

# ILAC MRA 2022 ANNUAL REPORT





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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, proficiency testing provider and biobank accreditation, with a membership consisting of accreditation bodies, regional cooperation bodies and stakeholder organisations throughout the world.

Note: Laboratories including medical laboratories, inspection bodies, reference materials producers, proficiency testing providers and biobanks 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 (CABs)\*. Each accreditation body undergoes peer evaluation according to international standards and ILAC rules and procedures prior to becoming a signatory to the ILAC Arrangement.

\*Note: The ILAC Arrangement is currently in the process of being extended to include the accreditation of biobanks as detailed later in this report under: On-going development of the ILAC MRA.

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 to 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 produced 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/



#### 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 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 2022 there were:

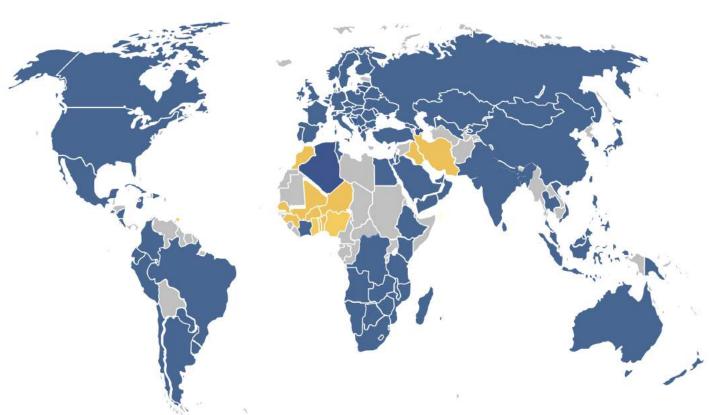
- 5 regional cooperation bodies recognised under the ILAC MRA African Accreditation Cooperation (AFRAC), Asia Pacific Accreditation Cooperation Incorporated (APAC), Arab Accreditation Cooperation (ARAC), European co-operation for Accreditation (EA) and Inter-American Accreditation Cooperation (IAAC);
- 109 accreditation body signatories to the ILAC MRA via the MRA/MLAs of these recognised regional cooperation bodies from 116 economies.

### **SCOPE OF THE ILAC MRA**

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

- ▼ Testing laboratories using ISO/IEC 17025;
- Medical testing laboratories using ISO 15189;
- Proficiency testing providers using ISO/IEC 17043; and
- Reference material producers using ISO 17034.

Note: 2023 update - Southern African Development Community Cooperation in Accreditation (SADCA) became a recognised region to the ILAC MRA in March 2023.



- ILAC MRA Signatories
- ILAC Associate Members

Significant changes to the list of signatories to the ILAC MRA in 2022, via the recognised regional processes, included the addition of the following new signatories for the accreditation scopes listed below:

- Systéme Ouest Africain d'Accréditation (SOAC WAAS), Cote D'Ivoire for calibration and testing (ISO/IEC 17025) and medical testing (ISO 15189)
- Georgian Accreditation Center The Unified National Body of Accreditation (GAC) Georgia for calibration and testing (ISO/IEC 17025), medical testing (ISO 15189) and inspection (ISO/IEC 17020)
- Quality and Accreditation Institute, Centre for Laboratory Accreditation (QAI CLA), India for testing (ISO/IEC 17025) and medical testing (ISO 15189)
- Latvian National Accreditation Bureau, (LATAK) Latvia for calibration and testing (ISO/IEC 17025), medical testing (ISO 15189) and inspection (ISO/IEC 17020)
- Uzbek Center for Accreditation (O'ZAKK), Uzbekistan for calibration and testing (ISO/IEC 17025)

In addition, the following signatories to the ILAC MRA extended their scope in 2022 as listed below:

- Belgian Accreditation Body (BELAC), Belgium extension for RMP (ISO 17034)
- Institute for Accreditation of Bosnia and Herzegovina (BATA), Bosnia and Herzegovina extension for medical testing (ISO 15189)
- Kyrgyz Centre for Accreditation (KCA), Kyrgyz Republic extension for inspection (ISO/IEC 17020)
- Organismo Nacional de Acreditacion (ONA), Paraguay extension for calibration (ISO/IEC 17025)
- Perry Johnson Laboratory Accreditation, Inc (PJLA), USA extension for PTP (ISO/IEC 17043).



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 and stakeholders have access to the latest information on the signatories to the ILAC MRA.



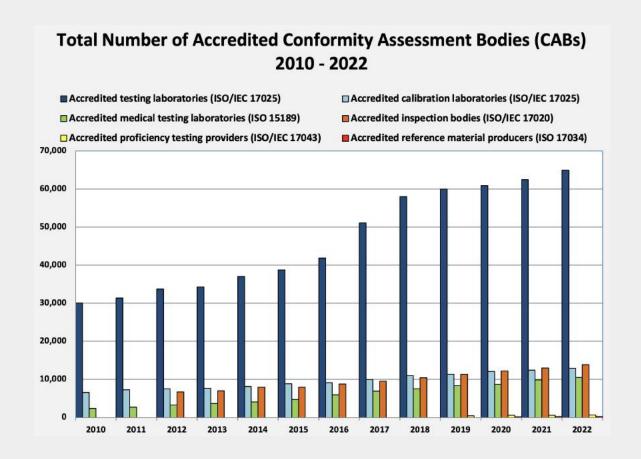
#### **GLOBAL GROWTH**

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.





This graph shows the number of signatories to the ILAC MRA by scope of signatory status.



#### 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, programs and materials.



#### **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.

ILAC, and its regional cooperation and 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.

The COVID-19 pandemic significantly changed how evaluations were conducted in 2020/21 and the early part of 2022, with travel restrictions necessitating increased use of information and communications technologies.

Evaluations therefore continued to be conducted in accordance with IAF/ILAC-A1/A2: Addendum 01/2021 – IAF/ILAC Approach to Remote Peer Evaluations of Regions and Single Accreditation Bodies during the COVID-19 Pandemic in early 2022 with a gradual transition to the return of on-site evaluation activities in the later part of 2022.

During 2022, the following evaluation activities occurred:

- scheduled re-evaluation of AFRAC was completed in October 2022 including scope extensions for RMP and PTP;
- scheduled re-evaluation of APAC continued:
- scheduled re-evaluation of ARAC continued:
- scheduled re-evaluation of EA commenced;
- scheduled re-evaluation of IAAC continued; and
- initial evaluation of SADCA continued.

In addition to these evaluations carried out directly by ILAC, the recognised regional cooperation bodies carried out the following peer evaluation activities in 2022:

- · AFRAC 3
- APAC 26
- ARAC 4
- EA 14
- IAAC 13
- · SADCA 1



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 one evaluation report based on the recommendation of the ILAC AMC in 2022.

## 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 2022:

- The regional cooperation body, the Southern African Development Community in Accreditation (SADCA), has applied for peer evaluation of their MRA to become a recognised regional cooperation body to the ILAC MRA. This evaluation commenced in April 2021. (Note: SADCA became a recognised region to the ILAC MRA in March 2023.)
- A resolution was adopted at the ILAC General Assembly in October 2019 noting that the standard applicable to biobank facilities for the purpose of accreditation is ISO 20387 *Biobanking General requirements for biobanking* as a standalone standard.

A further resolution was adopted in November 2021 endorsing the recommendation to extend the ILAC MRA to include the accreditation of biobanking as a Level 2 activity, to the criteria specified in the Level 3 normative document, ISO 20387. The applicable ILAC MRA documents to support the implementation of this resolution were revised and subsequently published in June 2022. The ILAC AMC accepted an application from APAC in December 2022 for an extension of the APAC recognition to the ILAC MRA to include the accreditation of biobanks. The evaluation activities for this extension will be carried out in 2023. On the successful completion of an evaluation of a region for this developing field the ILAC MRA will be able to be extended to include the accreditation of biobanks using ISO 20387.

#### **INTERNATIONAL STANDARDS**

There were no transition periods in place for the international standards included in Level 1 or 3 of the ILAC MRA in 2022.

### NEW AND REVISED PUBLICATIONS

ILAC regularly publishes requirements and information to support accreditation and conformity assessment processes. During 2022, ILAC issued the following publications:

- ILAC-P4:06/2022 ILAC Mutual Recognition Arrangement: Policy and Management.
- ILAC-P5:06/2022 ILAC Mutual Recognition Arrangement: Scope and Obligations.
- ILAC-R6:06/2022 Structure of the ILAC Mutual Recognition Agreement and Procedure for Expansion of the Scope of the ILAC Arrangement.
- ILAC-G19:06/2022 Modules in a Forensic Science Process.
- ILAC-G24:2022 Guidelines for the determination of calibration intervals of measuring equipment.



### ON-GOING PROMOTION OF THE ILAC MRA

Case studies from economies all around the world continue to be added to the <a href="https://publicsectorassurance.org/">https://publicsectorassurance.org/</a> 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 links the case studies to the United Nations Sustainable Development Goals (SDGs).

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 <a href="https://business-benefits.org">https://business-benefits.org</a> website.

#### **WORLD ACCREDITATION DAY 2022**

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.

World Accreditation Day was celebrated on 9 June 2022 with the theme:

### Accreditation: Sustainability in Economic Growth and the Environment

WORLD ACCREDITATION DAY

#### **ACCREDITATION**

Sustainability in Economic Growth and the Environment



This theme focused on the use of accreditation in supporting two core elements in the United Nations Sustainable Development Goals (SDGs), ie economic growth and environmental performance, simultaneously linked by a common desire for sustainable delivery of both of these objectives.

It provided the opportunity for ILAC and IAF members to share examples with stakeholders, regulators and consumers of how accreditation may be applied to meet objectives such as increasing trade, addressing environmental concerns, and improving the sustainability and quality of output in an economy.



### ADDITIONAL INFORMATION

The ILAC website provides information on the ILAC MRA and also includes brochures and information on World Accreditation Day celebrated on 9 June each year.

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www.voutube.com/channel/UCUMKbQYOBUnerGMHLmtU7ev