



>> ILAC MRA Annual Report 2018



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 schemes 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 schemes 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:

<https://ilac.org/publications-and-resources/ilac-policy-series/>

>> Scope of the ILAC MRA

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

- 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.

>> 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 May 2018, the members of the ILAC Arrangement Council reviewed and considered the final evaluation report on the evaluation of the African Accreditation Cooperation (AFRAC), in particular the processes and management of the AFRAC MRA. It was agreed via ballot that the AFRAC MRA 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).

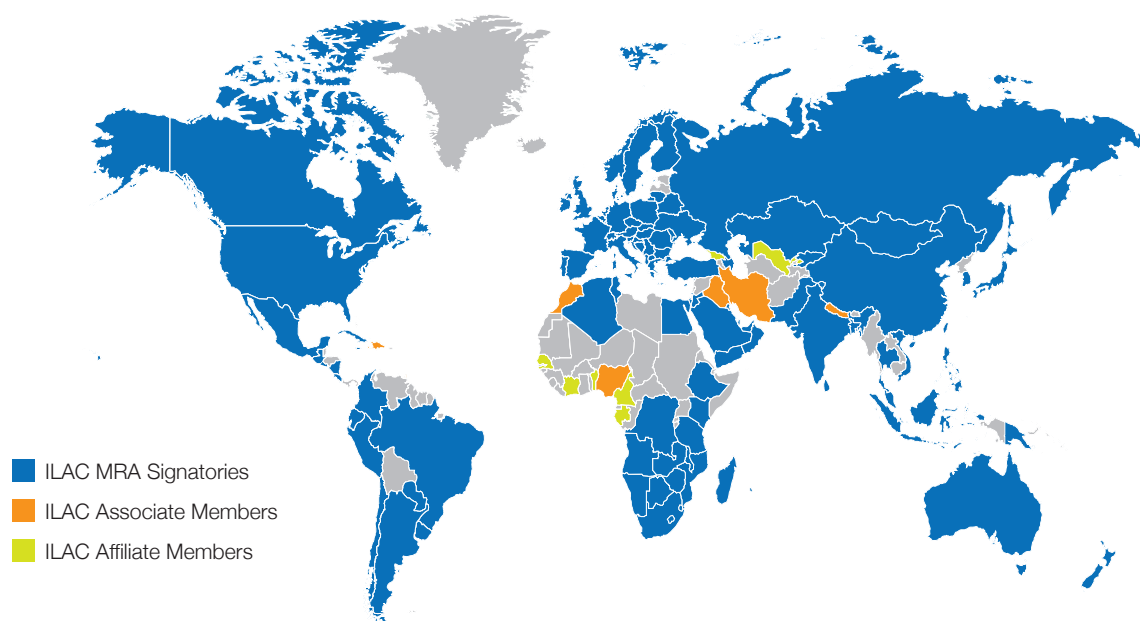
Accreditation bodies that are Associate members of ILAC and a signatory to a recognised regional MRA/MLA are automatically accepted as signatories to the ILAC MRA.

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 2018 there were:

- **5** regional cooperation bodies recognised under the ILAC MRA – African Accreditation Cooperation (AFRAC), Asia Pacific Laboratory Accreditation Co-operation (APLAC), Arab Accreditation Cooperation (ARAC), European co-operation for Accreditation (EA) and Inter-American Accreditation Cooperation (IAAC);
- **99** accreditation body signatories via the MRA/MLAs of these recognised regions from 102 economies; and
- **1** unaffiliated accreditation body – KCA from the The Kyrgyz Republic.

Resulting in a total of 100 signatories to the ILAC MRA from 103 economies.



>> Signatories to the ILAC MRA *continued*

Significant changes to the list of signatories to the ILAC MRA in 2018 included the addition of the following signatories (new and extensions) for the accreditation scopes listed below:

- Drejtoria e Përgjithshme e Akreditimit (DPA), Albania, extension for inspection (ISO/IEC 17020)
- Belarusian State Centre for Accreditation (BSCA), Republic of Belarus, testing (ISO/IEC 17025) and calibration (ISO/IEC 17025)
- Organismo Salvadoreño de Acreditación (OSA), El Salvador, extension for inspection (ISO/IEC 17020)
- National Center of Accreditation (NCA), Kazakhstan, extension for medical testing (ISO 15189)
- Kyrgyz Centre for Accreditation (KCA), Kyrgyz Republic, extension for calibration (ISO/IEC 17025)
- Lithuanian National Accreditation Bureau (LA), Lithuania, calibration (ISO/IEC 17025), testing (ISO/IEC 17025), medical testing (ISO 15189) and inspection (ISO/IEC 17020)
- Mauritius Accreditation Service (MAURITAS), Mauritius, testing (ISO/IEC 17025) and calibration (ISO/IEC 17025)
- National Accreditation Office (ONA), Nicaragua, extension for calibration (ISO/IEC 17025)
- GCC Accreditation Center (GAC), Saudi Arabia, extension for calibration (ISO/IEC 17025) and inspection (ISO/IEC 17020)
- Swiss Accreditation Service (SAS), Switzerland, extension for inspection (ISO/IEC 17020)
- Perry Johnson Laboratory Accreditation, Inc (PJLA), USA, extension for inspection (ISO/IEC 17020)

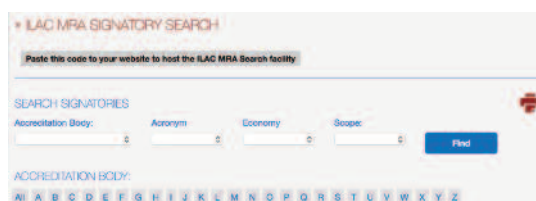
In addition, the ILAC Arrangement Council considered the report on the October 2017 evaluation of The Kyrgyz Center of Accreditation (KCA), The Kyrgyz Republic and agreed to re-instate the signatory status of KCA to the ILAC MRA for testing (ISO/IEC 17025) in October 2018.

At the end of December 2018 there was one accreditation body with suspended signatory status to the ILAC MRA:

- Papua New Guinea Laboratory Accreditation Scheme (PNGLAS)

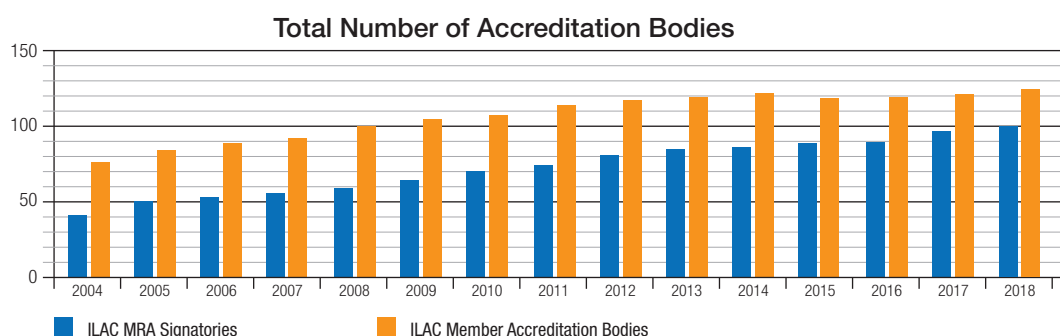
The current version of the list of signatories is available from <https://ilac.org/ilac-mra-and-signatories/>

The ILAC website includes a dedicated signatory search function available from <https://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.

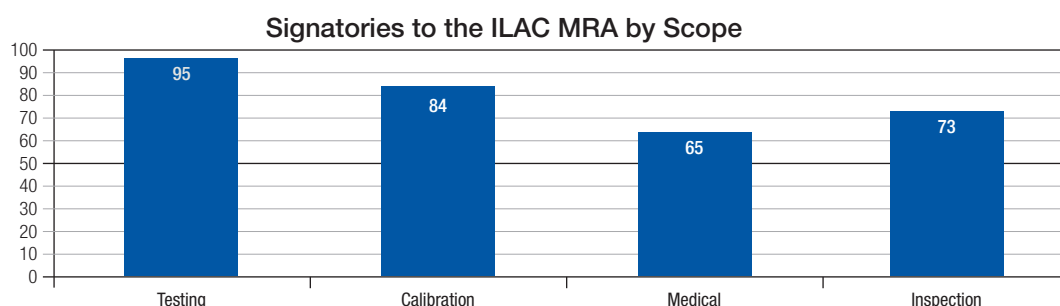


>> Global Growth

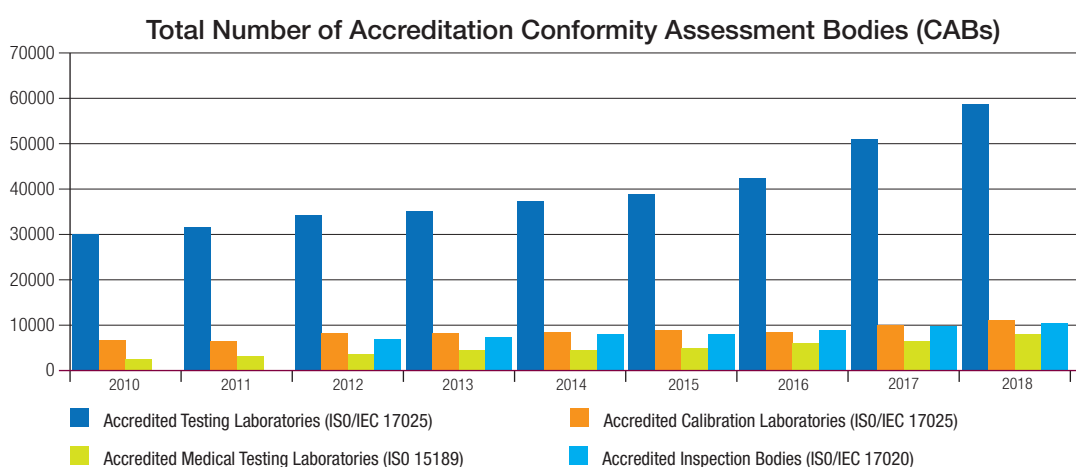
In recent years, there has been a steady geographic expansion of the membership of ILAC through the number of accreditation bodies that have become members of ILAC.



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 58000 testing laboratories and 11000 calibration laboratories



>> The ILAC MRA Mark



The signatories to the ILAC MRA and their accredited calibration and testing (including medical) 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.



>> 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 2018, the activities for the scheduled re-evaluation of three of the recognised regional cooperation bodies were in progress. Two of these include the on-site activities for an extension to include the accreditation of proficiency testing providers in accordance with ISO/IEC 17043. Also during 2018 an initial evaluation of a regional cooperation body was completed and an evaluation of a regional cooperation body requesting an extension to their recognition was also undertaken.

The re-evaluation of an unaffiliated accreditation body was finalised in 2018.

In addition to these evaluations carried out directly by ILAC, the recognised regional cooperation bodies carried out the following peer evaluation visits in 2018:

- AFRAC – 2
- APLAC – 10
- ARAC – 1
- EA – 18
- IAAC – 7

>> Evaluator Resources

Eighteen evaluators were involved in the evaluation visits directly carried out or finalised by ILAC in 2018. In addition one of these evaluations 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 stakeholder 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 three evaluation reports based on the recommendation of the ILAC AMC in 2018.



>> 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 2018:

- ILAC membership includes one regional cooperation body, the Southern African Development Community in Accreditation (SADCA), that is currently working towards peer evaluation of their MRA/MLA to become a recognised regional cooperation body to the ILAC MRA.
- 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. Applications for an extension of recognition to include PTP were received from 3 recognised regional cooperation bodies in 2016. An extraordinary evaluation was carried out in 2017 to address one of these applications. This evaluation was finalised in 2018 and resulted in the decision of the ILAC Arrangement Council to accept the extension to the recognition to the ILAC MRA for the European Cooperation for Accreditation (EA) for PTP however this decision will not be implemented until a second regional cooperation body has been accepted for PTP

The remaining two applications for PTP are included in the scheduled re-evaluations of the two regions that were in progress during in 2018.

- 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. Two applications were received in late 2017 and one in 2018 from recognised regions to extend their recognition to the ILAC MRA to include the accreditation of RMP. These applications are being evaluated as resources permit.



>> International standards

The ILAC AMC is responsible for monitoring the progress of the agreed 3 year transition periods for the 2017 versions of both ISO/IEC 17011 *Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies* and ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*.

These two key standards are used in the evaluations conducted by ILAC and the regional cooperation bodies and in the accreditation processes of the MRA signatories. A schedule for reporting on these transitions was issued to the relevant regions and unaffiliated accreditation bodies following the publication of the revised standards in November 2017.

Details of the resolution and the transition plan for ISO/IEC 17011 are available from the **Joint ILAC-IAF Documents (A-Series) page** in the Publications section of the ILAC website.

ISO and ILAC 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**.



>> New and revised Publications

ILAC regularly publishes requirements and information to support accreditation and conformity assessment processes. During 2018, ILAC issued the following publications:

- **IAF/ILAC A1:01/2018** *IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Requirements and Procedures for Evaluation of a Regional Group*
- **IAF/ILAC A2:01/2018** *IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Requirements and Procedures for Evaluation of a Single Accreditation Body*
- **IAF/ILAC A3:01/2018** *IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Template report for the peer evaluation of an Accreditation Body based on ISO/IEC 17011:2017*
- **IAF/ILAC A6:01/2018** *Approval Process for IAF/ILAC A-Series Documents*
- **ILAC-R1:03/2018** *Management of ILAC Documents*
- **ILAC-G28:07/2018** *Guideline for the Formulation of Scopes of Accreditation for Inspection Bodies*
- **ILAC-G26:11/2018** *Guidance for the Implementation of a Medical Accreditation Scheme*
- **IAF/ILAC B1:09/2018** *The route to signing the IAF or ILAC Arrangement*
- **IAF/ILAC B2:09/2018** *How do I gain confidence in an Inspection Body? Do they need ISO 9001 Certification or ISO/IEC 17020 Accreditation*
- **IAF/ILAC B6:09/2018** *Accreditation: Delivering confidence in the provision of energy*

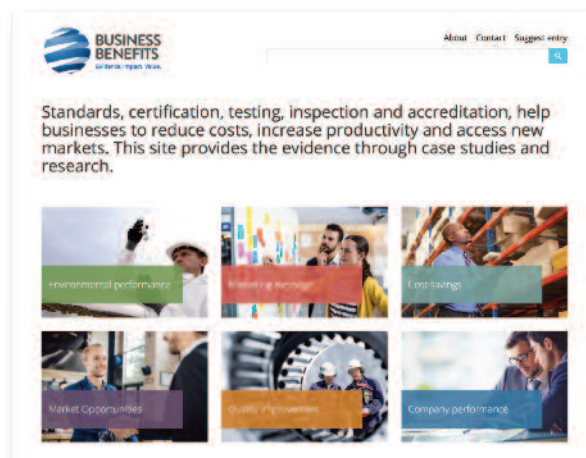
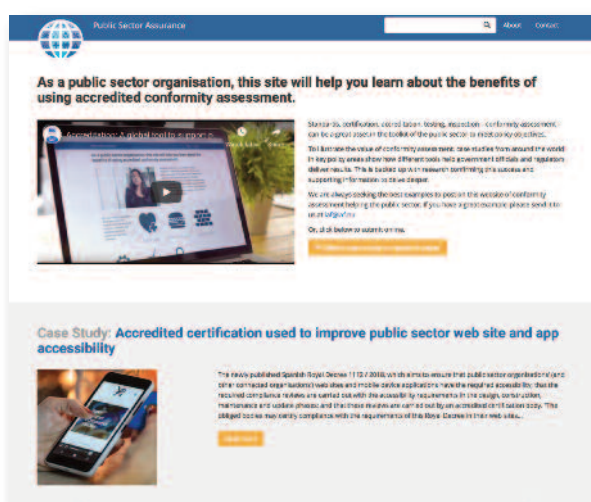
>> On-going promotion of the ILAC MRA

The two websites below, provide case studies and research from economies all around the world illustrating the value of accreditation as a tool to help government officials deliver results and to help businesses reduce costs, increase productivity and access new markets.

- The publicsectorassurance.org website which has been developed by the global quality infrastructure 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.

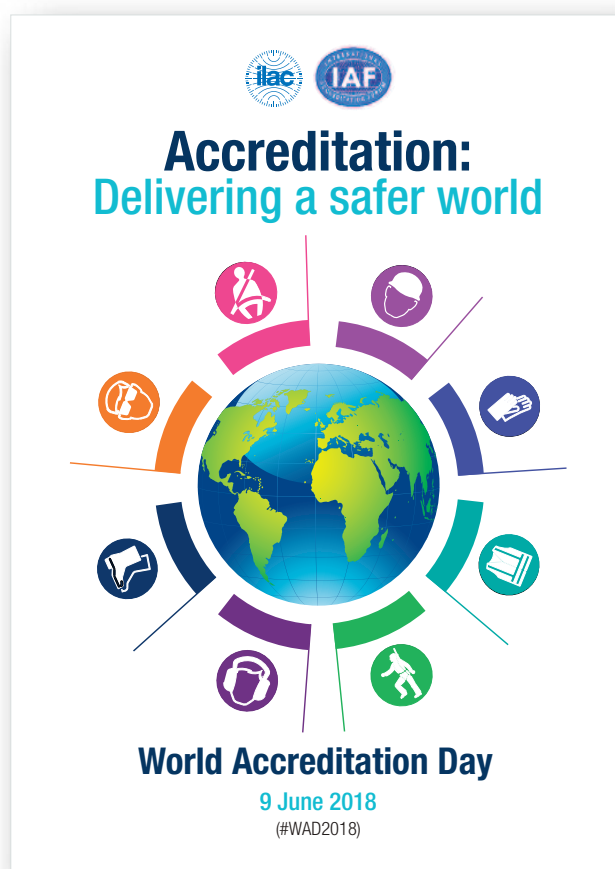
- The business-benefits.org website provides a the number of case studies, research papers and supporting materials demonstrating the value of standards and accredited conformity assessments have on businesses.



>> World Accreditation Day 2018

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, in checking that products and services are fit and safe for use against a standard, a code or practice or regulatory requirements.

The theme in 2018 focused on how accreditation delivers a safer world. In particular the expectation of safe workplaces, safe products, safe transport, safe food, in fact all aspects of our lives is universally shared. Statistics however show that the expectation is not always being matched by the reality and closing this gap is a vital consideration for government, regulators and businesses, aiming to keep people safer in their work, their domestic life, their journeys and all other parts of their lives.





>> 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/news-and-events/world-accreditation-day/) celebrated on the 9 June each year.

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