



Structure of the ILAC Mutual Recognition Arrangement and Procedure for Expansion of the Scope of the ILAC Arrangement

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.

For more information, please contact:

The ILAC Secretariat

PO Box 7507

Silverwater NSW 2128

Australia

Phone: +61 2 9736 8374

Email: ilac@nata.com.au

Website: www.ilac.org



[@ILAC_Official](https://twitter.com/ILAC_Official)



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PURPOSE

This document describes the structure of the ILAC Mutual Recognition Arrangement (hereinafter referred to as the ILAC Arrangement) as well as the process used by ILAC to consider and approve new conformity assessment activities (Level 2) and normative documents (Levels 3 and 4) for inclusion in the ILAC Arrangement.

The structure of the ILAC Arrangement described in this document includes all areas currently covered by the ILAC Arrangement as well as those areas where the ILAC General Assembly (GA) has agreed to initiate the expansion of the ILAC Arrangement. The expansion of the ILAC Arrangement may not have been launched in all of the areas listed herein. Details of the areas currently covered by the ILAC Arrangement can be found in ILAC-P5 ILAC Mutual Recognition Arrangement (Arrangement).

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

AUTHORSHIP

This document was developed by the ILAC Arrangement Committee (ARC) and approved for publication after being endorsed by the ILAC membership in 2007. This document was revised in February 2013 to include reference to the accreditation of proficiency testing providers and reference material producers. A scheduled review was carried out in 2018 and the document approved for publication in 2019. The review carried out in 2022 was for the inclusion of the accreditation of biobanks. The 2023 edition was for an update to Clause 3.4.1 only.

1 DEFINITIONS

The definitions relating to the conformity assessment activities covered by this document are detailed in the following documents: ISO/IEC 17000, ISO/IEC 17011, ISO/IEC 17025, ISO 15189, ISO/IEC 17020, ISO/IEC 17043, ISO 17034, ISO 20387 and ISO/IEC Guide 99 (VIM).

2 STRUCTURE OF THE ILAC ARRANGEMENT

2.1 There are five Levels in the ILAC Arrangement structure.

2.1.1 Level 1 – ISO/IEC 17011, which specifies the criteria for the accreditation body (AB).

2.1.2 Level 2 – Conformity assessment activities performed by conformity assessment bodies for which the accreditation body grants accreditation according to the generic, normative documents listed in Level 3.

- ◆ Testing
- ◆ Calibration
- ◆ Inspection
- ◆ Proficiency Testing Provision
- ◆ Reference Material Production
- ◆ Biobanking

2.1.3 Level 3 – The generic normative documents used by the AB to assess the competence of a conformity assessment body (CAB) for each activity in Level 2 are:

- ◆ For Testing: ISO/IEC 17025 and ISO 15189
- ◆ For Calibration: ISO/IEC 17025
- ◆ For Inspection: ISO/IEC 17020
- ◆ For Provision of Proficiency Testing: ISO/IEC 17043
- ◆ For Production of Reference Materials: ISO 17034
- ◆ For Biobanking: ISO 20387

2.1.4 Level 4 – Sector-specific normative documents which specify recognised applications of a generic normative document listed in Level 3. The application documents are used by the AB, in combination with the generic normative documents listed in Level 3, to assess the competence of a CAB in the relevant sector. Internationally recognised documents currently are:

- (a) Normative documents to be used in combination with ISO/IEC 17025:
- ◆ The WADA International Standard for Laboratories (ISL)
 - ◆ ISO 15195: Laboratory medicine - Requirements for the competence of calibration laboratories using reference measurement procedures

(b) Normative documents to be used in combination with ISO 15189:

- ◆ ISO 22870: Point-of-care testing (POCT) - Requirements for quality and competence

2.1.5 **Level 5** – The scope of accreditation of the CAB accredited by an ILAC Arrangement signatory.

Note: Annex A provides a diagrammatic representation of the ILAC Arrangement Structure.

2.2 ILAC is responsible for ensuring the signatories comply with the Level 1 document. The signatories (ABs) for a particular Level 2 scope must ensure the compliance of their accredited CABs for specific conformity assessment activities in accordance with Level 3 and 4 documents as relevant.

The scope of accreditation as required by Level 5 is maintained by the ILAC Arrangement signatory for each of its accredited CABs.

3 PROCEDURE FOR EXPANSION OF THE ILAC ARRANGEMENT

The procedure for expansion of the ILAC Arrangement within Levels 2, 3 and 4 has the following steps:

- 3.1 Proposal to expand the ILAC Arrangement
- 3.2 Review of the proposal to expand the ILAC Arrangement
- 3.3 Approval by the ILAC GA to expand the ILAC Arrangement
- 3.4 Development of the expansion of the ILAC Arrangement:

3.1 Proposal to expand the ILAC Arrangement

The proposal for expansion of the ILAC Arrangement could come from a number of sources including:

- ◆ Organizations (e.g CAB associations, industry and professional associations) which need independent recognition of the competence of CABs for activities not currently addressed by ILAC (or IAF or other parties);
- ◆ Regulators, specifiers, purchasers and other customers needing reassurance of the technical competence of organizations against commonly agreed criteria not currently addressed by ILAC;
- ◆ Recognised regional cooperation bodies that have established an MRA/MLA for an activity not currently covered by the ILAC Arrangement; and
- ◆ Accreditation bodies themselves may need confirmation of competence in areas which are complementary to areas already covered by their accreditation schemes.

Proposals for ILAC to consider expansion to the ILAC Arrangement shall first be presented to the ILAC Executive together with relevant supporting documentation identifying the new (or extended) area of accreditation and detailing the rationale for the proposal taking into consideration the following sources or needs:

1. A new Level 2 activity, not currently covered by an ISO Standard, but already subject to accreditation by a number of accreditation bodies and with potential for the development of a standard or normative document by ISO (or, if necessary, by ILAC itself).
2. A new Level 3 standard or normative document, applicable to a conformity assessment body and the attestation of its competence; or
3. A new Level 4 normative document which is a sector-specific application based on a Level 3 standard already used for accreditation by ILAC Members.

The ILAC Executive will review the proposal initially and may determine not to proceed if there are insufficient grounds to warrant further consideration. The Executive may also seek further information from the party making the proposal before making any determination to proceed to full review in accordance with 3.2.

3.2 Review of the proposal to expand the ILAC Arrangement

- 3.2.1 The ILAC Executive, following the determination to proceed will refer the specific proposal to the relevant ILAC committees for consideration of technical criteria issues, and/or ILAC Arrangement related issues, depending on the nature of the proposed expansion.

The relevant ILAC Committee(s) shall conduct a review of the proposal to the extent necessary, including the following considerations as appropriate:

- Background on the need for the new area including the relevance of accreditation of CABs
- Implications of the lack of inclusion of the new area, eg threat to ILAC leadership in accreditation and impact on any existing standard currently under the ILAC Arrangement
- Views of affected parties, including any external bodies that may have proposed such a need
- Whether the standard or other normative documents proposed have been produced by an international consensus process (including all relevant interested parties), and is of sufficient rigour to support the recognition of competence.
- If the proposal involves a new activity (Level 2) or a new generic, normative document (Level 3), consideration of impartiality of the AB in relation to services that CABs perform, as required by ISO/IEC 17011.
- Current experience of ILAC members in the area of the proposed expansion and a determination of whether there are sufficient numbers of ILAC members with an interest in the new area to justify inclusion in the ILAC Arrangement.
- Consultation with interested parties for comments, as relevant.
- Ensuring that the new area does not jeopardize the existing obligations already undertaken by ILAC Members under the ILAC Arrangement.

- The need for new or revised mandatory ILAC documents and/or IAF/ILAC A series documents.
- The evaluation process to be applied in accordance with Clause 3.4.2.
- If the proposal is based on an agreement between an accreditation scheme owner and ILAC, it will be necessary to ensure that:
 1. The scheme requirements do not conflict with ILAC objectives.
 2. The scheme does not discriminate against any member of the ILAC Arrangement and does not impose unnecessary requirements on them.
 3. The assessment process shall at least fulfil all the relevant requirements established in ISO/IEC 17011.
 4. Requirements established by the scheme owner are not in contradiction with ISO/IEC 17011 nor with the applicable generic normative document (Level 3).
 5. Decisions regarding the maintenance of an accreditation body in the ILAC Arrangement can only be taken within ILAC (for unaffiliated bodies) or the Recognised Regional Cooperation body where the accreditation body is a member.
 6. The information supplied to the market must always be transparent and not create barriers to competition amongst the affected bodies covered by the accreditation.

3.2.2 The relevant committee(s) shall prepare a report addressing the considerations in Clause 3.2.1 and including a recommendation for consideration by the ILAC Executive to proceed (or not) with the proposed expansion to the ILAC Arrangement.

3.3 Approval by the ILAC GA to expand the ILAC Arrangement

The decision on whether or not to proceed with the expansion of the ILAC Arrangement will be made by a formal ballot of the ILAC GA. Members will be provided with any relevant background information e.g. outcome of relevant Committee(s) review, as part of the ballot process.

If the ILAC GA agrees to the expansion of the ILAC Arrangement, the new area will be included in the Structure of the ILAC Arrangement (Annex A) and this document will be updated accordingly.

3.4 Development of the expansion of the ILAC Arrangement

3.4.1 The relevant ILAC Committee(s) shall draft and seek approval for inclusion of any additional criteria or peer evaluation processes in the relevant ILAC mandatory and IAF/ILAC A-series documents that are required to address the new area.

In addition, the ILAC AMC shall conduct a resource review with the regions to ensure a pool of qualified competent evaluators (and if required additional technical experts) is available prior to notifying members that applications are able to be submitted for the new scope.

3.4.2 The peer evaluation process established for the new area shall ensure that:

3.4.2.1 For Recognised Regional Cooperation bodies:

- (i) requesting an extension for a new Level 2 activity will require an on-site evaluation in which all the requirements of IAF/ILAC A1 and compliance of the region's MRA/MLA signatories with IAF/ILAC

A2 in relation to the new Level 2 activity and associated Level 3 normative documents are evaluated.

- (ii) requesting an extension for a new Level 3 generic normative document that is added for an existing Level 2 activity in the ILAC Arrangement will require an evaluation covering the relevant IAF/ILAC A1 requirements and demonstration of the compliance of the region's MRA/MLA signatories with IAF/ILAC A2 in relation to the new Level 3 normative documents.

3.4.2.2 For Accreditation Bodies:

- (i) ABs requesting signatory status for a new Level 2 activity will require an on-site evaluation, in which all requirements of ISO/IEC 17011 and compliance of the AB's accredited CABs with the relevant Level 3 normative document(s) are evaluated. The evaluation team shall be competent in that activity and witnessing shall be included.
- (ii) Where a new Level 3 generic normative document is added for an existing Level 2 activity in the ILAC Arrangement, the evaluation procedures will be determined based on the following factors:
 - ◆ Distinction or uniqueness of technical aspects;
 - ◆ Risk associated with the activity under accreditation;
 - ◆ Extent of difference of the new standard with the existing standard(s);
 - ◆ Complexity of the standard; and
 - ◆ Requests from the users of accreditation or other concerned parties in the marketplace.

The initial evaluation procedures may be:

- a) A full on-site evaluation of that activity including the implementation of the normative document(s);
- b) A partial on-site evaluation of selected requirements of ISO/IEC 17011 and evaluation of compliance of the ABs accredited CABs with the new level 3 normative document;

- c) Document review only.

Normally alternative (a) or (b) will be used, but there may be cases where the new Level 3 normative document is so similar to the existing ones that a document review may be adequate.

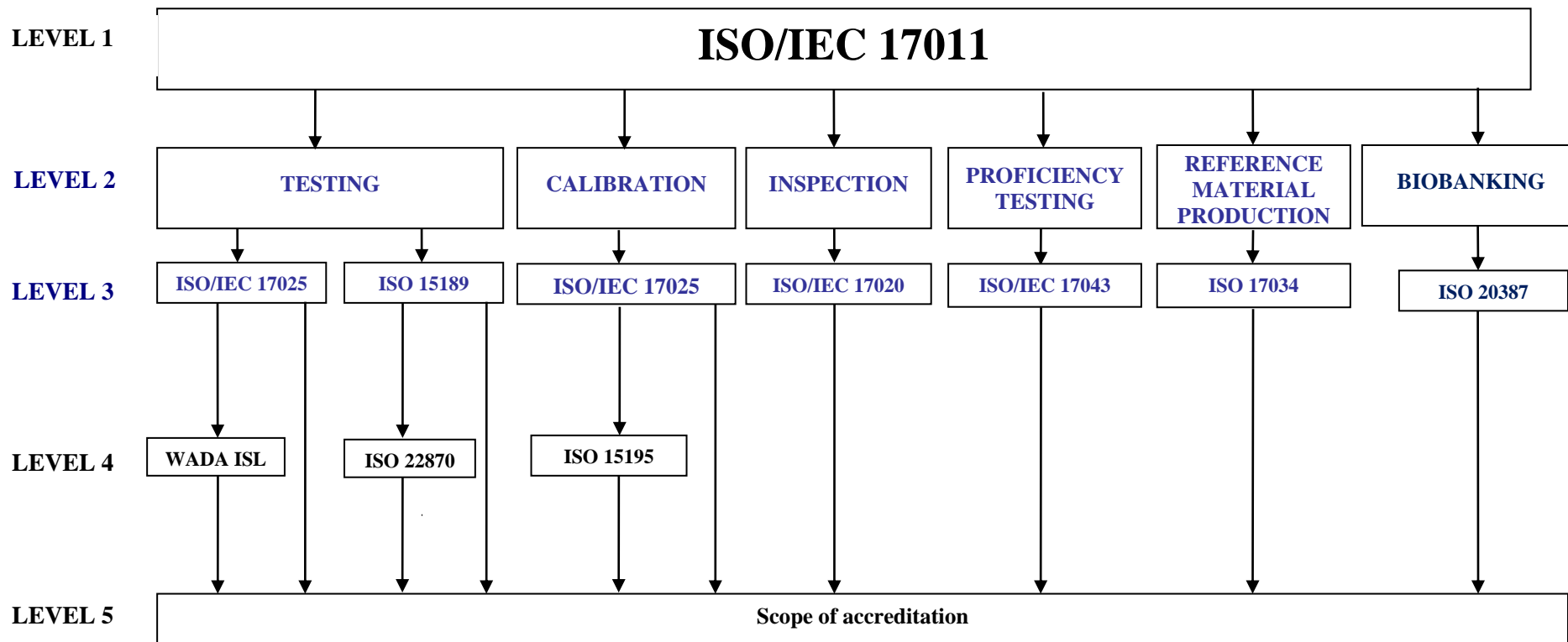
- (iii) Where a new Level 4 sector-specific normative document is added to the ILAC Arrangement, the evaluation of an AB which is already a signatory for the relevant Level 2 activity and Level 3 normative document may be recognised following self-declaration.

4 IMPLEMENTATION OF THE EXPANSION OF THE ILAC ARRANGEMENT

The expansion of the ILAC Arrangement will become effective following:

- the formal adoption of the new or revised ILAC mandatory and/or IAF/ILAC A series documents; and
- a positive vote on the evaluation of at least one recognised regional cooperation body by the ILAC Arrangement Council.

Annex A Structure of the ILAC Arrangement



ANNEX B

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

Section	Amendment
Clause 3.4.1	Addition of need for evaluator resource review