











MLA REPORT 2020













FOREWORD
1 - INTRODUCTION
2 - THE EA MLA
3 - SCOPE OF THE MLA
4 - SIGNATORIES OF THE MLA
5 - OPERATION OF THE MLA COUNCIL
6 - PEER-EVALUATION PROCESS AND ACTIVITIES
7 - PEER EVALUATORS
8 - IMPROVEMENT OF THE MLA AND PEER-EVALUATION PROCESS
AND PEER-EVALUATION PROCESS
AND PEER-EVALUATION PROCESS
AND PEER-EVALUATION PROCESS

# FOREWORD



The EA Multilateral Agreement (MLA), signed so far by 43 EA Members, has been managing to go through the pandemic year 2020.

Although only few of the scheduled peer evaluations could be finalised in 2020 owing to the COVID-19 outbreak and many of them should have been postponed until next year, the MAC Management Group came up with solutions to maintain the peer-evaluation system operational in compliance with the rules and procedures, and to make decisions without delay to avoid undermining both accreditation and accredited conformity assessment activities. Thus the number of signatories for each scope of the EA MLA remains stable during this period compared to 2019, with even a slight

increase in the number of signatories for several scopes. Besides 2 new applications for joining EA MLA signatories were received during 2020 and are being processed.

Moreover peer evaluations against the revised EN ISO/IEC 17011:2017 *Conformity Assessment - Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies* were completed by the end of November 2020, end of the 3-year transition period, when all 43 NABs signatories to the EA MLA successfully made the transition from previous version of the standard.

Obviously with fewer completed peer evaluations, the total number of man-days allocated to the peer evaluations performed in 2020 decreased by about 65% compared to the previous year.

The pandemic also led to a slight decrease in the total number of EA evaluators since, notably, the newcomer training scheduled in 2020 should have been put off until 2021. It is expected however that the number of evaluators in each qualification category will increase in 2021 as a result of postponed and scheduled peer evaluations. In order to support the further improvement of EA's pool of evaluators for a busiest peer-evaluation program in 2021, two remote refresher training sessions concentrated all training efforts in late 2020.

At the International level, EA's recognition as a regional cooperation body of IAF (International Accreditation Forum) and ILAC (International Laboratory Accreditation Cooperation) was confirmed in May 2020. Furthermore EA has increased its recognition of MRA scopes in ILAC. The formal decision on EA's peer evaluation by ILAC in favour of the extension of its MRA signatory status to the accreditation of reference material producers (RMP) using ISO 17034 was made in April 2020, when EA has become the first regional cooperation body member of the ILAC MRA for accreditation of RMP. EA has also been recognised for the IAF MLA scope extension to ISO/IEC TS 17021-10 and ISO 45001, setting out the requirements with guidance for use for occupational health and safety (OH&S) management systems, as of 5 February 2020.

During 2020, the MLA Council (MAC) has been learning from the unexpected COVID-19 crisis to rethink peer evaluations and decision-making process in a remote perspective in the future. The strongest commitment of all those involved in the EA MLA system, i.e. members of the EA MAC and its Management Group, peer-evaluation teams and trainers, and especially the MAC Secretariat, is helping to meet the substantial and lasting challenges imposed by the pandemic period. I am very grateful for their outstanding contribution to maintaining the EA MLA as both a sustainable and flexible mechanism for ensuring both European and International reliable equivalence and mutual acceptance of certificates and reports issued by accredited conformity assessment bodies. Preserving the confidence in the public service that we provide is our vital role.

Maria Papatzikou (ESYD) Chair of the Multilateral Agreement Council

3

# **1 - INTRODUCTION**

The EA Multilateral Agreement (EA MLA) report provides information on the signatories to the EA MLA, as well as an overview of the key activities completed in 2020 to further develop the coverage of the EA MLA and to strengthen the operation of the peer-evaluation system, including management of evaluators.

The main objective of peer-evaluation activities is to evaluate the ongoing compliance of national accreditation bodies (NABs) with the internationally-agreed requirements, as well as to ensure that regulators, stakeholders and the business community can have confidence in the certificates and reports issued by accredited conformity assessment bodies (CABs) under the EA MLA.

According to article 14 of Regulation (EC) No 765/2008 Setting out the requirements for accreditation, EA has been recognised by the European Commission (EC) as the European Accreditation Infrastructure and to operate the peer-evaluation system of national accreditation bodies.

Initially signed by the parties on 1 April 2009, the General Guidelines for Cooperation between the European co-operation for Accreditation and the European Commission, the European Free Trade Association and the Competent National Authorities aim to widen and strengthen the co-operation in order to reflect the developments in policy and legislation. It shall also stabilise the position of accreditation, accreditation bodies in EU and EFTA Member States and EA with the view to prepare a successful implementation of Regulation (EC) No 765/2008. On 13 December 2018, the third Framework Partnership Agreement (FPA) was signed with the European Commission for the period 2019-2022. A similar agreement was signed with EFTA in April 2019.

Following article 11 of Regulation (EC) No 765/2008, national authorities shall recognise the equivalence of services delivered by national accreditation bodies which have successfully undergone peer evaluation by EA. Furthermore, national authorities shall accept the reports and certificates issued by the conformity assessment bodies accredited by the national accreditation bodies that are EA MLA signatories.

EA and its member national accreditation bodies invest significant efforts and resources to maintain the integrity and robustness of the EA MLA through a rigorous peer-evaluation process. The purpose of evaluations is to verify that EA MLA signatories still comply with the provisions set out in Regulation (EC) No 765/2008 and the internationally-agreed criteria for accreditation bodies.

Maintaining a sound and reliable evaluation system also requires that EA supports the further improvement of EA's pool of evaluators through both newcomer and refresher training sessions.

# 2 - THE EA MLA

The EA MLA is an agreement signed between national accreditation bodies – Full and Associate Members of EA which are successfully peer evaluated – to recognise the equivalence, reliability and therefore acceptance by the European market of certification, verification, inspection and calibration certificates and test reports issued by accredited conformity assessment bodies.

EA Associate Members are eligible to enter into a Bilateral Agreement with signatories of the EA MLA with the aim of establishing mutual confidence in the respective accreditation systems and in their accredited attestations of conformity. Associate Members shall comply with the same requirements as Full Members when signing the Multilateral Agreement. MLA signatories apply the international standards for accreditation of conformity assessment bodies in a harmonised way and the services delivered by those national accreditation bodies are equivalent. Therefore, the marketplace can have confidence in activities of EA MLA signatories and their accredited conformity assessment bodies.

The EA MLA provides the European market with a network of conformity assessment bodies that are competent within their scope of accreditation to issue reliable and credible statements of conformity for products and services, thereby reducing costs and adding value to business and consumers. This contributes to the freedom of trade by eliminating technical barriers.



The EA MLA	covers th	ne following	activities	and standards:	

Accreditation of	Scope/Activity (Level 2)	Standards (Level 3)
Laboratories	Testing and Medical Examinations Calibration	EN ISO/IEC 17025 EN ISO 15189 EN ISO/IEC 17025
Certification Bodies	Certification of Products Certification of Persons Certification of Management Systems	EN ISO/IEC 17065 EN ISO/IEC 17024 EN ISO/IEC 17021-1
GHG Validation and Verification Bodies	Validation and Verification	EN ISO 14065 EN ISO/IEC 17029
Inspection Bodies	Inspection	EN ISO/IEC 17020
Proficiency Testing Providers (PTP)	Proficiency Testing	EN ISO/IEC 17043
Reference Materials Producers (RMP)	Reference Materials Production	EN ISO 17034

During 2020, EA Members delivered more than 36,000 accreditations under the scopes for which they have signed the EA MLA, representing a slight 1.5% decrease compared to 2019. This global contraction conceals however a small growth in the numbers of accreditations delivered under RMP (+ 31.6%), PTP (+ 4.5%), persons certification (+ 3.9%) and inspection (+ 0.9%) scopes.

Type of accreditation	2017	2018	2019	2020
Calibration	3,142	3,094	3,194	3,214
Testing	18,804	18,530	19,146	18,555
Medical Examinations	3,616	3,896	3,936	3,891
Products Certification	1,845	1,896	2,012	2,000
Management Systems Certification	1,365	1,367	1,461	1,441
Persons Certification	573	644	713	741
GHG Validation & Verification	145	142	156	155
Inspection	5,425	5,528	6,000	6,055
Proficiency Testing (PTP)	193	179	200	209
Production of Reference Materials (RMP)*	-	-	38	50
TOTAL	35,108	35,276	36,856	36,311

#### Numbers of accreditation certificates issued under the EA MLA since 2017

\* The EA MLA for Reference Materials Producers has been launched in 2019.

# **4 - SIGNATORIES OF THE MLA**

National accreditation bodies are accepted under the EA MLA only after stringent evaluation of their operations and activities.

The evaluation is conducted by a peer-evaluation team entrusted with the task to determine national accreditation bodies' compliance with the requirements laid down in:

- Regulation (EC) No 765/2008;
- EN ISO/IEC 17011, the internationally-accepted standard for accreditation bodies;

• the relevant standard for conformity assessment bodies including any additional requirements, e.g. those covered in relevant EA and IAF/ILAC documents as well as those set out by the European Commission in relevant sector-based legislations.

A list of EA MLA signatories (on 31 December 2020) is given in Annexes 1 and 2. For the latest information, please visit the <u>EA website</u>.

### **1 - FULL MEMBERS**

Out of 36 Full Members, 34 have signed the MLA.

The number of Full Member signatories for each scope of the EA Multilateral Agreement remains stable compared to 2019, with a slight increase in the number of signatories for products and persons certification scopes.

Type of accreditation	2016	2017	2018	2019	2020
Calibration	33	33	33	33	33
Testing	34	34	34	34	34
Medical Examinations	31	31	31	32	32
Inspection	32	33	34	34	34
Management Systems Certification	30	30	32	32	32
Products Certification	31	31	31	31	32
Persons Certification	28	28	28	28	29
GHG Validation and Verification	25	24	24	25	25
Proficiency Testing*	-	15	16	18	18
Production of Reference Materials**	-	-	-	8	8

#### Numbers of Full Member signatories to the EA MLA

\* The EA MLA for Proficiency Testing Providers has been launched in 2017.

\*\* The EA MLA for Reference Materials Producers has been launched in 2019.

## 2 - ASSOCIATE MEMBERS

Out of 14 Associate Members, 9 have signed the EA MLA.

The number of Associate Member signatories for each scope of the EA Multilateral Agreement remains stable compared to 2019, with a slight increase in the number of signatories for medical examinations, inspection and PTP scopes.

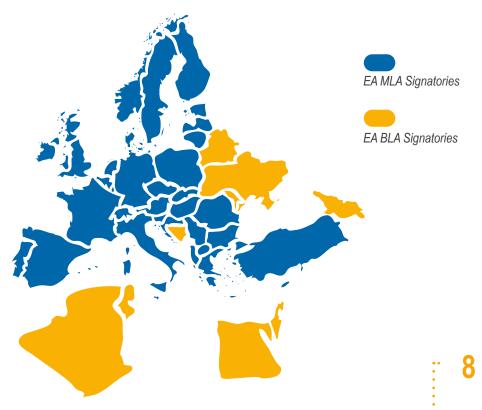
Type of accreditation	2016	2017	2018	2019	2020
Calibration	4	7	8	8	8
Testing	4	7	8	8	8
Medical Examinations	1	2	2	3	5
Inspection	4	7	7	7	8
Management Systems Certification	2	3	4	4	4
Products Certification	1	3	4	4	4
Persons Certification	1	2	3	3	3
GHG Validation & Verification	0	0	0	0	0
Proficiency Testing*	-	0	0	1	2
Reference Materials Production**	-	-	-	0	0

#### Numbers of Associate Member signatories to the EA MLA

\* The EA MLA for Proficiency Testing Providers has been launched in 2017.

\*\* The EA MLA for Reference Materials Producers has been launched in 2019.

#### Map of MLA and BLA signatories in December 2020



The EA MLA Council is responsible for the effective and impartial management and monitoring of the peer-evaluation process. It is the decision-making body for acceptance of national accreditation bodies' entering into the Multilateral Agreement (MLA) and Bilateral Agreement (BLA) of EA.

## **MLA Council (MAC)**

The MAC is composed of one representative from each Full Member and Associate Member, one observer from the EA Advisory Board and one observer from the European Commission. All EA MLA/BLA signatories have the voting right within the EA MAC on peer evaluations and MLA signatory status.

At the end of 2020, Paulo Tavares from IPAC (Portugal) terminated his fifth year as the MAC Chair. Maria Papatzikou from ESYD (Greece) has been elected at the General Assembly in November 2020 to take over from him for the term 2021-22.

Karine Vincent from COFRAC (France) vice-chaired the Council in 2020.

Due to the COVID-19 pandemic, the MAC cancelled its 43<sup>rd</sup> meeting planned on 22-23 April 2020 in Ljubljana, Slovenia, and hold remotely its 44<sup>th</sup> meeting on 7-8 October 2020.

### MAC Management Group (MG)

The MAC MG is composed of 12 members from different NABs who were elected by the MAC members. The task of the Management Group (MG) is to achieve a more effective management and harmonisation of the peer evaluations and operations of the MAC, including meetings.

In 2020, the MAC MG held a total of 10 web meetings.

# **5 - OPERATION OF THE MLA COUNCIL**

## **MAC Secretariat**

The MAC Secretariat is responsible for the daily management of the peer evaluations, including peer evaluators, and the organisation of MAC and MAC MG meetings.



Daniela lonescu is responsible for managing the MAC Secretariat.



Sandy Adonel is responsible at the Secretariat for the training and monitoring of EA evaluators in application of <u>EA-2/02</u>: <u>EA Procedure for the Evaluation of a National Accreditation Body</u>.

## Decisions made by the MAC

Upon decisions made by the MAC through electronic ballots in May and June 2020 due to the cancellation of the 43<sup>rd</sup> meeting in April 2020:

CYS-CYSAB, the Cyprus national accreditation body (NAB), became an MLA signatory in the field of certification of products (EN ISO/IEC 17065).

DPA, the Albanian NAB, became an MLA signatory in the field of certification of persons (EN ISO/IEC 17024).

BSCA, the Belarusian NAB, became a BLA signatory in the fields of medical examinations (EN ISO 15189), inspection (EN ISO/IEC 17020) and proficiency testing (EN ISO/IEC 17043).

NAAU, the Ukrainian NAB, became a BLA signatory in the field of medical examinations.

ESYD, the Greek NAB, remained a MLA signatory in the fields of calibration (EN ISO/IEC 17025), testing (EN ISO/IEC 17025) including medical examinations, inspection, proficiency testing, certification of management systems (EN ISO/IEC 17021-1), certification of products, certification of persons, and validation and verification (EN ISO 14065).

NAH, the Hungarian NAB, remained a MLA signatory in the field of certification of products.

SAS, the Swiss NAB, remained a MLA signatory in the fields of calibration, testing including medical examinations, inspection, certification of management systems, certification of products and certification of persons.

# **5 - OPERATION OF THE MLA COUNCIL**

BSCA remained a BLA signatory in the fields of calibration, testing, certification of management systems, certification of products and certification of persons.

NAAU remained a BLA signatory in the fields of calibration, testing, certification of management systems and certification of persons.

Upon decisions made by the MAC through electronic ballots carried out in July, September and October 2020:

FINAS, the Finnish NAB, remained a MLA signatory in the fields of calibration, testing including medical examinations, inspection, proficiency testing, certification of management systems, certification of products, certification of persons, and validation and verification.

HAA, the Croatian NAB, remained a MLA signatory in the fields of calibration, testing including medical examinations, inspection, certification of management systems, certification of products, certification of persons, and validation and verification.

IPAC, the Portuguese NAB, remained a MLA signatory in the fields of calibration, testing including medical examinations, inspection, certification of management systems and certification of products. *Note: IPAC is also a MLA signatory for certification of persons, and validation and verification. The peer evaluation of certification of persons and validation and verification has been completed and a decision is to be made in 2021.* 

OLAS, the Luxembourg NAB, remained a MLA signatory in the fields of calibration, testing including medical examinations, inspection and certification of management systems.

Note: OLAS is also a MLA signatory for certification of products. The peer evaluation of certification of products has been completed and a decision is to be made in 2021.

TURKAK, the Turkish NAB, remained a MLA signatory in the fields of calibration, testing including medical examinations, inspection, proficiency testing, certification of management systems, certification of products, certification of persons, validation and verification, and reference material production (EN ISO 17034).



The reliability of the MLA is maintained through a robust peer-evaluation process, whose main objectives are to evaluate the ongoing compliance of EA NABs to the internationally-agreed requirements, and to ensure that regulators, stakeholders and the business community can have confidence in those certificates and reports issued by conformity assessment bodies accredited by EA Members having signed the EA MLA.

### **1 - PEER-EVALUATION PROCESS**

The peer-evaluation process is carried out in accordance with <u>EA-2/02 M:2019 EA Procedure for the evaluation of</u> <u>a National Accreditation Body</u>.

The national accreditation body applies for MLA signatory status, specifying the scope for which it applies.

The MLA Council (MAC) Secretariat reviews the application documents and appoints a peer-evaluation team composed of a Team Leader, a Deputy Team Leader, Team Members and Trainees.

This peer-evaluation team performs the document review (management system documentation, statistical information on the NAB's activities, a self-assessment report performed by the NAB, information from the previous peer evaluation, etc.). Where applicable, a pre-evaluation is conducted. Then, the team carries out the on-site evaluation, which combines evaluation of the management system at the NAB's office and observation of assessments carried out by the NAB. At the end of the evaluation, the team drafts the evaluation report. Findings are agreed upon with the NAB at a closing meeting.

A task force group appointed by the MAC Management Group makes a careful study of the evaluation report in order to provide the MAC with a recommendation on the result of the peer evaluation. At its meetings or by electronic means, the MAC makes a final decision, which is reflected in relevant EA publications and on the website.

The European Commission attends MAC meetings and NABs are encouraged to invite national authorities to observe EA peer evaluations.

### **2 - PEER-EVALUATION ACTIVITIES**

For 2020, the MAC had scheduled 12 peer evaluations as follows:

- 8 re-evaluations: COFRAC (France), DANAK (Denmark), EGAC (Egypt), NA (Norway), PCA (Poland), SWEDAC (Sweden), TURKAK (Turkey) and UKAS (UK);
- 3 second and third stage evaluations: HAA (Croatia), IPAC (Portugal) and OLAS (Luxembourg);
- 1 extension evaluation: INAB (Ireland).

Due to the COVID-19 pandemic, only few of the scheduled peer evaluations were finalised:

- TURKAK re-evaluation;
- HAA second stage evaluation;
- OLAS second stage evaluation.

# **6 - PEER-EVALUATION PROCESS AND ACTIVITIES**

Therefore the MAC Management Group intensified their work and played a key role by proposing solutions to maintain the peer-evaluation system operational during this period and to enable decisions to be made without delay. Everything was made in compliance with the rules and procedures to avoid stopping the peer-evaluation system and undermining both accreditation and accredited conformity assessment activities.

The MAC agreed upon the contingency plan proposed by the MAC Management Group and, as a result:

- IPAC second stage evaluation, OLAS third stage evaluation and DANAK first stage re-evaluation were
  rescheduled for the second half of 2020. Only IPAC and OLAS re-evaluations have been completed
  before a decision is made in 2021;
- 7 re-evaluations (COFRAC, EGAC, NA, PCA, UKAS, SWEDAC and DANAK second stage) and 1
  extension evaluation (INAB) have been postponed to 2021.

Besides, during 2020, 2 new applications were received from ISAC, the Icelandic NAB, and ATCG, the Montenegrin NAB.

The evaluation teams reported a total of 62 non-conformities, 94 concerns and 56 comments for those peer evaluations finalised in 2020.

#### EA peer-evaluation activities

	2016	2017	2018	2019	2020
Total numbers of evaluations performed <sup>1</sup>	19	18	18	16	7
Total numbers of reports discussed <sup>2</sup>	9	21	14	17	<b>31</b> ³
Total man-days for evaluation	1,138	1,080	1,393	935	335
Extraordinary evaluations on site	1	2	0	3	0
Suspension	0	0	0	0	0

<sup>1</sup> Initial evaluations, re-evaluations with or without scope extensions and extraordinary evaluations (performed on site in the specific year).

<sup>2</sup> Reports of evaluations, but not necessarily conducted in the specific year.

<sup>3</sup> 31 reports, out of which 18 related to transition to EN ISO/IEC 17011:2017 (Option B - document review).

By the end of 2020, 1 first stage re-evaluation was in progress to be completed in 2021, when 26 other peer evaluations are envisaged as follows:

- 7 re-evaluations and 1 extension evaluation postponed from 2020;
- 13 regular peer evaluations planned for 2021;
- 1 initial evaluation;
- 1 pre-evaluation;
- · 2 extraordinary evaluations;
- 1 extension.

Although the postponements from 2020 to 2021 have a major impact on the programme of peer evaluations for 2021, no postponements from 2021 to 2022 have been planned in 2020.

# 7 - PEER EVALUATORS

EA peer evaluators are highly qualified and experienced national accreditation body staff members who attend training programs on a frequent and regular basis. Peer evaluators' performance is regularly reviewed by the MAC Secretariat. They can be mandated for peer evaluation at the ILAC or IAF levels.

### 1 - NUMBER OF EVALUATORS

By end of December 2020, a total number of 168 evaluators (including trainees) are authorised to perform peer evaluations on behalf of EA, i.e. acknowledged for having all technical competences to perform peer evaluations under specific accreditation scopes.

The total number of evaluators slightly decreased by 5% in comparison with 2019, because 9 evaluators retired or resigned in 2020 when no newcomer training session could be organised and compensate their departure. Thus no evaluator has been authorised for the first time.

In 2020, 44 evaluators have been re-approved for a period of three years.

### Number of evaluators per qualification

By end of December 2020, the 168 authorised evaluators are broken down as follows:

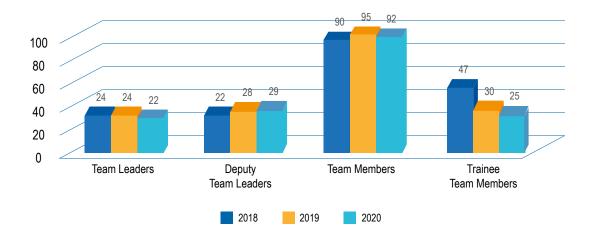
- 25 Trainee Team Members 17% compared to 2019
- 92 Team Members (TMs) 3% compared to 2019
- 29 Deputy Team Leaders (DTLs) + 4% compared to 2019
- 22 Team Leaders (TLs) 8% compared to 2019

The repetitive fall in the number of trainee Team Members is a result of the absence of a newcomer training in 2019 and 2020. Indeed the last two newcomer training sessions had been organised in 2018 when the evaluator resources had been considerably improved, enabling many trainee Team Members to be assigned to peer evaluations in 2019. Owing to the COVID-19 pandemic, the newcomer training scheduled in 2020 should have been postponed to 2021, when the number of trainee Team Members is expected to rise.

Regarding evaluators' upgrading based on their performance during peer evaluations, the fact that most peer evaluations should have been postponed to 2021 due to the pandemic made impossible to upgrade evaluators as Team Members in 2020, when there was only one new Deputy Team Leader. No evaluator was upgraded as Team Leader. It is expected that the number of evaluators in each qualification category will increase in 2021 as a result of postponed and scheduled peer evaluations.

The MAC Secretariat appointed a total of 54 evaluators (31 Team Leaders and 23 Team Members, among which 1 Trainee) who spent 335 man-days to carry out the peer evaluations and related activities completed in 2020. Among those, 18 Team Leaders were involved in the Option B document review for the transition to EN ISO/IEC 17011:2017.

# 7 - PEER EVALUATORS

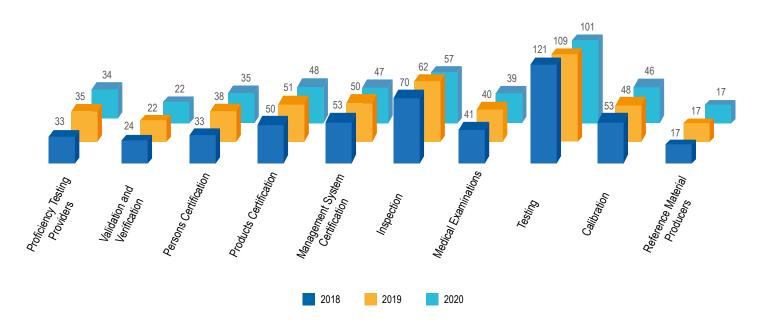


#### Number of evaluators per qualification

### Number of evaluators per scope

In the table below, the number of evaluators includes altogether trainee TMs, TMs, DTLs and TLs competent for each scope, knowing that one evaluator can be competent for several scopes.

The table shows that, like in previous years, the scope of testing gets a far much larger number of competent evaluators, i.e. near 25% of the total number of evaluators in 2020.



#### Number of evaluators per scope

# 7 - PEER EVALUATORS

## Number of evaluators per NAB

In December 2017, nearly half of the national accreditation bodies (NABs) had been identified as having few or no peer evaluators. Those NABs were contacted in priority so as to support them to send candidates to the newcomer training sessions in 2018 and to increase their numbers of EA evaluators.

The overall situation which had improved in 2019 did not evolve in 2020 when no new evaluators were added to the database, since the planned newcomer training was postponed to 2021. By the end of 2020:

- 5 NABs have no evaluator;
- 23 NABs have 1 to 4 evaluators;
- 10 NABs have 5 to 8 evaluators;
- 5 NABs have 9 to 11 evaluators.

## 2 - TRAINING OF PEER EVALUATORS

The issue of evaluator resources is still a priority issue on the MAC agenda. In order to support the further improvement of EA's pool of evaluators for the busiest peer-evaluation program in 2021, two refresher training sessions as mentioned below took place in 2020.

The newcomer training session scheduled on 9-11 December 2020 have been cancelled because training and approval of new evaluators were considered not appropriate to take place remotely. This session is postponed until December 2021.

### **Refresher training sessions**

In 2020 two refresher training sessions were organised remotely due to the health and travel conditions related to the COVID-19 pandemic.

The first session held on 17-18 November 2020 was dedicated to testing and calibration. The trainers were Tuija Sinervo (FINAS) for the testing group, Ilan Landesman (ISRAC) for the calibration group and Daniela Ionescu (MAC Secretary) for the general aspects related to the peer-evaluation process. Near 30 authorised evaluators discussed harmonisation issues for clauses of the new EN ISO/IEC 17011:2017 before gathering into two specific workshops for testing or calibration.

The second refresher training session, held on 15-16 December 2020, focused on inspection and certification of products. The trainers were Ian Ronksley (UKAS) for the product certification group, Gokhan Birbil (TURKAK) for the inspection group and Daniela Ionescu for the aspects related to the peer-evaluation process. 26 authorised evaluators discussed harmonisation issues for clauses of new EN ISO/IEC 17011:2017 before being split into two specific workshops for inspection or certification of products.

### Training on accreditation of validation and verification activities

Before the Covid-19 outbreak, the second session (first session in December 2019) of a train-the-trainer workshop on ISO/IEC 17029: *Conformity Assessment* — *General requirements for bodies performing validation and verification activities* was hosted on 29 January 2020 near Paris by the Secretariat. 13 representatives from EA NABs participated in this additional workshop, whose trainers were Nathalie Savéant (COFRAC, France) and Stefanie Vehring (VdTÜV, Germany).

### **1 - IMPROVING THE PEER-EVALUATION PROCESS**

The peer-evaluation process is under ongoing review by the MAC and EA internal auditors and peer evaluators as part of the evaluation program for regional cooperation.

#### MAC project on reengineering the peer-evaluation system

Regulation (EC) No 765/2008 reinforces the role of EA and its peer-evaluation system in both voluntary and regulated sectors. EA shall support and harmonise the implementation of stringent rules to achieve consistency throughout Europe, as well as greater transparency and acceptability to all interested parties, including national authorities. The peer-evaluation process is also further strengthened to accommodate the specific needs of regulatory fields in order to raise the reassurance of regulators and stakeholders that national accreditation bodies' technical competence is thoroughly assessed.

The MAC project to reengineer the peer-evaluation system, one of the key actions of the *EA Strategy 2025*, has been much progressing in 2020 and is nearing its goal.

After a commenting period at the MAC level, the papers related to the necessary competences of the MAC Secretariat to undertake more responsibilities for the operational management, the criteria for MAC Members, the tasks of the MAC Task Force Group (TFG) assigned to review the evaluation reports and the conditions to perform the witnessing in advance of the Head Office visit, were finalised and supported by the MAC at its meeting in October 2020. The MAC endorsed a new work item proposal for the revision of <u>EA-2/02</u>: <u>EA Procedure for the Evaluation of a National Accreditation Body</u> in order to include the principles agreed in this paper.

Regarding the elaboration of the guidance on peer-evaluation effort, a TFG composed of members of the MAC and MAC Management Group (MG) concluded a draft document to support a risk-based approach. Since the MAC MG considered important to test the document dispositions, 4 Team Leaders were invited to perform a validation exercise for recent cases where the standard document review has already been performed. The outcome of this validation exercise will be reviewed by the MAC MG.

The few remaining topics that still need to be covered will be discussed in 2021.

### Pandemic-triggered provisions for preserved confidence

During 2020 when many evaluations have been postponed, the MAC has been learning from the unexpected COVID-19 crisis to rethink peer evaluations in a remote perspective in the future.

At its meeting in October 2020, the MAC has already developed a new document *EA MAC Policy and Procedure for Remote Peer Evaluations during the COVID-19 Pandemic* in order to support keeping the necessary level of confidence in the EA peer-evaluation system during the COVID-19 pandemic, while considering that performing full remote peer evaluations is unavoidable during the pandemic.

# 8 - IMPROVEMENT OF THE MLA AND PEER-EVALUATION PROCESS

### 2 - DEVELOPMENT OF THE MLA

There was no EA MLA extension in 2020.

#### **3 - INCREASED VISIBILITY OF THE MLA**

EA has been working on having an EA MLA mark for the purpose of identifying MLA signatories and their accredited CABs. After the EA Members selected their preferred option for the MLA mark at the General Assembly in November 2019, the Executive Committee has been mandated to proceed with the formal registration of the MLA mark as a collective mark of the EU in a first stage, and then to extend registration at the international level based on the Madrid Agreement.

As part of the registration process, a set of rules for the use of the EA MLA mark shall be submitted to the registration authorities. Accordingly, the Horizontal Harmonisation Committee (HHC) has elaborated on these rules in <u>EA-3/01</u>: <u>EA Conditions for the Use of Accreditation Symbols, Logos and Other Claims of Accreditation and Reference to the EA MLA Signatory Status - Supplement 1: Rules for Use of the EA MLA Mark.</u> The rules, which were approved by the Members in October 2020, will enter into force once the MLA mark is formally registered presumably by summer 2021.

The application of the MLA mark should remain voluntary for NABs signatories of the EA MLA, which will be entitled to use the MLA mark in combination with their logo. Conformity assessment bodies (CABs) accredited by a MLA-signatory NAB will have the right to use the MLA mark in combination with the NAB accreditation symbol. The basic principle is that the mark can only be used in a country where it has been properly registered. It means that the mark will be registered (at least) in all the countries of the MLA/BLA signatories.

### 4 - MANAGEMENT OF TRANSITIONS OF STANDARDS

The MAC has strengthened its process for ensuring continuing compliance with the MLAs transitions. During 2020, the transition periods of the following 3 documents came to an end and the MAC carried out surveys on each transition to monitor the compliance by its members with the requirements:

- IAF MD 5:2019 Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems;
  - IAF MD 17:2019 Witnessing Activities for the Accreditation of Management Systems Certification Bodies;
- IAF MD 22:2019 Application of ISO/IEC 17021-1 for the Certification of Occupational Health and Safety Management Systems (OHSMS).

The feedback received from each survey indicated that, even though the application date was postponed by IAF, all members completed the transition within the agreed timeframe.

#### Implementation and monitoring of ISO/IEC 17011 transition period

The revised internationally-accepted standard EN ISO/IEC 17011:2017 *Conformity Assessment — Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies* has been published in November 2017. The peer evaluations done as from 1 July 2018 are performed according to the new standard.

By the end of November 2020, end of the 3-year transition period, the MAC confirmed that all 43 NABs signatories to the EA MLA successfully made the transition from EN ISO/IEC 17011:2004 to EN ISO/IEC 17011:2017.

## Implementation and monitoring of EN ISO/IEC 17025 transition period

Since the transition period for EN ISO/IEC 17025:2017 has been extended from 30 November 2020 to 1 June 2021, a fourth reporting was made to ILAC related to the implementation of the standard. The MAC carried out a survey between 17 November and 11 December 2020 in order to determine the progress of the transition of laboratories to the 2017 version of EN ISO/IEC 17025 made by national accreditation bodies. The results of the survey showed that MLA signatories for the calibration and testing scopes are keeping the transition under control.



EA is a regional cooperation body recognised by IAF and ILAC: the EA MLA is recognised by both organisations and covered by their respective arrangements. In concrete terms, a test report or certificate accredited by an EA MLA signatory is recognised by the signatories to the IAF and ILAC multilateral agreements. The EA MLA acts as a world-wide passport to trade.

### 1 - EXTENSION OF EA'S MLA SIGNATORY STATUS TO ISO/IEC TS 17021-10

Further to the approval of its application by IAF, EA has been recognised for the IAF MLA scope extension to ISO/ IEC TS 17021-10 and ISO 45001, setting out the requirements with guidance for use for occupational health and safety (OH&S) management systems, as of 5 February 2020.

Together with EA's recognition, the national accreditation bodies which had applied for, have been recognised by IAF for scope extension for the sub-scope ISO 45001.

### 2 - EXTENSION OF EA'S MRA SIGNATORY STATUS TO RMP

EA's application to ILAC for extending the signatory status of EA as a recognized region for the scope "Reference Material Producers – ISO 17034", as agreed at the EA General Assembly in May 2017, was accepted by the ILAC Arrangement Management Committee (AMC) in January 2018.

In April 2020, the ILAC Arrangement Council has endorsed the recommendation of the ILAC AMC to recognise the EA MLA for the accreditation of Reference Material Producers (RMP) using ISO 17034, as a result of EA's full reevaluation including this extension carried out during 2018 and 2019.

EA has become the first regional cooperation body member of the ILAC MRA for accreditation of RMP. Together with EA's recognition, the national accreditation bodies which had applied for, have been recognised by ILAC for scope extension for RMP (ISO 17034).

In addition, the recognition of the EA MLA to the ILAC MRA for the accreditation of calibration and testing (including medical) laboratories, inspection bodies and proficiency testing providers has been continued.

### **3 - FULL RE-EVALUATION OF EA BY IAF/ILAC**

The IAF/ILAC evaluation of EA has been concluded. EA was confirmed in May 2020 to remain a recognised regional cooperation body of IAF and ILAC.

The next re-evaluation of EA by IAF/ILAC is scheduled to begin no later than July 2022.

# ANNEX 1 - MULTILATERAL AGREEMENT SIGNATORIES (31 DECEMBER 2020)

	CALIBRATION LABORATO- RIES	TESTING LABORATO- RIES	MEDICAL LABORATO- RIES	INSPECTION BODIES	CERTIFICA- TION BODIES - PRODUCTS	CERTIFICATION BODIES - MANAGEMENT SYSTEMS	CERTIFICATION BODIES - PERSONS	VALIDATION & VERIFICATION BODIES	PROFICIENCY TESTING PROVIDERS	REFERENCE MATERIAL PRODUCERS
ALBANIA - DPA		$\checkmark$		$\checkmark$		$\checkmark$	O			
AUSTRIA - AA	$\checkmark$			$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$		
BELGIUM - BELAC	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	
BULGARIA – <b>BAS</b>	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$		
CROATIA - HAA	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	√	$\checkmark$	$\checkmark$	$\checkmark$		
CYPRUS – CYS	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	O					
CZECH REPUBLIC - CAI	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$		$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
DENMARK - DANAK	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	
ESTONIA - EAK	$\checkmark$		$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$		
FINLAND - FINAS	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	
FRANCE – COFRAC	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	
GERMANY - DAkkS	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$		$\checkmark$
GREECE - ESYD	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	
HUNGARY – NAH	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	
IRELAND - INAB	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$				$\checkmark$
ITALY - ACCREDIA	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$		$\checkmark$	$\checkmark$	$\checkmark$		
LATVIA - LATAK	$\checkmark$		$\checkmark$	$\checkmark$		$\checkmark$	$\checkmark$	$\checkmark$		
LITHUANIA - <b>LA</b>	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$		$\checkmark$	$\checkmark$			
LUXEMBURG - OLAS	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$				
Malta - Nab-Malta	$\checkmark$	$\checkmark$		$\checkmark$						
NORWAY - NA	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	
POLAND - PCA	$\checkmark$	$\checkmark$	√	$\checkmark$	√	$\checkmark$	√	$\checkmark$	√	
PORTUGAL - IPAC	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	√	$\checkmark$		
REPUBLIC OF NOR- TH MACEDONIA - IARNM	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$				
ROMANIA - RENAR			√	$\checkmark$		$\checkmark$	$\checkmark$	$\checkmark$	√	
SERBIA - ATS			$\checkmark$	$\checkmark$		$\checkmark$				
SLOVAKIA - SNAS			$\checkmark$				$\checkmark$			
SLOVENIA - SA		$\overline{\mathbf{v}}$								
SPAIN - ENAC			√							
SWEDEN – SWE- DAC	√			√					$\checkmark$	
SWITZERLAND - SAS	$\checkmark$			$\checkmark$						
NETHERLANDS - <b>RvA</b>	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
TURKEY – TURKAK	$\checkmark$		$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
UNITED KINGDOM - <b>UKAS</b>	$\checkmark$		$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$



# ANNEX 2 - BILATERAL AGREEMENT SIGNATORIES (31 DECEMBER 2020)

	CALIBRATION LABORATO- RIES	TESTING LABORATO- RIES	MEDICAL LABORATO- RIES	INSPECTION BODIES	CERTIFICA- TION BODIES - PRODUCTS	CERTIFICATION BODIES - MANAGEMENT SYSTEMS	CERTIFICATION BODIES - PERSONS	VALIDATION & VERIFICATION BODIES	PROFICIENCY TESTING PROVIDERS	REFERENCE MATERIAL PRODUCERS
ALGERIA - ALGERAC	$\checkmark$			$\checkmark$						
BELARUS - BSCA	$\checkmark$		O	O	$\checkmark$	$\checkmark$	$\checkmark$		0	
BOSNIA & HERZEGOVINA - <b>BATA</b>	$\checkmark$			$\checkmark$						
EGYPT - EGAC									$\checkmark$	
GEORGIA - GAC	$\checkmark$		$\checkmark$	$\checkmark$						
ISRAEL - ISRAC	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$						
REPUBLIC OF MOLDOVA - MOLDAC	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$					
UKRAINE - NAAU	$\checkmark$		O	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$			
TUNISIA - TUNAC	$\checkmark$	$\checkmark$		$\checkmark$		$\checkmark$				

Signatory in 2020













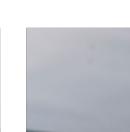




































With Support from EFTA



With Support from the **European Union** 

www.european-accreditation.org - secretariat@european-accreditation.org (C) @EAaccreditation

FOR MORE INFORMATION, CONTACT US: European co-operation for Accreditation

75 avenue Parmentier F-75 544 Paris Cedex 11 Tel: +33 1 40 21 24 62 - Fax: +33 1 40 21 24 00