement and testing services of all the interested economic partners, and may also contribute to the optimisation of such services.

Covering both calibration and testing, laboratory accreditation helps in adjusting the level and scope of national reference standards and the organisation of the traceability of measurements.

It assists also in externalising conformity testing from central administrations in relation with the implementation of regulations.

Achieving such aims implies however that:

- the scope of the accreditation body or bodies operating at the national level be as wide as possible, which may require that public funding supports the cost of developing accreditation services in fields where the market demand is not spontaneous or unable to cover such cost,
- the conditions for accreditation to be imposed as a prerequisite for the designation of operators in the context of legislation be clearly spelled out,

- when accreditation bodies are entrusted with de facto or even de jure national monopolies, mechanisms are in place, with the active participation of the laboratories and other stakeholders, to make sure that such a position leads neither to laxism nor to overdoing.

5 – Contribution of accreditation to the facilitation of international trade

Accreditation is expected to have a major contribution to the facilitation of international trade, by assisting in the international acceptance of calibration, test and inspection results, as well as certificates. The two mechanisms for this are:

- the mutual recognition agreements between the accreditation bodies themselves, under the auspices of ILAC, EA and other regional accreditation co-operations,
- the reference to accreditation as a means of qualifying services performed for assessing compliance to regulations in bilateral or multilateral treaties and arrangements (cf. GATT agreements, EU policy or agreements between the EU and third countries).

For the accredited operators, such agreements have two main consequences: their accredited services may be more easily recognised in the countries party to the MRAs between accreditation bodies or governmental authorities, which may bring them and their customers a commercial advantage. It means also that competition from foreign operators will be stimulated. Added value of accreditation in this case depends on the effectiveness of the agreements to have certificates, inspection reports or test or calibration results accepted abroad without impeding on the fairness of competition between operators and their direct customers.

For MRA's between laboratory accreditation bodies, the ILAC laboratory liaison committee has identified the key points to be examined to determine the true equivalence of accreditations delivered by bodies party to such agreements. They comprise such points as: the description of the scope of accreditation, the assessment to the scope, the participation in proficiency testing and inter-comparisons, the requirements for the maintenance and calibration of measuring and testing equipment, the grading of non-compliances, the presentation of accredited test and calibration results, the approach of expert judgement and conclusion on compliance of tested items, the rules for the commercial use of accreditation logos, the requirements for the quality assessment of software and automated equipment, and, last but not least, the content, procedure and transparency of the peer assessment between the accreditation bodies that leads to accepting the equivalence of the accreditations they deliver.

As many of the so called technical barriers to trade created by testing and certification concern the regulated sector, the effectiveness of accreditation to overcome them is directly related to the clarification of its use in this sector, which is far from being achieved. The need is generally recognised to distinguish between the "recognition" level (accreditation bodies) and the "acceptance" level (public authorities). Co-operation is needed with the regulators to express their needs in terms of requirements on the competence of operators, so that the referentials for accreditation be adapted accordingly, and their implementation harmonised. There again, current developments are underway to help address this issue: emergence of the ISO/IEC 17025 standard, EA working group on accreditation and notification, restructuring of the ISO guides and standards on conformity assessment and accreditation, mandate about to be given to CEN by the Commission on the adaptation of the modules to the emergence of the new ISO 9000 standards.

6 – Conclusion: adding value, a constant challenge for the accreditors

The number of accredited laboratories and other operators has grown considerably in the past decade, both because of the creation of new national schemes and of the expansion of the scopes of accreditation bodies. But will it grow in the future is not self-evident as some laboratories have started to question the added value of accreditation.

One could conclude that the added value of accreditation is therefore recognised by the market, since it is far from being free of charge to the operators and has therefore an impact on the cost of their services.

The interpretation should probably be more balanced, as an operator may have two different incentives to become accredited:

- the offensive approach: accreditation will improve its position on the market, it will open new opportunities, it will improve the service to its customers, i.a. by the broader recognition provided by accreditation,
- the defensive approach: accreditation is an obligation to stay on a given market and can not be avoided.

The approach is different whether the operator has a dominant position on its market or the contrary, and depends also on its ambitions for the world market.

Whether accreditation is experienced by the operators as a necessary ill or as a truly value adding process depends on the ability of the accreditation bodies to provide a cost effective, technically credible and widely recognised accreditation. International co-operation between accreditation bodies to harmonise their practices, in collaboration with their direct and indirect customers, the publication and implementation of international guides and a greater involvement of operators themselves in such developments are necessary conditions to achieve the latter.