The ILAC Arrangement

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Abstract

The aim of the ILAC Arrangement is to develop a global network of accredited testing and calibration laboratories that can be relied on to provide accurate results.

The ILAC Arrangement, entered into effect on 31 January 2001, provides technical underpinning to international trade by promoting cross-border stakeholder confidence and acceptance of accredited laboratory data. Until now, there has been no international mutual recognition agreement in laboratory accreditation. This has been a hindrance for some types of international trade, particularly those products which have had to undergo re-testing or re-calibration upon entry to importing countries. The Arrangement should facilitate this trade.

Background

The International Laboratory Accreditation Cooperation (ILAC) first started as a conference in 1978 with the aim of developing international cooperation for facilitating trade by promotion of the acceptance of accredited test and calibration results. In 1996, ILAC became a formal cooperation with a charter to establish a network of mutual recognition agreements among accreditation bodies that would fulfil this aim. The ILAC Arrangement is the culmination of 22 years of intensive work.

On 2 November 2000, 36 laboratory accreditation bodies, full members of the International Laboratory Accreditation Cooperation (ILAC), from 28 economies worldwide signed an "arrangement" in Washington, DC to promote the acceptance of technical test and calibration data for exported goods. The signing ceremony for this multi-lateral, mutual recognition arrangement (ILAC Arrangement) was held during the General Assembly meeting of ILAC.

As of April 2002, 40 laboratory accreditation bodies of ILAC have signed the multi-lateral, mutual recognition arrangement (the "ILAC Arrangement. The ultimate aim is increased use and acceptance by industry as well as government of the results from accredited laboratories, including results from laboratories in other countries. In this way, the free-trade goal of "a product tested once and accepted everywhere" can be realized.

The Foundation of the Arrangement

The principal elements for establishing confidence among the participating systems within ILAC are listed below. These elements are designed to ensure conformance with the requirements in

order to establish and maintain mutual confidence in the technical competence of ILAC members and their accredited laboratories. The elements are:

1. Exchange of information on the development and operation of ILAC member accreditation schemes;

2. Participation in the work and decision-making of the ILAC General Assembly and ILAC Committees where applicable;

3. Participation in international inter-laboratory comparisons and proficiency testing programs;

4. Participation in the work of ILAC Expert Groups and Task Forces held to discuss problems related to testing and calibration in various technical fields;

5. Evaluations of applicants and re-evaluations of signatories to this Arrangement are conducted in accordance with the relevant ILAC and regional cooperation documents;

6. Observations of applicant bodies' and signatories' assessments of their laboratories to determine if these laboratories meet the requirements of ISO/IEC 17025, December 1999 (and future versions thereof);[i]

7. Confidence in the metrology institutes of the signatory economies to which traceability is claimed by accredited laboratories and support for the measurement comparison activities of BIPM* and/or regional metrology organizations.[ii]

How Does the Arrangement Work?

This Arrangement is based on the results of an intensive evaluation of each body carried out in accordance with the relevant rules and procedures contained in several ILAC publications.[iii]

Each accreditation body signatory to the Arrangement agrees to abide by its terms and conditions and by the ILAC evaluation procedures and shall:

- Maintain conformance with ISO/IEC Guide 58 (and future versions thereof),[iv] related ILAC guidance documents, and a few, but important, supplementary requirements, and

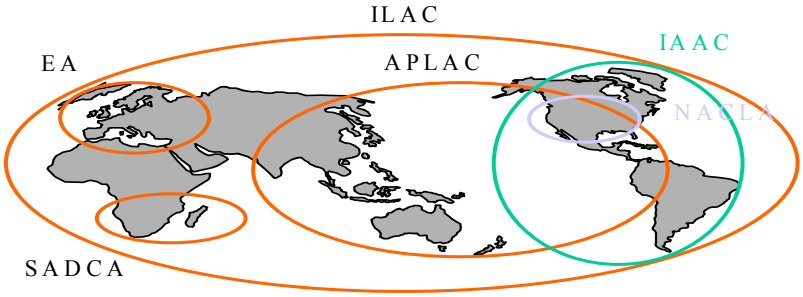
- Ensure that all accredited laboratories comply with ISO/IEC 17025 (and future versions thereof) and related ILAC guidance documents.

The signatories have, in turn, been peer-reviewed and shown to meet ILAC's criteria for competence.

The ILAC Arrangement builds upon existing or developing regional arrangements established around the world. The bodies participating in these regional arrangements are responsible for maintaining the necessary confidence in accreditation bodies from their region that are

signatories to the new ILAC Arrangement. Each recognized Regional Cooperation Body must abide by the procedures defined in ILAC requirements documents. Currently, the European cooperation for Accreditation (EA) and the Asia Pacific Laboratory Accreditation Cooperation (APLAC) are the only ILAC-recognized regions with acceptable mutual recognition arrangements (MRAs) and evaluation procedures.[v] The Inter-American Accreditation Cooperation and Southern African Development Cooperation for Accreditation (SADCA) are still developing their MRA evaluation processes before requesting recognition and approval by ILAC. Other regions being developed in other parts of the world are in their infancy. Bodies that cannot be affiliated with a recognized region may apply directly to ILAC for evaluation and recognition. See the Figure below.

The International Picture



EA	European co-operation for Accreditation
APLAC	Asia Pacific Laboratory Accreditation Cooperation
ILAC	International Laboratory Accreditation Cooperation
IAAC	Inter-American Accreditation Cooperation
SADCA	Southern African Accreditation Cooperation

The evaluation of an accreditation body to establish its qualifications to be a signatory involves a team of peers (generally senior staff of experienced accreditation bodies). Evaluations include time spent at the headquarters office of the applicant body to determine compliance with ISO/IEC Guide 58. Additionally, the evaluators witness the performance of the applicant's assessors during actual assessments to determine if the laboratories are in compliance with ISO/IEC 17025 and there is sufficient depth of examination to determine competence.

Maintenance of the Arrangement

In order to maintain the value and meaning of the Arrangement, the signatories agree to notify each other about any significant changes in the status or operation of the body. Issues of significance include changes in name or legal/corporate status; new agreements negotiated with other accreditation bodies or the revision, suspension or termination of any agreements; changes in key senior staff or the organizational structure; or significant changes in the operations of the body. Each signatory to the Arrangement must also designate a liaison officer to afford a consistent channel of communication between the accreditation bodies.

Future Steps

Now that the Arrangement is in place, the next crucial step is for governments and industries to take advantage of this Arrangement. Governments can use it to further develop or enhance trade agreements. Another important step that is already underway involves government acceptance of the results from accredited laboratories. Regulatory agencies around the world, including in the United States, are beginning to accept the results from testing and calibration laboratories that are accredited by bodies, such as the ILAC Arrangement signatories, without direct government review, including results from laboratories in other countries.

Many specifiers, like government agencies, have come to appreciate the importance of credible accreditation programs that are based on internationally recognized standards. With restricted budgets, many Government agencies can no longer do it all themselves; increasingly, they must rely on third-party laboratories to support their regulatory efforts. When they do so, they need a fair and meaningful basis for identifying qualified providers. Accreditation provides that and the Arrangement provides a means for recognition of acceptable accreditation bodies.

Industry users of test and calibration data similarly can take advantage of the ILAC Arrangement. Users will have greater confidence in the accuracy of the test or calibration report they are purchasing because it is been generated by a competent facility. This is particularly true for an educated client, one who is conscious of the scope of the laboratory's accreditation. Manufacturers also gain efficiency because of accreditation; instead of their own on-site assessments, they can defer to the assessments of competent accreditation authorities that are ILAC Arrangement signatories.

Conclusion

The ILAC Arrangement builds confidence among accreditation bodies and their ability to determine a laboratory's competence to perform testing or calibrations. Confidence facilitates the acceptance of testing and calibration results between countries when the results can be demonstrated to come from accredited laboratories. This ultimately helps to reduce some technical barriers to trade. Through the ILAC Arrangement, the foundation for realizing the ideal of having products "tested once and accepted everywhere" has been established.

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[i] International Organization for Standardization, International Electro-technical Commission, ISO/IEC 17025, "General requirements for the competence of testing and calibration laboratories," December 1999.

[ii] International Laboratory Accreditation Cooperation Mutual Recognition Arrangement, 2 November 2000, p. 4

[iii] International Laboratory Accreditation Cooperation MRA Policy Statement; ILAC P1, ILAC Mutual Recognition Arrangement (Arrangement): Requirements for Evaluation of Accreditation Bodies, 2001; ILAC P2, ILAC Mutual Recognition Arrangement (Arrangement): Procedures for the Evaluation of Regional Cooperation Bodies for the Purpose of Recognition, 2000; ILAC P3, ILAC Mutual Recognition Arrangement (Arrangement): Procedures for the Evaluation of Unaffiliated Bodies for the Purpose of Recognition, 2001.

[iv] International Organization for Standardization/International Electro-technical Commission, ISO/IEC Guide 58, "Calibration and testing laboratory accreditation systems -- General requirements for operation and recognition," 1993.

[v] EA 02/02, Policies and Procedures for the Multi-Lateral Agreement, 1998; APLAC MR-001, Procedures for Establishing and Maintaining Mutual Recognition Arrangements between Accreditation Bodies, 2000.