



# ILAC MRA 2019 ANNUAL REPORT

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# INTRODUCTION

ILAC and its accreditation body members invest significant effort and resources to maintain the integrity and consistency of the ILAC Mutual Recognition Arrangement (MRA), also known as the ILAC Arrangement, through a peer evaluation process. This report sets out the detailed activities that are carried out as part of the peer evaluation process, to ensure that regulators, specifiers, and businesses can 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.

*Note: Laboratories including medical laboratories, inspection bodies, reference materials producers and proficiency testing providers are commonly referred to as conformity assessment bodies or CABs.*



## - ILAC provides the infrastructure that supports the world-wide demonstration of competence and equivalence of accredited CABs. -

The essential purpose of accreditation is to provide confidence in the competence of CABs which support activities within and between economies including trade, protection of health, safety and the environment, for the public benefit.

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, proficiency testing programs and reference materials,

produced by accredited facilities. Each accreditation body undergoes peer evaluation according to 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 Arrangement. 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, proficiency testing programs and reference materials 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 and users of proficiency testing programs and reference materials confidence that the results, programs and materials have been generated by a technically competent CAB that has been accredited by an accreditation body that is a signatory to the ILAC Arrangement.

**The ILAC MRA provides assurance that CABs 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 their currency and relevance.

*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:

**01. CALIBRATION LABORATORIES  
USING ISO/IEC 17025**

**02. TESTING LABORATORIES  
USING ISO/IEC 17025**

**03. MEDICAL TESTING  
LABORATORIES USING  
ISO 15189**

**04. INSPECTION BODIES  
USING ISO/IEC 17020**

**05. PROFICIENCY TESTING  
PROVIDERS USING  
ISO/IEC 17043\*\***

**04. REFERENCE MATERIAL  
PRODUCERS USING ISO 17034\*\***



*\*\* The ILAC MRA was extended in May 2019 to include accreditation of Proficiency Testing Providers to ISO/IEC 17043 and Reference Material Producers to ISO 17034 in April 2020*

# 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.

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 to which an accreditation body can be a member or where the scope of recognition of a recognised regional cooperation body does not include all the available schemes, ILAC provides the opportunity for these accreditation bodies to be peer evaluated as an unaffiliated accreditation body.

As of December 2019 there were:

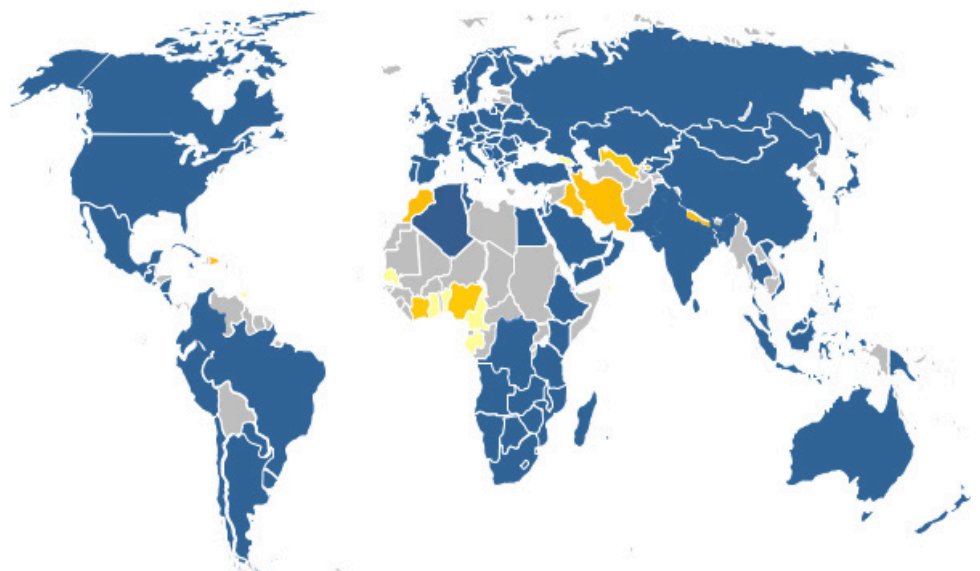
- **5 regional cooperation bodies recognised under the ILAC MRA** - African Accreditation Cooperation (AFRAC), Asia Pacific Accreditation Cooperation Incorporated (APAC), Arab Accreditation Cooperation (ARAC), European co-operation for Accreditation (EA) and Inter-American Accreditation Cooperation (IAAC);
- **101 accreditation body signatories via the MRA/MLAs of these recognised regional cooperation bodies from 103 economies; and**
- 1 unaffiliated accreditation body - KCA from The Kyrgyz Republic.

## COVERAGE OF THE ILAC MRA

April 15th, 2020

- ILAC MRA Signatories
- ILAC Associate Members
- ILAC Affiliate Members

**RESULTING IN A TOTAL OF 102 SIGNATORIES TO THE ILAC MRA FROM 104 ECONOMIES.**



As a result of the extension of the ILAC Arrangement to include the accreditation of proficiency testing providers (PTP) ILAC extended its recognition of the EA MLA for the accreditation of PTP.



## IN ADDITION, RECOGNITION OF THE APAC MRA WAS EXTENDED IN OCTOBER 2019 TO INCLUDE THE ACCREDITATION OF PTP.

An evaluation of SANAS (South Africa) was carried out in June 2019 for extensions to include the accreditation of PTP using ISO/IEC 17043 and reference material producers (RMP) using ISO 17034 because the recognition of the AFRAC MRA to the ILAC MRA does not currently include these schemes. As a result of the Arrangement Council ballot in December 2019, the signatory status of SANAS to the ILAC MRA was extended to include the accreditation of PTP (December 2019) and RMP (implemented in April 2020).

Significant changes to the list of signatories to the ILAC MRA in 2019, via the recognised regional processes, included the addition of the following signatories (new and extensions) for the accreditation scopes listed below:

- **National Centre of Accreditation (NCA), Kazakhstan, extension for medical testing (ISO 15189)**
- **Finnish Accreditation Service (FINAS), Finland, extension for PTP (ISO/IEC 17043)**
- **United Kingdom Accreditation Service (UKAS), United Kingdom, extension for PTP (ISO/IEC 17043)**
- **Raad voor Accreditatie (RvA), Netherlands, extension for PTP (ISO/IEC 17043)**
- **Entidad Nacional de Acreditacion (ENAC), Spain, extension for PTP (ISO/IEC 17043)**
- **Czech Accreditation Institute (CAI), Czech Republic, extension for PTP (ISO/IEC 17043)**
- **Slovenian Accreditation (SA), Slovenia, extension for medical testing (ISO 15189)**
- **Egyptian Accreditation Council (EGAC), Egypt, extension for PTP (ISO/IEC 17043)**
- **L'Ente Italiano di Accreditamento (AC-CREDIA), Italy, extension for PTP (ISO/IEC 17043)**
- **Danish Accreditation Fund (DANAK), Denmark, extension for PTP (ISO/IEC 17043)**
- **Slovak National Accreditation Service (SNAS), Slovakia, extension for PTP (ISO/IEC 17043)**
- **Deutsche Akkreditierungsstelle GmbH (DAkkS), Germany, extension for PTP (ISO/IEC 17043)**
- **Hellenic Accreditation System (ESYD), Greece, extension for PTP (ISO/IEC 17043)**
- **Belgian Accreditation Body (BELAC), Belgium, extension for PTP (ISO/IEC 17043)**
- **Turkish Accreditation Agency (TURKAK), Turkey, extension for PTP (ISO/IEC 17043)**
- **National Accreditation Authority (NAH), Hungary, extension for PTP (ISO/IEC 17043)**

- Swedish Board for Accreditation and Conformity Assessment (SWEDAC), Sweden, extension for PTP (ISO/IEC 17043)
- Emirates National Accreditation System (ENAS), UAE, granted for testing (ISO/IEC 17025) and calibration (ISO/IEC 17025)
- Romanian Accreditation Association (RENAR), Romania, extension for PTP (ISO/IEC 17043)
- Polish Centre for Accreditation (PCA), Poland, extension for PTP (ISO/IEC 17043)
- Perry Johnson Laboratory Accreditation, Inc. (PJLA), USA, extension for medical testing (ISO 15189)
- Norwegian Accreditation (NA), Norway, extension for PTP (ISO/IEC 17043)
- Pakistan National Accreditation Council (PNAC), Pakistan, extension for inspection (ISO/IEC 17020)
- Accreditation Office for Standards Conformity Assessment Capacity (AOSC), Vietnam, granted for testing (ISO/IEC 17025) and calibration (ISO/IEC 17025)
- Comité Français d'Accreditation (Cofrac), France, extension for PTP (ISO/IEC 17043)
- Philippine Accreditation Bureau (PAB), Philippines, extension for inspection (ISO/IEC 17020) and medical testing (ISO 15189)
- Organismo Nacional de Acreditación de Colombia (ONAC), Colombia, extension for medical testing (ISO 15189)
- Hong Kong Accreditation Service (HKAS), Hong Kong, China, extension for PTP (ISO/IEC 17043)
- Association of Analytical Centers "Analitica" (AAC Analitica), Russian Federation, extension for PTP (ISO/IEC 17043)
- American Association for Laboratory Accreditation (A2LA), USA, extension for PTP (ISO/IEC 17043)
- International Accreditation New Zealand (IANZ), New Zealand, extension for PTP (ISO/IEC 17043)
- ANSI National Accreditation Board (ANAB), USA, extension for medical (ISO 15189) and PTP (ISO/IEC 17043)
- Singapore Accreditation Council (SAC), Singapore, extension for PTP (ISO/IEC 17043)
- National Accreditation Board for Testing & Calibration Laboratories (NABL), India, extension for PTP (ISO/IEC 17043)
- Taiwan Accreditation Foundation (TAF), Chinese Taipei, extension for PTP (ISO/IEC 17043)
- Bureau of Laboratory Accreditation, Department of Science Service, Ministry of Science Technology (BLA-DSS), Thailand, extension for PTP (ISO/IEC 17043)
- National Accreditation Body of Indonesia (KAN), Indonesia, extension for PTP (ISO/IEC 17043)
- Japan Accreditation Board (JAB), Japan, extension for PTP (ISO/IEC 17043)
- China National Accreditation Service for Conformity Assessment (CNAS), China, extension for PTP (ISO/IEC 17043)
- National Association of Testing Authorities, Australia (NATA), Australia, extension for PTP (ISO/IEC 17043)
- entidad Mexicana de acreditación a.c. (ema), Mexico, extension for PTP (ISO/IEC 17043)
- Ethiopian National Accreditation Office (ENAO), Ethiopia, extension for inspection (ISO/IEC 17020)

At the end of December 2019 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 (<https://ilac.org/signatory-search/>). This directory of the signatories to the ILAC MRA is searchable by accreditation body name or 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.



» ILAC MRA AND SIGNATORIES

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**SEARCH SIGNATORIES** PASTE THIS CODE TO YOUR WEBSITE TO HOST THE ILAC MRA SEARCH FACILITY

Accreditation Body:  Acronym  Economy  Scope:

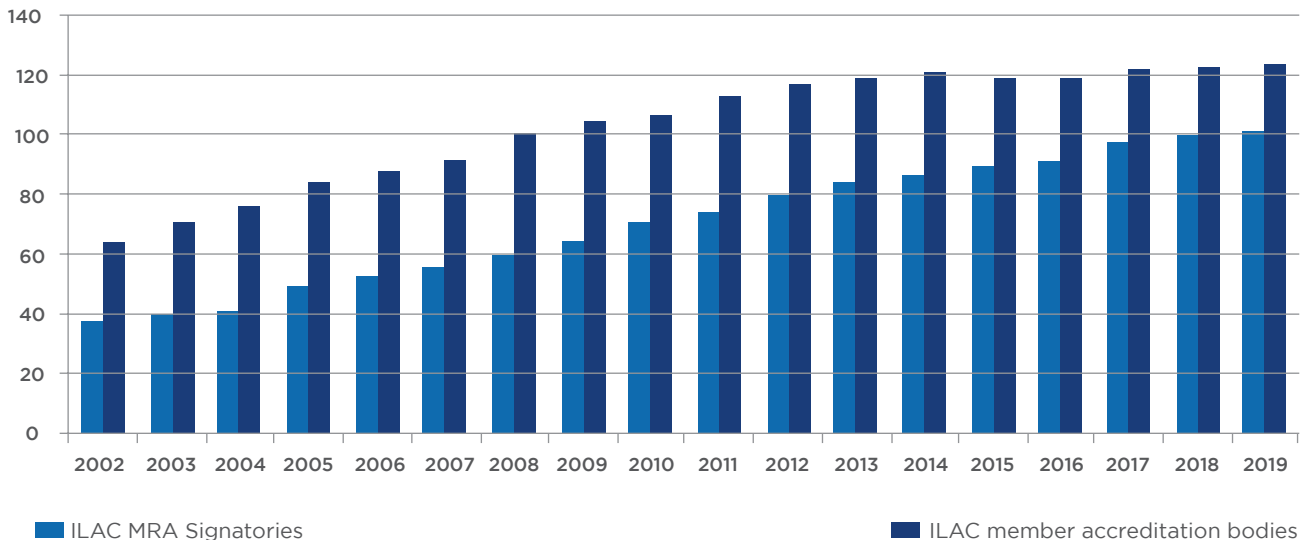
ACCREDITATION BODY:

All A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

# GLOBAL GROWTH

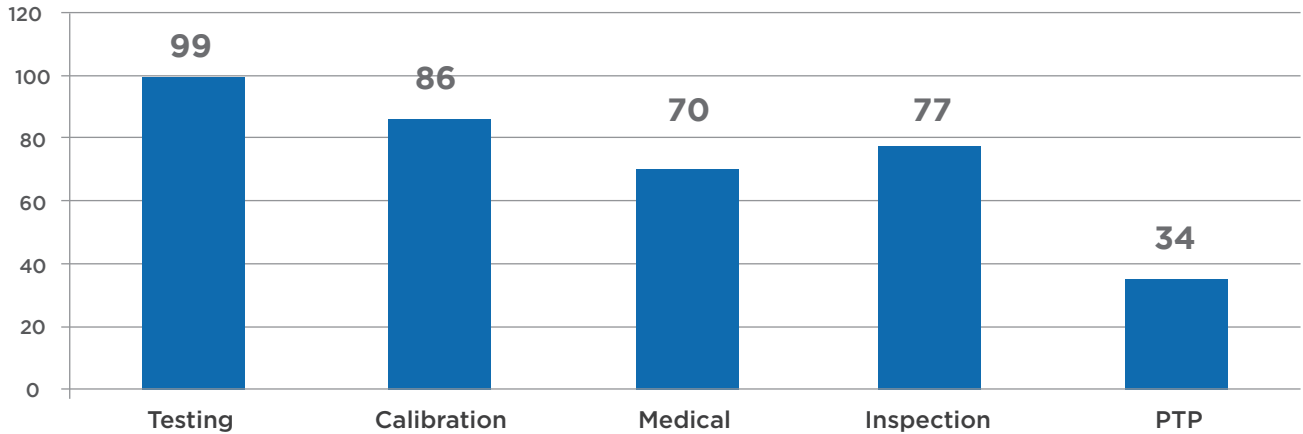
In recent years, there has been a steady geographic expansion of the membership of ILAC through the number of accreditation bodies that have become members of ILAC.

## TOTAL NUMBER OF ACCREDITATION BODIES



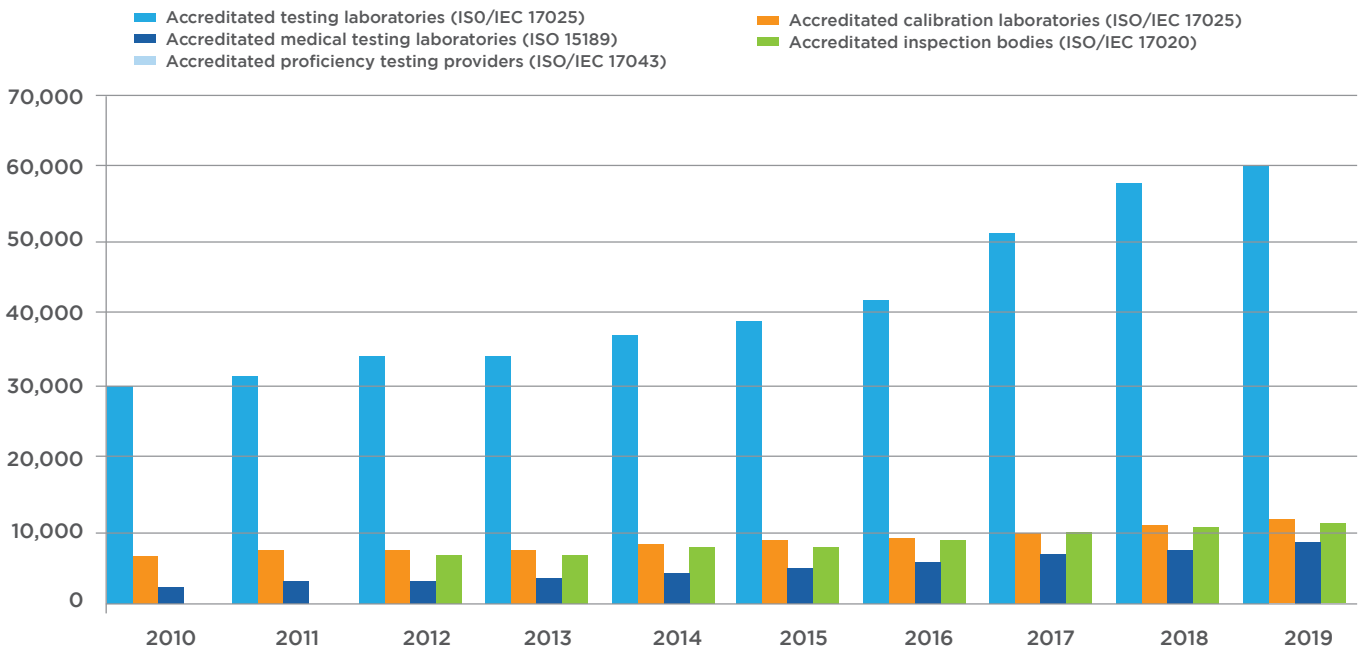
The number of signatories to the ILAC MRA by scope of signatory status is shown below.

### SIGNATORIES TO THE ILAC MRA BY SCOPE (DECEMBER 2019)



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

### TOTAL NUMBER OF ACCREDITED CONFORMITY ASSESSMENT BODIES (CABS) 2010 - 2019



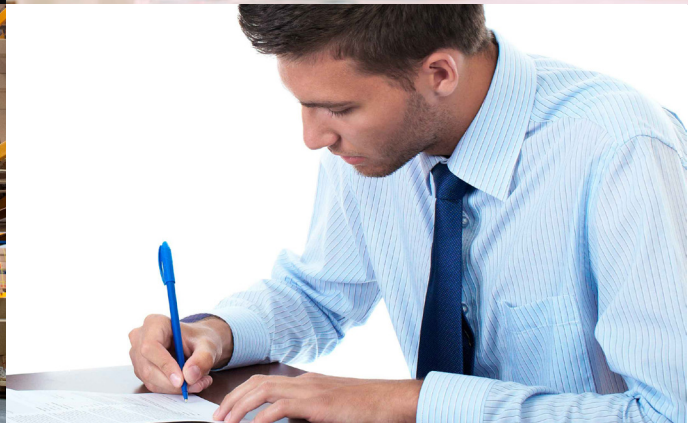
The logo features the text 'ilac-MRA' in a bold, blue, sans-serif font. It is centered within a white circle that has a blue border. The circle is surrounded by several concentric, dashed blue lines that create a ripple effect, suggesting a mark or a seal. The entire logo is set against a dark blue background.

ilac-MRA

## THE ILAC MRA MARK

The signatories to the ILAC MRA and their accredited CABs 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 CAB on reports or certificates in combination with the accreditation body's accreditation symbol, the Mark demonstrates that the calibration, testing, inspection, proficiency testing provision or reference material production 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 and programs.



# 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 in 2019 resulted in three types of findings that must be addressed as described below:

**A**

## 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.

**B**

## 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.

**C**

## 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 2019, the activities for the scheduled re-evaluation of two of the recognised regional cooperation bodies, IAAC (including an extension for PTP) and EA (including an extension for RMP) were in progress. Two extraordinary evaluations commenced during 2019 for extensions to include RMP, one for APAC and the other for IAAC. In addition, the on-site extraordinary evaluation activities for APAC were conducted in accordance with the October 2017 JGA resolution as a result of the merger of APLAC and PAC to form APAC.

The evaluation of SANAS for PTP and RMP was also carried out.

In addition to these evaluations carried out directly by ILAC, the recognised regional cooperation bodies carried out the following peer evaluation visits in 2019:

- AFRAC - 5 • APAC - 13 • ARAC - 1 • EA - 16 • IAAC - 6 •

## EVALUATOR RESOURCES



Eleven evaluators were involved in the evaluation visits directly carried out by ILAC in 2019

# 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 Arrangement. 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 two evaluation reports based on the recommendation of the ILAC AMC in 2019.

## 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 2019:

- In May 2019, ILAC published a revision to its procedural document *ILAC R6 Structure of the ILAC Mutual Recognition Arrangement and Procedure for Expansion of the Scope of the ILAC Arrangement* to enable ILAC to extend its Arrangement to new schemes once one recognised region has extended its Arrangement (MRA/MLA) for that scheme. This enabled ILAC to extend the ILAC MRA to include PTP and for EA, having already extended its MLA to include PTP, to be recognised under the ILAC Arrangement.



Looking forward, this change to ILAC's process for extending its Arrangement will enable it to react more quickly to market demand for the recognition of new and emerging schemes.

- The 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 to become a recognised regional cooperation body to the ILAC MRA.
- A resolution was adopted at the ILAC General Assembly in October 2016 to extend the ILAC MRA to include accreditation schemes 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 in the ILAC MRA to include the accreditation of RMP. The on-site evaluations for these applications have been conducted and the ILAC MRA was extended to include RMP in April 2020.

## 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. The transition reports received throughout 2019 as per the schedule indicated that the transition processes for both *ISO/IEC 17011* and *ISO/IEC 17025* were on schedule as at November 2019.

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 2019, ILAC issued the following publications:

- ILAC-P8:03/2019 ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Conformity Assessment Bodies
- ILAC-P4:05/2019 ILAC Mutual Recognition Arrangement: Policy and Management
- ILAC-P5:05/2019 ILAC Mutual Recognition Arrangement: Scope and Obligations
- ILAC-R6:05/2019 Structure of the ILAC Mutual Recognition Agreement
- and Procedure for Expansion of the Scope of the ILAC Arrangement
- ILAC B6:06/2019 Benefits for Laboratories participating in Proficiency Testing Programs
- ILAC G27:07/2019 Guidance on measurements performed as part of an inspection process
- ILAC G8:09/2019 Guidelines on Decision Rules and Statements of Conformity
- ILAC-R2A:11/2019 ILAC Rules: Articles of Association
- ILAC-R2B:11/2019 ILAC Rules: Bylaws





# ON-GOING PROMOTION OF THE ILAC MRA

Case studies from economies all around the world continue to be added to the [publicsectorassurance.org](http://publicsectorassurance.org) website to illustrate the value of accreditation in key policy areas and as a tool in supporting government officials and regulators deliver results.

The site 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, the number of case studies, research papers and supporting materials demonstrating the monetary value of standards, conformity assessment and accreditation for businesses continues to grow on the business benefits website <http://business-benefits.org/>



Public Sector Assurance About Contact

As a public sector organisation, this site will help you learn about the benefits of using conformity assessment.

Standards, certification, accreditation, testing, inspection - conformity assessment - can be a great asset in the toolkit of the public sector to meet policy objectives. To illustrate the value of conformity assessment, case studies from around the world in key policy areas show how different tools help government officials and regulators deliver results. This is backed up with research confirming this success and supporting information to delve deeper.

Each topic contains case studies of how government and regulators have used accredited conformity assessment, plus independent published research and supporting information.



Construction



Crime & Security



Economic development



Efficient delivery of public services



Energy



Environmental Protection



Food Safety & Agriculture



Health & Safety



Healthcare



Products & Services



Trade

# WORLD ACCREDITATION DAY 2019

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 for World Accreditation Day in 2019 was - Accreditation: Adding value to supply chains.

The theme focused on how accreditation provides added value to supply chains. In particular supply chains provide a vital role in delivering products and services for consumers, business and the public sector in a timely, cost-efficient and quality manner. Accreditation and, with it, other quality infrastructure tools such as standards, metrology and conformity assessment, provide widely accepted tools that help deliver value to the supply chain. These tools help with trust and assurance, enabling confidence in both final products and services and the manner in which they are placed on the market and used.



## Accreditation: Adding Value to Supply Chains




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**THE THEME  
FOR WORLD  
ACCREDITATION  
DAY IN 2019 WAS**

**ACCREDITATION:  
ADDING VALUE TO  
SUPPLY CHAINS.**

# ADDITIONAL INFORMATION

The ILAC website <https://ilac.org/> provides information on the ILAC MRA <https://ilac.org/ilac-mra-and-signatories/> and also includes brochures <https://ilac.org/publications-and-resources/ilac-promotional-brochures/> and information on World Accreditation Day <https://ilac.org/news-and-events/world-accreditation-day/> celebrated on the 9 June each year.



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