



ILAC Mutual Recognition Arrangement: Policy and Management

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ILAC – International Laboratory Accreditation Cooperation

ILAC is the international authority on laboratory, inspection body, proficiency testing provider and reference material producer 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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PREAMBLE

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

ILAC aims to demonstrate the equivalence of the operation of its Member Accreditation Bodies through this Arrangement. As a consequence, the competence (within the accredited scopes) of laboratories, inspection bodies, proficiency testing providers and reference material producers 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 the accredited laboratories, inspection bodies, proficiency testing providers and reference material producers.

At present, the Arrangement covers the accreditation of calibration and testing laboratories, inspection bodies, proficiency testing providers and reference material producers.

ILAC links the existing regional Mutual Recognition Arrangements of the Recognised Regional Cooperation Bodies and is encouraging the development of new regional bodies to complete world-wide coverage. Formal recognition of a regional cooperation body for the ILAC Arrangement is based on an evaluation of the competence to operate a Mutual Recognition Arrangement by an ILAC team composed of independent peer evaluators from other ILAC Regional Cooperation Bodies and Accreditation Bodies.

For the purposes of the Arrangement and based on ILAC's evaluation and recognition of the Recognised Regional Mutual Arrangements, ILAC delegates authority to its Recognised Regional Cooperation Bodies for the evaluation, surveillance, re-evaluation and associated decision making relating to the signatory status of the ILAC Full Members to the ILAC Arrangement. Details of the current Recognised Regional Cooperation Bodies and ILAC Full Members (signatories to the ILAC Arrangement) are available from the ILAC website at www.ilac.org.

Evaluation relating to the development and maintenance of the ILAC Arrangement operates at two levels:

- the evaluation of a Regional Cooperation Body's competence in managing the operations of regional Mutual Recognition Arrangements; and
- the evaluation of competence of individual ILAC Member Accreditation Bodies to accredit laboratories, inspection bodies, proficiency testing providers and reference material producers.

The requirements and procedures used by ILAC when evaluating a Regional Cooperation Body are set out in document IAF/ILAC A1.

The requirements and procedures used by ILAC Recognised Regional Cooperation Bodies when evaluating individual accreditation bodies and by ILAC when evaluating unaffiliated accreditation bodies for the purposes of the ILAC Arrangement are set out in IAF/ILAC A2.

PURPOSE

This document provides the ILAC statement of policy 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) (formerly known as the ILAC Accreditation Policy Committee) and initially endorsed for publication by the ILAC General Assembly in 2000. A revision was carried out and published in 2003. A further revision primarily addressing the inclusion of inspection bodies and procedures covering the decision making process was carried out in 2011 and approved for publication in 2012. A further review was carried out in 2013 to clarify the use of proficiency testing in the accreditation of inspection bodies and provide details on the process for a signatory to a recognised region to become a signatory to the ILAC Arrangement. The document was endorsed for publication in 2013. In 2016, criteria for the competence of those involved in the evaluation report review process was added. In addition this document was revised to include the accreditation of proficiency testing providers and reference material producers in the ILAC MRA.

1. THE OBJECTIVE

- 1.1 ILAC's central role in the development and on-going operation of a recognition arrangement for laboratories, inspection bodies, proficiency testing providers and reference material producers (among accreditation bodies recognised in their own economies) is highlighted in the ILAC Rules.
- 1.2 ILAC's objective in developing and maintaining a Mutual Recognition Arrangement (among recognised accreditation bodies) is to assist in the removal of technical barriers to trade and promote the acceptance of the equivalence of reports and certificates issued by laboratories, inspection bodies, proficiency testing providers and reference material producers accredited by signatories to the ILAC MRA. This is achieved through a world-wide network of mutual recognition of accreditation bodies that operate to recognised international standards; and that have established the competence of the accredited laboratories, inspection bodies, proficiency testing providers and reference material producers.
- 1.3 In order to accomplish the objective of the Arrangement, three conditions need to be fulfilled:
 - (1) Signatories to the ILAC MRA need to fulfil the requirements for competently assessing the performance of accredited laboratories, inspection bodies, proficiency testing providers and reference material producers.
 - (2) Accredited laboratories, inspection bodies, proficiency testing providers and reference material producers need to fulfil the requirements for competently performing the conformity assessment services provided.

- (3) The requirements referred to in (1) and (2) need to be formulated, interpreted and implemented in such a way that end-users of the conformity assessment services can have confidence in the reported outcomes.

1.4 In particular, it is ILAC's mission to ensure that:

- ◆ Signatories to the Arrangement operate in accordance with ISO/IEC 17011 and apply it in a mutually consistent manner, as well as applying relevant ILAC mandatory and IAF/ILAC A-series requirements;
- ◆ 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 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 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 Arrangement operate in accordance with ISO 17034 as well as any relevant mandatory ILAC and IAF/ILAC A-series documents;
- ◆ Testing, calibration, inspection, provision of proficiency testing and production of reference material services accredited by signatories to the Arrangement are supported by appropriate traceability of measurement;
- ◆ Adequate proficiency testing activity is undertaken by laboratories and, where applicable, by proficiency testing providers, reference material producers and inspection bodies accredited by signatories to the ILAC Arrangement;

Note 1: 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.

Note 2: Participation in proficiency testing programs may not be relevant to all proficiency testing providers and reference material producers, especially those that subcontract the testing activities associated with these services.

ILAC shall implement procedures to ensure that these requirements are met and maintained by all signatory members.

2. THE FOUNDATION OF THE ARRANGEMENT

ILAC bases the operation of its Arrangement on the following fundamental premises:



- ◆ ILAC maintains a light but authoritative role in directing the Arrangement while devolving most action to its Recognised Regional Cooperation Bodies;
- ◆ In relation to the Arrangement, ILAC operates primarily at the technical level. That is, it will put in place a means whereby any ILAC Associate may be evaluated against the agreed criteria and, if found in conformity with these, 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;
- ◆ Authority in relation to the Arrangement rests with the signatories (ILAC Full Members) which, in turn, form the peer group responsible for the evaluation of applicant members and the decision on their admission to the Arrangement. In the final analysis, each signatory recognised by the Arrangement is responsible for the competence of their accredited laboratories, inspection bodies, proficiency testing providers and reference material producers.

3. THE MANAGEMENT OF THE ARRANGEMENT

- 3.1** The ILAC General Assembly is the approving authority for policies regarding the operation of the Arrangement and the evaluation procedures employed.
- 3.2** The ILAC Arrangement Council is the body responsible for decision making regarding signatory status of the 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 convened alongside the annual ILAC General Assembly. Voting on Arrangement decisions is restricted to the signatories, i.e. ILAC Full Members, on the basis of one vote per Full Member.
- 3.3** The ILAC Arrangement Management Committee (AMC) is responsible for the day-to-day management of the evaluation processes, for monitoring the performance of signatories and for co-ordinating the selection, training and monitoring of evaluators and making recommendations to the Arrangement Council. The membership of the AMC is defined in the ILAC Rules.

4. THE OPERATION OF THE ARRANGEMENT

The principles of operation of the Arrangement are:

- ◆ The ILAC Arrangement shall be operated through the linking and strengthening of the existing regional Arrangements whilst encouraging the development of new regional structures.
- ◆ Regional Cooperation Bodies shall undertake the evaluation and re-evaluation of their own member bodies.
- ◆ ILAC shall peer-evaluate the Regional Cooperation Bodies to establish their competence in management of Arrangements and formally recognise this competence.

- ◆ ILAC shall recognise the evaluation and re-evaluation of its member accreditation bodies carried out by the Recognised Regional Cooperation Bodies.
- ◆ Recognised Regional Cooperation Bodies (whose admission criteria may include other elements) are under no obligation to admit to their membership, any accreditation body which may be geographically close to the region and, for convenience, may have been evaluated for ILAC Arrangement purposes by that Recognised Regional Cooperation Body on behalf of ILAC.
- ◆ ILAC shall delegate to its Recognised Regional Cooperation Bodies the detailed decision making regarding admission of member bodies of that Regional Cooperation Body to, and continuing membership of, the ILAC Arrangement. These decisions are endorsed by means of an annual summary report submitted by the Recognised Region Cooperation Body to the AMC.
- ◆ Decisions regarding the recognition of Regional Cooperation Bodies and signatory status for unaffiliated accreditation bodies will be taken by the Arrangement Council based on a recommendation from the AMC.
- ◆ Members and representatives involved in the discussion and voting process will advise of any conflicts of interest prior to the commencement of the discussion and voting stages of the decision making process.
- ◆ Members and representatives from an organisation subject to an Arrangement Council decision (i.e. Regional Cooperation Bodies and unaffiliated accreditation body applicants or signatories to the Arrangement) shall not be present during the final decision making (vote) stage, but may be present for any preceding discussion.
- ◆ Decisions taken by the Arrangement Council relating to recognition of Regional Cooperation Bodies and signatory status of unaffiliated accreditation bodies should preferably be taken by consensus. In the event of a vote being necessary in a Council meeting, decisions shall be carried by a 75% majority of those voting members present.
- ◆ Accreditation bodies that have been accepted as ILAC Associate members, but that are not eligible to be part of a current Recognised Regional Cooperation, or whose Regional Cooperation has not been formally recognised, may apply as an unaffiliated accreditation body for signatory status to the ILAC Arrangement. 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 Arrangement Council for decision;
 - The unaffiliated accreditation body may gain signatory status to the ILAC Arrangement via a bilateral agreement with an ILAC Recognised Regional Cooperation Body; or
 - May be evaluated directly by an evaluation team appointed by ILAC.

5. IMPLEMENTATION

- 5.1** ILAC uses several documents to implement the Arrangement which have been approved by the General Assembly. These documents are designated under the P-series classification of ILAC and the A-series classification of IAF/ILAC and are available on the ILAC website: www.ilac.org.
- 5.2** ILAC acknowledges the need to continuously develop and improve its evaluation procedures in the light of experience and shall actively monitor the evaluations of accreditation bodies and of Regional Cooperation Body Members to achieve this. To this end it shall also take note of regional initiatives, and introduce international initiatives as appropriate, to improve the evaluation process and assume the role of incorporating consequent recommendations for improvement into an internationally harmonised set of documents (the A-series documents) in cooperation with the International Accreditation Forum (IAF) .

It has been a basic principle of mutual recognition in the laboratory, inspection body, proficiency testing provider and reference material producer and accreditation community 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 has been beneficial in providing non-mandatory, supplementary information to the standards in relation to certain applications and their use has assisted and promoted consistency of operation of arrangement signatory bodies. ILAC, in relation to the operation of its Arrangement, provides its members with these additional internationally harmonised guidance documents.

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.

- 5.3** Applicants for signatory status to the Arrangement are Associate members of ILAC and have met the current financial obligations.

Note: 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.

- 5.4** 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, can apply for signatory status to the ILAC MRA without the need for further evaluation or decision making activities.

5.4.1 The criteria for gaining signatory status to the ILAC MRA via this path are:

- the scope of the accreditation body's signatory status to the recognised regional MRA/MLA is within the Recognised Regional Cooperation Body's scope of recognition to the ILAC MRA; and
- the accreditation body is an Associate member of ILAC.

Note: 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.

5.4.2 Accreditation bodies that satisfy the criteria in 5.4.1 and wish to become a signatory to the ILAC MRA shall apply by completing the Full Member application form available from the ILAC Secretariat.

5.4.3 To process the application, the ILAC Secretariat shall:

- review the completed application and clarify any queries with the ILAC AMC Chair or applicant as required;
- confirm the signatory status to the regional MRA/MLA via the website or the Secretariat of the Recognised Regional Cooperation Body; and confirm all membership fees have been paid;
- prepare ILAC Signature Sheets in accordance with ILAC P5, a formal letter of welcome as a signatory to the ILAC MRA and Full Member of ILAC and update all records in accordance with the Secretariat Procedures Manual.

5.4.4 When the steps in 5.4.3 have been completed, the ILAC Secretariat shall advise the ILAC Members of the new signatory to the ILAC MRA via the ILAC website and the AMC, Arrangement Council and General Assembly reports.

6. REVIEW AND DECISION MAKING PROCESS

6.1 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 ILAC AMC and the Full Members of ILAC for review. This step will be completed within 30 days of receipt of the final report.

To be able to effectively review a wide range of evaluation reports, the AMC members to be appointed to a report review task force must have:

- experience at levels 1, 2 and 3 (as defined in ILAC R6) of the ILAC Arrangement,
- knowledge of the IAF/ILAC A-series and ILAC P-series documents, and
- experience in the evaluation process.

The competencies required would be consistent with those of an individual with experience as an accreditation body assessor or a person involved in the decision making process. To achieve this, the members of the AMC report review task force will need to:

- understand the planning and conduct of an evaluation including the breadth and depth of these activities;
- understand the findings and their classification;
- understand the adequacy of the conclusions and recommendations;

- possess good communication skills to effectively correspond with the evaluation team and/or the evaluated body as required.

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 above listed criteria. 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 unable to be appointed to an AMC report review task force.

- 6.2** The feedback received from the review of the final 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 AMC report review task force, in conjunction with the evaluation team leader and the applicant as appropriate and completed within 30 days.
- 6.3** On completion of the review of the final report as per Clause 6.2, an evaluation summary report and recommendation will be prepared by the ILAC AMC report review task force in accordance with Annex 6 of IAF/ILAC A1 or Annex 5 of A2. This package will be distributed to the Full Members of the ILAC Arrangement Council for the decision making process as described in Clause 4 of this document and Annex 7 of IAF/ILAC A1 or Annex 6 of A2.
- 6.4** The decision making process will be included on the agenda for the next scheduled ILAC Arrangement Council meeting, provided the final report is received at least 90 days before the meeting. This will ensure all Full Members are openly involved in the important decision and comment process for signatory status to the ILAC MRA.
- 6.5** The final evaluation report must be distributed to the members of the 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 Arrangement Council meeting, the evaluation summary report may be distributed within the same week as the scheduled Arrangement Council meeting, but at least two days prior to the meeting, as the evaluation summary report may only be finalised at the AMC meeting held just prior to the Arrangement Council meeting.
- 6.6** If the final evaluation report is received more than 90 days prior to the next scheduled ILAC Arrangement Council meeting it will be processed via the electronic ballot process.
- 6.7** In the case of decision making process being carried via electronic ballot the final evaluation report and the evaluation summary report will be distributed to the Full Members of ILAC with a voting form for a 30 day ballot.

7. APPEALS AND ALTERNATIVE DISPUTE RESOLUTION

- 7.1** An Accreditation Body may appeal an ILAC decision not to grant signatory status in the Arrangement or to suspend or withdraw signatory status. A decision to withdraw signatory status in the Arrangement may result in immediate withdrawal of recognition

of the equivalence of reports by the other signatories, prior to implementation of an appeals process.

- 7.2** An appeal shall be sent to the ILAC AMC, in writing, within 30 days of notification of the decision of the Arrangement Council. The appeal shall then be dealt with in accordance with Schedule 1 of the ILAC Rules (ILAC-R2).

During the course of an Accreditation Body's appeal of the withdrawal of its existing signatory status by ILAC, the signatory status shall remain in effect.