



ILAC MRA 2020

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.

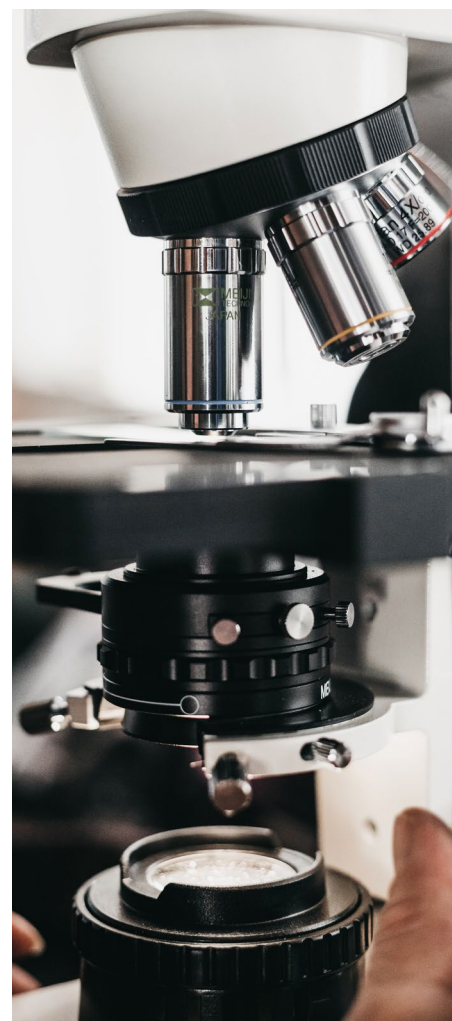
ABOUT ILAC

ILAC is the international authority on laboratory, inspection body, reference material producer, proficiency testing provider and biobanking 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 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: Laboratories including medical laboratories, inspection bodies, reference materials producers, proficiency testing providers and biobanking facilities are commonly referred to as conformity assessment bodies or CABs.

**Note: The ILAC Arrangement is currently in the process of being extended to include the accreditation of biobanking facilities as detailed in the later section of this report: 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.



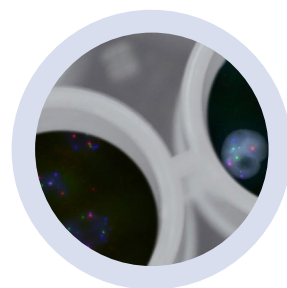
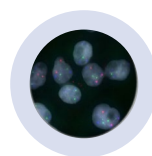
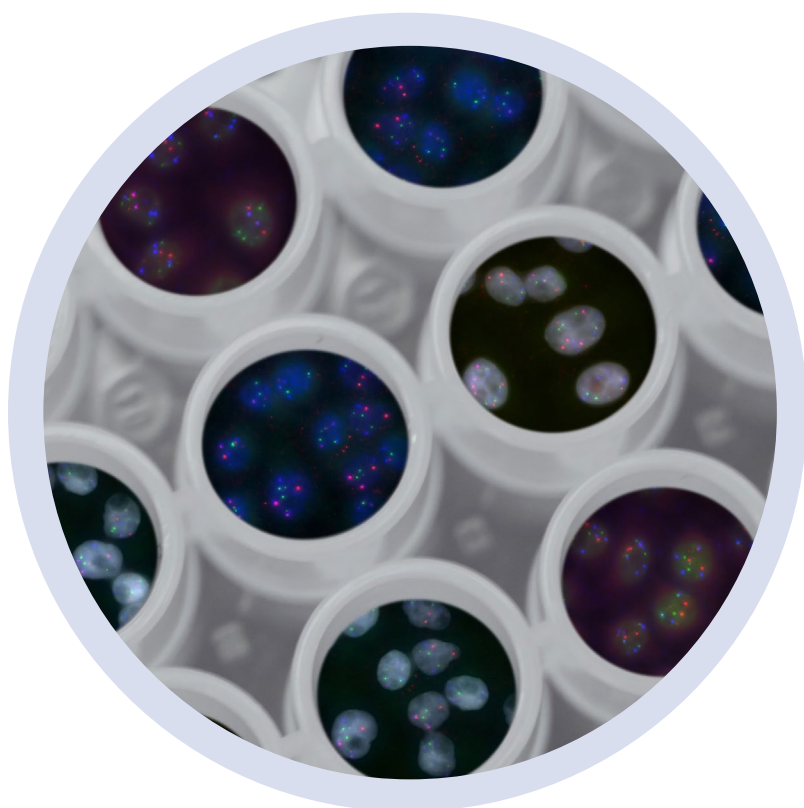
THE ILAC MRA

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 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/>



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.



SCOPE OF THE ILAC MRA

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



ISO/IEC 17025 Testing laboratories

99 signatories
60.9k accredited CABs



ISO 15189 Medical testing laboratories

71 signatories
8.7k accredited CABs



ISO/IEC 17025 Calibration laboratories

87 signatories
12.1k accredited CABs



ISO/IEC 17043 Proficiency testing providers

37 signatories
558 accredited CABs



ISO/IEC 17020 Inspection bodies

80 signatories
12.2k accredited CABs



ISO 17034 Reference material producers

23 signatories
200 accredited CABs

Note: The ILAC MRA was extended to include the accreditation of Reference Material Producers (RMP) using 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 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 2020 there were:

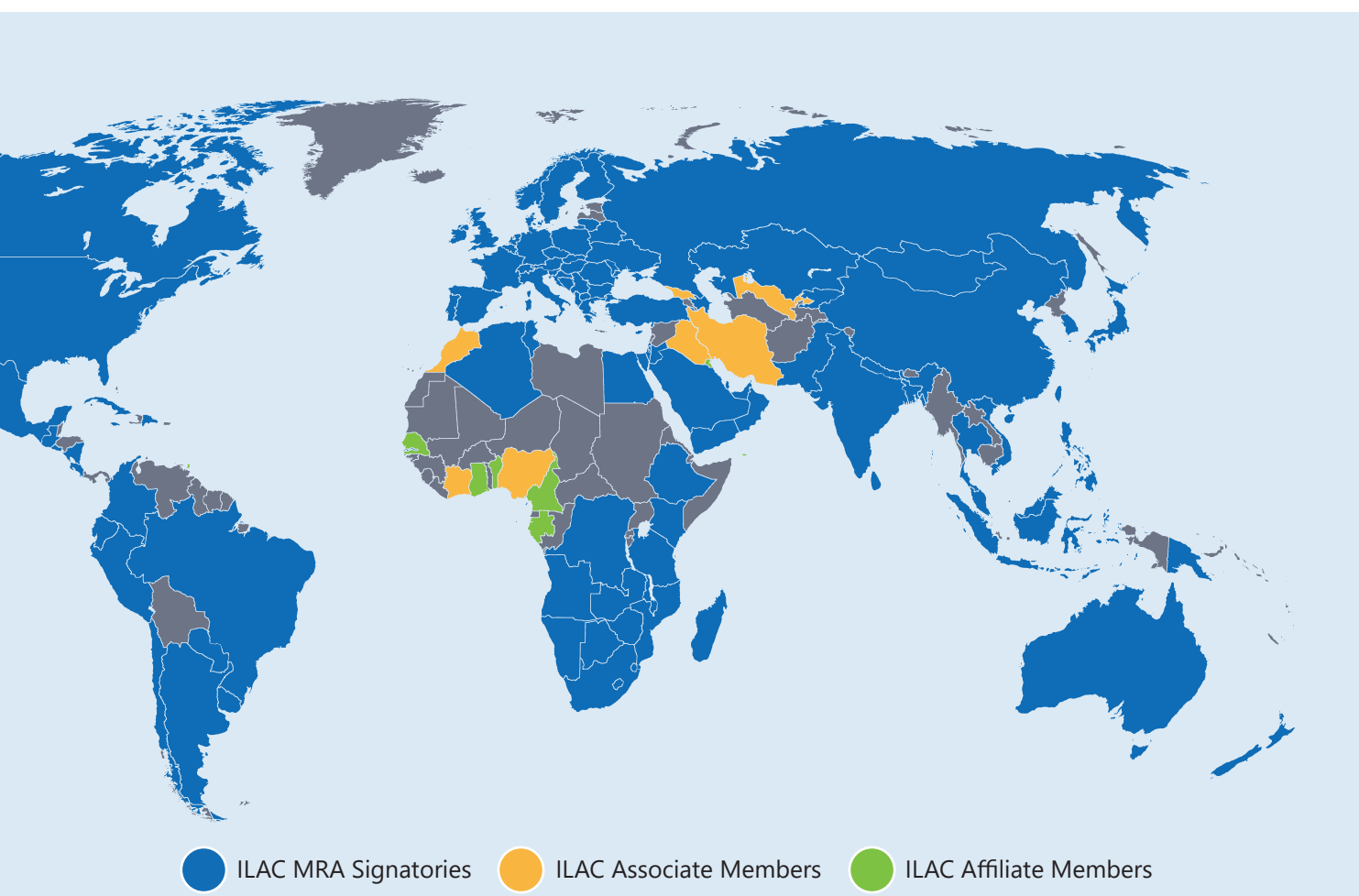
- 5 regional cooperation bodies recognised under the ILAC MRA:
 - ▷ African Accreditation Cooperation (AFRAC)
 - ▷ Asia Pacific Accreditation Cooperation Incorporated (APAC)
 - ▷ Arab Accreditation Cooperation (ARAC)
 - ▷ European co-operation for Accreditation (EA)
 - ▷ Inter-American Accreditation Cooperation (IAAC);
- 102 accreditation body signatories to the ILAC MRA via the MRA/MLAs of these recognised regional cooperation bodies from 104 economies.



The ILAC MRA was extended in April 2020 to include the accreditation of Reference Material Producers using ISO 17034 as a result of the decision of the members of the ILAC Arrangement Council to recognise the EA MLA for the accreditation of RMP. This was a result of the re-evaluation of EA that included the extension for RMP carried out in 2018/2019.

In addition, recognition of the APAC MRA was extended in July 2020 to include the accreditation of RMP using ISO 17034 as a result of an extraordinary evaluation of APAC carried out in 2019 for this scope.

The recognition of the IAAC MLA to the ILAC MRA was extended in June 2020 to include the accreditation of Proficiency Testing Providers using ISO/IEC 17043.



The signatory status of SANAS to the ILAC MRA was extended to include the accreditation RMP in April 2020 as a result of an evaluation carried out in June 2019 by ILAC because the recognition of the AFRAC MRA to the ILAC MRA does not currently include this scheme.

Significant changes to the list of signatories to the ILAC MRA in 2020, via the recognised regional processes, included the addition of the following signatories (new and extensions) for the accreditation scopes as listed:

- National Association of Testing Authorities, Australia (NATA), Australia, extension for RMP (ISO 17034)
- Bangladesh Accreditation Board (BAB), Bangladesh, extension for medical testing (ISO 15189) and inspection (ISO/IEC 17020)
- Belarusian State Centre for Accreditation (BSCA), Belarus, extension for medical testing (ISO 15189), inspection (ISO/IEC 17020) and PTP (ISO/IEC 17043)
- Coordenação Geral de Acreditação General Coordination for Accreditation (CGCRE), Brazil, extension for PTP (ISO/IEC 17043)
- China National Accreditation Service for Conformity Assessment (CNAS), China, extension for RMP (ISO 17034)
- Organismo Nacional de Acreditación de Colombia (ONAC), Colombia, extension for PTP (ISO/IEC 17043)
- Czech Accreditation Institute (CAI), Czech Republic, extension for RMP (ISO 17034)
- Organismo Dominicano de Acreditación (ODAC), Dominican Republic granted signatory status to the ILAC MRA for calibration and testing (ISO/IEC 17025) and inspection (ISO/IEC 17020).
- Deutsche Akkreditierungsstelle GmbH (DAkkS), Germany, extension for RMP (ISO 17034)
- Hong Kong Accreditation Service (HKAS), Hong Kong, China, extension for RMP (ISO 17034)
- National Accreditation Board for Testing & Calibration Laboratories (NABL), India, extension for RMP (ISO 17034)
- Irish National Accreditation Board (INAB), Ireland, extension for RMP (ISO 17034)
- L'Ente Italiano di Accreditamento (ACCREDIA), Italy, extension for RMP (ISO 17034)
- Jamaica National Agency for Accreditation (JANAAC), Jamaica, extension for inspection (ISO/IEC 17020)
- International Accreditation Japan (IAJapan), Japan, extension for RMP (ISO 17034)
- Japan Accreditation Board (JAB), Japan, extension for RMP (ISO 17034)
- Dutch Accreditation Council (RvA), Netherlands, extension for RMP (ISO 17034)
- International Accreditation New Zealand (IANZ), New Zealand,

extension for RMP (ISO 17034)

- Association of Analytical Centers "Analitica" (AAC Analitica), Russian Federation, extension for RMP (ISO 17034)
- Entidad Nacional de Acreditacion (ENAC), Spain, extension for RMP (ISO 17034)
- Taiwan Accreditation Foundation (TAF), Chinese Taipei, extension for RMP (ISO 17034)
- Bureau of Laboratory Accreditation, Department of Science Service, Ministry of Science Technology (BLA-DSS), Thailand, extension for RMP (ISO 17034)
- The Bureau of Laboratory Quality Standards, Department of Medical Sciences, Ministry of Public Health, Thailand (BLQS-DMSc), Thailand, extension for RMP (ISO 17034)
- Turkish Accreditation Agency (TURKAK), Turkey, extension for RMP (ISO 17034)
- United Kingdom Accreditation Service (UKAS), United Kingdom, extension for RMP (ISO 17034)
- American Association for Laboratory Accreditation (A2LA), United States of America, extension for RMP (ISO 17034)
- ANSI National Accreditation Board (ANAB), United States of America, extension for RMP (ISO 17034)
- Perry Johnson Laboratory Accreditation, Inc. (PJLA), United States of America, extension for RMP (ISO 17034)

The signatory status of PNGLAS (Papua New Guinea) to the ILAC MRA was withdrawn in August 2020 as a result of the voluntary withdrawal by PNGLAS of their signatory status to the APAC MRA.

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](#). 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.

» ILAC MRA AND SIGNATORIES

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

Accreditation Body: [dropdown] Acronym: [dropdown] Economy: [dropdown] Scope: [dropdown] [Find]

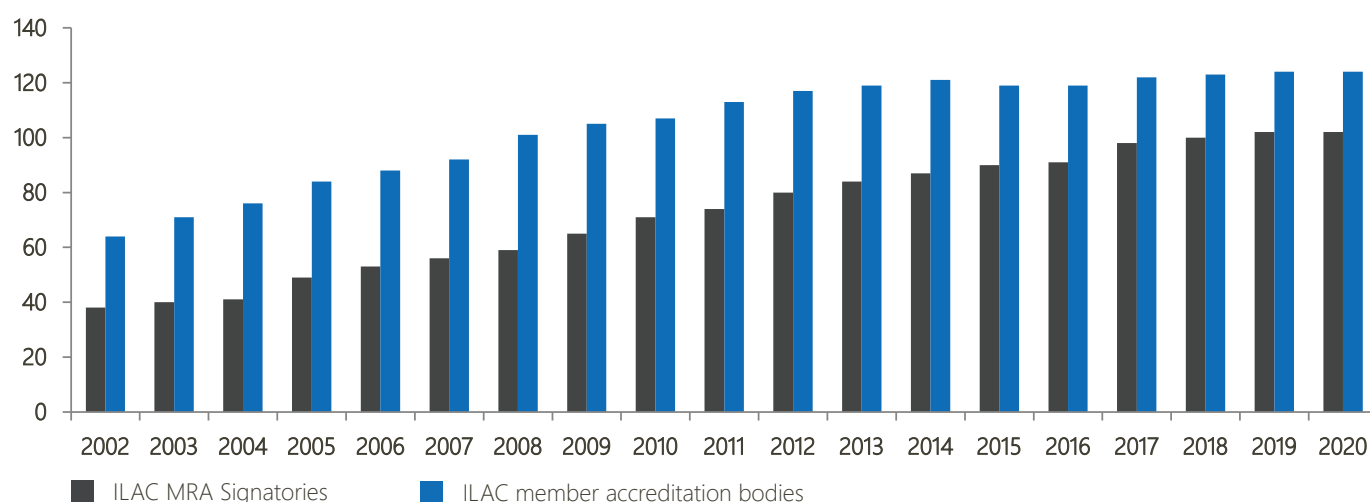
ACCREDITATION BODY:

[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]

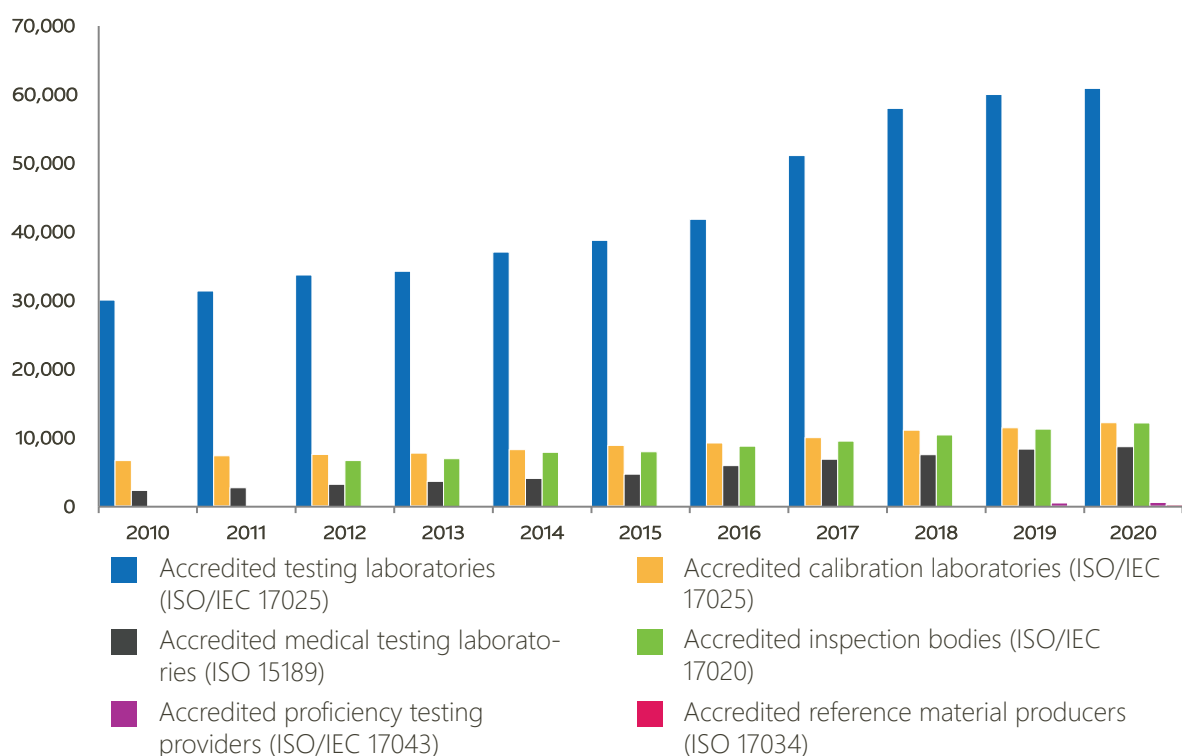
GLOBAL GROWTH

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. 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 ACCREDITATION BODIES



TOTAL NUMBER OF ACCREDITED CABS



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 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, with travel bans and lockdowns necessitating increased use of information and communications technologies.

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 was published to help maintain the harmonization of processes and the robustness of the IAF, ILAC and Regional peer evaluation systems.

This addendum to IAF/ILAC A1 and IAF/ILAC A2, which will remain in effect for the duration of the pandemic, provides policies for the role and conduct of remote peer evaluations and allows for a more flexible approach to remote witnessing activities during this period.

As a result of the publication of this addendum, an individual evaluation plan identifying the activities that



can be evaluated remotely (or exempted) was developed for each IAF/ILAC evaluation in progress in 2020 or scheduled to commence in 2021.

During 2020, the activities for the scheduled re-evaluation of ARAC commenced. The extra-ordinary evaluation of IAAC for an extension to include RMP continued. In addition, the extraordinary evaluation activities for APAC were completed in accordance with the October 2017 JGA resolution as a result of the merger of APLAC and PAC to form APAC and resulted in the continued recognition of the APAC MRA to the ILAC MRA. Finally the scheduled re-evaluations of EA and IAAC were completed resulting in the continued recognition of the EA MLA to the ILAC MRA and an extension to include RMP and the continued recognition of the IAAC MLA to the ILAC MRA with an extension to include PTP.

In addition to these evaluations carried out directly by ILAC, the recognised regional cooperation bodies carried out the following peer evaluation visits in 2020:



Eleven evaluators and report reviewers were involved in the evaluation activities directly carried out by ILAC in 2020.



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 four evaluation reports based on the recommendation of the ILAC AMC in 2020.



ON-GOING DEVELOPMENT

ILAC ARRANGEMENT

ILAC is committed to extending the ILAC MRA in terms of geographic coverage and technical scope. The following developments took place in 2020:

- The ILAC membership includes one regional cooperation body, the Southern African Development Community in Accreditation (SADCA), that has applied for 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 2019 noting that the standard applicable to biobank facilities for the purpose of accreditation will be ISO 20387 *Biobanking - General requirements for biobanking as a standalone standard*. The ILAC Arrangement Committee is now working on the requirements for the extension of the ILAC MRA to include accreditation schemes covering Biobanking using ISO 20837 in accordance with ILAC R6:05/2019 *Structure of the ILAC Mutual Recognition Arrangement and Procedure for Expansion of the Scope of the ILAC Arrangement*.



NEW AND REVISED PUBLICATIONS

ILAC regularly publishes requirements and information to support accreditation and conformity assessment processes. During 2020, ILAC issued the following publications:

- **IAF/ILAC B7:03/2020 Accreditation:** *Supporting the Delivery of Health and Social Care*
- **IAF/ILAC B10:03/2020 Accreditation:** *Delivering a safer world*
- **IAF/ILAC B11:03/2020 Accreditation:** *Adding value to supply chains*
- **ILAC B13:03/2020** *Why become an accredited reference material producer*
- **IAF/ILAC A1:03/2020 IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements):** *Requirements and Procedures for Evaluation of a Regional Group*
- **IAF/ILAC A3:03/2020 IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements):**

Template report for the peer evaluation of an Accreditation Body based on ISO/IEC 17011:2017

- **ILAC-P15:05/2020** *Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies*
- **ILAC-G29:06/2020** *Guidelines for harmonization of scopes of ISO/IEC 17025 accreditation of WADA anti-doping laboratories*
- **ILAC P10:07/2020** *ILAC Policy on Metrological Traceability of Measurement Results*
- **ILAC P14:09/2020** *ILAC Policy for Measurement Uncertainty in Calibration*

INTERNATIONAL STANDARDS

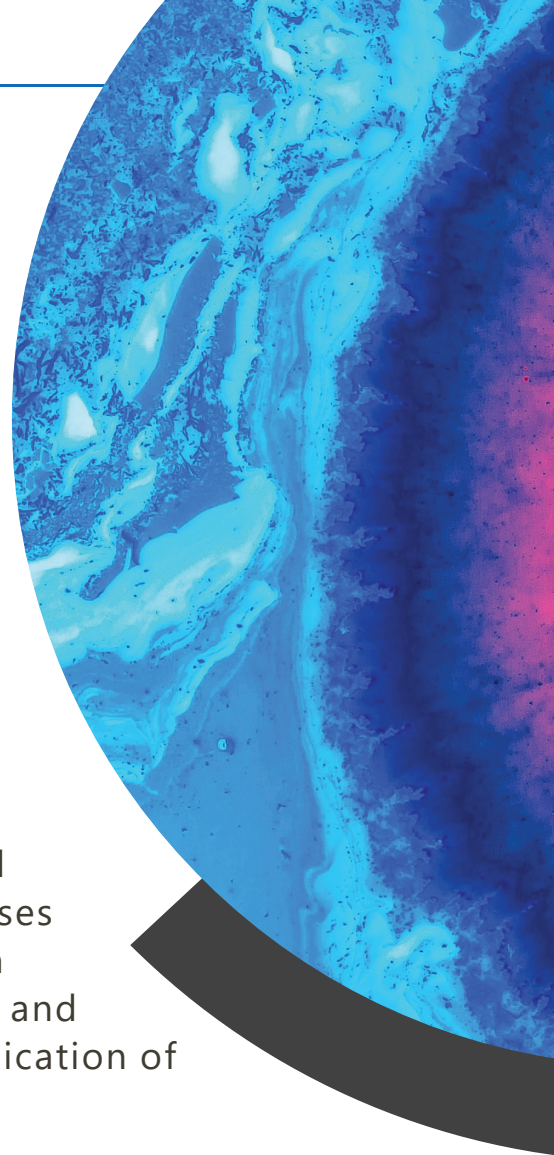
The ILAC AMC is responsible for monitoring the progress of the agreed 3 year transition periods for the 2017 versions of both ISO/IEC 17011 *Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies* and ISO/IEC 17025 *General requirements for the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

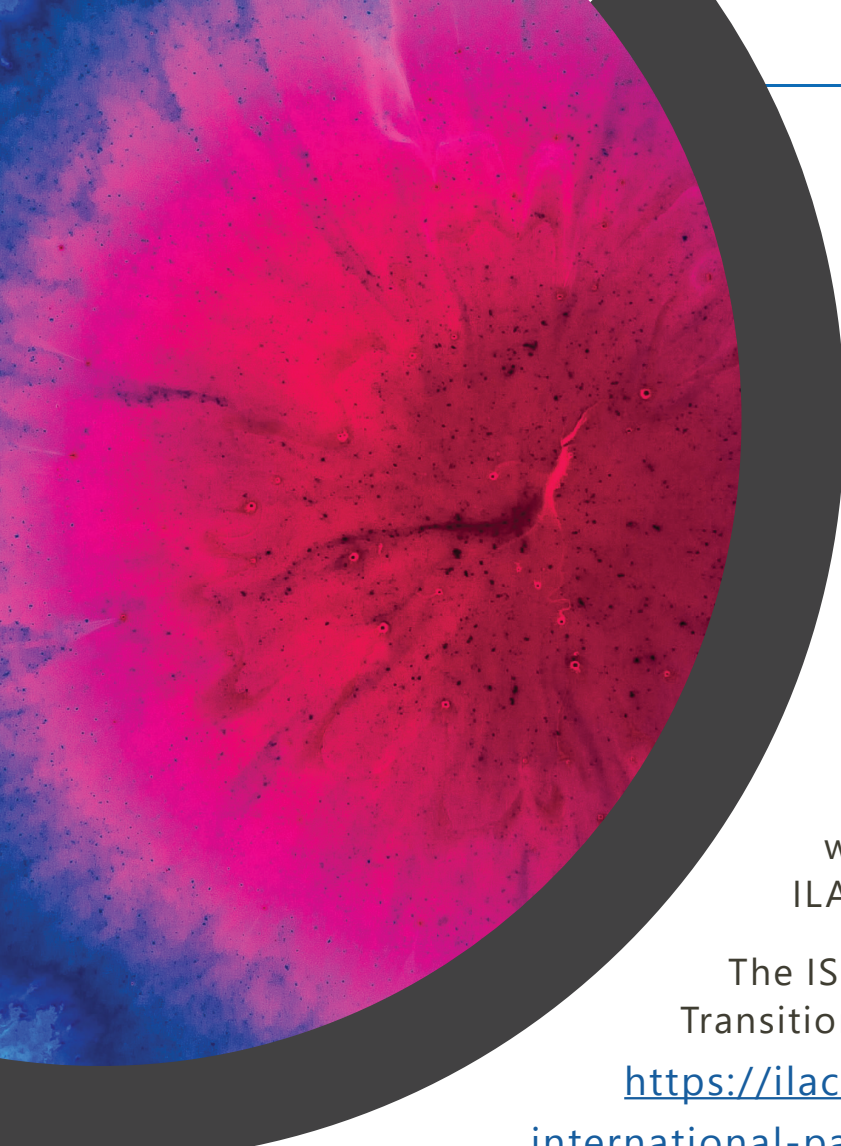
The final reports on the ISO/IEC 17011:2017 transition process were received from the regional cooperation bodies in December 2020. These were reviewed by the members of the ILAC AMC and IAF MLA MC confirming this transition had been completed in accordance with the IAF/ILAC ISO/IEC 17011:2017 Transition Plan and the IAF/ILAC JGA resolutions: 2016 JGA Resolution Delhi Resolution 1 – Transition to ISO/IEC 17011:2017 and 2017 JGA Vancouver Resolution 2 Implementation of transition to ISO/IEC 17011:2017.

All the accreditation bodies that are signatories to the ILAC MRA completed the transition to the 2017 version of ISO/IEC 17011 by the deadline (November 2020).

The transition period for ISO/IEC 17025:2017 adopted as part of the ILAC Resolution GA 20.15 (November 2016) was extended in June 2020 from 30 November 2020 to 1 June 2021.

This extension was granted to ensure all accreditation bodies and the accredited laboratories are able to achieve the remaining transitions in





a robust manner under the restrictions imposed as a result of the global coronavirus disease 2019 (COVID-19) outbreak.

At the end of the transition period, the accreditation of a laboratory to ISO/IEC 17025:2005 will not be recognised under the ILAC Arrangement.

The ISO/ILAC ISO/IEC 17025:2017 Transition Communique available from <https://ilac.org/about-ilac/partnerships/international-partners/iso/> was updated to reflect this extension to the transition period.

The reports from the regions on the transition to ISO/IEC 17025:2017 were reviewed by the members of the AMC in December 2020. These reports demonstrated good progress towards achieving the revised June 2021 deadline with 12 accreditation bodies confirming (as at 30 November 2020) that 100% of their laboratories accredited to ISO/IEC 17025 had transitioned to the 2017 version and a further 73 ABs confirming more than 75% had completed this transition.

ON-GOING PROMOTION OF THE ILAC MRA

Case studies from economies all around the world continue to be added to the [Public Sector Assurance 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 [businessbenefits website](#).

WORLD ACCREDITATION DAY 2020

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 2020 with the theme:

“Accreditation: Improving food safety”

This theme focused on how accreditation improves food safety, supporting the confidence of consumers, suppliers, purchasers, regulators and specifiers in the quality and safety of food. In particular focussing on how it ensures competent and impartial inspection, certification and testing services in all parts of local, national and international food chains. In doing so, also demonstrating how accreditation supports the United Nations' Sustainable Development Goals (SDGs), particularly Good Health and Well-being (SDG 3).



Accreditation:
Improving food safety



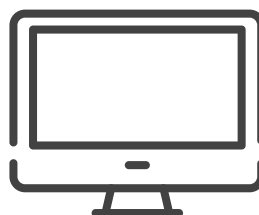


ADDITIONAL INFORMATION

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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