



Secretariat

INTERNATIONAL ELECTROTECHNICAL COMMISSION

**IEC SCHEME FOR CERTIFICATION TO STANDARDS FOR SAFETY OF
ELECTRICAL EQUIPMENT FOR EXPLOSIVE ATMOSPHERES (IECEX
SCHEME)**

Ex Management Committee, ExMC, ExTAG and WG1

**Title: C/1259/DV Draft ISO/IEC Guide 68: Arrangements for the
recognition and acceptance of conformity assessment results**

Introductory Note

Doc C/1259/DV Draft ISO/IEC Guide 68: Arrangements for the recognition
and acceptance of conformity assessment results has been issued to IEC
National Committees for comment.

The IECEX Secretariat is circulating this document to members of ExMC,
ExTAG and WG1 for useful information and for consideration in the revision
of the IECEX Scheme Rules and Procedures.

Should you wish to submit any comments you may do so through your
National Committee of the IEC

As this document may be discussed within CAB the Secretary would also be
pleased to receive any comment that might be considered relevant to the
Scheme.

Address: IECEX Secretariat c/o QAS GPO Box 5420 Sydney NSW 2000 Australia	Visiting Address: 286 Sussex Street Sydney NSW 2140 Australia	Tel: +61 2 8206 6000 Fax: +61 2 8206 6032 Email: chris.agius@qas.com.au Internet address: www.iecex.com
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C/1259/DV

2002-02-15

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COUNCIL

SUBJECT

Draft ISO/IEC Guide 68: Arrangements for the recognition and acceptance of conformity assessment results

BACKGROUND

Draft ISO/IEC Guide 68 has been prepared in accordance with the ISO/IEC Directives, Part 1 2001, Annex A by CASCO WG 11: Mutual Recognition Agreements. Drafts were circulated to IEC National Committees for comment under references C/1145/DC in February 1999 and C/1205/DC in October 2000.

The draft is now circulated for voting for approval of publication as ISO/IEC Guide 68, in accordance with clause A.4 of the Directives.

ACTION

National Committees should submit their votes using the voting form 1259e.doc to gb@iec.ch before **2002-06-15**.



DRAFT ISO/IEC GUIDE 68

Secretariat: **CASCO**

Voting begins on
2002-01-10

Voting terminates on
2002-05-10

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Arrangements for the recognition and acceptance of conformity assessment results

Accords concernant la reconnaissance et l'acceptation des résultats d'évaluation de la conformité

ICS 03.120.20

In accordance with the ISO/IEC Directives, Part 1, 2001, clause A.5, this draft Guide is submitted to the ISO and IEC national bodies for approval. Ballot papers should be returned to the ISO Central Secretariat by the date shown above.

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

Guides are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft Guides adopted by the responsible Committee or Group are circulated to the national bodies for voting. Publication as a Guide requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this Guide may be the subject of patent rights. ISO and IEC shall not be held responsible for identifying any or all such patent rights.

ISO/IEC Guide 68 was prepared by ISO Committee on Conformity Assessment (ISO/CASCO).

Annex A of this Guide is for information only.

Introduction

The primary objective of conformity assessment is to provide confidence for users that requirements applicable to products, services and systems have been met. Such confidence, in turn, directly contributes to the market acceptance (which may include regulatory compliance) of those products, services and systems.

One of the reasons why internationally traded goods and services are subject to repetitive conformity assessments 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, regulators and other users.

Such user confidence can be achieved through cooperation among conformity assessment bodies and/or accreditation bodies, resulting in mutual recognition and promotion of each participant's work across borders.

The elements and procedures used so far and found practical for establishing and maintaining such cooperations are described in this Guide.

Arrangements for the recognition and acceptance of conformity assessment results

1 Scope

This Guide provides an introduction to the development, issuance and operation of agreements for the recognition and acceptance of results produced by bodies undertaking similar conformity assessment and related activities. The activities to which this guidance is intended to apply are those related to the conduct of unregulated marketplace transactions extending across borders from one country to another. While agreements among governments pertaining to transactions of regulated goods and services may take into account the agreements addressed by this Guide, the guidance provided here is introductory and general in nature and does not specifically address any special requirements that governmental agreements might generate.

Some countries may be concerned about having the necessary human and institutional resources with respect to conformity assessment infrastructures which would permit them to participate in such agreements. Guidance on the acquisition and development of the resources required for this is beyond the scope of this Guide.

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this Guide. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this Guide are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO/IEC Guide 2:1996, *Standardization and related activities — General vocabulary*

3 Terms and definitions

For the purposes of this Guide, the terms and definitions given in ISO/IEC Guide 2 and the following apply.

NOTE Clauses 12 to 17 of ISO/IEC Guide 2:1996 (on conformity assessment) are under revision as ISO/IEC 17000, *Conformity assessment — General vocabulary*, which is under development.

3.1

recognition arrangement

arrangement whereby participating bodies acknowledge to others that the conformity assessment results of the participants have been produced by competently performed, equivalent procedures

3.2

acceptance arrangement

arrangement whereby participating bodies use participants' results when these are acknowledged as having been produced by competently performed, equivalent procedures

3.3

agreement group

bodies that are signatories to the agreement on which an arrangement is based

3.4

peer assessment

evaluation of a body, against specified requirements, by representatives from other bodies in, or candidates for, an agreement group

NOTE In this Guide “agreement” refers to the document signed by the participants of an agreement group.

4 Elements of an agreement

4.1 General

A comprehensive list of elements contained in agreements related to conformity assessment results is given in 4.2 to 4.12. Not all elements are required in every agreement, but generally most of the elements will be addressed in an agreement.

4.2 Title

The term “mutual recognition agreement” (MRA) is sometimes used when the agreement has a legally binding nature, such as a mutual recognition agreement in regulatory fields among government authorities from different countries. Consequently, the term “mutual recognition arrangement” (MLA) is commonly used in voluntary applications, such as accreditation and certification/registration systems.

4.3 Introduction

Normally, the text of an agreement has an introduction or preamble briefly describing the reason for the agreement, the history behind its establishment, and details of the needs which it is intended to address (for example, facilitation of trade or reduction of multiple assessment activities).

4.4 Signatories

Typically, the text specifies the organizations or types of organization which are signatories to the agreement, including, if needed, details of the legal status of the signatories and geographical or other eligibility conditions for existing or future signatories.

4.5 Scope

This section normally clearly specifies the category of product and/or sector and conformity assessment activity covered by the agreement.

4.6 Conditions for eligibility

Agreements usually specify a set of prerequisites for entry of eligible bodies into the agreement. These conditions are generally document-based (see the bibliography) and include satisfactory demonstration of the following:

- a) conformity with all requirements of the relevant ISO/IEC Guides and International Standards that are applicable to the bodies eligible to be signatories;
- b) procedures that result in competently performed evaluation utilizing ISO/IEC Guides and International Standards within the scope of the agreement;
- c) availability of resources to sustain commitment and the ability to continue to meet the obligations to signatories.

4.7 Individual obligations of signatories

A significant part of the agreement is the statement of what the signatories agree to undertake or other requirements to which they commit themselves. Typical items of commitment included in existing agreements are as follows:

- a) recognition of the equivalence of the conduct of activities within the scope of the agreement by its signatories;
- b) acceptance of results produced by other signatories as applicable within the scope of the agreement;
- c) promotion of public awareness of the equivalence of the performance and, where applicable, the results of the signatories to the agreement;
- d) maintenance of the confidentiality of information so designated with respect to other signatories;
- e) acceptance of legal and liability responsibilities, as well as responsibility for notifying other signatories of significant changes in status.

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

4.8 Collective obligations of signatories

Another significant part of the agreement is the statement of what the signatories agree to undertake collectively. Items of collective responsibility often appearing in agreements elaborate on conditions for the following:

- a) evaluation and resolution of complaints relative to the operation of the agreement;
- b) maintenance and operation of an ongoing system of surveillance and/or re-assessment on a periodic basis;
- c) processing and resolution of disputes occurring within the group within the scope of the agreement;
- d) use of a common logo and/or document by the signatories, if so agreed.

NOTE Signatories may limit the scope of the arrangement before accepting the use of common logos since they must first develop confidence among themselves.

4.9 Relationships with other agreement groups

Some international agreements provide for relationships with other agreement groups. The typical relationship is with regional groupings of similar scope. To effect these relationships, an agreement will probably have conditions for entry and continuing membership of the regional grouping, which ensure adherence by regional group signatories to the conditions given in 4.7.

4.10 Duration of the agreement

The commencement date of the agreement will be indicated and possibly also the period of validity of the agreement and the conditions under which participation by one or more of the signatories may be suspended or withdrawn, or the agreement as a whole may be terminated.

4.11 Points of contact

Most agreements include identification of the signatory contact personnel who are responsible for updating and exchanging information, publishing details of the arrangement in their respective territories, and identifying when a signatory is unable to fulfil its obligations under the arrangement.

4.12 Official signatures

The text of an agreement normally contains the signatures and titles of personnel of appropriate authority representing each body which is a signatory to the agreement. The date of each signature is also recorded.

4.13 Conditions for amendment

The text of an agreement normally contains conditions with which (and the procedures by which) the terms of the agreement may be amended or otherwise altered.

NOTE Annex A lists some organizations that have agreements in place and gives uniform resource locations (URLs) for their websites that contain the texts of the agreements. These can be consulted to see how the elements documented here are actually represented in agreements.

5 Establishing the agreement group

5.1 Demonstrating compliance to internationally agreed requirements

5.1.1 In order to establish an agreement group, signatories need full confidence that potentially eligible bodies are all competent and work in an appropriately similar way. The process for building and maintaining confidence utilizes methods for demonstrating conformity with internationally agreed requirements for the bodies involved.

5.1.2 Several methods of demonstrating conformity to the requirements set out in ISO/IEC Guides and International Standards are commonly used. Their choice is often negotiated according to the conformity assessment or accreditation activities within the scope of the agreement. The methods are described in 5.2.1 and 5.2.2 and may be applied when two or more bodies are involved.

5.2 Methods for demonstrating compliance

5.2.1 Direct method

The direct method is chosen when confidence among the potential signatories can be created through direct contacts among them. Its technical basis is a peer assessment 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 assessment team that carries out the assessment of conformity on behalf of the others.

NOTE Peer assessment is the subject of ISO/IEC 17040, *Peer assessment of conformity assessment bodies* (under development); when completed, detailed information on the subject will be found there.

In addition to this assessment of conformity, the partners may cooperate operationally by arranging meetings, witnessing or discussing typical applications, or sharing training sessions. Where applicable, methods such as proficiency testing may be relied upon as a means of demonstrating equivalency of performance. Such cooperation builds confidence among the partners on an ongoing basis.

5.2.2 Indirect method

In the indirect method, confidence among the participants is based on the recognition of assessment results provided by external assessment systems. In particular, accreditation of the participants by accreditation bodies using equivalent procedures is a commonly relied upon method. These may include accreditation bodies that are themselves members of an agreement. Thus, arrangements among accreditation bodies by which they recognize each other's work may support agreements among conformity assessment bodies.

Alternatively, participants may be assessed by one or more bodies, often specified in the agreement. These bodies are selected for their competence but are not part of those conducting the conformity assessment activities covered by the arrangement. Thus, this method does not directly involve the conformity assessment bodies interacting with one another in the confidence-building process.

5.2.3 Other methods

The direct and indirect methods described above are not necessarily mutually exclusive and may be combined for use for other purposes such as direct assessment of the signatory product certification bodies and indirect assessment of the testing laboratories they use. Another example is an international arrangement in which eligibility to become a signatory can be demonstrated directly (i.e. the body is assessed) or indirectly (i.e. by virtue of acceptance of participants from a regional grouping).

Regardless of the method, bodies that participate in such assessments should have similar competence and should operate in an equivalent manner. In any case, the principle of operational cooperation among them should apply.

5.3 Internationally agreed principles and requirements

Some key measures to facilitate the process of providing confidence in conformity assessment results may include the harmonization of

- procedures for ensuring transparency and document accessibility,
- the requirements for testing and inspection methods to be employed,
- the elements tested, inspected or assessed, which together make up the approval procedure,
- the methods of evaluation of measurement facilities and calibration of test equipment,
- the methods of control of environmental test conditions,
- the test, inspection or assessment report form,
- procedures for evaluation of the report, resulting in a decision on approval or not,
- the means used to communicate a positive or negative result of the approval procedure to involved parties (e.g. certificates, marks of approval),
- assessment and decision-making procedures,
- the application procedures followed by the testing, inspection and certification/registration bodies involved,
- the methods of evaluation of the competence of personnel, and
- the accreditation procedures.

Internationally agreed requirements for conformity assessment and accreditation bodies have been documented in ISO/IEC Guides and International Standards. The relevant documents are listed in the bibliography.

6 Examples of operational agreements

6.1 General

Bi-lateral, regional and international arrangements have been implemented and have associated agreement groups of accreditation bodies and agreement groups of conformity assessment bodies. Below are examples of regional and international agreements, and agreements among accreditation bodies and among certification/registration bodies. All of the examples provided are bound by agreements comprised of the items introduced in clause 4, and in their operation provide mechanisms for maintaining the agreement in line with those used to establish them (see clause 5).

6.2 Arrangements involving accreditation bodies

6.2.1 International

One example is the International Accreditation Forum, Inc. [Multilateral Recognition Arrangement (IAF MLA)]. The IAF MLA is a recognition arrangement. This agreement is based on the equivalence of accreditation programmes operated by accreditation body members and is verified through peer assessment among accreditation body members of IAF.

Participating accreditation bodies (i.e. those that accredit quality management system certification/registration bodies) recognize each other's competence. A peer assessment process operated by the signatories provides the confidence-building mechanism for this mutual recognition arrangement.

Peer assessments of signatories to the arrangement take place at intervals of approximately 4 years for the purpose of ensuring that the signatory bodies continue to meet the relevant requirements.

6.2.2 Regional

One example is the Asia Pacific Laboratory Accreditation Cooperation [Mutual Recognition Arrangement (APLAC MRA)]. APLAC MRA is a regional arrangement. This is a typical regional arrangement among laboratory accreditation bodies, as a means by which accreditation bodies recognize the technical equivalence of reports/certificates issued by one another's accredited laboratories and promote their acceptance by users.

Peer assessments of signatories to the arrangement take place at intervals of approximately 4 years for the purpose of ensuring that the signatory bodies continue to meet the relevant requirements.

6.3 Arrangements involving certification bodies

6.3.1 Acceptance of test reports

One example is the International Electrotechnical Commission (IEC) – CB scheme (CB is a certification body). The CB scheme is an acceptance arrangement since the signatories agree to accept under prescribed conditions test data reports from the other signatories. Confidence is built using peer assessment of testing capability. Legal limitations exist for this, since some of the signatories have legal obligations regarding how they may operate as a certification body. Stakeholder limitations may exist as well. The CB scheme is a multilateral approximation of similar bilateral mutual recognition arrangements between product certifiers.

6.3.2 Recognition of certification results

One example is the International Certification Network (IQNet). IQNet is a network of certification bodies which operate a multilateral recognition arrangement in the field of management system certification/registration. Equivalence of competence and confidence are ensured by an initial assessment and periodic reassessment of its members to ISO/IEC Guides, International Standards and peer assessment rules. IQNet partners recognize each other's certificates. The members use the IQNet Mark and the IQNet presentation registration documents.

Another example is the International Electrotechnical Commission (IEC) – IECEx scheme. The IECEx scheme is an acceptance arrangement. This 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 being 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 9001. 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 the worldwide acceptance of a single standard, a single certificate and a single mark.

Annex A

(informative)

Websites which can be consulted for examples of agreements

A.1 Accreditation body signatories

International Accreditation Forum, inc. (IAF)	http://www.iaf.nu
International Laboratory Accreditation Cooperation (ILAC)	http://www.ilac.org
European Co-operation for Accreditation (EA)	http://www.european-accreditation.org
Pacific Accreditation Cooperation (PAC)	http://www.apec-pac.org
Asia-Pacific Laboratory Accreditation Cooperation (APLAC)	http://www.ianz.gov.nz.aplac

A.2 Certification/registration and certification body signatories

IECEE - CB scheme	http://www.cbscheme.org
IECEX scheme	http://www.iecex.com
International Certification Network (IQNet)	http://www.iqnet-certification.com

Bibliography

- [1] ISO/IEC Guide 58:1993, *Calibration and testing laboratory accreditation systems — General requirements for operation and recognition*
- [2] ISO/IEC Guide 61:1996, *General requirements for assessment and accreditation of certification/registration bodies*
- [3] ISO/IEC Guide 62:1996, *General requirements for bodies operating assessment and certification/registration of quality systems*
- [4] ISO/IEC Guide 65:1996, *General requirements for bodies operating product certification systems*
- [5] ISO/IEC Guide 66:1999, *General requirements for bodies operating assessment and certification/registration of environmental management systems (EMS)*
- [6] ISO/IEC TR 17010:1998, *General requirements for bodies providing accreditation of inspection bodies*
- [7] ISO/IEC 17020:1998, *General criteria for the operation of various types of bodies performing inspection*
- [8] ISO/IEC 17025:1999, *General requirements for the competence of testing and calibration laboratories*
- [9] ISO 9001:2000, *Quality management systems — Requirements*

NOTE In the future, new guides and standards currently under development may be added to the above list.