



ILAC Mutual Recognition Arrangement: Scope and Obligations

ILAC-P5:02/2016

ILAC – International Laboratory Accreditation Cooperation

ILAC is the international authority on laboratory and inspection body accreditation, with a membership consisting of accreditation bodies and stakeholder organisations throughout the world.

ILAC provides the infrastructure that supports the world-wide demonstration of competence and equivalence of testing (including medical) and calibration laboratories, inspection bodies and other types of bodies serving or supporting laboratories and inspection bodies through accreditation. Accreditation of laboratories and inspection bodies supports activities within and between economies including trade, protection of health, safety and the environment for the public benefit. Its fundamental purpose is to provide confidence in the competence of bodies supporting these activities.

The ILAC Arrangement is an international, multilateral mutual recognition arrangement for accreditation bodies. Participating accreditation bodies agree to promote acceptance of the equivalence of calibration, test and inspection reports produced by accredited facilities. Each accreditation body undergoes peer evaluation according to ILAC rules and procedures prior to becoming a signatory to the ILAC Arrangement.

ILAC values the critical complementary and supportive activities of its Regional Cooperation Body members in the realisation of its vision, mission, goals and associated strategies. The Regional Cooperation Body members through the implementation of their multilateral mutual recognition arrangements provide all of the peer evaluation resources and much of the technical inputs to ILAC documents.

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TABLE OF CONTENTS

PREAMBLE4

PURPOSE5

AUTHORSHIP5

MUTUAL RECOGNITION ARRANGEMENT: Scope and Obligations6

ANNEX A8

ANNEX B9



PREAMBLE

ILAC denotes the collaboration of accreditation bodies that accredit calibration laboratories, testing laboratories, inspection bodies, proficiency testing providers and reference material producers

This document describes the elements of a Mutual Recognition Arrangement (hereinafter referred to as the Arrangement) for testing and calibration laboratory, inspection body and proficiency testing provider accreditation. Signatories to the ILAC Arrangement for testing and/or calibration and/or inspection and/or proficiency testing provision recognise with mutual confidence one another's accreditations within each signatory's scope of recognition under this Arrangement. The ILAC Signature Sheet, signed by each signatory to the Arrangement, is shown in Annex A.

This Arrangement is a major co-operative effort to enhance the objective of free trade throughout the world. The criteria for the operation of the accreditation bodies are currently specified in ISO/IEC 17011, and supplemented by ILAC mandatory and IAF/ILAC A series documents where necessary. The criteria for the operation of accredited organisations are currently specified in ISO/IEC 17025, ISO 15189, ISO/IEC 17020 and ISO/IEC 17043 or other standards for conformity assessment bodies ILAC deems to be suitable for accreditation. The full list of standards covered by this Arrangement can be found in Annex B.

Note: A resolution must be adopted by the ILAC General Assembly, following the updating of the ILAC documentation such as ILAC P4, to include the accreditation of reference material producers. Once such a resolution is adopted, this document will require further revision to include the accreditation of reference material producers prior to the acceptance of applications for reference material producers and extension of the ILAC Arrangement to include reference material producers.

The principal elements for establishing confidence among the participating accreditation bodies within ILAC are listed below. These elements are designed to ensure conformity with the requirements of the standards, verified by peer evaluation, in order to establish and maintain mutual confidence in the technical competence of ILAC members and their accredited organisations. The elements are:

1. Exchange of information on the development and operation of accreditation programs of ILAC Full Members, Associates and Affiliates;
2. Participation in the work and decision making of the ILAC General Assembly and ILAC committees and regional cooperations where applicable;
3. Participation of accredited laboratories and, where applicable, proficiency testing providers and inspection bodies in domestic and international interlaboratory comparisons and proficiency testing programs;
Note: Proficiency testing may be used in some types of inspection where available and justified by the inclusion of testing activities that directly affect and determine the inspection result or when required by law or by regulators. It is, however, recognised that Proficiency Testing is not a usual and expected element in the accreditation of most types of inspections.
4. Participation in the work of ILAC with other scientific and technical organisations to address issues related to testing, calibration, inspection and the provision of proficiency testing programs in various technical fields;

5. Evaluations of applicants and re-evaluations of signatories to this Arrangement conducted in accordance with the relevant ILAC, joint IAF/ILAC and regional cooperation documents;
6. Observations of assessments undertaken by applicant accreditation bodies and Arrangement signatories, during which the bodies determine whether their customers meet the requirements of ISO/IEC 17025, ISO 15189, ISO/IEC 17020, or ISO/IEC 17043 or other standards for conformity assessment bodies that ILAC deems to be suitable for accreditation; and
7. Confidence in the metrology institutes which underpin the traceability claims of the laboratories, proficiency testing providers and, where applicable, inspection bodies which are accredited by the Arrangement signatories and support for the measurement comparison activities of CIPM (Comité International des Poids et Mesures) and/or regional metrology organisations.

This Arrangement does not affect other recognition required by laws and regulations in the economies of the signatories.

PURPOSE

To provide details of the scope and policies of the ILAC MRA as well as the obligations of the signatories to this Arrangement.

This document is effective from the date of publication on the ILAC website.

AUTHORSHIP

This document was reviewed by the ILAC Arrangement Management Committee (AMC) and the ILAC Arrangement Committee (ARC) in 2011 to include the accreditation of inspection bodies in preparation for the extension of the ILAC MRA to cover inspection. It was published in November 2011 following endorsement by the ILAC membership. A further review was carried out in 2013 to clarify the use of proficiency testing in the accreditation of inspection bodies and endorsed for publication in 2013.

In 2016, information was included in Annex B regarding the policy relating to the transition periods for the implementation of revised standards covered by the ILAC MRA. In addition the document was reviewed and amended to include the accreditation of proficiency testing providers in the ILAC MRA.

MUTUAL RECOGNITION ARRANGEMENT: Scope and Obligations

1. This Arrangement is based on the results of the evaluations carried out in accordance with the relevant standards, rules, policies and procedures contained in the ILAC mandatory and IAF/ILAC A series documents.
2. Each accreditation body signatory to this Arrangement:
 - (i) Agrees to abide by its terms and conditions,
 - (ii) Maintains conformity with ISO/IEC 17011, the supplementary requirements defined in the IAF/ILAC A2 document and relevant ILAC mandatory and IAF/ILAC A series documents,
 - (iii) Ensures that all accredited laboratories, inspection bodies and proficiency testing providers comply with the relevant standard listed in Annex B, and
 - (iv) Upon changes to requirements of this Arrangement, ensure conformity with the new requirements within the period specified by the ILAC General Assembly.
3. Each recognised regional cooperation shall abide by the requirements defined in IAF/ILAC A1.
4. Each signatory:
 - (i) recognises within its scope of recognition of this Arrangement the accreditation of an organisation by other signatories as being equivalent to an accreditation by its own organisation,
 - (ii) accepts, for its own purposes, endorsed* certificates or reports issued by organisations accredited by other signatories on the same basis as it accepts endorsed* certificates or reports issued by its own accredited organisations,
 - (iii) recommends and promotes the acceptance by users in its economy of endorsed* certificates and reports,
 - (iv) investigates all complaints initiated by other signatories to the Arrangement resulting from certificates or reports issued by the organisations it has accredited within its accreditation programs,
 - (v) notifies the ILAC Secretariat as soon as possible of any significant changes that have occurred or will occur in its status, in the operational practices of its system or in its accreditation programs,
 - (vi) contributes to the work of the ILAC Arrangement Council,
 - (vii) participates in the work of ILAC including return of ballots,
 - (viii) provides evaluators for the evaluation and re-evaluation of accreditation bodies and regional co-operations as appropriate to its size and to the need of the Arrangement Management Committee (AMC) as agreed periodically by the AMC with the concurrence of the affected recognised regional cooperation,

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- (ix) co-operates with other accreditation bodies so that the Arrangement may be extended to include other accreditation bodies and regional co-operations,
 - (x) uses all information obtained from the peer evaluation process in a confidential and professional manner, and
 - (xi) abides by the rules for use of the ILAC-MRA Mark.

** The word "endorsed" means a certificate or report bearing an Arrangement signatory's accreditation symbol (or mark) preferably combined with the ILAC-MRA Mark.*

5. To participate in the ILAC Arrangement, an accreditation body shall be evaluated in accordance with the relevant rules and procedures defined in the IAF/ILAC A series and ILAC mandatory documents and shall complete a signature sheet authorised by the ILAC Arrangement Council Chair (Annex A of this Arrangement). The same procedures shall be followed if a decision is taken to extend its recognition.
6. The scope of recognition of a signatory may be extended or reduced following re-evaluation in accordance with the relevant rules, policies and procedures.
7. If a signatory wishes to withdraw from this Arrangement, or withdraw parts of its scope of recognition for any reason whatsoever, that body shall notify the ILAC Secretariat in writing not later than three months in advance of withdrawal. The ILAC Secretariat shall notify other signatories. Upon withdrawal of a body, that body's signature sheet shall be deleted and the list of signatories amended accordingly.
8. In the event of the ILAC Arrangement Council making an adverse decision or finding against a signatory, the procedures for appeal are defined in ILAC P4.
9. Any amendment of the text of this Arrangement shall be approved by the ILAC General Assembly.
10. It is recognised and accepted by each of the signatories that this Arrangement does not create any rights, liabilities or obligations that would have binding effect in domestic or international law. This Arrangement by itself does not provide any recognition or accreditation under any law or regulation in the economy of any signatory.
11. This Arrangement consists of twelve (12) clauses plus two Annexes.
12. The Arrangement takes effect upon signing by both the signatory accreditation body and the Chairman of the ILAC Arrangement Council.

ANNEX A



ILAC MUTUAL RECOGNITION ARRANGEMENT

SIGNATORIES

We, the undersigned, endorse the terms of the ILAC Arrangement and agree to abide by them, to the best of our ability.

Accreditation Body:

Economy:

Scope and date:

Authorised Representative:

Signature: _____ Date:

Chairman, ILAC Arrangement Council:

Signature: _____ Date:



ANNEX B

ILAC Mutual Recognition Arrangement signatories operate in accordance with the criteria specified in the current version of ISO /IEC 17011, supplemented by ILAC mandatory and IAF/ILAC A series documents where necessary.

ILAC Mutual Recognition Arrangement signatories accredit laboratories, inspection bodies and proficiency testing providers and other conformity assessment bodies for compliance with the current versions of the Standards detailed in the table below.

Generic Policy for Transition Periods for Implementation of Revised Standards

When revised standards are published, ILAC decides on the transition period for the implementation of the revised standard. After the close of the transition period, all accreditation certificates shall appropriately reference the revised standard. Compliance is determined during normal surveillance or reassessment activities or as a separate activity.

After the close of the transition period, conformity assessment bodies accredited to older versions of the revised standard will not be recognised under the ILAC Mutual Recognition Arrangement.

The ILAC decisions for the transition period for each revised standard, in the form of a General Assembly resolution, are published on the ILAC website.

The Standards for conformity assessment bodies currently recognised as meeting the accreditation requirements of ILAC and covered by the ILAC Mutual Recognition Arrangement are:

ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories	Calibration laboratories
ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories	Testing laboratories
ISO 15189 (Note 1)	Medical laboratories – requirements for quality and competence	Medical testing laboratories
ISO/IEC 17020	Conformity assessment - Requirements for the operation of various types of bodies performing inspection	Inspection bodies
ISO/IEC 17043	Conformity assessment - General requirements for proficiency testing	Proficiency testing providers

Notes:

1. ILAC Resolution GA 16.21

Noting the results of the ISO ballot completed for ISO FDIS 15189 on 11 October 2012, the General Assembly agrees that by 1 March 2016, all references to ISO 15189 in accreditation certificates (as defined and described in ISO/IEC 17011), shall refer to the latest edition of ISO 15189. Compliance will be determined during normal surveillance or reassessment activities or as a separate activity.

At the end of the transition period, accreditation of a laboratory to ISO 15189:2007 will not be recognised under the ILAC Arrangement.