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CONFORMITY ASSESSMENT

Mutual recognition and the role of accreditation in international trade

Recognition of ISO 900 certificates

Note by the Rapporteur on Conformity Assessment

1. Actions and parties involved in recognition

The primary objective of conformity assessment is to provide confidence for users that requirements applicable to products, services and systems have been met.

One of the reasons why internationally traded goods and services are subject to repetitive conformity assessment is a lack of confidence by users of conformity assessment in one country regarding the competence of bodies carrying out conformity assessment activities in other countries. Confidence in the work of conformity assessment bodies and accreditation bodies is therefore essential to private and public purchasers and regulators.

Such confidence by the user can be achieved through co-operation among conformity assessment bodies and also among accreditation bodies across the borders, resulting in mutual recognition and promotion of each other's work in the market place.

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Government to Government MRAs

In Government to Government Mutual Recognition Agreements (MRAs) or agreements between regulatory authorities *acceptance* and *recognition* of conformity assessment procedures have specific binding connotations. Through typical MRAs, each party is given the authority to test and certify products against the regulatory requirements of the other party, in its own territory and prior to exports. They do not require or presuppose harmonization of each party substantive requirements or recognition of their equivalence.

The key elements for reliable conformity assessment are the building of confidence through competence and transparency, and the setting up of a comprehensive policy and framework for the required conformity assessment.

The differences of third party conformity assessment infrastructures used by the parties are *minimized* by accreditation systems giving confidence in the fulfilling of the requirements laid down in the respective regulatory requirements.

However, that does not mean that the services provided by the third party bodies designated by the parties have the same technical or commercial value for their clients.

Agreements between accreditation bodies

Agreements between accreditation bodies usually mean that each party recognises the technical equivalence of accreditation systems operated by the other parties. Agreements will however not change the fact that accredited bodies will never be uniform...even if EA, the European coordination for accreditation, claims on its Web site that "*Through the Multilateral Agreement (MLA) a uniform level of competence of the accredited bodies involved is assured and the need for multiple assessment is diminished or eliminated. This means that a supplier will only need one certificate or report to satisfy the entire European market and all governments* "

This statement should mean at least that MLA members accept to grant their own accreditation to bodies accredited under the other systems as if they were directly accredited under their own...In fact, not yet; it might be a further (but difficult) step to develop such "second generation" agreements between accreditors.

In the real world of the clients of accredited conformity assessment bodies and the "users" of their certificates, the levels of competence - technical and otherwise - are not uniform, and it makes a difference which accredited body performs the service required and issues the report or certificate.

The buyer of a conformity assessment service may therefore have some good reasons to prefer one or the other body as the issuer of its certificate. Such preferences are not only based on pricing, location or other factors, such as the force of habit..

2. Objective statements on equivalence

Equivalence of certificates and reports should not remain a magic formula based on confusing statements. For a better understanding of the complexity of the subject, the most significant issue is the clarification of the statement of what the signatories agree to undertake or other requirements to which they commit themselves .

In practice, participating bodies may simply acknowledge to others that the conformity assessment results of the participants have been produced by competently performed, "equivalent" procedures, while in other agreements participating bodies agree to use (as their own) the results of participants acknowledged as produced by competently performed, "equivalent" procedures.

In other words, agreements vary in the extent to which they call for the acceptance of results by the signatories. Some agreements are without the a requirement for acceptance of any results, while other require one signatory to use in their entirety the results produced by other signatories, thus avoiding redundant work by a signatory in its decision making process.

In mathematics, the statement that $A > M$ and $B > M$, is not used to conclude that $A=B$. It means also that the statement that two Conformity Assessment Bodies (CABs) fulfil requirements should not be used to conclude that these two CABs offer identical services.

Such a formal clarification is not sufficiently explicit as long as the reality of "equivalence" is not perceived as an activity ensuring only the fulfilment of *minimum requirements*.

In the case of the assessment of conformity assessment bodies (CABs), the reality is that:

- CABs are assessed toward minimum requirements
- accredited CABs assess themselves their clients toward minimum requirements.

Differences between accredited bodies and accordingly differences in meaning between issued certificates or reports will still exist. In addition, the variation in the meaning of issued certificates *within* accredited organizations, can differ, as much as the variation of issued certificates *between* accredited organizations.

In practice, the level of confidence associated with certificates/reports is built up by elements such as:

- confidence in the certificate (i.e. the content covered by the certificate)
- confidence in the certifying body (i.e; the process of granting a certificate)
- confidence in accreditation (i.e. the content covered by accreditation)
- confidence in accreditation bodies (i.e. the process of granting accreditation)

The existing certification/accreditation/recognition principles and practices still leave such uncertainties; They may be minimized by a better formulation of the requirements when they are considered to offer a too wide range of different possible implementations on important issues. However, all the interested parties do not have the same needs and objectives.

3. Recognition of ISO 9000 certificates

Co-ordination of accreditation of ISO 9000 certification bodies

The International Accreditation forum (IAF) maintains confidence in the accreditation programs operated by its accreditation bodies members by the means of a multilateral agreement (MLA) signed by 27 members (June 2000), including the regional MLA-groups of the European co-ordination for Accreditation and the Pacific Accreditation Cooperation.

Certification bodies accredited by members of the MLA are allowed to claim "world wide recognition for the certificates they issue, based on the accreditation body's membership of the IAF MLA."

What the agreement does not do is set up the basis for accreditation bodies accepting each other's results, so that those having doubts about the usefulness of the MLA for industry, consider it as a simple agreement permitting to say, in essence, that "my accreditation is as good as yours".

Evolution wished for the tool "accreditation "

Due to its search for universality (as illustrated by the multiplication of recognition agreements), accreditation shall be perceived as a "driving licence" for accredited operators, and not as an excellence label. It is important that it can be granted and supervised as far as possible in the most homogeneous way at a world level, in order to avoid creating unfair competition between operators and their clients, at the same time it has precisely for its objective to qualify the services offered.

That implies that the reference standards limit as far as possible the latitude for the interpretation of requirements and the need for interpretation guides, in which the temptation may be high to introduce additional requirements. Insofar as such guides would appear necessary, it is important to give the operators and their clients the leadership for what affects the requirements related to their profession; while the accreditors have to lead what is related to the harmonization of their practices.

Accreditation is not the sole tool

Accreditation is not the sole mechanism, which can be implemented for the facilitation of international acceptance of tests and certificates. Moreover, it has its limits, as the mutual recognition agreements are hardly anything more than the claim by the accreditors themselves of the equivalence of accreditations. In fact the market players, in practice, validate or not such an equivalence. The peer evaluation has widely preceded accreditation as an alternative solution. Developed between laboratories or certifiers, it is based on agreements at the level of the operators who keep order between themselves and propose recognition schemes precisely oriented and commercially efficient as managed directly by the concerned actors. Beside accreditors, new regional and international actors have appeared for organizing interfaces, exchanges of experience and/or the defence of relevant interests.

Agreements between ISO 900 certification bodies

Even if nationally accredited by an IAF MLA member, certification bodies have significant differences in their activities so that the development of their links may be limited to one or more of the following levels in the field of quality management system certification :

1. Ignorance of the other body's certificates
2. Positive statement on the other body's activities and certificates
3. Co-operation level
 - 3.1 Performance of joint audits
 - 3.2 Exchange of information
4. Acceptance of the other body's certificates for requirements regarding purchased materials
5. Unilateral statement of equivalence on the certificate of the issuing body
6. Issue, case by case, of an annex, signed by both of the bodies, to the certificate), on the basis of the other body's certificate and report
7. Systematic issue of an annex, signed by both of the bodies, to the certificate, on the basis of the other body's certificate
8. issue, case by case, of a traceable certificate on the basis of the other body's certificate and report
9. systematic issue of a traceable certificate on the basis of the other body's certificate
10. issue, case by case, of a non-traceable certificate on the basis of the other body's certificate and report

11. systematic issue of a non-traceable certificate on the basis of the other body's certificate.

For steps 8, 9, 10 and 11, a certificate is said to be "traceable" when its contents highlight the fact that it is based on results provided by another certification body, party to the agreement. When "non-traceable", the certificate does not introduce potential discrimination as to its origin.

Improving coordination between conformity assessment bodies is not only a technical issue but a commercial one. Bodies complying with the ISO/IEC guides or standards relevant for their activities may have different commercial objectives, as they may be:

- nationally or internationally oriented
- non-profit or profit organizations
- non-consulting versus consulting
- operating on broad scopes versus small scopes

At world level, certification bodies are organized by affinity in two distinct groupings. The rift has been based on their origins the Independent International Organization for Certification (IIOC) gathering multinational operators stemming from inspection activities, the British Standard Association (BSI) has joined this Club after acquiring an important inspection activity, and the International Certification network (IQNet) gathering operators stemming or near from the circle of standardization and certification of conformity to standards. IQNet is a network of non profit distributing bodies. Equivalence of competence and confidence is ensured by an initial evaluation and periodic assessment of its members to ISO/IEC Guides, International standards and peer assessment rules. The members use the IQNet mark and the IQNet presentation for certification documents. Beyond that, the IQNet members may be prepared to sign bilateral agreements beyond the sole IQNet objectives.

4. Additional issues in transition economies

Weakness of their certification offer

In market economies, confidence of market players in the quality of the services provided by conformity assessment bodies is widely based on the proper functioning of the market itself, competition eliminates the less efficient structures. In order to satisfy their foreign customers, the exporting companies of transition economies have a tendency to privilege multinational operators, to the prejudice of their national operators, especially late in their development because the demand for certification remains very low compared to other economies (98% of the European ISO 9000 certificates (-200000 certificates still originates from western Europe).

Weak international representation

Difficulties of transition economies are also related to the lack of active participation in the many activities carried out at regional and international level. The resulting requirements are conceived on the sole basis of market economy practices; transition economies have often to deeply reconsider their practices to be recognized.

Accreditation systems play an important role. Transition economies are not, not enough, represented in the formal structures co-ordinating since several years the accreditation bodies. They should adopt without delay structures compatible with a subsequent participation to mutual recognition agreements, such as those of IAF or EA.

Tracks for the future

In the field of ISO 9000 certification the problems perceived by transition economies cannot be considered as the result of foreign legal requirements. It is the free play of market demand i.e. there is no influence from the public authority beyond national policies promoting quality, in particular encouraging companies to improve their management systems. The means for their gradual removal should be sought on the one hand in the improvement of the management of companies to enable their certification, and, on the other, in measures to promote national structures for accreditation and ISO 9000 certification which could be competitive and open to outsiders.

As a matter of fact, in the context of the globalization of economies, it is observed that for keeping market share, operators have to evolve and present a global certification offer: all functions in all fields, with an international recognition. The newly industrialized countries and many developing countries have created their own laboratories and certification /accreditation bodies, expected to be used for access to the global market. One attends to mergers and connections aimed at offering to companies a genuine conformity engineering service, stocked with the full range of associated services.

In the field of ISO 9000 certification, mutual recognition agreements belong to the private sectors. They may only be achieved if the following conditions are met :

- the differences in the methods of organisation, functioning and technical interpretation between the different existing systems in the countries are not so important as to hinder, in practice, any kind of co-operation ;
- the qualifications of the bodies intervening on behalf of these procedures are accepted and, above all, the economic partners who have played a major part in the national consensus of the existing procedures in the different countries are called upon to play an important part in the implementation of a consensus on the elaboration of procedures.

The difficulties faced by many industries expecting benefits from recognition agreements and the associated infrastructures of conformity assessment bodies are inherent in the principles of free competition: competition means that companies and conformity assessment bodies persistently strive for market differentiation. The evolutions observed at global level are now irreversible. That should encourage transition economies to take appropriate actions and so doing, improve the development of mutual understanding and confidence with their commercial partners.
