



**Procedure for Expansion
of the Scope of
the ILAC Mutual Recognition
Arrangement**

ILAC-R6:09/2009

Previously published as ILAC-S6:10/2007

© Copyright ILAC 2009

ILAC encourages the authorized reproduction of this publication, or parts thereof, by organisations wishing to use such material for areas related to education, standardisation, accreditation, good conformity assessment practice or other purposes relevant to ILAC's area of expertise or endeavour.

Organisations seeking permission to reproduce material from this publication must contact the ILAC Secretariat in writing or via electronic means such as email.

The request for permission must clearly detail:

- 1) the part thereof, for which permission is sought;
- 2) where the reproduced material will appear and what it will be used for;
- 3) whether the document containing the material will be distributed commercially, where it will be distributed or sold, and what quantities will be involved;
- 4) any other background information that may assist ILAC to grant permission.

ILAC reserves the right to refuse permission without disclosing the reasons for such refusal.

The document in which the reproduced material appears must contain a statement acknowledging the ILAC contribution to the document.

Permission to reproduce this material only extends as far as detailed in the original request. Any variation to the stated use of the material must be notified in advance in writing for additional permission.

ILAC shall not be held liable for any use of its material in another document.

Any breach of the above permission to reproduce or any unauthorized use of this material is strictly prohibited and may result in legal action.

To obtain permission or for further assistance, please contact:

The ILAC Secretariat
PO Box 7507
Silverwater NSW 2128
Australia
Fax: +61 2 9736 8373
Email: ilac@nata.com.au

TABLE OF CONTENTS

PREAMBLE4

PURPOSE4

AUTHORSHIP4

1. BACKGROUND.....5

2. THE ILAC PROCEDURE.....6

3. STEP (A).....6

4. STEP (B).....7

5. STEP (C).....7

6. STEP (D).....8

7. STEP (E).....8

8. STEP (F).....9

9. STEP (G).....9



PREAMBLE

This document was developed as a result of the following resolution taken during the 2005 ILAC General Assembly.

ILAC Resolution GA 9.25

The General Assembly supports the ARC's development of a discussion paper that proposes processes to expand or extend the scope of the MRA into other areas considering also the following criteria for inclusion of a standard or other normative document in the ILAC MRA:

- 1. Significant relevance to accreditation of laboratories/inspection bodies and bodies involved in relevant activities.*
- 2. Sufficient substance to enhance the recognition of competence.*
- 3. Fulfils appropriate needs on an international basis.*
- 4. Lack of inclusion poses threats to ILAC leadership in accreditation.*
- 5. Complementary to or supportive of any other standard being currently used.*
- 6. Does not dilute the substance of any existing standard under the ILAC MRA*
- 7. Document must be produced by an international consensus process (including all relevant interested parties).*

PURPOSE

This Procedure describes the steps to be used by ILAC to consider and potentially approve new international accreditation programs for inclusion in the ILAC Arrangement.

AUTHORSHIP

This document was developed by the ILAC Arrangement Committee (ARC) and approved for publication after being endorsed by all ILAC membership in 2007.

Following the publication of ILAC-R1:09/2009 Classification and Publication of ILAC Documents, which includes a revision of the ILAC document classification system, all documents previously published as Secretariat or S Series documents have been relocated to the newly created category of ILAC-R or Rules (Requirements) documents. This document, previously published as ILAC-S6:10/2007 Procedure for Expansion of the Scope of the ILAC Mutual Recognition Arrangement, has been revised to reflect the new classification systems and to update document references where necessary. The content of this document has otherwise not been reviewed or amended.

1. BACKGROUND

During the ILAC 2005 Conference in Auckland a discussion on the development of ILAC's accreditation activity was started. The fundamental question: "What can be accredited?". was followed by the question: "Can this accreditation activity be included in an ILAC Mutual Recognition Arrangement (MRA)?"

ILAC Resolution GA 9.25

The General Assembly supports the ARC's development of a discussion paper that proposes processes to expand or extend the scope of the MRA into other areas considering also the following criteria for inclusion of a standard or other normative document in the ILAC MRA:

1. *Significant relevance to accreditation of laboratories/inspection bodies and bodies involved in relevant activities.*
2. *Sufficient substance to enhance the recognition of competence.*
3. *Fulfils appropriate needs on an international basis.*
4. *Lack of inclusion poses threats to ILAC leadership in accreditation.*
5. *Complementary to or supportive of any other standard being currently used.*
6. *Does not dilute the substance of any existing standard under the ILAC MRA*
7. *Document must be produced by an international consensus process (including all relevant interested parties).*

The proposal for accreditation in a new area may arise from a number of sources. These include:

- Organisations which need independent recognition of their competence 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 organisations against commonly agreed criteria not currently addressed by ILAC; and
- Accreditation bodies themselves may need confirmation of competence in areas which are complementary to areas already accredited by them. For example, historically, laboratory accreditation bodies needed confidence in *calibration* laboratories (through their accreditation) to support their accreditation of *testing* laboratories. More recently in ILAC it has been recognised that other activities supporting confidence in accredited testing and calibration laboratories (certified reference materials and proficiency testing) may need an accreditation process to provide the necessary confidence.

When there is a potential need for a new area of international recognition (and particularly in activities relevant to ILAC's traditional focus of laboratories) it is important that ILAC has a transparent and consistent process to deal with development of an international recognition system for these needs.

This Procedure describes the steps to be used by ILAC to consider and potentially approve new international accreditation programs for inclusion in the ILAC Arrangement.

2. THE ILAC PROCEDURE

The ILAC Procedure has the following steps:

- (a) Identification of a new need for international recognition through accreditation of relevance to ILAC Members;
- (b) Initial consultation with ILAC Members, the joint working group for ILAC, IAF and ISO, ISO CASCO and other interested parties;
- (c) A fundamental discussion in the ILAC General Assembly (GA) if the proposed accreditation involves operation in a new area for ILAC (especially if it is outside the fields mentioned in ISO/IEC 17011). Documents concerning the issue should be distributed to the members at least 30 days before the General Assembly. If the ILAC GA decides to expand ILAC's work into the new area, the procedure will continue as follows:
- (d) Survey of existing experience amongst ILAC Members in accreditation or other forms of recognition for the new area;
- (e) Identification of potential harmonised criteria for accreditation or the need for further development or establishment of such criteria;
- (f) Identification of the processes, standards and other documents of potential relevance to an ILAC MRA, in addition to ISO/IEC 17011 and IAF/ILAC A and ILAC P series documents; and
- (g) Formal agreement by the ILAC GA to proceed with an expansion or extension of the scope of the ILAC MRA, taking account of steps (a) to (f) above.

3. STEP (a)

The proposal for an expansion or extension of scope for the ILAC MRA could come from a number of sources. These include individual ILAC Members, ILAC's Regional Cooperations, regulators, trade bodies, industry or professional associations, groups of affected conformity assessment bodies (however defined), etc.

In the conformity assessment market, there has been an increasing tendency to create sector specific requirements for existing ISO standards. Sometimes this leads to development of a new ISO standard (such as ISO 15189). Mostly, however, only specific requirements are added to the currently used standard, as with the requirements for accreditation of medical reference measurement laboratories. An ILAC agreement with The World Anti-Doping Authority (WADA) is another example of some additional special requirements being added to the core standard and usual accreditation practices.

It is important to note also that the development of ISO Standards or other normative documents may need to follow development by ILAC itself of appropriate initial requirements. Historically, this was the case for a number of the standards and guides now adopted as ISO Standards, but initially developed in ILAC/IAF (eg ISO/IEC Guide 58, Guide 25, Guide 43 etc).

This means that there may be three different situations:

1. A new accreditation scheme is based on the internationally recognized standards already used for accreditation by ILAC Members, (ISO/IEC 17025, ISO 15189 or ISO/IEC 17020);
2. The scheme is for a completely new standard or normative document, covering a conformity assessment body or attestation of competence of a body; or
3. The need may be for an area, not currently covered by an ISO Standard, but already in general use by a number of accreditation bodies and with potential for future development by ISO (or if necessary by ILAC itself, such as with ILAC G12:2000 *Guidelines for the Requirements for the Competence of Reference Material producers* and ILAC G13:07/2007 *Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes*).

The criteria for acceptance of a scheme or an agreement for type 1, 2 or 3 above may be different, but in all cases a process in ILAC to consider the relevance and need for the program, as well as a process for acceptance are needed. Acceptance of a new accreditation activity of any type may also have an impact on the MRA.

4. STEP (b)

Proposals for ILAC to consider new areas for accreditation and their potential MRA relevance should first be presented to the ILAC Executive for initial examination. This examination includes background on the need for the new activity, the current experience within ILAC members in the area, the views of affected parties, including any external bodies that may have proposed such a need, and the availability of initial criteria etc.

The ILAC Executive will consult its members, the joint working group for ILAC, IAF and ISO, ISO CASCO and other interested parties for comments.

5. STEP (c)

If the proposed accreditation involves operation in new areas for ILAC, the ILAC Executive will invite a fundamental discussion in the ILAC General Assembly concerning expansion of the working field of ILAC to the proposed area. If the ILAC General Assembly accepts the expansion, the process will continue.

The Executive Committee then refers the specific proposal for accreditation to both the Accreditation Committee (AIC) (for consideration of technical criteria issues) and Arrangement Committee (ARC) (for MRA related issues), and (depending on the nature of the activity) to other potentially interested ILAC committees (Laboratory Committee (LC), Proficiency Testing Consultative Group (PTCG) etc).

These referrals then lead to step (d).

6. STEP (d)

The ARC or AIC or other relevant ILAC Committee then undertakes a survey of ILAC Members (and sometimes other parties) of their existing experience or future interest in the proposed new area of activity. These Committees will also ensure that the new activity does not jeopardise the existing obligations already undertaken by ILAC Members under the ILAC Arrangement.

The results of such surveys shall be used to determine if there are sufficient numbers of ILAC members with an interest in the new area to justify its further development and consideration for inclusion in an expanded ILAC MRA.

7. STEP (e)

As part of their consideration of the new proposal, the ARC or AIC and/or any other relevant ILAC Committee shall consider whether the standard, or other normative documents proposed for the new accreditation activity, meet the seven (7) criteria described in ILAC Resolution GA 9.25 (above).

If the proposed scheme is based on an agreement between a scheme owner (like WADA) and ILAC, it will be necessary to make sure that:

1. The scheme does not exclude any member of the relevant MRA.
2. The assessment process shall at least fulfil all the relevant requirements established in ISO/IEC 17011.
3. The accreditation body is the only body responsible for the decisions taken in respect of accreditation.
4. Decisions regarding the maintenance of an accreditation body in the MRA can only be taken within ILAC (for unaffiliated bodies) or the Recognised Regions where the accreditation body is a member.
5. The information supplied to the market must always be transparent and not create barriers to competition amongst the affected bodies covered by the accreditation.
6. The scheme does not jeopardise the current obligation ILAC members took upon themselves in the current Arrangement.

8. STEP (f)

After completion of steps (a) to (e) above (or in parallel) the ARC will examine whether the existing criteria for compliance with MRA Signatory status, i.e. ISO/IEC 17011 and the relevant documents in the IAF/ILAC A and ILAC P series (amended as needed for the new activity) can be used for an extension of the ILAC MRA, and draft any additional criteria or peer evaluation practices that might be needed to address the new activity.

9. STEP (g)

After completion of steps (a) to (f), including any balloting on criteria, the relevant Committee or Committees shall make a formal draft resolution for the ILAC GA, including details of the normative or other documents for criteria, for extension of the ILAC MRA.