



**ILAC Mutual Recognition Arrangement (Arrangement):
Supplementary Requirements for the
Use of Accreditation Symbols and for Claims of
Accreditation Status by Accredited Conformity Assessment
Bodies**

ILAC-P8:11/2023

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 material 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.

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1. PREAMBLE

Accreditation provides formal recognition that a conformity assessment body (CAB) is capable of meeting certain standards. These are standards of competence, impartiality and consistency of operations.

Once accredited, a CAB may wish to make reference to its accreditation status in its reports or certificates. Accreditation normally entitles the accredited CAB to endorse the relevant documents in the name of the accreditation body, by using an accreditation symbol and/or by using appropriate words, in accordance with prescribed procedures and rules.

Such endorsed documents can enjoy wide acceptance nationally and also internationally through the ILAC mutual recognition arrangement (MRA). Use of the Accredited CAB Combined ILAC MRA Mark on endorsed CAB reports reinforces such acceptance. The rules for use of this mark are provided in the *ILAC R7: Rules for the Use of the ILAC MRA Mark*.

An accredited CAB may also wish to use accreditation symbols and the Accredited CAB Combined ILAC MRA Mark to claim its accreditation status for promotional purposes, on pre-printed letterhead or on quotations for conformity assessment activities covered under the scope of accreditation, advertisements, websites and other documents.

ISO/IEC 17011:2017, clause 4.3 requires an accreditation body to have a policy governing the use of its accreditation symbols and claims of accreditation status by its accredited organisations. This document provides supplementary requirements for the use of accreditation symbols and for claims of accreditation status by accredited CABs in the context of the ILAC MRA.

2. PURPOSE

The requirements in this document have been developed to ensure a more uniform approach to the use of accreditation symbols and for the manner in which a CAB may refer to its accreditation status and make claims to the ILAC MRA. Unless otherwise stated, the requirements apply to accredited laboratories, inspection bodies, reference material producers (RMP), proficiency testing providers (PTP) and biobanks.

The date of implementation for the requirements related to the accreditation of biobanks is . the date the ILAC MRA is extended to include the accreditation of biobanks.

3. AUTHORSHIP

This publication was reviewed by the ILAC Arrangement Committee (ARC) for the inclusion of biobanks and endorsed for publication by the ILAC voting membership in 2023.

For historical purposes, it is noted that the inclusion of inspection bodies was made in the December 2012 edition. The review of the 2012 edition began in 2016 to include reference material producers and proficiency testing providers. An extensive review was undertaken in 2019.

4. TERMINOLOGY

- 4.1 For the purposes of this document, the terms and definitions given in ISO/IEC 17000 and ISO/IEC 17011 apply.
- 4.2 In this document, endorsed reports or certificates means reports and certificates bearing an accreditation body's accreditation symbol and/or by using appropriate words referencing the CAB's accreditation in accordance with prescribed procedures and rules and irrespective of the mechanism used for applying the 'endorsement' (e.g. digital, stamp, etc).

5. GENERAL REQUIREMENTS

- 5.1 An accreditation body may provide accreditation for more than one type of conformity assessment activity, e.g., testing, calibration, sampling (associated with subsequent testing or calibration), medical testing, inspection, reference material production, proficiency testing, biobanking. The accreditation symbol shall have, or be accompanied with, a clear indication as to which activity e.g., testing, calibration, inspection the accreditation is related.

The use of accreditation symbols by an accredited CAB may be mandatory or voluntary according to the policies of the accreditation body. An accredited CAB, however, should be encouraged to issue reports or certificates bearing the accreditation symbol when the conformity assessment activities come under the scope of accreditation. Only reports or certificates bearing the accreditation symbol or a text reference to the accreditation of the CAB can benefit fully from the recognition that the ILAC MRA and its regional counterparts bring.

- 5.2 Where reports and certificates contain the results of conformity assessment activities covered by the scope of accreditation, the accreditation body concerned shall specify the requirements for the incorporation of the accreditation symbol or for making reference to accreditation. The accreditation body shall also publish a policy governing the use of accreditation symbols and their protection. Examples of formats may be included in publications issued by the accreditation body, which contain the policy and rules for the use of accreditation symbols.
- 5.3 The accreditation body shall ensure that only accredited CABs are permitted to use its accreditation symbols or make reference to accreditation status and shall set the conditions governing their use. The accreditation body policy shall ensure that:
- ♦ the accreditation symbol shall not be used by a CAB's external service providers that are not accredited by the accreditation body;
 - ♦ the accreditation symbol shall not be used by applicants for accreditation;
 - ♦ the accreditation symbol shall be used by an accredited CAB only under the name or the registered trade name of the legal entity in which it holds accreditation;
 - ♦ accreditation symbols shall not be placed on the products or items which have been subjected to conformity assessment (except on calibration/inspection/reference material/biobanking labels, see Clause 8.)

6. REPRODUCTION OF ACCREDITATION SYMBOLS

- 6.1 To assist an accredited CAB in the use of accreditation symbols, examples of the types of accreditation symbol available and when and how they can be used shall be published.
- 6.2 Information shall include, when applicable:
- ♦ format and proportions of the accreditation symbols;
 - ♦ sizes and colours of the accreditation symbols;
 - ♦ location of accreditation number in relation to the accreditation symbols;
 - ♦ positioning of accreditation symbols on reports, certificates and labels and of any text to be included in association with the accreditation symbols;
 - ♦ availability of photographic and/or electronic copies of the accreditation symbols for use by the accredited CAB;
 - ♦ any relevant instructions on the reproduction of the accreditation symbols when they are used on electronic documents.

7. REPORTING RESULTS NOT COVERED BY THE SCOPE OF ACCREDITATION

- 7.1 Customers of an accredited CAB may request endorsed reports or certificates which contain, or are based upon, some results of conformity assessment activities not performed under the CAB's scope of accreditation.

If an accreditation body allows an accredited CAB to include results, or outcomes based on results, for conformity assessment activities not covered by the scope of accreditation in its endorsed reports or certificates, in order to ensure that results cannot be interpreted as being for conformity assessment activities covered by the scope of accreditation, the policy of the accreditation body shall include:

- a) a requirement that the accreditation symbols cannot be used, and that neither reports nor certificates nor any enclosed letters (including the paper on which they are printed) can include any reference to accreditation, if none of the results are for conformity assessment activities within the scope of accreditation; and
 - b) a requirement that, where any endorsed reports or certificates which contain, or are based upon, some results of conformity assessment activities not performed under the CAB's scope of accreditation, the reported results or outcomes are clearly identified by a disclaimer (e.g. "The conformity assessment activities marked * are not covered by the scope of accreditation."; "The result/conclusion is based on conformity assessment activities outside of the scope of accreditation.")
- 7.2 There shall be nothing in any conformity assessment report or certificate or in any attachments or other materials that implies, or may lead any user of the results or any interested party to believe that the conformity assessment activity is covered by the scope of accreditation when it is not.

Note: For the correct interpretation of reporting results, or outcomes of results, not covered by a CAB's scope of accreditation, the meaning of "conformity assessment activities" in this context includes tests and examinations performed to support conformity assessment decisions, e.g. inspection.

8. CALIBRATION LABELS, INSPECTION LABELS, REFERENCE MATERIAL DOCUMENTS AND LABELS, PROFICIENCY TESTING DOCUMENTS AND BIOBANKING DOCUMENTS AND LABELS

8.1 Calibration Labels on Equipment

An accreditation body may allow the use of calibration labels containing the accreditation symbol, and which are attached to the item of equipment calibrated by the accredited calibration laboratory. Calibration labels containing the accreditation symbol shall not give the impression that the accreditation body approved or calibrated the equipment. The calibration label would usually include the following information:

- ◆ the name of the accredited calibration laboratory and its accreditation number;
- ◆ equipment identification;
- ◆ date of current calibration;
- ◆ cross reference to the calibration certificate issued in respect of the calibration.

The accreditation body shall restrict the use of calibration labels containing the accreditation symbol to equipment that has been calibrated using calibration methods covered by the calibration laboratory's scope of accreditation.

8.2 Inspection Labels on Inspected Items

An accreditation body may allow the use of inspection labels containing the accreditation symbol, and which are attached to the specified inspected item. Inspection labels containing the accreditation symbol shall not give the impression that the accreditation body approved or inspected the item. The label shall clearly indicate that the item has been inspected, e.g., "inspected by ..," or inspected on ..." etc. In addition, the inspection label would usually include the following information:

- ◆ the name and accreditation number of the accredited inspection body;
- ◆ equipment identification;
- ◆ date of the inspection;
- ◆ cross reference to the inspection report issued in respect of the inspection.

The accreditation body shall restrict the use of inspection labels containing the accreditation symbol to the items inspected using the inspection services covered by the inspection body's scope of accreditation.

8.3 Reference Material Documents and Labels

An accreditation body may allow the use of RM labels containing the accreditation symbol. RM certificates and RM labels containing the accreditation symbol shall not give the impression that the accreditation body approved or produced the RM. In addition to the information required in ISO 17034, the label would usually include the following:

- ♦ the name and accreditation number of the accredited reference material producer;
- ♦ designation of the product and batch number;
- ♦ cross reference to the reference material certificate.

8.4 Proficiency Testing Documents

An accreditation body may allow the use of the accreditation symbol on the documents related to the PT schemes covered by the scope of accreditation of the PT provider.

8.5 Biobanking Documents and Labels

An accreditation body may allow the use of the accreditation symbol on labels, certificates and documents related to biological material and the associated data covered by the scope of accreditation. These shall not give the impression that the accreditation body approved, acquired or generated the material or data.

In addition to the requirements of ISO 20387, labels would usually include:

- ♦ the name and accreditation number of the accredited biobank;
- ♦ designation of the biological material; and
- ♦ cross-reference to the report, certificate or associated data, as relevant.

9. ADVERTISING AND PUBLICITY

9.1 An accredited CAB and its parent, subsidiaries or sister companies may wish to incorporate in publicity and/or advertising material, statements concerning the CAB's accreditation.

Materials may include:

- ♦ website(s);
- ♦ publicity and advertising material;
- ♦ brochures and organisation publications;
- ♦ technical literature;

- ♦ business reports;
- ♦ quotations or proposals for conformity assessment activity.

An accreditation body shall have rules to govern the claiming of accreditation status in advertising and publicity materials by an accredited CAB and its parent, subsidiaries and sister companies. Such rules shall require the use of the accreditation symbols and claims of accreditation status in a way that is not misleading as to which conformity assessment activities are actually covered by the CAB's scope of accreditation.

- 9.2 The use of the accreditation symbols or material implying accreditation should enhance the reputation and value of accreditation for all stakeholders. It is the responsibility of the accreditation body to ensure that the general use of its accreditation symbols and other claims of accreditation by a CAB do not misrepresent the CAB's accreditation status and do not bring the accreditation body into disrepute. ISO/IEC 17011:2017, clause 4.3.1 a), requires that an accredited organisation "fully conforms with the requirements of the accreditation body for claiming accreditation status, when making reference to its accreditation in communication media".
- 9.3 ISO/IEC 17011:2017, clause 4.3.3, requires that an accreditation body shall have a policy governing its accreditation symbol's protection and use. The policy and other requirements of the accreditation body for claiming accreditation status shall at least include:
- ♦ the accreditation claim is related to or associated with only the conformity assessment activities that are covered by the scope of accreditation, and not with any other activities in which the CAB or its related organisation may be involved. In proposals or quotations, it is necessary to distinguish conformity assessment activities that are covered by the scope of accreditation from those which are not;
 - ♦ an accreditation symbol or accreditation claim is not affixed to an item or product (or part of it) or used to imply that an item or product has been certified (for calibration labels and inspection labels, see clauses 8.1 and 8.2 respectively);
 - ♦ an accreditation symbol or an accreditation claim is not used in any manner which gives the impression that the accreditation body accepts responsibility for conformity assessment results, or for any opinion or interpretation derived from those results, or that the accreditation body approves a tested, calibrated or inspected product or item, or reference material or biobank material (for requirements for accreditation symbols on calibration, inspection, reference material and biobank material labels, see clauses 8.1, 8.2, 8.3 and 8.5 respectively);
 - ♦ where an accreditation symbol is printed on letterhead and/or other corporate paper, such items are not used for work proposals or quotes if none of the activity is within the scope of accreditation, nor for reporting of conformity assessment results if none of them are within the scope of the accreditation, nor for certifying a product or item.

- 9.4 A laboratory accredited to ISO/IEC 17025 may mention that it operates a quality management system on its reports and certificates using the following statement:

“This laboratory is accredited in accordance with the recognised International Standard ISO/IEC 17025. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint ISO-ILAC-IAF Communiqué dated April 2017)”

An accredited laboratory choosing to use the above statement on its reports or certificates should also either supply, or provide access to (via a website), the Joint ISO-ILAC-IAF Communiqué as part of the package for its customers.

A medical testing laboratory accredited to ISO 15189 may use an equivalent statement quoting ISO 15189 as the accreditation standard and referring to the joint ISO-ILAC-IAF Communiqué dated January 2015.

An inspection body accredited to ISO/IEC 17020 may use an equivalent statement quoting ISO/IEC 17020 as the accreditation standard and referring to the joint ISO-ILAC-IAF Communiqué dated September 2013.

10. MUTUAL RECOGNITION CLAIMS

- 10.1 Where an accreditation body has a mutual recognition arrangement with one or more other accreditation bodies, its accredited CABs may, in appropriate words, make claim to such recognition on their reports or certificates.
- 10.2 An accreditation body who is a signatory to the ILAC MRA, and who has signed the *ILAC R7-F1 Agreement for the use of the ILAC MRA Mark* and obtained approval for the use of the combined mark from the ILAC Secretariat, may approve the use of the ILAC-MRA Mark by its accredited CABs. The accreditation body shall meet the obligations and provisions of the *ILAC R7:05/2015 - Rules for the Use of the ILAC MRA Mark*.
- 10.3 The use of accreditation symbols of mutual recognition partners on endorsed reports or certificates shall not be permitted by an accreditation body unless it has specific one-to-one agreements with its partner(s) whose accreditation symbols are to be used.

11. MISUSE OF ACCREDITATION SYMBOL OR ACCREDITATION STATUS

- 11.1 Misuse of an accreditation symbol, the ILAC-MRA Mark or claim of accreditation status by any organisation should be treated seriously. It could significantly undermine the credibility of the whole international conformity assessment process.

ISO/IEC 17011:2017, clause 4.3.5, states “*the accreditation body shall take suitable action to deal with incorrect or unauthorized claims of accreditation status, or misleading or unauthorized use of accreditation symbols and the accreditation body logo.*”

Note: Suitable actions include requests for corrective action, suspension, withdrawal of accreditation, publication of the transgression and if necessary, legal action.”

An accreditation body shall have rules and procedures for sanctions, where

misrepresentation of accreditation status is discovered. In some situations, and particularly where misuse was by an organisation that is not accredited, legal actions under copyright or fair trading or other laws of the relevant jurisdiction may be necessary.

- 11.2 An accreditation body shall have procedures to ensure that an accredited CAB discontinues the use of the accreditation symbols or ceases to make any reference to accreditation status in reports, certificates, promotional material, letterhead, internet web sites, etc. for an activity immediately upon suspension or withdrawal of the accreditation for that activity.

However, discretion is required in cases of temporary suspension (e.g. resulting from the temporary absence of resources) provided that no endorsed reports are being issued.

12. CONCLUSION

The integrity of accreditation depends on accreditation bodies and their accredited CABs taking joint responsibility for the proper claims of accreditation status and use of accreditation symbols, and for improving the reputation and value of accreditation for the benefit of all accredited CABs, their customers and other users of conformity assessment results.

13. REFERENCES

- 13.1 ISO/IEC 17000 Conformity assessment – Vocabulary and general principles.
- 13.2 ISO/IEC 17011 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.
- 13.3 ISO/IEC 17020 Conformity assessment – Requirements for the operation of various types of bodies performing inspection.
- 13.4 ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories.
- 13.5 ISO 17034 Conformity assessment - General requirements for the competence of reference material producers.
- 13.6 ISO/IEC 17043 Conformity assessment - General requirements for proficiency testing.
- 13.7 ISO 15189 Medical laboratories - Requirements for quality and competence.
- 13.8 ISO 20387 General requirements for biobanking

APPENDIX A - Revision table

<u>Section</u>	<u>Amendment</u>
Whole document	General revision to include biobanking.
Section 4.2	Reference to digital endorsement added
Section 8.5	Specific requirements for biobanking documents and labels added