ILAC MRA 2021
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 biobank 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.

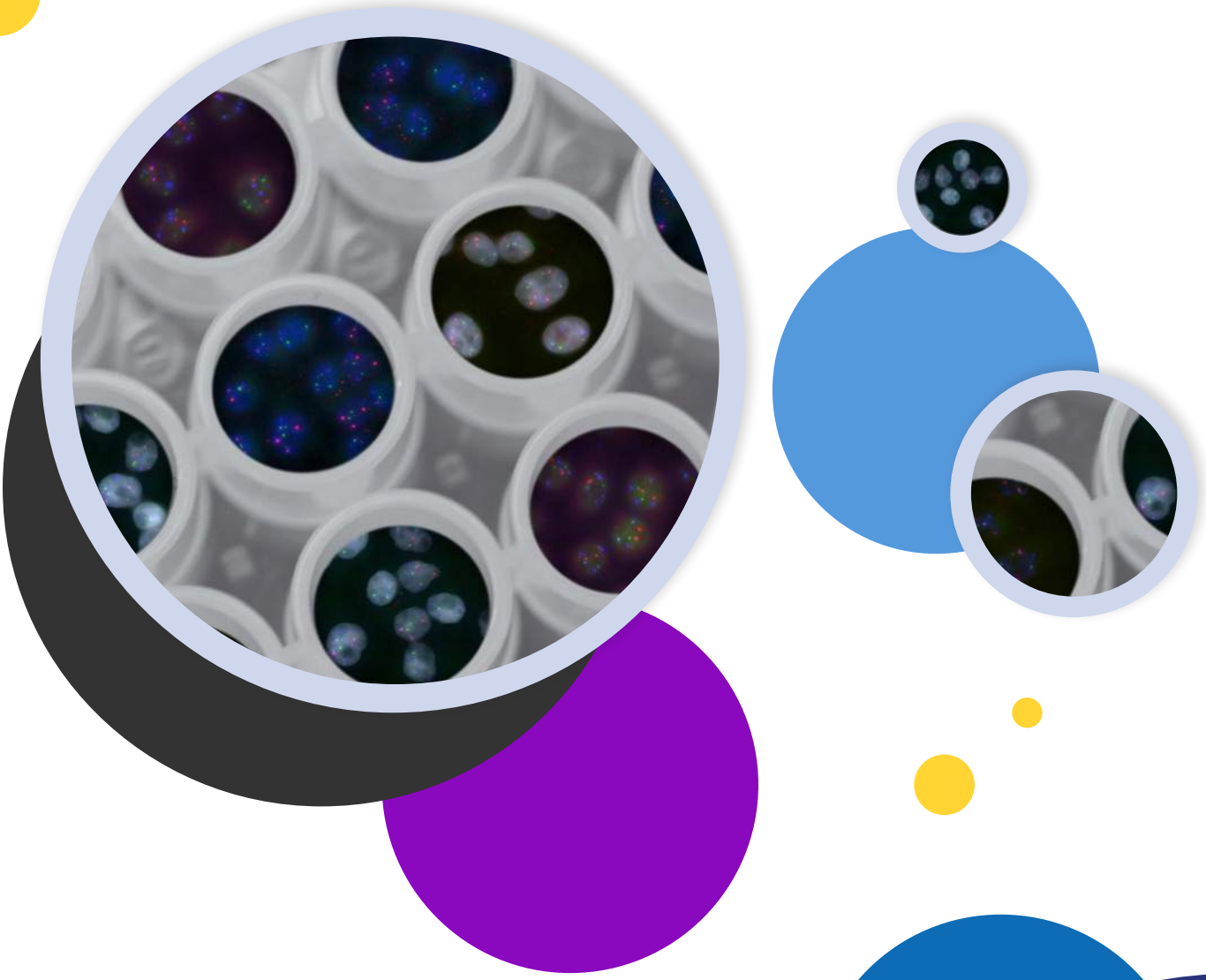
The essential purpose of accreditation is to provide confidence in the competence of CABs which support activities within and between economies including trade, protection of health, safety and the environment, for the public benefit.

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 biobanks 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 biobanks 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.



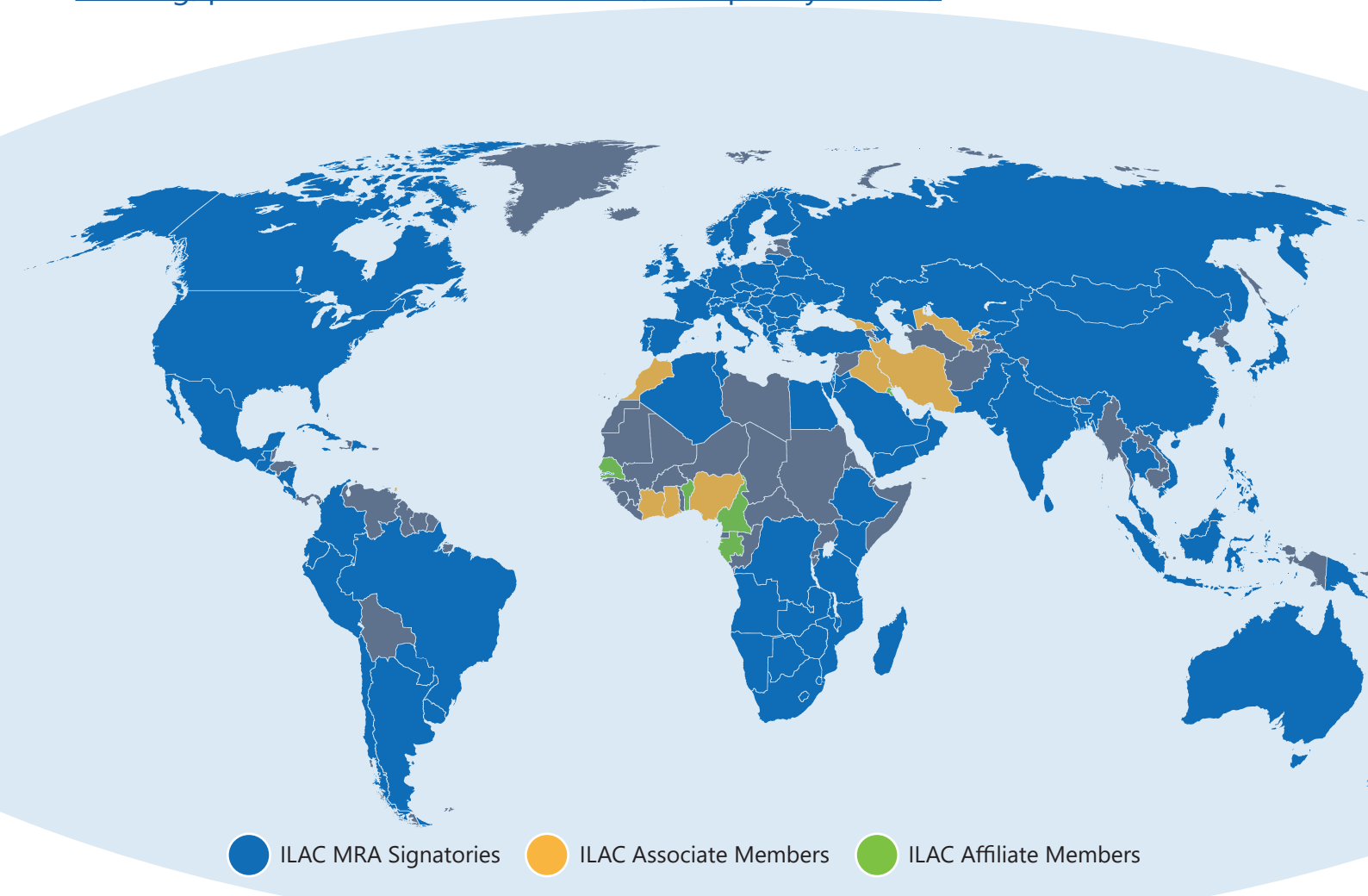
THE ILAC MRA

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.

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 2021 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);
- 104 accreditation body signatories to the ILAC MRA via the MRA/MLAs of these recognised regional cooperation bodies from 105 economies.

The recognition of the IAAC to the ILAC MRA was extended in June 2021 to include the accreditation of reference material producers using ISO 17034.

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

SCOPE OF THE ILAC MRA

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

ISO/IEC 17025 Testing laboratories
100 signatories
62.5k accredited CABs

ISO 15189 Medical testing laboratories
75 signatories
9.8k accredited CABs

ISO/IEC 17025 Calibration laboratories
90 signatories
12.4k accredited CABs

ISO/IEC 17043 Proficiency testing providers
40 signatories
621 accredited CABs

ISO/IEC 17020 Inspection bodies
83 signatories
12.9k accredited CABs

ISO 17034 Reference material producers
28 signatories
250 accredited CABs

Significant changes to the list of signatories to the ILAC MRA in 2021, via the recognised regional processes, included the addition of the following signatories (new and extensions) for the accreditations scopes listed below:

- Accreditation Education Research & Scientific Services Centre Pvt. Ltd. (AESSC), Nepal, for Testing (ISO/IEC 17025) and Medical Testing (ISO 15189)
- Accreditation Office for Standards and Conformity Assessment Capacity (AOSC), Vietnam, extension for Medical Testing (ISO 15189).
- Coordenação Geral de Acreditação General Coordination for Accreditation (CGCRE), Brazil, extension for RMP (ISO 17034)
- Danish Accreditation Fund (DANAK), Denmark, extension for RMP (ISO 17034)
- Comite Francais d'Accreditation (Cofrac), France, extension for RMP (ISO 17034)
- Entidad mexicana de acreditaición a.c. (ema), Mexico, extension for RMP (ISO 17034)
- Federal Service for Accreditation (RusAccreditation), Russian Federation, extension for inspection (ISO/IEC 17020) and PTP (ISO/IEC 17043)
- GCC Accreditation Center (GAC), Saudi Arabia, extension for Medical Testing (ISO 15189)
- Polskie Centrum Akredytacji (PCA), Poland, extension for RMP (ISO 17034)
- Saudi Accreditation Center (SAAC), Saudi Arabia, for testing (ISO/IEC 17025), calibration (ISO/IEC 17025) and inspection (ISO/IEC 17020)

The signatory status of the National Accreditation Agency of Ukraine (NAAU) to the ILAC MRA for the accreditation of inspection bodies using ISO/IEC 17020 was re-instated effective 6 October 2021 following suspension on 24 March 2021. These actions were taken in accordance with IAF/ILAC A2 Annex 7 as a result of the suspension and subsequent re-instatement of the signatory status of NAAU to the EA MLA for inspection.

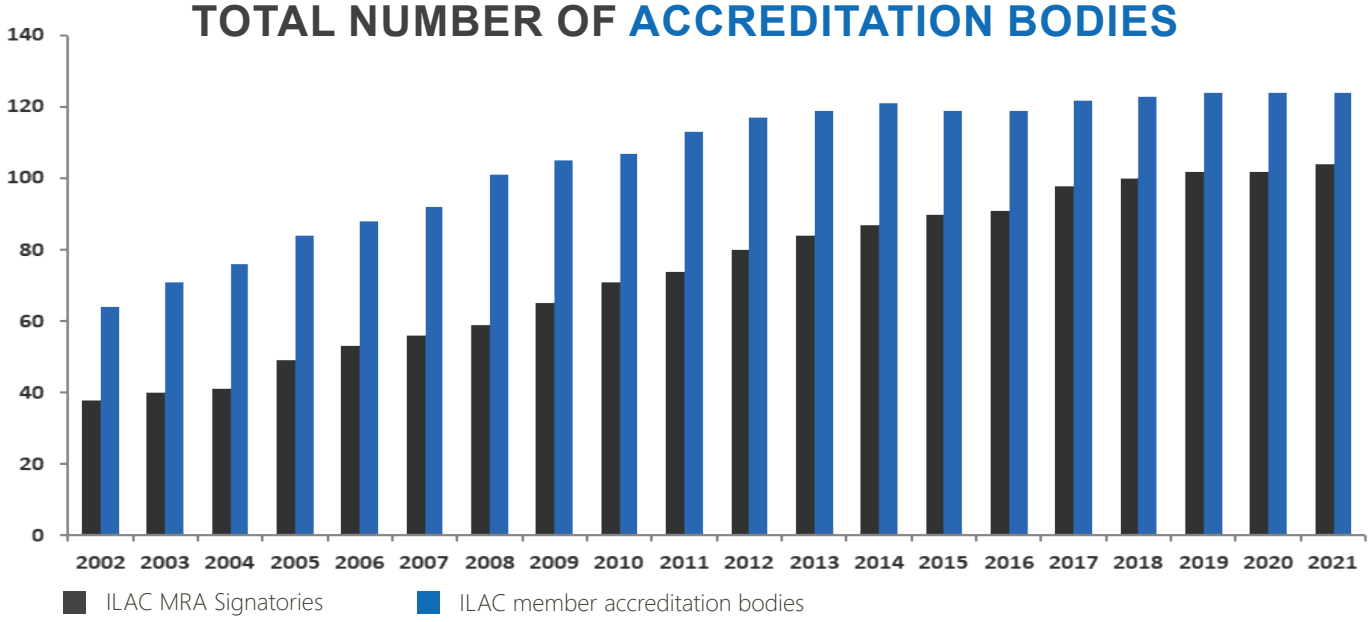
The current version of the list of signatories is available from https://ilac.org/ilac-mra-and-signatories/

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.

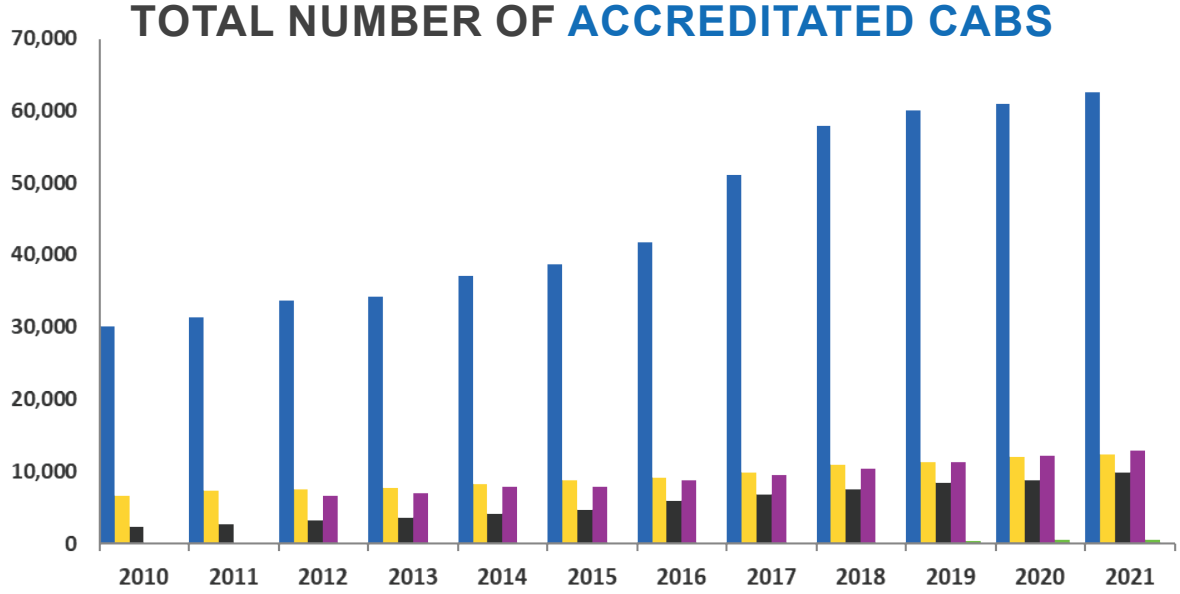
GLOBAL GROWTH

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



TOTAL NUMBER OF ACCREDITATED 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 and this continued in 2021, 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 harmonisation 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 2021, the following evaluation activities occurred:

- scheduled re-evaluation of AFRAC commenced including scope extensions for RMP and PTP;
- scheduled re-evaluation of APAC commenced;
- scheduled re-evaluation of ARAC continues;
- extra-ordinary evaluation of IAAC for an extension to include RMP was completed;
- scheduled re-evaluation of IAAC commenced; and
- initial evaluation of SADCA commenced.

In addition to these evaluations carried out directly by ILAC, the recognised regional cooperation bodies carried out the following peer evaluation visits in 2021:

AFRAC	APAC	ARAC	EA	IAAC
2	12	0	25	11

Twelve evaluators and report reviewers were involved in the evaluation activities directly carried out by ILAC in 2021.

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 2021.

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 2021:

- 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.
- 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 are currently being revised to support the implementation of this resolution and allow the acceptance of applications for recognition in this developing field.

NEW AND REVISED PUBLICATIONS

ILAC regularly publishes requirements and information to support accreditation and conformity assessment processes. During 2021, ILAC issued the following publications:

- **ILAC B14:01/2021 ISO 20387** *Accreditation for Biobanking Facilities*
- **ILAC G17:01/2021** *ILAC Guidelines for Measurement Uncertainty in Testing*
- 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*
- **ILAC B15:03/2021** *Specifying accreditation for COVID-19 (SARS-CoV-2)*
- **Statement 03/2021** *Replacement of Assessments During the COVID-19 Pandemic*
- **ILAC G7:04/2021** Accreditation Requirements and Operating Criteria for Horseracing Laboratories
- **ILAC-R1:12/2021** *Management of ILAC Documents*
- **ILAC-G18:12/2021** *Guideline for describing Scopes of Accreditation*

INTERNATIONAL STANDARDS

The ILAC AMC was responsible for monitoring the progress of the agreed 3 year transition period for the 2017 version of ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*. This key standard is used by the MRA signatories in implementing their accreditation schemes. A schedule for reporting on the transition for this standard was issued to the regional cooperation bodies and unaffiliated accreditation bodies following the publication of the revised standard in November 2017.

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. 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.

This extension was granted to ensure all accreditation bodies and the accredited laboratories were 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 is no longer recognised under the ILAC Arrangement.

The regions provided reports on the final transition data to ISO/IEC 17025:2017 in June 2021.

The reports were subsequently reviewed by the members of the ILAC AMC in July 2021.

ARAC, EA and IAAC confirmed all the accreditation bodies that are signatories to the MRA/MLAs had completed the transition process and

therefore 100% of their laboratories accredited to ISO/IEC 17025 had transitioned to the 2017 version by the deadline.

In the case of APAC, AFRAC and SADCA supporting information was provided advising of the actions taken (e.g. suspension or withdrawal of accreditation) by the accreditation bodies in relation to the accredited laboratories that had not completed the transition by the deadline.

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 now 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 businessbenefits website.

WORLD ACCREDITATION DAY 2021

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 2021 with the theme:

"Accreditation: Supporting the implementation of the SDGs"

This theme focused on the use of accreditation in supporting the implementation of the United Nations Sustainable Development Goals (SDGs). 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 environment and health and safety concerns, and improving the general overall quality of output in an economy.

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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