



**IAF/ILAC Multi-Lateral
Mutual Recognition Arrangements
(Arrangements):
Application of
ISO/IEC 17011:2004**

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PREAMBLE

Accreditation reduces risk for business and its customers by providing formal recognition that accredited conformity assessment bodies are competent to carry out the work for which they are accredited. Accreditation bodies that are members of the International Accreditation Forum, Inc. (IAF) and/or the International Laboratory Accreditation Cooperation (ILAC) are required to operate in accordance with international standards and to ensure that the organizations they accredit also comply with appropriate international standards for competence and IAF/ILAC criteria on the application of these standards.

Accreditation body members of the IAF and/or ILAC Multi-Lateral Mutual Recognition Arrangements (MLA/MRA) have the equivalence of their accreditation programmes recognized through a regular programme of evaluation by their peer accreditation bodies within the MLA/MRA. This demonstrated equivalence of the accreditations granted provides a basis for companies, organizations or persons with a certificate or report from an accredited conformity assessment body in one part of the world to seek recognition or acceptance of these documents everywhere else in the world, thereby contributing to the facilitation of international trade.

PURPOSE

The purpose of this document is to enable accreditation bodies to better harmonize their application of the standards against which they assess conformity assessment bodies (CABs).

AUTHORSHIP

This publication was prepared by a joint IAF/ILAC working group on guidance to the application of ISO/IEC 17011:2004 and approved for publication by the IAF and ILAC memberships in 2009. The requirements included in the issue IAF/ILAC-A5:04/2009 were effective from the date of publication, that is April 2009.

Addition of Clause M.7.5.7.3 was prepared by a Working Group under the IAF TC and approved for publication by the IAF and ILAC memberships in March 2011. The requirements under Clause M.7.5.7.3, included in the issue IAF/ILAC-A5:03/2011, have a 12 month transition period and will therefore be effective from March 2012.

INTRODUCTION

ISO/IEC 17011 is an International Standard that sets out the general requirements for bodies operating accreditation systems for conformity assessment bodies (CABs). The objective of this document is to enable accreditation bodies to better harmonize their application of the standards against which they assess CABs and it shall be applied, as applicable, to the IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (MLA/MRA). This document can also serve as a useful reference for CABs, particularly in regards to Clause 8, Responsibilities of the accreditation body and the CAB.

ISO/IEC 17011 forms the basis of mutual recognition arrangements between accreditation bodies, and this document is considered necessary for the consistent application of ISO/IEC 17011. Accreditation body signatories and applicants for signatory status to the MLA/MRA evaluate each other's implementation of ISO/IEC 17011. This document shall be adopted by accreditation bodies as part of their general rules of operation and will be used by peer evaluation teams in the evaluation of accreditation bodies.

This document does not include the text of ISO/IEC 17011. Users must purchase that document from the appropriate Standards organization. The requirements against which conformity is determined are found in ISO/IEC 17011. This document does not create additional requirements.

This document is divided into two parts. Part 1 contains mandatory applications for accreditation body signatories, or applicants for signatory status, to the MLA/MRA. Part 2 contains non-mandatory applications reflecting best practice, and is intended to assist accreditation bodies with effectively implementing ISO/IEC 17011. At this time, Part 2 has been restricted to Inspection Body accreditation only.

PART 1: Mandatory Application

In ISO/IEC 17011, the term “shall” denotes a requirement and the term “should” denotes a guideline or recommendation. The term “shall” is used throughout Part 1 to indicate those provisions which, reflecting the requirements of ISO/IEC 17011, have to be fulfilled. The term “should” is used to indicate those applications which are provided by IAF/ILAC as the suggested means of meeting requirements. Accreditation bodies whose systems do not follow the IAF/ILAC provisions in Part 1 denoted by a “should” must be able to demonstrate to peer evaluation teams that their own systems meet the relevant clause of ISO/IEC 17011 and the IAF/ILAC provisions in an equivalent way.

Mandatory applications in Part 1 are identified with the letter “M” followed with a reference number that incorporates the related requirements clause in ISO/IEC 17011, e.g. ISO/IEC 17011, clause 7.8.3 is supported with clauses M.7.8.3.1 to M.7.8.3.2 of this document. In all cases a reference in the text of this document to "clause XXX" refers to a clause in ISO/IEC 17011 unless otherwise specified.

PART 2: Non-mandatory Application

Part 2 provides non-mandatory applications of ISO/IEC 17011 to the accreditation of inspection body services. Non-mandatory applications in Part 2 are identified with the letter “N” followed with a reference number that incorporates the related requirements clause in ISO/IEC 17011, e.g. ISO/IEC 17011, clause 7.8.3 is supported with clauses N.7.8.3.1 to N.7.8.3.2 of this document. In all cases a reference in the text of this document to "clause XXX" refers to a clause in ISO/IEC 17011 unless otherwise specified.

The non-mandatory nature of the applications in Part 2 means peer evaluation teams shall not raise nonconformities or concerns against these guidance clauses, but may raise comments based on them.

PART 1: Mandatory Application of ISO/IEC 17011:2004

- 1. Scope**
- 2. Normative references**
- 3. Terms and definitions**
- 4. Accreditation body**

4.1 Legal responsibility

M.4.1.1 Accreditation bodies that are part of government, or are government departments, shall have their status and structure formally documented by government, e.g. Act of Parliament, legislation, administrative act, Memorandum of Understanding or other written statement by an appropriate authority within government, as determined by the government.

M.4.1.2 In the case where the accreditation body is a separate legal entity within or owned by a larger body, the other parts (the other legal entities) of the larger body are related bodies and therefore provisions of clause 4.3.7 shall apply to the other entities. In the case where the accreditation body is the same legal entity as the larger body, the provisions of clause 4.3.6 shall apply to the entire body.

Note: An accreditation body that is part of a larger body may operate under a different name and be recognized nationally and by the MLA/MRA group under that name.

4.2 Structure

M.4.2.2.1 Accreditation decisions shall not be subject to approval by any other organization or person.

4.3 Impartiality

M.4.3.6.1 *Consultancy services* (refer clause 3.11 of ISO/IEC 17011) and *conformity assessment services that CABs perform* (as defined in clause 1 of ISO/IEC 17011) are considered services that can affect impartiality and shall not be *offered nor provided* by accreditation bodies (irrespective of whether the accreditation body accredits or does not accredit the conformity assessment service).

Note: Accreditation bodies may carry out, for example, the following duties that are not considered a threat to impartiality:

- (a) Arranging and participating as a lecturer in training, orientation or educational courses, provided that these courses confine themselves to the provision of generic information that is freely available in the public domain, i.e. they should not provide specific solutions to a CAB in relation to the activities of that organization;
- (b) Adding value during assessments and surveillance visits, e.g. by identifying opportunities for improvement, as they become evident, during the assessment without recommending specific solutions.

M.4.3.7.1 If the accreditation body and a CAB are both part of the same parent organization (including government) and are separate legal entities (see M.4.1.2 above), the CAB is a related body to the accreditation body and the two bodies shall not directly report to a person or group having operational responsibility for both bodies [clause 4.3.7 a)]. The accreditation body shall be able to demonstrate, through its documented analysis of the relationship with its related bodies and with its specific implementation of procedures that the CAB receives no advantage, and the accreditation body's impartiality is ensured at all times.

- 4.4 Confidentiality**
- 4.5 Liability and financing**
- 4.6 Accreditation activity**
- 5. Management**
 - 5.1 General**
 - 5.2 Management system**
 - 5.3 Document control**
 - 5.4 Records**
 - 5.5 Nonconformities and corrective actions**
 - 5.6 Preventive actions**
 - 5.7 Internal audits**
 - 5.8 Management reviews**
 - 5.9 Complaints**

- M.5.9.1 The decisions in response to a complaint should be made by, or reviewed and approved by, individual(s) who are not directly involved in the matters that are the subject of the complaint.
- M.5.9.2 The conclusions of the investigation of the complaint shall be communicated to the complainant subject to confidentiality requirements.

6. Human resources

6.1 Personnel associated with the accreditation body

6.2 Personnel involved in the accreditation process

6.3 Monitoring

- M.6.3.1.1 Personnel to be monitored also includes experts involved in the assessment.

6.4 Personnel records

7. Accreditation process

7.1 Accreditation criteria and information

7.2 Application for accreditation

7.3 Resource review

7.4 Subcontracting the assessment

7.5 Preparation for assessment

M.7.5.7.1 Inspection Body accreditation

Inspection activities are normally performed on the premises of the client. The requirements of this paragraph refer to the premises of the inspection body and not necessarily to the premises where inspection activities take place. In inspection, the decisions on the result of the conformity assessment are often made by the inspector on-site and form part of the inspection itself. With reference to the Note on clause 7.5.7, it is not necessary to visit every inspection site where a decision on conformity is made.

Guidance to Note to clause 7.5.7:

In the inspection field, the Note to clause 7.5.7 should be understood as follows:

- (i) Key activities include:
- ◆ policy formulation;
 - ◆ process and/or procedure development;
 - ◆ process of initial selection of inspectors and, as appropriate;
 - ◆ contract review;
 - ◆ planning conformity assessments;
 - ◆ review and approval of conformity assessments.
- (ii) When considering whether a premise is one where key activities are carried out, the accreditation body should consider issues which have an influence on the outcome of inspection. Some of these issues are outlined in Part 2 (non-mandatory) of this document.

M.7.5.7.2 Product Certification Body accreditation

In the product certification field, the Note to clause 7.5.7 should be understood as follows:

Key activities include:

- ◆ policy formulation and approval;
- ◆ process and/or procedure development and approval;
- ◆ initial assessment of competence, and approval of technical personnel and subcontractors;
- ◆ control of the monitoring process of competence of personnel and subcontractors and its outcomes;
- ◆ contract review including technical review of applications and determining the technical requirements for certification activity in new technical areas or areas of limited sporadic activity;
- ◆ decision on certification including technical review of evaluation tasks (see IAF GD5:2006 G.4.2.26).

In determining the need to conduct, and for the duration of on-site activities, the accreditation body should also consider the:

- ◆ effectiveness of planning conformity assessments;
- ◆ availability of records, documents and information that can be reviewed electronically, by web conference or otherwise instead of during the visit;
- ◆ availability of appropriate staff for interview by teleconference, videoconference, or otherwise instead of during the visit;
- ◆ liaison with market operators and schemes to avoid duplication of work and ensure efficient utilization of competence available.

M.7.5.7.3 Management System Certification Body accreditation

In the management system certification field, the Note to clause 7.5.7 should be understood as follows:

Key activities include:

- ◆ Policy formulation;
- ◆ Process and/or procedure development;
- ◆ Initial approval of auditing personnel, or control of their training;
- ◆ On-going monitoring of auditing personnel;
- ◆ Application review;
- ◆ Assignment of auditing personnel;
- ◆ Control of surveillance or recertification audits;
- ◆ Final report review or certification decision or approval.

M.7.5.8.1 Inspection Body accreditation

The reference to key activities in criteria M.7.5.7.1 above also applies to clause 7.5.8.

M.7.5.9.1 Note: The *schedule* referred to in clause 7.5.9 relates to the content of the assessment plan for a particular assessment of a CAB.

7.6 Document and record review

M.7.6.1.1 The assessment team shall record the results of their document and record review. [Clauses 7.8.1 and 7.14.3 b) of ISO/IEC 17011 refer].

7.7 On-site assessment**M.7.7.3.1 Inspection Body accreditation**

The choice of inspectors and inspections to be witnessed by the accreditation body shall be made by the accreditation body (not the inspection body), and shall take into account critical factors (e.g. new employees, the risks and the complexity of the inspection activity, physical capabilities of staff). See Part 2 (non-mandatory) of this document. However, it is not intended that every inspector has to be witnessed.

The accreditation body should document the analysis and/or rationale used for sampling of inspectors to be witnessed to cover the scope of accreditation.

National legal requirements, regulations, standards or other relevant authority may stipulate levels of witnessing. Any such adjustments

should be made explicit in scope statements by reference to the relevant law, regulation, etc.

7.8 Analysis of findings and assessment report

M.7.8.3.1 In clause 7.8.3 b), *comments on competence and conformity* included in the assessment report shall be adequate to support the conclusions arising from the assessment (the CAB's fulfillment of the specified accreditation requirements) and should be adequate to support a judgment on future surveillance activities and surveillance / reassessment frequency.

M.7.8.3.2 If the report on the outcome of the assessment [clause 7.8.3 b)] differs from the report of the findings of the assessment [clause 7.8.3 a)], the accreditation body should provide an explanation to the assessed CAB.

7.9 Decision-making and granting accreditation

M.7.9.4.1 The *effective* date of initial accreditation, as referenced in 7.9.4 e), shall be the date of or a date after the accreditation decision.

7.10 Appeals

7.11 Reassessment and surveillance

M.7.11.2.1 Certification Body accreditation

As part of the surveillance procedures, accreditation bodies shall assess the performance of personnel involved in the certification process, including certification audit teams.

7.12 Extending accreditation

7.13 Suspending, withdrawing or reducing accreditation

7.14 Records on CABs

7.15 Proficiency testing and other comparisons for laboratories

M.7.15.2.1 Note: The *involvement of another body* refers to competent organizations or experts outside the accreditation body that may assist the accreditation body in organizing (in full or in part) proficiency testing. For example, an accreditation body may organize calibration measurement audits using artifacts and expertise from a national metrology institute.

M.7.15.2.2 The *list of appropriate proficiency testing and other comparison programmes* should as far as possible cover the scope of laboratories

accredited. It represents a collation of general practice and is not intended to be exhaustive or fixed.

M.7.15.3.1 ILAC-P9 applies.

8. Responsibilities of the accreditation body and the CAB

8.1 Obligations of the CAB

8.2 Obligations of the accreditation body

8.3 Reference to accreditation and use of symbols

M.8.3.1.1 Note: The *clear indication as to which activity the accreditation related* may be accomplished by such means as:

- ◆ Reference to the accreditation standard, e.g. ISO/IEC 17025 (supplemented by words and/or commonly understood abbreviations to describe either calibration or testing), ISO 15189, ISO/IEC 17020, ISO/IEC 17021 (supplemented by words and/or commonly understood abbreviations to describe the management system standard), ISO/IEC Guide 65, ISO/IEC 17024; and/or
- ◆ Words and/or commonly understood abbreviations, e.g. testing (laboratory), calibration (laboratory), inspection (body), (QMS/EMS/product/personnel) certification (body); and/or
- ◆ Reference to the unique accreditation number of the accredited CAB (enabling linkage to the published scope of accreditation).

M.8.3.2.1 Certification Body accreditation

Withdrawal of an accreditation has consequences on the customers of the certification body. The *effective measures* required by clause 8.3.2 d) shall include provisions for the withdrawal of certificates issued by certification bodies under their scope of accreditation. The accreditation body shall require the CAB to provide its customers with information on the withdrawal of its accreditation and on its consequences.

PART 2: Non-mandatory Application of ISO/IEC 17011:2004: Inspection Body Accreditation**7.5 Preparation for assessment**

N.7.5.7.1 With reference to M.7.5.7.1, issues for consideration as to whether a premise is one where key activities are carried out may include:

- ◆ Contract review separate from head office;
- ◆ Maintenance of records not kept at head office;
- ◆ Maintenance of management system documentation not kept at head office;
- ◆ Maintenance and calibration of specific equipment kept separate from head office.

7.7 On-site assessment

N.7.7.3.1 With reference to M.7.7.3.1, as the most critical contribution to inspection decisions is the inspector, it follows that some inspectors must also be witnessed performing inspections. The witnessing of inspectors needs to be such that the effectiveness of systems can be verified, and the competence of individual inspectors conforms to the inspection body's own records.

A key purpose of the assessment is to verify that the inspection body has a robust quality system with records showing witnessing activities of its own inspectors.

The following should be considered when determining the appropriate level of witnessing. The list is not exhaustive and in any given case, an accreditation body may not use all of these to make a decision.

- ◆ Scope of accreditation requested;
- ◆ The extent to which inspectors are required to exercise professional judgment;
- ◆ Total number of inspectors;
- ◆ Frequency of each type of inspection;
- ◆ Number of locations of the inspection body;
- ◆ Past history of performance during (re)assessment;
- ◆ Personnel certification or other formal qualifications held by inspectors;
- ◆ The training system of the inspection body;
- ◆ Effectiveness of internal monitoring of inspectors;
- ◆ Organizational stability and risk awareness of the inspection body;
- ◆ Any statutory requirements.

It should also be recognized that the factors influencing the level of witnessing may change over time as knowledge of the inspection body is gained and records of performance are established.