



# **ILAC Mutual Recognition Arrangement: Scope and Obligations**

**ILAC-P5:11/2023**

## About ILAC

ILAC is the global association for the accreditation of laboratories, inspection bodies, proficiency testing providers, reference material producers and biobanks, with a membership consisting of accreditation bodies, regional cooperation bodies and stakeholder organisations throughout the world.

It is a representative organisation that is involved with:

- the development of accreditation practices and procedures,
- the promotion of accreditation as a trade facilitation tool,
- supporting the provision of local and national services,
- the assistance of developing accreditation systems,
- the recognition of competent testing (including medical) and calibration laboratories, inspection bodies, proficiency testing providers, reference material producers and biobanks around the world.

ILAC actively cooperates with other relevant international organisations in pursuing these aims.

ILAC facilitates trade and supports regulators by operating a worldwide mutual recognition arrangement – the ILAC Arrangement - among Accreditation Bodies (ABs). The data and results issued by laboratories, inspection bodies, proficiency testing providers, reference materials producers and biobanks collectively known as Conformity Assessment Bodies (CABs), accredited by ILAC Accreditation Body members are accepted globally via the ILAC Arrangement. Thereby, technical barriers to trade, such as the re-testing of products each time they enter a new economy is reduced, in support of realising the free-trade goal of “accredited once, accepted everywhere”.

In addition, accreditation reduces risk for business and its customers by assuring that accredited CABs are competent to carry out the work they undertake within their scope of accreditation.

Further, the results from accredited facilities are used extensively by regulators for the public benefit in the provision of services that promote an unpolluted environment, safe food, clean water, energy, health and social care services.

Accreditation Bodies that are members of ILAC and the CABs they accredit are required to comply with appropriate international standards and the applicable ILAC application documents for the consistent implementation of those standards.

Accreditation Bodies having signed the ILAC Arrangement are subject to peer evaluation via formally established and recognised regional cooperation bodies using ILAC rules and procedures prior to becoming a signatory to the ILAC Arrangement.

The ILAC website provides a range of information on topics covering accreditation, conformity assessment, trade facilitation, as well as the contact details of members. Further information to illustrate the value of accredited conformity assessment to regulators and the public sector through case studies and independent research can also be found at [www.publicsectorassurance.org](http://www.publicsectorassurance.org).

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## PREAMBLE

This document describes the elements of the ILAC Mutual Recognition Arrangement (hereinafter referred to as the ILAC Arrangement) for the accreditation of conformity assessment bodies (CABs) in accordance with ILAC R6 *Structure of the ILAC Mutual Recognition Arrangement and Procedure for Expansion of the Scope of the ILAC Arrangement*. Signatories to the ILAC Arrangement recognise with mutual confidence one another's accreditations within each signatory's scope of recognition under the ILAC Arrangement. The ILAC Arrangement Signature Sheet, signed by each signatory to the ILAC Arrangement, is shown in Annex A.

The ILAC Arrangement is a major co-operative effort to enhance the objective of free trade throughout the world, support the implementation of a quality infrastructure and improve the supply of public benefit services such as health, water, food and energy. The criteria for the operation of the accreditation bodies and accredited CABs are currently specified in ILAC R6.

ILAC R6 also provides details relating to the structure and defined levels of the ILAC Arrangement.

The principal elements for establishing confidence among the participating accreditation bodies are listed below. These elements are designed to ensure conformity with the requirements of the standards which is verified by on-going peer evaluations, in order to establish and maintain mutual confidence in the technical competence of signatories to the ILAC Arrangement and their accredited CABs. The elements are:

1. Participation in the work and decision making of the ILAC General Assembly, ILAC Arrangement Council and ILAC committees and regional cooperations where applicable;
2. Participation in the work of ILAC with other scientific and technical organisations to address issues related to testing, calibration, inspection, biobanking, provision of proficiency testing programs and production of reference materials in various technical fields;
3. Exchange of information on the development and operation of accreditation schemes of ILAC members;
4. Evaluations of applicants and re-evaluations of signatories to the ILAC Arrangement in accordance with the relevant ILAC and joint IAF/ILAC documents and documents issued by recognised regional cooperations; and
5. Observations of assessments undertaken by applicant accreditation bodies and ILAC Arrangement signatories, during which the bodies determine whether the CABs meet the requirements of the standards for CABs identified in ILAC R6.

The ILAC Arrangement does not affect other recognition required by laws and regulations in the economies of the signatories but can be used to support such recognition programs.

## PURPOSE

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

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

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## AUTHORSHIP

Key revision to this document by the ILAC Arrangement Management Committee (AMC) and the ILAC Arrangement Committee (ARC) occurred in:

- 2011 to include the accreditation of inspection bodies;
- 2016 to include the policy for transition periods for the implementation of revised standards covered by the ILAC Arrangement and to include the accreditation of proficiency testing providers;
- 2017 to include the accreditation of reference material producers;
- 2022 to include the accreditation of biobanks; and
- 2023 revision to Annex B only

## MUTUAL RECOGNITION ARRANGEMENT: Scope and Obligations

1. The ILAC 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 recognised regional cooperation body shall abide by the requirements defined in IAF/ILAC A1.
3. Each accreditation body signatory to the ILAC Arrangement agrees to:
  - (i) Abide by its terms and conditions,
  - (ii) Maintain 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) Ensure that all accredited CABs comply with the relevant standard listed in ILAC R6 and relevant ILAC mandatory and ILAC/IAF A-series documents, and
  - (iv) Upon changes to requirements of the ILAC Arrangement, ensure conformity with the new requirements within the period specified by the ILAC General Assembly.
4. Each signatory:
  - (i) recognises within its scope of recognition of the ILAC Arrangement the accreditation of a CAB by other signatories as being equivalent to an accreditation by its own accreditation body,
  - (ii) accepts, for its own purposes, endorsed certificates or reports\* issued by CABs accredited by other signatories on the same basis as it accepts endorsed certificates or reports issued by its own accredited CABs,  
  
*\* The definition of “endorsed certificate or report” is detailed in ILAC P8.*
  - (iii) recommends and promotes the acceptance by users in its economy of endorsed certificates and reports issued by CABs accredited by a signatory to the ILAC Arrangement for the relevant scope,

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- (iv) investigates all complaints initiated by other signatories to the ILAC Arrangement resulting from certificates or reports issued by the CABs it has accredited within its accreditation schemes,
  - (v) notifies the ILAC Secretariat as soon as possible of any significant changes affecting its ability to fulfil the requirements for recognition for level 2 conformity assessment activities or level 3 documents, or major organisation changes,
  - (vi) contributes to the work of the ILAC Arrangement Council,
  - (vii) participates in the work of ILAC including committees and voting in ballots,
  - (viii) provides evaluators for the evaluations of accreditation bodies and regional cooperations as appropriate to its size and to the needs of the AMC with the concurrence of the affected recognised regional cooperation,
  - (ix) co-operates with other accreditation bodies so that the ILAC Arrangement may be extended to include other accreditation bodies and regional co-operations, and
  - (x) uses all information obtained from the peer evaluation process in a confidential and professional manner
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 the ILAC Arrangement). The same procedures shall be followed if a decision is taken to extend its scope of 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 the ILAC 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 the ILAC Arrangement shall be approved by the ILAC General Assembly.
  10. It is recognised and accepted by each of the signatories that the ILAC Arrangement does not create any rights, liabilities or obligations that would have binding effect in domestic or international law. The ILAC Arrangement by itself does not provide any recognition or accreditation under any law or regulation in the economy of any signatory.
  11. The ILAC Arrangement consists of twelve (12) clauses plus three Annexes.

12. The ILAC Arrangement takes effect upon signing by both the signatory accreditation body and the Chair of the ILAC Arrangement Council.

**ANNEX A - ILAC ARRANGEMENT SIGNATURE SHEET**



**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:

**Chair, ILAC Arrangement Council:**

Signature: \_\_\_\_\_ Date:





## **ANNEX B - 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. Irrespective of the specific date of publication, the end of the transition period will be based on the final day of the month of publication.

During the transition period both the superseded and revised published version of the standard are valid under the ILAC MRA for the entirety of the transition period.

After the close of the transition period, the information provided by the accreditation body to the accredited conformity assessment body (eg the accreditation certificates) shall appropriately reference the revised standard. Compliance is determined during normal surveillance or reassessment activities or as a separate activity.

At the conclusion of the transition period, accreditation to the superseded version of a standard is not valid under the ILAC MRA. Therefore, conformity assessment bodies not accredited to the current version of the standard are not recognised under the ILAC MRA in accordance with Clause 3 (iv).

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.

*Current resolutions:*

### **ILAC Resolution GA 26.08**

*As the revised version of ISO 15189 is scheduled for publication in 2022 or early 2023, the General Assembly endorses the recommendation of the AIC that a transition period of 3 years from the date of publication be adopted.*

*Noting that the requirements for Point of Care Testing (POCT) contained in ISO 22870:2016 have been incorporated into the revised ISO 15189, ISO 22870:2016 in conjunction with ISO 15189:2012 will still be recognised as a Level 4 standard for POCT for the duration of the transition period.*

*At the end of the transition period, accreditation of a medical laboratory to ISO 15189:2012 and accreditation of POCT to ISO 22870:2016 in conjunction with ISO 15189:2012 will not be recognised under the ILAC Arrangement.*

Note: ISO 15189:2022 was published in December 2022 and therefore the transition period will end 31 December 2025.

### **ILAC Resolution GA 26.09**

*As the revised version of ISO/IEC 17043 is scheduled for publication in 2022 or early 2023, the General Assembly endorses the recommendation of the AIC that a transition period of 3 years from the date of publication be adopted.*

*At the end of the transition period, accreditation of a proficiency testing provider to ISO/IEC 17043:2010 will not be recognised under the ILAC Arrangement.*

Note: ISO/IEC 17043:2023 was published in May 2023 and therefore the transition period will conclude on 31 May 2026.

## ANNEX C

**Revision Table** – The table provides a summary of the key changes to this document from the previous version.

<b>Section</b>	<b>Amendment</b>
Annex B	Add reference ISO 15189 and ISO/IEC 17043 transition periods. Clarify end of transition period and validity of accreditations to superseded version of a standard.