



# **ILAC Mutual Recognition Arrangement: Policy and Management**

**ILAC-P4:06/2022**

## 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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<https://www.youtube.com/user/IAFandILAC>

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## PREAMBLE

The international community of regional accreditation cooperations, accreditation bodies and stakeholders cooperate through ILAC. A principal objective of ILAC is the maintenance of its world-wide Mutual Recognition Arrangement also known as the ILAC Arrangement.

ILAC aims to demonstrate the equivalence of the operation of its Member Accreditation Bodies through the ILAC Arrangement. As a consequence, the competence (within the accredited scopes) of laboratories, inspection bodies, proficiency testing providers, reference material producers and biobanks (ie, conformity assessment bodies - CABs) accredited by these accreditation bodies is demonstrated and recognised by all signatory accreditation bodies. The market can then be confident in accepting certificates and reports issued by these accredited CABs.

At present, the ILAC Arrangement covers the accreditation of calibration and testing (including medical) laboratories, inspection bodies, proficiency testing providers and reference material producers. The accreditation of biobanks was approved for inclusion in the ILAC MRA in October 2021.

## PURPOSE

This document provides the policy statement for the ILAC Arrangement and the management processes for the implementation of the ILAC Arrangement. The effective date for application of this document is the date of its publication on the ILAC website.

## AUTHORSHIP

This publication was prepared by the ILAC Arrangement Committee (ARC) and initially endorsed for publication by the ILAC General Assembly in 2000. Key revisions include the addition of inspection to the scope of the ILAC Arrangement in 2012 and proficiency testing providers and reference material producers in 2016. A revision was published in 2019 that addressed updates to the standards used and improvements to the evaluation processes. This revision, approved for publication in 202X, includes the addition of the accreditation of biobanks.

## 1. THE OBJECTIVE

- 1.1 ILAC's objective in developing and maintaining a Mutual Recognition Arrangement (among accreditation bodies - ABs) is to assist in the removal of technical barriers to trade and promote the acceptance of the equivalence of reports and certificates issued by CABs accredited by signatories to the ILAC Arrangement. This is achieved through a world-wide network of mutual recognition of accreditation bodies that operate to recognised international standards.
- 1.2 In order to accomplish the objective of the ILAC Arrangement, two conditions must be fulfilled:
  - (1) Signatories to the ILAC Arrangement must fulfil the requirements for competently assessing the CABs; and
  - (2) Accredited CABs must fulfil the requirements for competently performing the conformity assessment services provided.

**1.3** In particular, ILAC aims to ensure that:

- ◆ Signatories to the ILAC Arrangement operate in accordance with ISO/IEC 17011 and apply relevant ILAC mandatory and IAF/ILAC A-series requirements in a mutually consistent manner;
- ◆ Laboratories accredited by signatories to the ILAC Arrangement operate in accordance with ISO/IEC 17025 and/or ISO 15189, as well as any relevant mandatory ILAC and IAF/ILAC A-series documents;
- ◆ Inspection bodies accredited by signatories to the ILAC Arrangement operate in accordance with ISO/IEC 17020 as well as any relevant mandatory ILAC and IAF/ILAC A-series documents;
- ◆ Proficiency testing providers accredited by signatories to the ILAC Arrangement operate in accordance with ISO/IEC 17043 as well as any relevant mandatory ILAC and IAF/ILAC A-series documents;
- ◆ Reference material producers accredited by signatories to the ILAC Arrangement operate in accordance with ISO 17034 as well as any relevant mandatory ILAC and IAF/ILAC A-series documents;
- ◆ Biobanks accredited by signatories to the ILAC Arrangement operate in accordance with ISO 20387 as well as any relevant mandatory ILAC and IAF/ILAC A-series documents.

**1.4** ILAC aims to achieve the objective of the ILAC Arrangement using the following principles and authorities:

- ◆ An accreditation body is evaluated against the agreed criteria and, if found to be in conformity with these criteria, will be admitted to the ILAC Arrangement. This admission, and its subsequent continuance, or exclusion, is solely on the basis of the evaluation of its competence conducted in accordance with ILAC's published evaluation procedures and compliance with the membership Rules;
- ◆ No accreditation body shall be required to have a policy or practice that is in violation of any existing laws of its economy, provided such laws are not in conflict with the requirements of ISO/IEC 17011 or relevant ILAC mandatory and IAF/ILAC A-series requirements.
- ◆ Authority in relation to the ILAC Arrangement rests with the signatories (ILAC Full Members) that form the peer group responsible for the evaluation of members and the decisions on their admission (and on-going recognition) to the ILAC Arrangement. Each signatory recognised by the ILAC Arrangement is responsible for the accreditations granted to its CABs.
- ◆ ILAC acknowledges the need for signatories to the ILAC Arrangement to cooperate and collaborate in accordance with ILAC policies and procedures.
- ◆ A basic principle of mutual recognition in the conformity assessment accreditation community is that Mutual Recognition Arrangements are based on

broad equivalence of competence and not on identical implementation. Nevertheless, within the regional Mutual Recognition Arrangements, the use of internationally harmonised guidance documents is beneficial in providing non-mandatory, supplementary information to the standards in relation to certain applications. Their use has assisted and promoted consistent interpretation of the requirements by signatory bodies. ILAC, in relation to the operation of its ILAC Arrangement, provides its members with these additional internationally harmonised guidance documents.

- ♦ ILAC acknowledges the need for continuous development and improvement of its evaluation procedures and actively monitors the evaluations of accreditation bodies and of Regional Cooperation Body Members to achieve this. In addition, regional initiatives are also reviewed and used to improve the international evaluation process as appropriate.

## **2. THE MANAGEMENT OF THE ILAC ARRANGEMENT**

- 2.1 The ILAC General Assembly is the approving authority for policies regarding the operation of the ILAC Arrangement and the evaluation procedures to be implemented.
- 2.2 The ILAC Arrangement Council is the body responsible for decision making regarding signatory status of the ILAC Arrangement. The Arrangement Council is composed of a representative from each of the Associate and Full Members and Regional Cooperation Bodies of ILAC and is chaired by the Chair of ILAC. Meetings of the Council are generally convened alongside the annual ILAC General Assembly. A representative from the Stakeholder members also attends the Arrangement Council meetings as an observer.
- 2.3 The ILAC Arrangement Management Committee (AMC) is responsible for the day-to-day management of the evaluation processes and making recommendations to the ILAC Arrangement Council. The membership of the AMC is defined in the ILAC Rules.
- 2.4 Members of the ILAC Arrangement Council and AMC must maintain all information relating to evaluations as confidential.

## **3. THE OPERATION OF THE ILAC ARRANGEMENT**

The principles of operation of the ILAC Arrangement are:

1. The ILAC Arrangement shall be operated through the linking and strengthening of the existing regional Arrangements whilst encouraging the development of new regional structures.
2. ILAC shall peer-evaluate the Regional Cooperation Bodies to establish their competence in managing the operation of regional Mutual Recognition Arrangements and shall formally recognise this competence in a documented scope of recognition.
3. ILAC shall recognise the evaluation and re-evaluation of its member accreditation bodies carried out by the Recognised Regional Cooperation Bodies.

4. Accreditation bodies that have been accepted as ILAC Associate members, but that are not eligible to be part of a current Recognised Regional Cooperation body, or whose Regional Cooperation body has not been formally recognised, may apply as an unaffiliated accreditation body for signatory status to the ILAC Arrangement.
5. ILAC shall undertake the evaluation of the competence of unaffiliated AB members to accredit CABs and shall formally recognise this competence in a documented scope of recognition.
6. Recognised Regional Cooperation Bodies are under no obligation to admit to their membership an accreditation body which it may have evaluated on behalf of ILAC.
7. ILAC shall delegate to its Recognised Regional Cooperation Bodies the detailed decision making regarding admission of member accreditation bodies of that Regional Cooperation Body to, and continuing membership of, the ILAC Arrangement.
8. Decisions regarding the recognition of Regional Cooperation Bodies and signatory status for unaffiliated accreditation bodies will be taken by the ILAC Arrangement Council based on a recommendation from the AMC.

#### 4. IMPLEMENTATION

- 4.1 The requirements approved by the General Assembly used to implement the ILAC Arrangement are described in the ILAC mandatory and the IAF/ILAC A-series documents and are available on the ILAC website: [www.ilac.org](http://www.ilac.org).
- 4.2 Regional cooperation body applicants for recognition status to the ILAC Arrangement must be members of ILAC and meet the requirements detailed in IAF/ILAC A1 to submit an application for evaluation in accordance with IAF/ILAC A1.
- 4.3 Accreditation bodies seeking signatory status to the ILAC Arrangement must be Associate members of ILAC and meet the current financial obligations.

*Note 1: If the accreditation body is not an Associate member of ILAC, then the accreditation body should contact the ILAC Secretariat. The ILAC Secretariat will provide the necessary application forms and details of the process for becoming an Associate member in accordance with the ILAC Rules for membership.*

*Note 2: An application for signatory status may be submitted concurrently with an application for Associate membership, but shall only be processed by ILAC on receipt of the payment of the requisite fees for Associate membership.*

- 4.3.1 An accreditation body that has been evaluated and accepted as a signatory to a Recognised Regional Cooperation Body MRA/MLA, on either a multilateral or bilateral basis, will be granted signatory status to the ILAC Arrangement without the need for further evaluation or decision making activities.

In this case the scope of the accreditation body's signatory status to the recognised regional MRA/MLA must be within the Recognised Regional Cooperation Body's scope of recognition to the ILAC Arrangement.

4.3.1.1 Accreditation bodies that satisfy the criteria in 4.3 and 4.3.1 and wish to become a signatory to the ILAC Arrangement shall apply by completing the Full Member application form available from the ILAC Secretariat.

4.3.2 Accreditation bodies applying for signatory status as an unaffiliated accreditation body in accordance with Clauses 3(3) and 4.3 must meet the requirements detailed in IAF/ILAC A2 to submit an application for evaluation in accordance with IAF/ILAC A2. In such cases:

- ILAC may invite one of the Recognised Regional Cooperation Bodies to undertake the evaluation of such applicants and to present an evaluation report via the AMC to the ILAC Arrangement Council for decision; or
- The unaffiliated accreditation body may gain signatory status to the ILAC Arrangement via a bilateral agreement with an ILAC Recognised Regional Cooperation Body; or
- The applicant may be evaluated directly by an evaluation team appointed by ILAC.

## 5. REVIEW AND DECISION MAKING PROCESS

5.1 On receipt of the final report package from the evaluation team leader, requiring a decision regarding signatory status, the ILAC Secretariat shall forward the final report to the members of the Report Review Groups (TFG) in accordance with IAF/ILAC A1 or A2 as appropriate. This step will be completed within 30 days of receipt of the final report.

5.1.1 To ensure appointment of appropriate AMC members to Report Review TFG, the members of the AMC, on appointment to the AMC, will complete and return to the ILAC Secretariat the *Competency in Reviewing Evaluation Reports* form (ILAC FP4.1 – 201X available from the ILAC Secretariat). This form will be reviewed by the ILAC Secretariat and AMC Chair for compliance with the criteria for TFG included in IAF/ILAC A1 and A2. Where the form is completed by the AMC Chair, the Secretariat shall identify another member of the AMC to undertake the review. If the criteria are not met then the AMC member will be ineligible for appointment to a Report Review TFG.

5.2 On receipt of the summary report from the Report Review TFG, the ILAC Secretariat shall forward the final evaluation report from the evaluation team and the summary report from the Report Review TFG to the members of the ILAC AMC and the Full Members of ILAC for review.

5.3 The feedback received from the review of the final report and the summary report will be collated by the ILAC Secretariat. Where additional information or clarification is required as a result of the review process this will be followed-up by the Report Review TFG, in conjunction with the evaluation team leader and the applicant as appropriate and completed within 30 days.



- 5.4** On completion of the review of the final report and the summary report as per Clause 5.3, an AMC evaluation summary report and recommendation will be prepared by the ILAC AMC Chair and Secretariat. This package will be distributed to the Full Members of the ILAC Arrangement Council for the decision making process as described in this document and IAF/ILAC A1 or IAF/ILAC A2.
- 5.5** The decision making process will be carried out via electronic ballot unless the ILAC AMC identifies a need and recommends the outcome of an evaluation should be discussed at an ILAC Arrangement Council meeting (refer to 5.8).
- 5.6** The following criteria apply to decisions taken by the ILAC Arrangement Council:
- 5.6.1 Voting on ILAC Arrangement decisions is restricted to the signatories, i.e. ILAC Full Members, on the basis of one vote per Full Member
- 5.6.2 Decisions should preferably be taken by consensus. In the event of a vote being necessary, decisions shall be carried by a 75% majority of those voting members participating.
- 5.6.3 Members and representatives from an organisation subject to an ILAC Arrangement Council decision (i.e. Regional Cooperation Bodies and signatories to the regional Arrangement or unaffiliated accreditation bodies) shall not participate during the final decision making (vote) stage, but may be present for any preceding discussion.
- 5.6.4 Members and representatives involved in the discussion and voting process shall advise of any conflicts of interest prior to the commencement of the discussion and voting stages of the decision making process.
- 5.7** In the case of the decision making process being carried out via electronic ballot, the final evaluation report, the Report Review TFG summary report and the AMC recommendation summary report will be distributed to the Full Members of ILAC with a voting form for a 30 day ballot.
- 5.8** In the case that the outcome of an evaluation is to be discussed at an ILAC Arrangement Council meeting as per 5.6, the final evaluation report must be distributed to the members of the ILAC Arrangement Council 30 days prior to the date of the decision making process to ensure all members have adequate time to review the full report. In the case of decisions made during an ILAC Arrangement Council meeting, the evaluation summary reports may be distributed within the same week as the scheduled ILAC Arrangement Council meeting, but at least two days prior to the meeting, as the evaluation summary reports may only be finalised at the AMC meeting held just prior to the ILAC Arrangement Council meeting.
- 5.9** In the case of decisions delegated to the Recognised Regional Cooperation Bodies in accordance with 3(6), these decisions are endorsed by means of an annual summary report submitted by the Recognised Region Cooperation Body to the AMC.

**6. APPEALS AND ALTERNATIVE DISPUTE RESOLUTION**

- 6.1** An Accreditation Body may appeal an ILAC decision not to grant signatory status in the ILAC Arrangement or to suspend or withdraw signatory status. A decision to withdraw signatory status in the ILAC Arrangement may result in immediate withdrawal of recognition of the equivalence of reports by the other signatories, prior to implementation of an appeals process.
- 6.2** An appeal shall be sent to the ILAC AMC, in writing, within 30 days of notification of the decision of the ILAC Arrangement Council. The appeal shall then be dealt with in accordance with IAF/ILAC A1 or A2, as appropriate.

## ANNEX A

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

<b>Section</b>	<b>Amendment</b>
Preamble, The Objective and Section 1.3	Addition of accreditation of biobanks
Sections 4.3.1.2 and 4.3.1.3	Administrative details moved to Secretariat manual