

# The ILAC Arrangement

## Support for International Trade

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**O**n Nov. 2, 2000, 36 laboratory accreditation bodies, full members of the International Laboratory Accreditation Cooperation, from 28 economies worldwide signed a multilateral mutual recognition arrangement in Washington, D.C. — the ILAC Arrangement to promote the acceptance of technical test and calibration data for exported goods. 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.

### BACKGROUND

ILAC was established as a conference in 1978 with the aim of developing international cooperation for facilitating trade by promoting 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 fulfill this aim. ILAC was incorporated in 2002. The ILAC Arrangement was the culmination of 22 years of intensive work.

Now almost four years later from its effective date of January 2001, 46 laboratory accreditation bodies are signatories to the ILAC Arrangement. This Arrangement provides significant technical underpinning to international trade. There had been no international mutual recognition agreement in laboratory accreditation up until then. This has been a hindrance for some types of international trade. The key to the Arrangement is the development of a global network of accredited testing and calibration laboratories that are assessed and recognized as competent by ILAC Arrangement signatory accreditation bodies. The signatories have, in turn, been peer-reviewed and shown to meet ILAC's criteria for competence. Governments are taking advantage of it to further develop or enhance trade agreements. 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 interlaboratory 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 labora-

tories to determine if these laboratories meet the requirements of International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025, General Requirements for the Competence of Testing and Calibration Laboratories, December 1999 (and future versions thereof) or equivalents.

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 the Bureau International des Poids et Mesures and/or regional metrology organizations.<sup>1</sup>

#### 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.<sup>2</sup>

Each 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, Calibration and Testing Laboratory Accreditation Systems — General Requirements for Operation and Recognition, 1993 (and future versions thereof), 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 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 recog-

nized Regional Cooperation Body must abide by the procedures defined in ILAC requirements documents. Currently, the European Cooperation for Accreditation and the Asia Pacific Laboratory Accreditation Cooperation are the only ILAC-recognized regional organizations with acceptable mutual recognition arrangements, or MRAs, and evaluation procedures. The Inter-American Accreditation Cooperation and Southern African Development Cooperation for Accreditation are still under development. Other regional organizations 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.

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.

#### THE BENEFITS

Government and industry are taking advantage of this Arrangement. Governments are using it to develop or enhance trade agreements further. Another important step that is already under way involves government acceptance of the results from accredited laboratories. Regulatory agencies around the world 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, such as 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 can similarly 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 being 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.

#### SUCCESS STORIES FROM NEW ZEALAND

Our friends at the New Zealand accreditation body, International Accreditation New Zealand, have had great success in making the ILAC Agreement work in the way it is intended and they offer some examples of the effectiveness of the ILAC Arrangement in facilitating trade.

##### *New Zealand Mussels to Italy*

Preserved mussels exported from New Zealand must be accompanied by an export certificate based on microbiological tests for *E. coli* bacteria. A shipment of mussels worth \$50,000 was en route to Canada when the customer went bankrupt. The exporter found another customer in Italy but by the time the mussels reached Italy the export certificate had expired. The New Zealand Ministry of Agriculture was aware that IANZ was a signatory to the ILAC Arrangement, as was the Italian accreditation body, Sistema Nazionale per L'Accreditamento de Laboratori. Through SINAL, IANZ

was able to locate a laboratory near the port that was accredited for the necessary tests, and the mussels were retested. The New Zealand Ministry of Agriculture accepted these test results, because of SINAL's signatory status in the ILAC Arrangement, and issued a replacement export certificate. This saved the exporter (and their insurance company) a great deal of money and provided a gourmet extravaganza for Italian palates.

#### *Bottled Drinking Water into an Asian Country*

The conclusion of the Uruguay Round opened many markets to products that had previously been banned. One such product is bottled drinking water. Drinking water is, however, required to be tested for chemical characteristics and microbiological content. The authorities may also require historical tests of the water at source and following processing. A major New Zealand exporter was able to have his fresh, clean water from New Zealand accepted in a new market in Asia because his test reports came from an IANZ-accredited laboratory. The Asian regulator accepted the New Zealand test reports because IANZ is a signatory of the ILAC Arrangement.

#### *Electrical Products in New Zealand*

Electrical products are required to satisfy electromagnetic compatibility regulations before being placed on the New Zealand market. The regulator will accept test reports from an IANZ-accredited laboratory or from a laboratory accredited by any accreditation body recognized by IANZ, i.e., an ILAC Arrangement signatory. IANZ frequently receives enquiries from manufacturers of electrical products in nations such as Germany, Hong Kong, Taiwan, and the United States, asking where they should get their products tested in order to satisfy the New Zealand regulations. They are delighted when IANZ tells them that, since their products have already been tested by a laboratory accredited by the American Association for Laboratory Accreditation or the National Voluntary Laboratory Accreditation Program in the United States, the Chinese National Laboratory Accreditation in Taiwan, or a Deutscher Akkreditierungsrat affiliate in Germany, their products do not need to be retested in New Zealand. Their ex-

isting test reports will be accepted by New Zealand regulators because of the ILAC Arrangement to which the American, Taiwanese and German accreditation bodies and IANZ are signatories.

#### *Sports Floors into New Zealand*

A contractor contacted IANZ because he was involved in the construction of a new sports center in New Zealand and wanted to import a sports floor from Denmark. The contractor's customer was insisting that he ensure that the floor had passed certain tests. The importer was in a quandary because he could not see how he could have the floor tested without bringing it into New Zealand and he did not want to go to the expense of importing the floor without some assurance that the floor would be suitable. He already had test reports from a laboratory accredited by Danish Accreditation, or DANAK. Because DANAK and IANZ were both signatories to the ILAC Arrangement, IANZ was able to assure him that IANZ- and DANAK-accredited test reports were equivalent, so he could go ahead and import the floor without concern.

#### *Fire Extinguishers from Singapore into New Zealand*

The New Zealand Insurance Council is responsible for approving fire extinguishers sold in New Zealand. The Insurance Council contacted IANZ over a shipment of fire extinguishers from Singapore. The extinguishers had already been tested in an accredited laboratory in Singapore. IANZ checked with Singapore's accreditation body, Singapore Laboratory Accreditation Scheme, that the laboratory was accredited for the specific tests and were able to assure the Insurance Council that the extinguishers did not need to be retested in New Zealand because both the New Zealand and Singaporean accreditation bodies are signatories to the ILAC Arrangement. Indeed, the New Zealand Insurance Council regulations now document that test reports from laboratories accredited by IANZ agreement partners in the ILAC Arrangement are acceptable in New Zealand.

#### *Electrical Products from Europe into New Zealand*

A New Zealand manufacturer was importing components from Europe,

undertaking further processing and then re-exporting the finished article. The components had been tested for electromagnetic compatibility in Western Europe. He asked IANZ whether the European test reports would be acceptable in New Zealand. Unfortunately, the test reports lacked detail and the results were not clearly expressed. IANZ checked with the accreditation body in the economy from which the test reports originated and were advised that the particular laboratory was not accredited. Neither was it a notified body for electromagnetic compatibility testing under the European regulations. ILAC advised the New Zealand manufacturer that these test results were not acceptable and he would need to have the product retested in an accredited laboratory. He passed this information back to his European supplier. We understand the European laboratory is now in the process of upgrading its systems and has applied for accreditation to make use of the benefits afforded by the ILAC Arrangement.

#### *Crayons from Spain, Britain and Hong Kong Arrive Without Incident in New Zealand*

Because children will often suck crayons, importers who bring this product to New Zealand must ensure the crayons have been tested for heavy metals before the New Zealand Ministry of Health allows the product to be put on shop shelves. Fortunately, most of the crayons being imported to New Zealand are accompanied by test reports from laboratories that are accredited by signatories of the ILAC Arrangement. IANZ endorses test reports from laboratories accredited by IANZ's agreement partners. The Ministry of Health wants to protect children's health and has confidence in test reports issued by laboratories that have been accredited by overseas accreditation authorities participating in mutual recognition agreements (such as the ILAC Arrangement) with IANZ.

#### *Electrical Meters to Finland*

A New Zealand company exporting electrical meters to Finland was pleasantly surprised to discover that their products would automatically be accepted in the voluntary sector because of the ILAC Arrangement. The test report for the electrical meters was issued by a laboratory accredited by IANZ, and the Finnish Accredita-

tion Service accepted the New Zealand laboratory's test report because both FINAS and IANZ are signatories to the ILAC Arrangement. This saved considerable time and money for the New Zealand exporter who, without the ILAC Arrangement in place, would otherwise have needed to have their product retested in Finland, at considerable expense.

#### *Baby Bottle Nipples Arrive from Britain*

Ensuring their children's safety is a concern for all parents, and this extends to items usually taken for granted as safe, such as the rubber nipple on a baby bottle. However, nipples must be tested for nitrosamine, a substance that occurs in rubber products, as there is evidence that nitrosamines may cause brain tumors. The Ministry of Health recognizes the importance of ensuring that nipples arriving in New Zealand are nitrosamine free, and tests undertaken in accredited laboratories have ensured a safe supply of baby bottle nipples in New Zealand. The Ministry of Health insists nitrosamine tests be undertaken in accredited laboratories, and test reports for imported nipples are rightly expected to be from accredited laboratories as well. Recently, British nipples have arrived in New Zealand, their integrity assured by the test report being from a laboratory accredited by the United Kingdom Accreditation Service, the British equivalent to IANZ. UKAS and IANZ are both signatories to the ILAC Arrangement, whereby tests from British accredited laboratories are considered as equivalent to tests undertaken in laboratories accredited by IANZ.

#### **SUCCESS STORIES FROM THE UNITED STATES**

From the United States, the ILAC-accredited American Association for Laboratory Accreditation offers similar success stories, which not only demonstrate that the ILAC Agreement works to reduce redundant testing, but also that sharing resources among accreditation bodies can result in assessment cost savings for accredited laboratories.

#### *U.S.-Manufactured Pipettes Arrive in France*

A U.S. manufacturer of state-of-the-art pipettes tested its product in its own A2LA-accredited laboratory

before shipping them to France for distribution by their France-based sales team. Once the pipettes arrived in France, the manufacturer was asked to have them retested before they could be sold in France. A2LA offered to talk with the French accreditation body, Comite Francais d'Accreditation, and after discussions between all involved parties, the testing performed in the United States was accepted by the French officials, without the need for retesting.

#### *Hydraulic Testing of Amalgam Separators for Dental Industry*

Prior to marketing, manufacturers of amalgam separators have to have their products tested in accordance with ISO 1143, Metals — Rotating Bar Bending Fatigue Testing, by one of two laboratories located in Europe in order to have the amalgam separators included on a list of approved separators as part of the Voluntary Amalgam Recovery Program. This program is implemented jointly by the Metropolitan Council Environmental Services and Minnesota Dental Association. A2LA, MCES and MDA discussed other testing possibilities to relieve the burden on the manufacturers and improve the efficiency of the approval process. As a result, the requirements for the hydraulic testing of flow through amalgam separators were amended. Now, the flow testing must be performed by independent laboratories that have been accredited by a signatory to the ILAC Agreement. Ultimately, improvement in the process to test and approve the separators and get them to foreign and domestic markets will result in savings to the dentists and their clients.

#### *U.K.-Based Assessor Performs A2LA Assessment*

A2LA had accredited a U.S.-based calibration laboratory that offered field calibration services in the United Kingdom. It was necessary for A2LA to ensure that the field service technician operating in the United Kingdom was competent to perform the cali-

brations found on the laboratory's scope of accreditation. It would have been very expensive to send a U.S.-based A2LA assessor to the United Kingdom, so A2LA contacted UKAS and asked to use the assessment services of one of their trained and qualified calibration assessors. A2LA provided the UKAS assessor with all of the A2LA policies, procedures and assessor forms and laboratory information that were needed and a thorough assessment was performed at minimal cost to the laboratory.

#### **CONCLUSION**

The ILAC Arrangement builds confidence among accreditation bodies regarding their ability to determine a laboratory's competence to perform testing or calibrations. Confidence facilitates the acceptance of testing and calibration results within and 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.

#### **References**

- 1 International Laboratory Accreditation Cooperation Mutual Recognition Arrangement, 2 November 2000, p. 4.
- 2 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.

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