>> ILAC MRA Annual Report 2017

Accreditation:
Delivering Global Confidence

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>> Introduction

ILAC and its accreditation body members invest significant effort and resource to maintain the integrity and consistency of the MRA through a peer evaluation process. This report sets out the detailed activity that is carried out as part of the peer evaluation process, to ensure that regulators, specifiers, and businesses are able to have confidence in the Arrangement.

>> About ILAC

ILAC is the international authority on laboratory, inspection body, reference material producer and proficiency testing provider accreditation, with a membership consisting of accreditation bodies and stakeholder organisations throughout the world.

ILAC provides the infrastructure that supports the world-wide demonstration of competence and equivalence of testing (including medical) and calibration laboratories, inspection bodies and other types of bodies such as reference material producers and proficiency testing providers that support laboratories and inspection bodies through accreditation.

Accreditation of laboratories and inspection bodies supports activities within and between economies including trade, protection of health, safety and the environment for the public benefit. Its essential purpose is to provide confidence in the competence of bodies performing and supporting these activities.

The ILAC Arrangement is an international, multilateral mutual recognition arrangement for accreditation bodies. Participating accreditation bodies agree to promote acceptance of the equivalence of calibration, test and inspection reports produced by accredited facilities. Each accreditation body undergoes peer evaluation according to the International standards and ILAC rules and procedures prior to becoming a signatory to the ILAC Arrangement.

ILAC, the recognised regional cooperation bodies of ILAC and the accreditation body signatories all commit significant time and resources through the peer evaluation process to maintain and improve the integrity, consistency and recognition of the ILAC Mutual Recognition Arrangement (MRA). This annual report provides information on the activities carried out as part of the peer evaluation process to ensure that regulators and consumers of laboratory and inspection data are able to maintain confidence in the results produced under the ILAC MRA.

>> The ILAC MRA

The ILAC MRA is an agreement signed by the signatory accreditation bodies to recognise the equivalence of the accreditation programs operated within the scope of their signatory status.

The aim of the ILAC MRA is provide recipients of laboratory and inspection body reports confidence that the results have been generated by a technically competent facility through accreditation by an accreditation body that is a signatory to the ILAC MRA.

The ILAC MRA provides assurance that laboratories and inspection bodies in different economies are operating to the same international standards. The accreditation programs offered by the accreditation bodies that are signatories to the ILAC MRA are all evaluated on an on-going basis to confirm equivalence.

The details of the ILAC MRA are included in ILAC P5 *ILAC Mutual Recognition Arrangement: Scope and Obligations* available from:
http://ilac.org/publications-and-resources/ilac-documents/procedural-series/

>> Scope of the ILAC MRA

The scope of the ILAC MRA covers the following accreditation programs:

- Calibration laboratories using ISO/IEC 17025;
- Testing laboratories using ISO/IEC 17025;
- Medical testing laboratories using ISO 15189; and
- Inspection bodies using ISO/IEC 17020.

Accreditation: Supporting protection from terrorism

The Department of Homeland Security's BioWatch Program provides early detection of a bioterrorism event and helps communities prepare a coordinated response. The combination of detection, rapid notification, and response planning helps federal, state, and local decision-makers take steps to save lives and mitigate damage.

The BioWatch Quality Assurance (QA) Program ensures that the BioWatch Program continues to provide actionable results with high confidence to local public health decision makers. The QA Program was established in 2011 to ensure field and laboratory operations are conducted according to program policies, protocols, and QA and quality control (QC) requirements to ensure the defensibility of results. Laboratories must be accredited to participate.

>> Signatories to the ILAC MRA

The ILAC MRA is based on the established and peer evaluated multi-lateral arrangements (MRA/MLAs) of the recognised regional cooperation bodies.

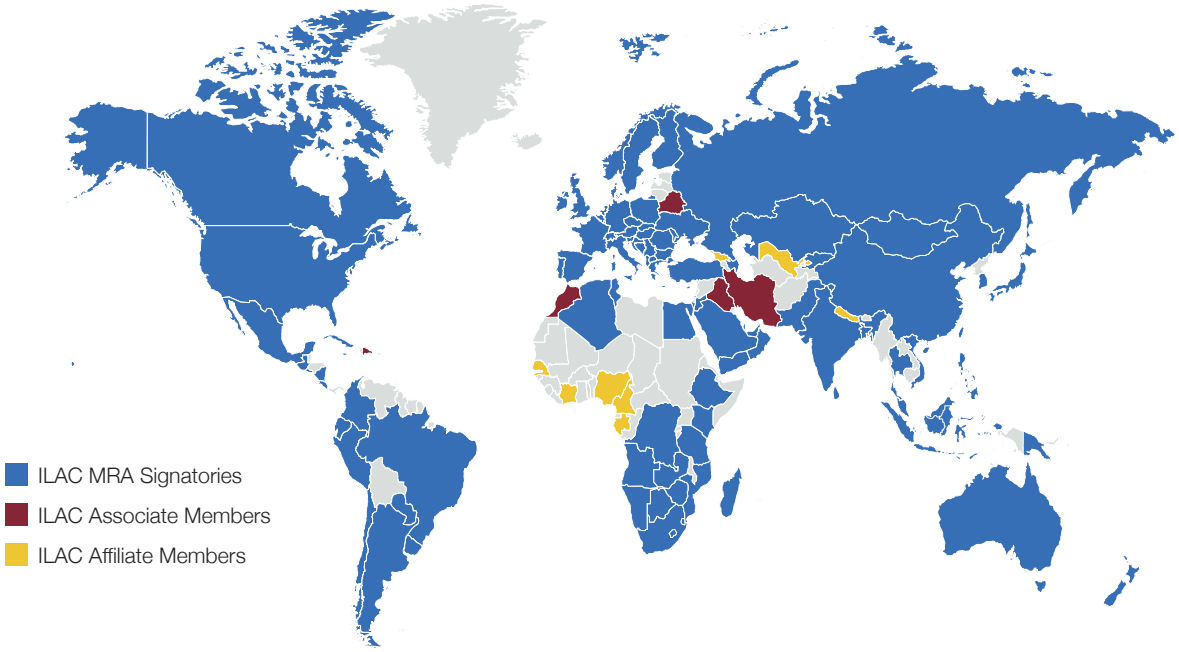
In October 2017, the members of the ILAC Arrangement Council reviewed and considered the final evaluation report on the evaluation of the Arab Accreditation Cooperation (ARAC), in particular the processes and management of the ARAC MLA. It was agreed via ballot that the ARAC MLA be recognised to the ILAC MRA for the accreditation of calibration (ISO/IEC 17025), testing (ISO/IEC 17025) and medical testing (ISO 15189) laboratories and inspection bodies (ISO/IEC 17020).

Accreditation bodies that are Associate members of ILAC and a signatory to a recognised regional MRA/MLA are automatically accepted as signatories to the ILAC MRA.

Where there is no recognised regional cooperation body available for an accreditation body to be a member, ILAC provides the opportunity for these accreditation bodies to be peer evaluated as an unaffiliated accreditation body.

As of December 2017 there were:

- **4** regional cooperation bodies recognised under the ILAC MRA - Asia Pacific Laboratory Accreditation Co-operation (APLAC), Arab Accreditation Cooperation (ARAC), European co-operation for Accreditation (EA) and Inter-American Accreditation Cooperation (IAAC);
- **94** accreditation body signatories via the MRA/MLAs of these recognised regions from 85 economies; and
- **3** unaffiliated accreditation bodies – SADCAS (Secretariat – Botswana and also covering Angola, Democratic Republic of Congo, Lesotho, Madagascar, Malawi, Mozambique, Namibia, Seychelles, Swaziland, Tanzania, Zambia and Zimbabwe), KCA (The Kyrgyz Republic) and SANAS (South Africa).
- **Resulting in a total of 97 signatories to the ILAC MRA from 100 economies.**



>> Signatories to the ILAC MRA *continued*

Significant changes to the list of signatories to the ILAC MRA in 2017 included the addition of the following signatories (new and extensions) for the accreditation scopes listed below:

- Algerian Accreditation Body (ALGERAC), Algeria, calibration (ISO/IEC 17025), testing (ISO/IEC 17025) and inspection (ISO/IEC 17020)
- Southern African Development Community Accreditation Service (SADCAS), Botswana, extension for medical testing (ISO 15189) and inspection (ISO/IEC 17020)
- Ente Costarricense De Acreditacion (ECA), Costa Rica, extension for medical testing (ISO 15189)
- National Accreditation Body of Republica de Cuba (ONARC), Cuba, extension for inspection (ISO/IEC 17020)
- Organismo Salvadoreño de Acreditación (OSA), El Salvador, extension for calibration (ISO/IEC 17025)
- Ethiopian National Accreditation Office (ENAO), Ethiopia, testing (ISO/IEC 17025) and medical testing (ISO 15189)
- National Accreditation Authority (NAH), Hungary, calibration (ISO/IEC 17025), testing (ISO/IEC 17025), medical testing (ISO 15189) and inspection (ISO/IEC 17020)
- Jordan Accreditation & Standardization Systems - Accreditation Unit (JAS-AU), Jordan, calibration (ISO/IEC 17025), testing (ISO/IEC 17025) and medical testing (ISO 15189)
- Kenya Accreditation Services (KENAS), Kenya, calibration (ISO/IEC 17025), testing (ISO/IEC 17025), medical testing (ISO 15189) and inspection (ISO/IEC 17020)
- Korea Laboratory Accreditation Scheme (KOLAS), Korea, extension for medical testing (ISO 15189)
- National Centre of Accreditation of the Republic of Moldova (MOLDAC), Moldova, calibration (ISO/IEC 17025), testing (ISO/IEC 17025), medical testing (ISO 15189) and inspection (ISO/IEC 17020)
- Federal Service for Accreditation (RusAccreditation), Russian Federation, calibration (ISO/IEC 17025), testing (ISO/IEC 17025)

There are currently two accreditation bodies with suspended signatory status to the ILAC MRA:

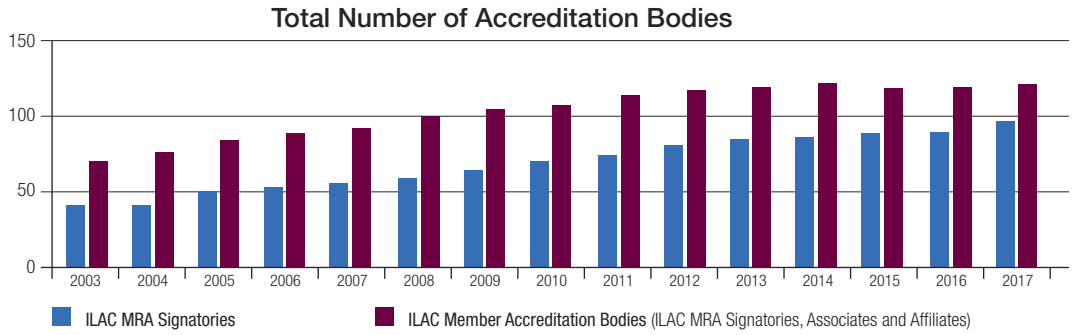
- The Kyrgyz Centre of Accreditation (KCA)
- Papua New Guinea Laboratory Accreditation Scheme (PNGLAS)

The current version of the list of signatories is available from http://ilac.org/ilac-mra-and-signatories/.

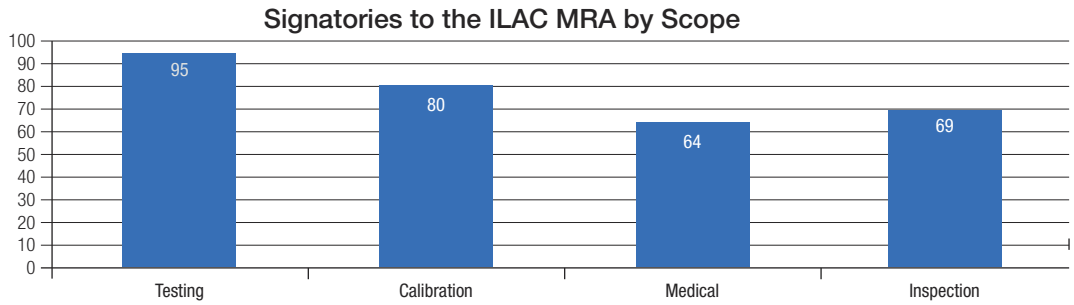
The ILAC website includes a dedicated signatory search function available from http://ilac.org/signatory-search/. This database of the signatories to the ILAC MRA is searchable by accreditation body name and acronym, economy and scope of signatory status to the ILAC MRA. In addition, this search facility can be hosted directly on your website (via the code provided at the above link) to ensure your customers have access to the latest information on the signatories to the ILAC MRA.

>> Global Growth

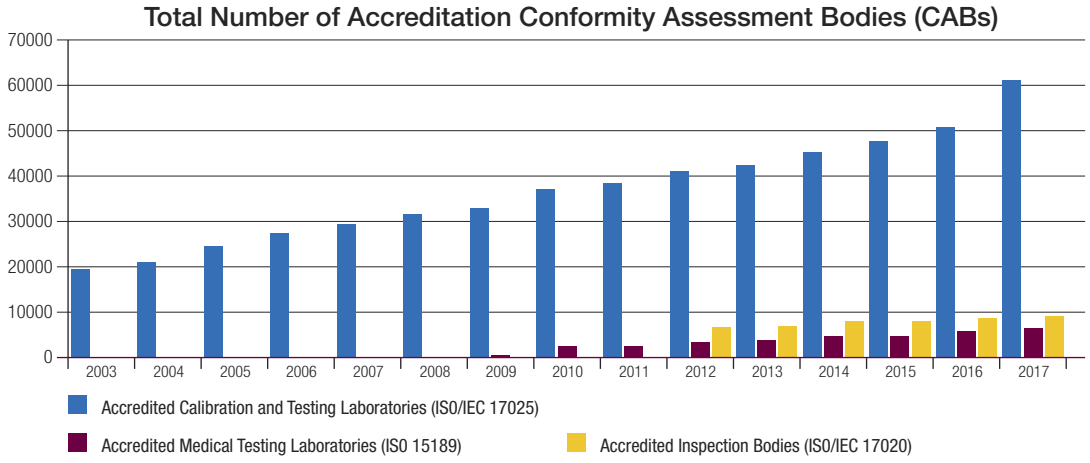
In recent years, there has been a steady geographic expansion of the membership of ILAC through the number of accreditation bodies that have become members of ILAC.



The number of signatories to the ILAC MRA by scope of signatory status is shown below.



There has also been a corresponding growth in the number of laboratories and inspection bodies that are accredited by ILAC MRA signatories.



The total number of calibration and testing laboratories accredited to ISO/IEC 17025 in the above graph includes over 51,000 testing laboratories and 9000 calibration laboratories.

>> The ILAC MRA Mark

The signatories to the ILAC MRA and their accredited calibration and testing laboratories and inspection bodies are able to use the ILAC MRA Mark via licensing agreements and in accordance with ILAC R7 *Rules for the Use of the ILAC MRA Mark.*

When used by a conformity assessment body (CAB) on reports or certificates of calibration/testing/inspection activities in combination with the accreditation body's accreditation symbol, the Mark demonstrates that the calibration, testing or inspection activity has been carried out by an organisation that is accredited by an ILAC MRA signatory for that activity, providing assurance and confidence in the results.

As at December 2017, 70 signatories to the ILAC MRA had signed licensing agreements to use the ILAC MRA Mark.

Accreditation: Steel mesh testing introduced due to failing products

Some steel mesh marketed in New Zealand as Grade 500E ductile steel mesh was not achieving the required 10 per cent elongation when tested to the standard. As a result, the Ministry of Business, Innovation and Employment has published Amendment 14 to Acceptable Solutions and Verification Methods for Building Code clause B1. The amendment clarifies how testing of Grade 500E ductile steel mesh must meet AS/NZS 4671:2001 Steel reinforcing materials.

Testing laboratories must be accredited by a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).

>> Evaluations

Accreditation bodies are admitted to the ILAC MRA following a stringent evaluation of their operations by a peer evaluation team which is tasked with ensuring the accreditation body fully complies with both international standards and ILAC requirements. The evaluation process results in three types of findings that must be addressed as described below:

- **Non-conformity** – a finding where the accreditation body does not meet a requirement in the International standards, the ILAC or regional requirements or the requirements of its own system. Evidence of the implementation of the changes required by the accreditation body to address these findings must be provided prior to the results of the evaluation proceeding to the decision making process.
- **Concern** – a finding that may lead to a non-conformity. A plan for addressing these findings must be provided and agreed by the evaluation team.
- **Comment** – a finding that may result in an improvement to the accreditation programs offered by the accreditation body.

ILAC, and its accreditation body members, invest significant time and resources to operate a robust peer evaluation process. It is an on-going process, with full re-evaluations carried out every four years, covering all economies and all activities covered by the ILAC MRA

During 2017, the activities for the scheduled re-evaluation of two of the recognised regional cooperation bodies were commenced, the initial evaluation of one regional cooperation body seeking recognition by ILAC was commenced and another initial evaluation completed. An evaluation of a regional cooperation body requesting an extension to their recognition was also undertaken.

The re-evaluation of two unaffiliated accreditation bodies and initial evaluations of two applicant unaffiliated accreditation bodies were finalised in 2017. In addition, the evaluation activities for an extension to signatory status for an unaffiliated accreditation body was carried out and finalised in 2017 and an evaluation was carried out to review the suspended status of an unaffiliated accreditation body.

In addition to these evaluations carried out directly by ILAC, the recognised regional cooperation bodies carried out the following peer evaluation visits in 2017:

- APLAC – 12;
- ARAC – 3;
- EA – 18; and
- IAAC – 9.

>> Evaluator Resources

Thirteen evaluators were involved in the evaluation visits directly carried out by ILAC in 2017. In addition one of these visits included a trainee evaluator funded by ILAC.

>> Decisions by the ILAC Arrangement Council

The ILAC Arrangement Council consists of representatives from the accreditation bodies that are signatories to the ILAC MRA as well as Associate members of ILAC, the regional cooperation bodies and a stake-holder member. It is responsible for the decisions relating to the signatory status of both regional cooperation bodies and unaffiliated accreditation bodies to the ILAC MRA.

On completion of a peer evaluation, the final report prepared by the evaluation team and including information on the close out of any findings is forwarded to the members of the ILAC Arrangement Management Committee (AMC). This committee is responsible for the day to day management of the ILAC MRA. The report is thoroughly reviewed by this committee including where necessary seeking additional information from the evaluation team to clarify any issues. On completion of the review process the AMC prepares a recommendation for consideration by the Arrangement Council.

The ILAC Arrangement Council considered six evaluation reports based on the recommendation of the ILAC AMC in 2017.

Accreditation: Assuring the quality of steel in India

The Indian Directorate General of Foreign Trade has relaxed its import rules of steel and steel products, and will rely on the ILAC and IAF arrangements to maintain quality assurance.

Quality certification should be either from a product certification body (ISO Guide 65/ISO 17065) accredited by an IAF MLA signatory, or from an ISO/IEC 17020 inspection body accredited by an ILAC Signatory.

Further information is available from the DGFT website.

>> On-going development of the ILAC MRA

ILAC is committed to extending the ILAC MRA in terms of geographic coverage and technical scope. The following developments took place in 2017:

- ILAC membership currently includes 2 regional cooperation bodies, African Accreditation Cooperation (AFRAC) and Southern African Development Community in Accreditation (SADCA), that are working towards peer evaluation of their MRA/MLAs to become recognised regional cooperation bodies to the ILAC MRA. The evaluation activities for one of these regional bodies commenced in 2017.

- A resolution was adopted at the ILAC General Assembly in October 2014 to extend the ILAC MRA to include accreditation programs covering Proficiency Testing Providers (PTP) using ISO/IEC 17043. The updating of the ILAC requirements documentation and procedures was completed in 2015 to allow the acceptance of applications for the evaluation of proficiency testing provider accreditation programs. Applications for an extension of recognition to include PTP were received from the 3 recognised regional cooperation bodies in 2016. An extraordinary evaluation was carried out in 2017 to address one of these applications and the other two applications are included in the scheduled re-evaluations of two regions that commenced in 2017.

- A resolution was adopted at the ILAC General Assembly in October 2016 to extend the ILAC MRA to include accreditation programs covering Reference Material Producers (RMP) using ISO 17034. The ILAC requirements documentation and procedures were updated in 2017 to allow the acceptance of applications for the evaluation of reference material producer accreditation programs. Two applications were received in late 2017 from recognised regions to extend their recognition to the ILAC MRA to include the accreditation of RMP. These applications will be evaluated as part of the scheduled re-evaluations currently in progress.

Accreditation: Reduces the need for regulatory audits and the associated costs

Accreditation of laboratories under the Drinking Water Testing Standard Scheme (DWTS) significantly reduces the burden of Drinking Water Inspectorate (DWI) audits, as the need for the Regulator to routinely audit or inspect the laboratory is removed. Conversely, if a laboratory chooses not to adopt DWTS, they will be subject to risk-based vertical audits, including audits of samplers by the DWI. The costs of DWI audits or inspections of laboratories used by water companies are recovered by the DWI, and so there are clear financial benefits of being accredited under the scheme.

>> International standards

ILAC representatives actively participated throughout 2016 and in early 2017 in the ISO-CASCO Working Groups that were reviewing ISO/IEC 17011 and ISO/IEC 17025. These are key standards used in the evaluations conducted by ILAC and the regional cooperation bodies and in the accreditation processes of the MRA signatories. The latest revisions of these standards were published on 30 November 2017.

The ILAC General Assembly (GA) and IAF GA agreed during the Joint General Assembly in 2016 that a transition period of 3 years from the date of publication be adopted for the revised ISO/IEC 17011:2004 *Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies,* that is November 2020. The ILAC and IAF members adopted a resolution during the 2017 Joint General Assembly on the implementation of the transition to the 2017 version of the standard *(JGA Vancouver Resolution 2 – Implementation of transition to ISO/IEC 17011:2017).* Details of the resolution and the transition plan are available from the **Joint ILAC-IAF Documents (A-Series) page** in the Publications section of the ILAC website.

The ILAC GA agreed that a transition period of 3 years from the date of publication be adopted for the revised version of ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories,* that is November 2020.

ISO and ILAC have issued a joint communiqué that re-confirms the three-year transition period for accredited laboratories to transition to the 2017 version of the ISO/IEC 17025. While both the 2005 and 2017 versions of ISO/IEC 17025 will remain valid during the three-year transition period, accreditations to ISO/IEC 17025: 2005 will be invalid from 30 November 2020, as per the ILAC Resolution GA 20.15 adopted in November 2016. The ISO/ILAC 17025: *2017 Transition Communiqué* is available from the **ILAC-ISO Partnerships page.**

The ILAC AMC is responsible for monitoring the progress of both the transition periods for ISO/IEC 17011 and ISO/IEC 1025. A schedule for reporting on these transitions has been issued to the relevant regions and unaffiliated accreditation bodies.

Accreditation: Japanese local governments and public agencies rely on accredited testing in the ready-mixed concrete and building material industries

In Japan, Testing Laboratory Accreditation System based on the JIS Law (Japan National Laboratory Accreditation System, JNLA) for concrete strength testing and metallic materials tensile testing are adopted in specifications or guidance documents issued by local governments and public agencies as part of requirements for third party testing facility.

Based on these requirements, for example in the ready-mixed concrete and building material industries, testing facilities are accredited according to ISO/IEC 17025 as testing laboratories so that they can deliver confidence in their test results and contribute in ensuring the safety of public construction and built environment.

>> New and revised Publications

ILAC regularly publishes requirements and information to support accreditation and conformity assessment processes. During 2017, ILAC issued the following publications:

- **ILAC B9:02/2017** *ISO 15189 Medical Laboratory Accreditation*
- **ILAC B11:02/2017** *Why become an accredited inspection body*
- **ILAC B12:02/2017** *How does accredited inspection benefit Government and Regulators*
- **IAF/ILAC A1:03/2017** *IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Requirements and Procedures for Evaluation of a Regional Group*
- **IAF/ILAC A2:03/2017** *IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Requirements and Procedures for Evaluation of a Single Accreditation Body*
- **ILAC-G27:06/2017** *Guidance on measurements performed as part of an inspection process*
- **ILAC-P4:06/2017** *ILAC Mutual Recognition Arrangement: Policy and Management*
- **ILAC-P5:06/2017** *ILAC Mutual Recognition Arrangement: Scope and Obligations*

Accreditation: The safe management of asbestos in commercial property

The UK's Health and Safety Executive (HSE) introduced regulations to protect workers and the wider community from the risks of exposure to asbestos. Amongst other requirements, the Control of Asbestos Regulations require testing for the presence of asbestos to be carried out by a laboratory that is accredited against the requirements of ISO/IEC 17025, the international standard for testing laboratories.

HSE also recommends that, where surveys are carried out for the presence of asbestos, they should be carried out by inspection bodies that are accredited against the requirement of ISO/IEC 17020, the international standard for bodies performing inspection. HSE strongly recommends the use of an accredited surveyor to safely manage asbestos. The regulator recognises that accreditation provides clients with an assurance of a surveyor's competence. A review of the effectiveness of the Regulations concluded that:

- The Regulation minimised the risks from exposure to asbestos, keeping workers and the community safe. The review stated that the fall in exposures to asbestos between 1980 and 2015 will lead to 25,700 fewer deaths from mesothelioma and lung cancer in the 100 years between 2001 and 2100.
- Costs to business and government/taxpayers, as well as costs to the individuals affected, both in terms of financial costs and the impact of quality of life and loss of life, when applied to those estimates to the yearly profile of prevented cancer deaths between 2001 and 2100, the present value of the benefits to society of preventing those cases of cancer is estimated at £20.9 bn.

>> On-going promotion of the ILAC MRA

Case studies from economies all around the world continue to be added to the **publicsectorassurance.org** website to illustrate the value of accreditation in key policy areas as a tool to help government officials and regulators deliver results.

The site, which has been developed by **IAF, ILAC, ISO, IIOC** and **IEC,** also contains links to independent research and information to provide additional supporting evidence.

By showcasing the policy areas where accreditation of conformity assessment is, and can be used, such as **economic development, healthcare, environmental protection, energy, food safety, construction, crime and security,** the site continues to provide inspiration for central government, local government and regulators to deliver positive benefit by the use of more conformity assessment tools.

Supporting the needs of government, regulators and the public sector remains a core objective of the conformity assessment community.

In addition, a website dedicated to providing examples of the benefits of accredited conformity assessment activities to business was launched in 2017. It is the business benefits website **http://business-benefits.org/** and contains case studies, research papers and supporting material demonstrating the monetary value of standards, conformity assessment and accreditation for businesses.

>> World Accreditation Day 2017

The global accreditation community celebrates each year with the World Accreditation Day on 9 June to raise awareness of the value that accreditation plays in facilitating global trade or in checking that products are fit and safe for consumption against a standard, a code or practice or regulatory requirements.

The theme for World Accreditation Day in 2017 was **"Accreditation: Delivering confidence in construction and the built environment".**

Accreditation is a global tool that helps to address local, national and international needs for governments. Standards, conformity assessment and accreditation are all market based tools that can be used by Government policy makers to deliver better regulation, environmental protection, public safety, fraud prevention, fair and efficient markets and public trust.

>> Additional Information

The ILAC website (www.ilac.org) provides information on the ILAC MRA (www.ilac.org/ilac-mra-and-signatories/) and also includes brochures (www.ilac.org/publications-and-resources/ilac-documents/promotional-brochures/) and information on World Accreditation Day (www.ilac.org/media-centre/world-accreditation-day/) celebrated on the 9 June each year.

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