

Committee on Technical Barriers to Trade

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COMMUNICATION FROM THE ISO

The attached communication¹, dated 16 June 1998, has been received from the ISO with the request that it be circulated to Members of the Committee.

Comité des obstacles techniques au commerce

COMMUNICATION DE L'ISO

L'ISO a fait parvenir au Secrétariat la communication ci-après, datée du 16 juin 1998, en lui demandant de la distribuer aux membres du Comité.

Comité de Obstáculos Técnicos al Comercio

COMUNICACIÓN DE LA ISO

Se ha recibido de la ISO, con ruego de que se distribuya a los Miembros del Comité, la comunicación adjunta de fecha 16 de junio de 1998.

¹In English only/En anglais seulement/En inglés solamente

DRAFT GUIDELINES ON MRAS UNDER DEVELOPMENT AT ISO/CASCO

1 The ISO General Assembly agreed in September 1994 that ISO/CASCO should prepare guidelines on MRAs in the non-regulatory sector, having noted that one of the reasons why internationally traded goods and services were subject to repetitive conformity assessment was 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. ISO/CASCO suggested that confidence by the user could be achieved through cooperation among conformity assessment bodies (calibration or testing laboratories, inspection bodies, certification bodies or others) and also among accreditation bodies, resulting in mutual recognition and promotion of each other's work in the market-place. ISO/CASCO Working Group 11 "CASCO working group for the development and maintenance of mutual recognition agreements (MRAs)" was established in 1994 to prepare the working draft.

2 The attached working draft (Annex 1) gives information (general background, essential elements and general procedure) on what seems to be the accepted best practice for establishing MRAs among conformity assessment bodies and among accreditation bodies within the non-regulatory sector.

3 The ISO Workshop on Mutual Recognition Agreements was held on 7 May 1998 in order to obtain input from attendees on MRAs so as to develop a document that adequately meets market needs for information (see the attached programme for the Workshop – Annex 2). This working document was circulated to Workshop participants for their consideration and comments in advance of the Workshop.

4 ISO/CASCO WG 11 intends feedback on this draft including input from Workshop participants (written comments on this draft and the results of discussion at the Workshop) to contribute to revision of this working draft and subsequent reissuance as a new ISO/IEC Guide.

5 The working draft focuses on guidance pertaining to MRAs among conformity assessment bodies and among accreditation bodies within the non-regulatory sector. ISO/CASCO would welcome any observation and comments from WTO/TBT Committee Members that might allow to increase the document's relevance, broaden its scope and ensure its compatibility with the views of the regulatory sector.

TBT members interested in submitting comments to be considered during the preparation of the next draft, as well as other interested parties, are invited to submit observations and comments on the working draft **by 31 October 1998**, to the attention of:

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**CASCO WG 11
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**ANNEX 1
(WORKING DRAFT)**

**CONSIDERATIONS ON ENTERING INTO
MUTUAL RECOGNITION AGREEMENTS FOR
THE ACCEPTANCE OF CONFORMITY ASSESSMENT RESULTS**

Report for the Workshop on MRAs

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CONSIDERATIONS ON ENTERING INTO MUTUAL RECOGNITION AGREEMENTS FOR THE ACCEPTANCE OF CONFORMITY ASSESSMENT RESULTS

Foreword

As the needs of industry, government and society change and grow, national conformity assessment systems acquire new elements and new layers of potential complexity. Suppliers of goods and services in today's world marketplace may fear that such activities could be created or implemented in an uncoordinated and redundant fashion. Mutual recognition of assessment results between the involved bodies is a step in the right direction.

Conformity assessment encompasses measures taken by suppliers, their customers, regulatory authorities and third parties to assess and attest conformity to specified requirements, in order to increase the confidence that goods and services actually conform to these requirements. The first level of conformity assessment covers evaluations - e.g. comparison to a standard - conducted by manufacturers, laboratories, inspection bodies, certification, registration bodies, or other bodies. The competence of the bodies operating at this first level is evaluated at a second level of conformity assessment, today structured within accreditation systems.

In response to commercial and public sector demands, agreements for the mutual recognition of conformity assessment results, frequently referred to as mutual recognition agreements, can be made between bodies providing services within each of these two levels of conformity assessment.

ISO/IEC Guide 2, Standardization and related activities - General vocabulary, paragraph 16.2 restricts the use of the term recognition arrangement to those "based on the acceptance by one party of results, presented by another party, from the implementation of one or more designated functional elements of a conformity assessment system". Willingness to accept the results presented by others, in other words "confidence", is inherent in the concept of mutual recognition agreements.

Considerable effort can be required to develop the confidence necessary for the mutual recognition agreement to deliver its intended benefits. The availability of ISO/IEC Guides specifying requirements to be met by bodies offering conformity assessment services makes this task easier. These Guides have been prepared by CASCO, the ISO's development committee on conformity assessment; its current work programme includes the review of existing guides and new responsibilities in the preparation of International Standards for new conformity assessment fields or the revision of existing Guides. Currently Guides exist for calibration and testing, product certification, quality system certification/registration, inspection, and accreditation. Determining that such bodies meet requirements from the applicable guides can contribute substantially to developing the confidence needed for successful mutual recognition agreements.

Introduction

The primary objective of conformity assessment is to provide confidence for users that requirements applicable to products, services, 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 cooperation between conformity assessment bodies and also between accreditation bodies across the borders, resulting in mutual recognition and promotion of each other work in the market place.

The principles and procedures of such a co-operation are described in this report.

1. Scope

This Report gives information (general background, essential elements and general procedure) on what seems to be the accepted best practice for establishing mutual recognition agreements (MRAs)² between bodies having similar conformity assessment activities carried out in the open market such as:

- the supply of conformity assessment in the non-regulated sector, intended to attest conformity with voluntary industrial requirements. Such services are provided by bodies which may be, among others calibration or testing laboratories, inspection bodies, certification bodies, called hereafter conformity assessment bodies.³
- the formal recognition of such bodies based on assessment by accreditation bodies that they are competent to carry out their specific tasks.

This Report is not intended to apply to Government-to-Government MRAs within the regulated area. However, the implementation of such agreements may be facilitated by MRAs covered by this Report.

2. Concepts of recognition/acceptance and types of agreements

Many different types of MRAs are possible; the wide range of possibilities does not permit a systematic presentation. However distinctions between private sector MRAs can be made on various different grounds such as:

- the subject related to: products, services, management systems...;
- the agreeing parties, their number (bilateral or multilateral), the geographical positions of the parties and their potential clients;
- the conformity assessment activities covered;

²Mutual recognition agreements are hereafter abbreviated MRAs, although they may be otherwise labelled (see 4.1)

³For the sake of clarity this Report considers accreditation activities separately from conformity assessment activities, due to the specific role of accreditation towards conformity assessment bodies. In this Report, MRAs between accreditation bodies are specifically considered.

- the obligations resulting from the agreements, e.g. in terms of recognition or acceptance;
- the legal liabilities of the parties;
- the trade benefits for the clients of the MRA's signatories.

From the point of view of a client of a conformity assessment body that is part of an MRA, the most important point may be to identify how to optimise the use of facilities offered by the MRA, for obtaining the attestations required on its different markets.

Example: Getting a certificate from body B on the basis of an assessment by body A, recognized by body B, may not have the same efficiency in time, cost and market acceptance as the reverse (getting the recognition by A of an assessment made by B). The choice of A or B as entry point depends also on the underlying assessment requirements, whether they are or are not harmonized.

2.1. Recognition and acceptance

2.1.1 Recognition and acceptance within an MRA

The formal definition of a recognition arrangement in ISO/IEC Guide 2 refers to the acceptance by one party of the work of another party, but does not distinguish between recognition and acceptance. However MRAs may have different binding effects which could be reflected by a more precise terminology.

MRAs may be such that the parties agree on the validity of the results of each other's activity, so that they declare that their services have the same credibility and, when the relevant requirements or criteria have been harmonized, that they are equivalent. Beyond such statements, they may also need and agree to use the assessment work of the other parties to grant their own certificates/conformity assessment documents.

In other words, the first degree of recognition, a positive judgment of value, can be followed by a second which implies a transfer of responsibility for the conformity assessment work: legal action can be taken against the accepting party for mistakes in the external assessment results used for its own decisions.

Some MRAs may not require a party to use the services provided by another party. When the purpose of a MRA is to give evidence that the services directly offered by each party are equivalent, the essence of the MRA is the *recognition* by each party of the equivalence of the activities of the other parties. For example, MRAs between accreditation bodies are related to fully harmonized accreditation activities, so that accreditors which are parties in an MRA can refrain from re-accrediting bodies already accredited by their counterparts in the MRA.

In other MRAs, the activity of the signatories may be based on the *acceptance* by one party of results presented by another party as arising from the implementation of one or more designated functional elements of a conformity assessment system. There is unrestricted acceptance of each other's work to produce such results. The typical example is an MRA between product certification bodies providing for the recognition of each other's certificates.

In brief, recognition and acceptance should be linked to a precise context in order to have their full significance. From the above, they might most usefully be defined as follows:

« recognition » refers to the endorsement/statement of equivalence of an other body's certificate, the issuer of which remains legally liable for the activities covered by it.

« acceptance » refers to the use of another conformity assessment body's specific results, with transference of legal responsibility to the party using those results.

2.1.2 Acceptance is a term also used in another context. "Technical level" and "acceptance level" are used to cover respectively the production of results by the parties to an MRA, e.g. harmonized accreditation certificates) and their possible acceptance by bodies which are not parties to the MRA as a basis of their decision whether or not to rely on such results for their own needs e.g. use of accreditation certificates as (sole) basis for the designation of conformity assessment bodies in the regulated sector.

In all cases, the parties to an MRA will undertake to promote such an acceptance by the potential users of their services of the work of the other signatories on the same basis as their own.

2.1.3 In Government to Government MRAs or agreements between regulatory authorities *acceptance* and *recognition* of conformity assessment procedures have specific binding connotations. The objective of such agreements is to provide effective access throughout the territories of the Parties (the States, the Authorities). Conformity assessment bodies designated to perform the relevant conformity assessment procedures provide their services without direct involvement in recognition or acceptance of their work, which is an issue under the sole responsibility of the governments/authorities.

2.2. Signatories and related bodies

The signatories to an MRA between conformity assessment bodies may have relationships with other conformity assessment bodies within or outside that MRA. For example:

- The signatories to an MRA may be a sub-grouping of a broader grouping of similar conformity assessment bodies. That broader group may itself have established a formal relationship amongst its members, such as a Memorandum of Understanding listing their common interests and objectives. Some MOUs include the establishment of an MRA as one of the group's objectives and may define the acceptance criteria and procedures to be used for establishing it.
- Most MRAs do not preclude the rights of their signatories to hold other bilateral or multilateral agreements with other signatories or non-signatories. These separate agreements do not, however, place any obligations for them to be accepted by the other members of an MRA.
- Some MRAs may allow the use of subcontracting, where a signatory may have part of its conformity assessment activity undertaken by another body which is not a signatory to the MRA. Such MRAs would usually set clear limits for such subcontracting and the need for a formal contract between the parties.

2.3. Determining factors

In each national market the structure for conformity assessment meets specific needs expressed by the legislator and by the behaviour of buyers, users and consumers. Consequently, manufacturers may have to subject their products to different checks according to the markets on which they intend to sell the products.

The provisions of the Agreement on technical barriers to trade (TBT agreement) of the World Trade Organization contribute to ensure that the signatory Governments do not impose or favour conformity assessment procedures which create unnecessary obstacles to international trade. Where, on the other hand, these obstacles are the result, not of legal requirements, but of the free play of market demand - i.e. there is no direct or indirect influence from the public authority - the means for their gradual removal must be sought on the one hand in the harmonization of the operation of national conformity

structures and, on the other hand, in measures to promote MRAs between these structures to bring them gradually towards the establishment of common systems of conformity assessment.

The difficulties faced by many industries expecting benefits from MRAs and the associated infrastructure 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. In general the difficulties in mutual recognition rise sharply for products characterized by short market lives and associated high innovation rates (catalysed by fierce global competition), by rising complexity and by global consumer and industrial markets.

Action taken on three levels - namely harmonization of requirements in the regulated and non regulated sectors, mutual recognition of national regulations and the approximation of structures within systems of voluntary conformity assessment - may be ineffective in practice unless they solve the same problem and satisfy the same need, that is to say the need to create the conditions which will enable confidence to grow and become fundamental to the operation of mutual recognition.

Confidence in the new systems will only be developed if the systems not only work properly but are seen to work properly. Thus transparency and competence are both equally essential in order to generate confidence.

2.4. Facilitation

MRAs can facilitate trade whether or not underlying requirements are or can be harmonized. MRAs may however bring the greatest trade benefits in sectors where relevant requirements have been harmonized; the necessary confidence between MRAs' partners may be more rapidly gained and maintained in these circumstances. Harmonization of the assessment of the competence of such bodies through accreditation has reached international level with the development of international organizations (IAF, ILAC).

The TBT agreement encourages the recognition by its Members of the conformity assessment procedures of other Members, even if these differ from their own. The key objective for each country is to improve the access of its products to the market of the other country, to facilitate trade and to reduce the costs and the time taken to have a product tested and approved for the other country's market.

The recognition of equivalence of applicable technical regulations or standards remains a difficult issue, so that many government-to-government mutual recognition agreements are less ambitious. Such agreements typically provide for the acceptance or recognition by each party of results of conformity assessment procedures produced by the other party's conformity assessment bodies or authorities in assessing conformity to the importing party's requirements; and for the competence of the conformity assessment bodies to be assessed by accreditation bodies which are signatories of a MRA.

In terms of the specific requirements applied by the parties, the fact that parties may base their product standards, regulations, and criteria for accepting bodies on established international or regional standards/guides should enable more bodies to participate in the agreement and offer their services to exporters.

Signatories of MRAs have the responsibility to consider how they assess their own competence and that of the bodies providing conformity assessment services used in the MRA. Their needs may be satisfied, at least partly, by assessment results provided by external systems such as national accreditation systems. As decision makers, and according to the extent of their involvement in the

acceptance of conformity assessment results (see 2.1.1), they add their own assessment when their criteria are not already covered.

Different types of conformity assessment activities may be interrelated in a hierarchical manner. For example, metrology provides a basis for testing which in turn plays a key role in many forms of certification of products. Similarly, certification of personnel who conduct quality system auditing plays a key role in certification/registration of quality management systems. MRAs in such related conformity assessment disciplines can also be related. Specifically, MRAs at lower levels of these hierarchies can generally facilitate MRAs at the higher levels. For example, an MRA between metrology authorities significantly facilitates MRAs between laboratories relying upon these authorities. Such MRAs among testing labs may facilitate MRAs between product certifiers.

3 Building confidence in conformity assessment bodies

3.1 General

A prerequisite for MRAs is full confidence between the signatories that the involved conformity assessment bodies all possess the same competence and work in an appropriately similar way. The process for building confidence can utilise internationally agreed requirements for conformity assessment bodies as well as methods for demonstrating compliance with those requirements.

3.2 Internationally agreed requirements

Internationally agreed requirements for conformity assessment bodies have been documented in the ISO/IEC Guides. The relevant Guides are described in Annex B.

3.3 Demonstrating compliance to internationally agreed requirements

Several methods of demonstrating conformity to the requirements set out in ISO/IEC Guides are commonly used. Their choice is often negotiated as part of the MRA, according to the level of conformity assessment at stake: e.g. the level of testing/inspection/certification bodies, the level of accreditation bodies or the level of regulatory authorities involved in approval. Within an MRA, the two basic methods described hereafter are not exclusive and may be used for different purposes: e.g. direct evaluation of the signatories acting as product certification bodies and indirect evaluation of the testing laboratories they use.

3.3.1 Direct method

This method is chosen when confidence between the potential signatories of an MRA can be created through direct contacts between them. The technical tool is a « peer evaluation » in which each of the potential signatories is evaluated by or on behalf of all the others.

For practical reasons the involved bodies often set up an evaluation group which carries out the demonstration of conformity on behalf of the other members.

In addition to this evaluation of conformity, the partners may cooperate operationally by arranging meetings, witnessing, or discussing practical test cases. This cooperation builds confidence between the partners on an ongoing basis.

3.3.2 Indirect method

In this method, confidence between the participants is based on the recognition of assessment results provided by external assessment systems, in particular accreditation of the participants by harmonized accreditation bodies, e.g. accreditors which are members of an MRA.

Participants are assessed by one or more bodies, often specified in the MRA, selected for their competence, excluding those conducting the conformity assessment activities covered by the MRA. This method does not directly involve the conformity assessment bodies in the confidence building mechanism for the MRA.

The selected bodies may utilise a variety of mechanisms to provide ongoing confidence that requirements continue to be met. Current use of the indirect method is within Government-to-Government MRAs, e.g. the MRAs between the European Union and various third countries. In practice, the usual mechanism is to require formal accreditation of the bodies producing conformity assessment results.

A MRA between accreditation bodies by which they recognize each other's work may support the MRA between the bodies being evaluated for conformity with international requirements.

Whatever the method, all bodies or individuals that carry out such evaluations under a MRA should have the same competence and operate in an identical or compatible manner. Thus the principle of operational cooperation between them should apply in any case.

4 Elements of the agreement

The following description is intended to provide a comprehensive list of possible elements in MRAs without implying that all such elements are required in all agreements. Several agreements are presented in Annex A, as illustration of the material presented below.

4.1 Background

Normally the text of a mutual recognition agreement will have an Introduction or Preamble describing briefly the history behind the establishment of the agreement or details of the needs which it is intended to address. (For example, facilitation of trade, reduction or elimination of multiple assessment activities, support for regulatory requirements etc.).

After that the text will define the types of organizations which are signatories to the agreement, including, if needed, the details of the legal status of the signatories and geographical or other limitations on existing, or future, signatories.

The titles chosen for mutual recognition agreements vary. Words such as "agreements" and "arrangements" may have a specific use in a government context; some countries prefer the use of the terminology "mutual recognition arrangements" in the voluntary sector rather than "mutual recognition agreements". Accreditation bodies are used to signing "multilateral agreements", called MLAs. Certification bodies often refer to "certification agreements".

4.2 Objectives and scope of an agreement

A mutual recognition agreement should clearly state:

- the purposes or aims of the agreement together with the types of redundant conformity assessment activities to be eliminated;
- the sectoral areas covered, which may be restricted to conformity assessment of specified industrial technical, regulatory, voluntary or geographical sectors;
- the activities or outcomes of conformity assessment that will be recognized or accepted upon full implementation of the MRA. For example, existing MRAs between accreditation bodies recognize

the compliance with international codes of practice of other signatory accreditation bodies as well as the equivalence of competence of the bodies they accredit;

- the obligations beyond recognition or acceptance of the results of conformity assessment activities; the scope may include obligations to mutually promote the acceptance of other parties to an agreement in their own economies or regions, and to provide mechanisms to investigate and resolve any problems in terms of their recognitions. For example, accreditation bodies recommend and promote, to all users in their own countries, the acceptance on an equal basis with those of their own accredited bodies of the reports/certificates from the bodies that are accredited by the other accreditation bodies, which are signatories to the MRA.

4.3 Conditions for entry into an agreement, openness principle

Mutual recognition agreements usually prescribe a set of pre-conditions for entry into the agreement. Often these conditions relate to:

- the confidence building mechanism or activities needed to fully implement the MRA such as demonstrating competence and compliance with the relevant ISO/IEC Guides or other codes of practice (see chapter 3);
- the openness of the agreement. Applicant wishing to join a MRA should be treated on the same basis as the existing members of the agreement without discrimination or privilege.

The first potential applicants may be those belonging to a group of bodies initiating the MRA, eg signatories of a Memorandum of Understanding (MoU) acknowledging their intention to progress toward the MRA. A legitimate concern for the acceptance of applicants from third countries - not involved in the initiation of the MoU - is the reciprocity of access to the use of established national conformity assessment schemes run by an applicant, in at least his own country. It is of course provided that in case of such reciprocity the MRA signatories also have to meet the requirements of that foreign scheme.

The financial investment undertaken over the years by the existing members of a MRA may be compensated by administrative conditions on new members (e.g. probationary period, entrance fee) as long as these conditions are reasonable and non-discriminatory.

Agreements with other MRAs may facilitate the recognition of activities in third countries (see 4.4).

The pre-conditions for entry into a MRA may be defined in the text of the agreement itself or in a separate set of policy or procedure documents.

4.4 Relationships with other agreements or activities

Some mutual recognition agreements may interact with other related activities. For example, a MRA in the voluntary sector may be used for acceptance purposes in a regulated sector. Additionally, some MRAs may interact directly with other MRAs. For example, there is an emerging trend to utilize agreements between regional mutual recognition agreement groups to make the establishment and maintenance of international networks of agreements more cost-effective. (See also paragraph 2.4). A description of these interactions should be included in the text of the agreement.

4.5 Activities and obligations resulting from the agreement

The most significant part of a mutual recognition agreement is the statement of the activities which the parties to the MRA formally agree to undertake, recognize or accept.

Typical items included in existing agreements are:

- 4.5.1 Activities and outcomes of conformity assessment mutually recognized or accepted by the signatories;
- 4.5.2 Promoting the equivalence of such activities or outcomes in the respective territories of the signatories;
- 4.5.3 Codes of conduct and ethics for the parties of a MRA to safeguard fair competition in the market place;
- 4.5.4 Investigation and resolution process for any complaints resulting from the mutual recognition;
- 4.5.5 Obligations to advise other signatories to the MRA of any significant changes occurring in the status or operational practices of a signatory;
- 4.5.6 Commitments or agreed conditions for entry to and continuing membership of a mutual recognition agreement group (or partnership in a bilateral MRA);
- 4.5.7 Details of any ongoing surveillance activities, and their frequency, which the signatories agree are necessary to maintain confidence in the competence of the conformity assessment bodies under the MRA;
- 4.5.8 Conditions under which the terms of the agreement may be changed or terminated;
- 4.5.9 Where relevant, any matters which the signatories agree to maintain as confidential information;
- 4.5.10 Details of any dispute resolution procedure agreed by the signatories.
- 4.5.11 Any legal obligations or liabilities which the signatories agree to undertake as a result of their membership of a MRA, and possibly requirements on insurance to cover their liability related to their acts or omissions occurring whilst operating the MRA. An alternative in respect of claims is that the indemnities are provided to the body by its government.

4.6 Duration of an agreement

The agreement will indicate its commencement date and may state a period for its validity and/or the conditions under which it may be terminated.

4.7 Information exchange

Mutual recognition agreements may include text identifying the contact personnel who are responsible for updating and exchanging information between the signatories to an agreement and/or publishing details of the agreement in their respective territories.

4.8 Common marks and documents

Mutual recognition agreements may describe conditions for use of a common mark and/or document by the signatories, or rules for making reference to other signatories' or parties' marks and/or documents as a result of participation in the agreement.

4.9 Agreement documentation

Mutual recognition agreements may list documentation relevant to the agreement. Examples of such references may be codes of practice or requirements such as ISO/IEC Guides, any special definitions needed for the purposes of the agreement, or any separate published procedures or policies covering preconditions for membership of the agreement.

4.10 Signatories

The text of a mutual recognition agreement will normally contain the titles and signatures of personnel of appropriate authority representing each signatory including the date when each signature was given.

ANNEX A

Examples of practices and mutual recognition agreements

The concepts noted above are used in the following examples to characterize various mutual recognition agreements now in use or under development.

1. Possible binding effects

Seen from the extent to which mutual recognition agreements have a binding effect, the following agreements exist;

1.1 A mutual declaration of unrestricted acceptance of each other's work.

This type of agreement obliges the signatories to promote the acceptance of the work of the other signatories on the same basis as their own.

This type of agreement sometimes precludes the signatories from performing work in each other's territorial jurisdiction.

1.2 The mutual acceptance of each other's test, inspection and assessment reports.

This type of agreement obliges the signatories to accept the test or assessment report of another signatory, but can leave open the possibility to perform additional tests, as well as verification tests, before deciding whether the product fully conforms to local requirements. Mutual commitment of the signatories to exchange information is a must.

This type of agreement is useful, e.g. in case the report of Signatory A does not cover all criteria of Signatory B, or if one signatory only performs a testing, inspection or an assessment function. The agreement, of course, is then limited to the mutual use of each other's reports. This agreement is also helpful to solve the geographical problems of marketing goods in countries other than the one in which they are manufactured.

This type of agreement helps an applicant in obtaining the certificate/mark/registration or accreditation of more signatories.

1.3 A central register or list is formed which contains all products, quality systems, etc. that are "approved" by each single signatory to the agreement.

This type of agreement obliges at least one signatory to accept that his own approvals appear in a single register or list, together with the approvals of the other signatories. The sheer volume of information involved obviously limits such a system to a few participants.

The registration is often accompanied by the name or other identification of the signatory that gave the "approval". This type of agreement is useful if the results of the mutual recognition agreement need not be communicated by a uniform certificate and/or mark directed at the general public, but are rather directed at industrial buyers or government agencies.

1.4 The signatories offer activities to a particular applicant, on behalf of the other signatories.

In this type of agreement, it is possible that Signatory A issues its own approval, and/or the approval of Signatory B. This type of agreement is useful if several bodies have an established reputation in a particular territorial area or branch.

This type of agreement may make use of a uniform mark in combination with the mark or symbol of each signatory, the approval of which was obtained.

1.5 A single system (e.g. a certification or inspection system) which participants from one or more countries agree to abide by.

A single system offers the optimum solution in relation to the removal of barriers to trade particularly when a uniform marking procedure is included into the system, and this can lead automatically to an international system.

Participation in the system is based on an undertaking to follow the procedures laid down in the system. A simple system can be managed by a steering committee which establishes and revises the general regulations of the system. In this steering committee all participating bodies should have the possibility of monitoring the running of the agreement and of resolving any dispute that may arise. A single system is useful if no other individual mark or certificate of the participants exists, or is desired.

2. Harmonization of requirements

Some "basic" requirements to accelerate the process of obtaining confidence in conformity assessment results are:

- harmonized requirement of testing and inspection method to be employed;
- harmonization of the elements tested, inspected or assessed, that together make up the approval procedure;
- harmonization of the test, inspection, or assessment report form;
- harmonization of procedures for evaluation of the report, resulting in a decision on approval or not;
- harmonization of the means used to communicate a positive or negative result of the approval procedure to involved parties (e.g. certificates, marks of approval);
- harmonized application procedures followed by the testing, inspection, and certification bodies involved;
- harmonized methods of evaluation of measurement facilities and calibration of test equipment;
- harmonized methods of control of environmental test conditions;
- harmonization of accreditation procedures;
- harmonized methods of evaluation of personnel.

3. Examples in use or under development

3.1 Agreements between accreditation bodies

- International Accreditation Forum - Multilateral recognition agreement (IAF MLA).

This Agreement is based on the equivalence of accreditation programmes operated by accreditation body Members verified through peer review among accreditation body Members. IAF encourages the establishment of regional groupings of accreditation bodies.

The participating accreditors of quality system certification registration bodies will recognize each other's competence. A peer evaluation process operated by the signatories provides the confidence building mechanism for this mutual recognition agreement. Stakeholders may limit this mutual recognition agreement since they must first develop confidence in all the other signatories before further accepting the common logo as equivalent to the logos of the individual signatories.

In January 1998, the IAF-MLA had 13 signatories evaluated either by IAF Peer evaluation, or by a Regional Peer evaluation, recognized after IAF Peer evaluation of the Regional MRA involved (the multilateral agreement of the European Accreditation of Certification).

- Asia Pacific Laboratory Accreditation Co-operation. Mutual recognition arrangement (APLAC MRA)

This is a typical regional agreement between laboratory accreditation bodies, as a means by which 20 accreditors who are signatories of a Memorandum of Understanding (MoU) can more formally recognize one another's accredited laboratories.

Assessments (peer evaluation) of signatories to the Arrangement take place at intervals of approximately four years for the purpose of assuring that the signatory bodies continue to meet the requirements of ISO/IEC Guide 58.

This Arrangement by itself does not provide any recognition or accreditation under any law or regulation in the economy of any signatory body. However, the signatories intend to promote to their governments the use of this Arrangement in support of recognition arrangements in the regulated sector.

3.2 Agreements between certification bodies

- International Electrotechnical Commission (IEC) - CB Scheme (CB = certification body)

IECEE CB Scheme -The CB scheme is an acceptance mutual recognition agreement since the signatories agree to accept under prescribed conditions test data reports from the other signatories. Confidence is built using peer evaluation of testing capability. Legal limitations exist for this mutual recognition agreement since some of the signatories have legal obligations regarding how they may operate as a certification body. Stakeholder limitations may exist as well. However, this mutual recognition agreement between the testing laboratory functions of certification bodies is being used a precursor to discussions for a new scheme to encompass a broader range of certification functions. The CB scheme is multilateral approximation of similar bilateral mutual recognition agreements between product certifiers.

- The International Certification network (IQNET)

IQNET is a network of non-profit distributing bodies which operates a multilateral agreement in the field of quality system certification/registration. Equivalence and confidence are assured by an initial

evaluation and periodic assessment of its members to ISO/IEC Guides, International standards and peer review rules. IQNET partners support each other's certificates and certification marks in presentations and publications. The members use the IQNET Mark and the IQNET Registration documents.

- International Electrotechnical Commission (IEC) - IECEX Scheme

IECEX Scheme provides a means for manufacturers of electrical equipment for explosive atmospheres to obtain certificates of conformity that will be accepted in all participating countries as equivalent to their national certification. A certificate of conformity may be obtained from any certification body accepted into the Scheme. The certificate will attest that the manufacturer operates a quality system meeting the requirements of this Scheme and ISO 9002. Manufacturers holding certificates of conformity may affix the IECEX Mark of Conformity to equipment that they have verified as complying with the certified design. The objective of the Scheme is world-wide acceptance of a single standard, a single certificate and a single mark.

This MRA is a typical example of certification of regulated products with potential involvement of Governments.

ANNEX B

International requirements

The following ISO/IEC Guides contain requirements for the indicated type of conformity assessment body:

ISO/IEC Guide 25:1990	General requirements for the competence of calibration and testing laboratories
ISO/IEC Guide 39:1988	General rules for a model third-party certification system for products
ISO/IEC Guide 58:1993	Calibration and testing laboratory accreditation systems - General requirements for operation and recognition
ISO/IEC Guide 61:1996	General requirements for assessment and accreditation of certification/registration bodies
ISO/IEC Guide 62:1996	General requirements for bodies operating assessment and certification/registration of quality systems
ISO/IEC Guide 65:1996	General requirements for bodies operating products certification systems

In addition, as a complement to these documents, some accreditation bodies have cooperatively produced interpretative documents for some of the guides in order to provide for their uniform interpretation. The interpretative documents were originally meant for the accreditation bodies themselves but have become of great importance also for the bodies that are the objects of accreditation. It is expected that the elaboration of the interpretative documents/guidelines should be open to the interested parties to ensure general acceptance and adherence. Such documents after experimentation with their application would become part of the published literature available on the subject.

ANNEX C

DEFINITIONS (from ISO/IEC Guide 2: 1996)

Conformity assessment (12.2)

any activity concerned with determining directly or indirectly that relevant requirements are fulfilled.

NOTE - Typical examples of conformity assessment activities are sampling, testing and inspection; evaluation, verification and assurance of conformity (supplier's declaration, certification); registration, accreditation and approval as well as their combinations.

conformity assessment body (12.3)

body that conducts conformity assessment

conformity assessment system (12.4)

system that has its own rules of procedure and management for carrying out conformity assessment

certification (15.1.2)

procedure by which a third party gives written assurance that a product, process or service conforms to specified requirements.

accreditation (12.11)

procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks

accreditation body (17.2)

body that conducts and administers an accreditation system and grants accreditation

approval (16.1)

permission for a product, process or service to be marketed or used for stated purposes or under stated conditions

recognition arrangement (16.2)

agreement that based on the acceptance by one party of results, presented by another party, from the implementation of one or more designated functional elements of a conformity assessment system

NOTES

- 1 Typical examples of recognition arrangements are testing arrangements, inspection arrangements and certification arrangements
2. Recognition arrangements may be established at national, regional or international level
3. An agreement limited to declaration of equivalence of procedures without acceptance of results does not meet the above definition

unilateral arrangement (16.2)

recognition arrangement that covers the acceptance of one party's results by another party

bilateral arrangement (16.4)

recognition arrangement that covers the acceptance of each other's results by two parties

multilateral arrangement (16.5)

recognition arrangement that covers the acceptance of each other's result by more than two parties

third party (12.9)

person or body that is recognized as being independent of the parties involved, as concerns the issue in question

NOTE - Parties involved are usually supplier (« first party ») and purchaser (« second party ») interests

ANNEX 2

ISO Workshop on Mutual Recognition Agreements 7 May 1998 Programme

09:00 Opening of the Workshop

Welcome

Lawrence D. Eicher, ISO Secretary-General

Introduction

John L. Donaldson, Chairman, ISO Committee on Conformity Assessment (CASCO)

Workshop moderator:

Takashi Ohtsubo, Japan Accreditation Board (JAB)

09:30 The CASCO Perspective

Lucien Tronel, Association française de normalisation (AFNOR)

A Regional Perspective

John Hulbert, Joint Accreditation System of Australia and New Zealand (JAS-ANZ)

A World Perspective

Vivien Liu, World Trade Organization (WTO)

10:30 Coffee break

Keynote speeches

(There will be an opportunity to ask questions after each presentation)

11:00 Conditions for Establishing MRAs

Bill Henderson, International Laboratory Accreditation Cooperation (ILAC)

11:20 Implementing Agreements

Clif Johnston, International Electrotechnical Commission (IEC)

13:00 Lunch

14:30 Break-out sessions

1) Accreditation bodies

Rapporteur: Harry Gundlach, International Accreditation Forum (IAF)

Facilitator: George Lofgren, Registrar Accreditation Board (RAB)

2) Conformity assessment bodies

Rapporteur: Ian Day, Independent International Organization of Certification (IIOC)

Facilitator: Ivar Paljak, Standardiseringsen i Sverige (SIS)

3) Producers, suppliers, distributors

Rapporteur: Klaus Greefe, Zentralverband Elektrotechnik- und Elektronikindustrie e.V. (ZVEI/IEC)

Facilitator: David Rundle, AMP Incorporated

4) Developing country interests

Rapporteur: Gene Hutchinson, Trinidad and Tobago Bureau of Standards (TTBS)

Facilitator: Reinaldo Balbino Figueiredo, Instituto Nacional de Metrologia, Normalização e Qualidade Industrial (INMETRO)

5) General interest

Rapporteur: Drew Andison, APEC Standards Conformance Sub-Committee - Department of Industry, Science and Tourism (Australia)

Facilitator: John McDonald, Consultant and BSI Technical Committee Chair

11:40 *Benefits of MRAs*

John Wilson, Transatlantic Business
Dialogue
(TABD) - ITI

12:00 *Questions of Liability*

Sven Nystrom, Swedish Board for
Accreditation and Conformity Assessment
(SWEDAC)

12:20 *Measures of Effectiveness*

Gordon Gaddes, European Organization for
Testing and Certification (EOTC)

12:40 *Regulatory Implications*

Andreas Julin, European
Commission/Direction générale III (EC/DG III)

16:30 Reporting session

Presentations by rapporteurs

17:20 Concluding remarks

John L. Donaldson, CASCO Chairman

17:30 Close of the Workshop
