



Application of ISO/IEC 17011 for the Accreditation of Proficiency Testing Providers

ILAC-P13:10/2010

© Copyright ILAC 2010

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.asn.au

TABLE OF CONTENTS

PREAMBLE4

PURPOSE5

AUTHORSHIP5

POLICY5



PREAMBLE

Over recent years there has been a need and market demand for the competence of Proficiency Testing (PT) providers to be recognized through accreditation. However, many Accreditation Bodies (ABs) have historically organised proficiency tests and/or interlaboratory comparisons and now about half of the ILAC Members are currently accrediting PT providers or preparing for such accreditation.

In recognition of the need for an international standard to cover this activity, work started in December 2006 on the production of ISO/IEC 17043 *Conformity assessment – General requirements for proficiency testing*. This new standard has now been published, replacing ISO/IEC Guide 43, and provides common criteria for the assessment and accreditation of PT Providers which has previously been conducted using ISO/IEC Guide 43:1 and/or ILAC G-13.

PT provision is recognised as a conformity assessment activity in ISO/IEC 17043. This assists all relevant stakeholders of PT activities as it provides a harmonized set of requirements for the accreditation of PT Providers and, therefore, the development of a Mutual Recognition Arrangement (MRA).

In preparation for the inclusion of PT Provider accreditation in the ILAC MRA, the ILAC Proficiency Testing Consultative Group (PTCG) has undertaken an analysis of ISO/IEC 17011 *Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies* to determine the suitability of its application to ABs accrediting PT Providers.

This analysis identified that ISO/IEC 17011 is wholly relevant and is a suitable standard to be applied to ABs that accredit PT Providers. If PT Providers are to be recognized as Conformity Assessment Bodies (CABs), which is necessary to ensure the relevance of ISO/IEC 17011, a conflict arises because the standard currently allows ABs to organise Proficiency Testing but does not allow ABs to offer conformity assessment services that CABs perform.

ISO/IEC 17011 clearly recognises that PTs and other interlaboratory comparisons (ILCs) are valuable tools for ABs to use when evaluating the competence of laboratories. Accordingly, it is not practical to resolve the conflict by completely disallowing ABs the opportunity to organise PTs/ILCs. This would result in a loss of information concerning laboratories' competence that would not benefit end users, including both participating laboratories and their accreditation bodies. This is particularly important for measurement audit activities (where these may involve a PT or ILC) that are conducted as part of the assessment process, and also for ABs situated in developing countries or involved with accrediting new or developing technical areas where no appropriate PT/ILC activity from other providers is currently available.

Note: Measurement audits that are conducted as a part of the assessment process are not considered as a conformity assessment activity but as an integral component of the on-site assessment.

Whilst ABs should not offer PT as a 'commercial' activity, there are some circumstances under which it is acceptable for ABs to provide PT. These circumstances are described in the following policy.

Note: For the purposes of this document 'commercial' should be understood as a competitive activity that is undertaken for economic gain.

PURPOSE

The purpose of this Policy document is to harmonise the application of ISO/IEC 17011 for accreditation bodies in regard to their organisation of Proficiency Testing and/or accreditation of Proficiency Testing (PT) Providers.

AUTHORSHIP

This policy document was prepared by the ILAC Proficiency Testing Consultative Group (PTCG) and finalised in 2010.

POLICY

1. ABs offering accreditation of PT Providers shall do so in accordance with the requirements of ISO/IEC 17011.
2. Until such time as ISO/IEC 17011 is amended to include PT Provision within its scope, the following application of the specified clauses shall apply:

2.1 *ISO/IEC 17011:2004 Clause 3.11* (Definition of Consultancy)

ABs may provide inputs to assist PT providers in the formulation of their PT schemes where the AB uses the information from those schemes in its assessment process. This input shall not include the provision of any advice or assistance to the PT Provider in relation to any application or maintenance of PT Provider accreditation and shall be limited to input as a stakeholder in relation to the use of PT to provide information concerning the competence of laboratories. The information shall be provided in a non-discriminatory way and shall not affect the impartiality of the AB.

2.2 *ISO/IEC 17011:2004 Clauses 4.3.6 a) and 7.15.2*

2.2.1 Where an AB does not accredit PT Providers but organizes proficiency testing or other interlaboratory comparisons in accordance with clause 7.15.2, this shall not be considered to be an activity that affects the impartiality of the AB. However the AB shall ensure that its activities in this area do not have an adverse impact on the PT services within its economy.

2.2.2 Where an AB accredits PT Providers it shall not act as a PT Provider offering PT schemes as a commercial activity. The AB can however organize PT or other interlaboratory comparison activities, including measurement audits, as an integral part of its assessment process to assist the AB in establishing competence of the laboratory in particular areas. The AB shall justify, with the participation of its interested parties (as described in clause 4.3.2 of ISO/IEC 17011:2004), its role in the provision of such a scheme to ensure that its impartiality as an AB is not compromised. This justification shall be documented and should be on the basis that no alternative independent scheme or program exists or is available to the laboratories that would provide an equivalent mechanism to assist in the AB establishing competence.

3. Any PT, interlaboratory comparison or measurement audit activity provided by the AB should be conducted in accordance with the relevant requirements of ISO/IEC 17043.
4. ABs shall declare any PT or other comparisons they organize to any MRA evaluation teams so that these activities are included within the scope of the evaluation with regard to the AB's competence and impartiality.
5. Where an AB conducts measurement audit activities it shall consider the acceptance of alternative, equivalent means by which a laboratory can provide information to assist in establishing its competence, where these alternatives exist.
6. An AB, with the participation of its interested parties as described in clause 4.3.2 of ISO/IEC 17011:2004, shall routinely review its PT/ILC and/or measurement audit activities to ensure it is not restricting the development of the operations of alternative providers. This review shall include consideration of the availability of suitable PT schemes, as evidence of the viability of independently operated PT schemes. This review shall be documented.

Note: This review could form part of the annual management system review.