

MLA REPORT 2022



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FOREWORD



The EA Multilateral Agreement (MLA) was signed by 44 EA Members by end of 2022.

Following the huge increase of peer evaluations in 2021 on account of the postponements from 2020 due to pandemic restrictions, the number of peer evaluations performed in 2022 decreased to a level comparable to 2019. Besides, due to the removing of pandemic restrictions, on-site evaluations restarted in 2022 and the MLA Council (MAC) decided that the whole of peer evaluations will be carried out on-site in 2023.

Moreover, because there had been none since 2018 owing to the sanitary crisis, two newcomer training sessions (usually planned every two years) took place in 2022, resulting in 46 new peer evaluators, i.e. a quarter of the total number of evaluators authorised by end of 2022. To still improve the priority issue of peer evaluators resources, an additional newcomer training session will be organised in 2023.

The MAC project on reengineering the peer-evaluation system is now nearing its completion. The revised EA-2/02: *EA Procedure for the Evaluation of a National Accreditation Body* has been published together with five supplements to EA-2/02. Two of them build upon the experience gained during the pandemic: EA-2/02 S4 describes the *Procedure for Remote Peer Evaluations during the COVID-19 Pandemic*, and EA-2/02 S5 sets out the *MAC Procedure for Making the EA MLA Decisions by Online Ballot*.

The number of signatories for each scope of the EA MLA remains quite stable in 2022 compared to 2021, with a slight progress in the number of signatories for medical examinations, persons certification and inspection.

The MAC decided to launch the EA MLA for validation and verification bodies against EN ISO/IEC 17029 in October 2022 based on at least one successful transition to EN ISO/IEC 17029 (level 3) and EN ISO 14065:2020 (level 4) declared by a national accreditation body (NAB), or at least one successful peer evaluation of a NAB against EN ISO/IEC 17029. The MAC also decided to start the peer evaluations in the field of validation and verification against EN ISO/IEC 17029. Four NABs already signed the MLA for this scope by end of 2022.

Furthermore, in November 2022, the EA General Assembly decided to expand the EA MLA with immediate effect to include biobanking as a level 2 conformity assessment activity using EN ISO 20387 *Biotechnology — Biobanking — General Requirements for Biobanking* as a new level 3 normative document. The prerequisites for the launch of the MLA on biobanking will be defined in 2023.

The strongest commitment of all those involved in the EA MLA process made the progress achieved in 2022 possible. I am very grateful for their outstanding contribution to maintaining and improving the EA MLA as a sustainable mechanism for ensuring both European and international reliable equivalence and mutual acceptance of certificates and reports issued by accredited conformity assessment bodies. Strong but also flexible accreditation and peer-evaluation systems are vital to maintain the confidence in the public service that we provide.

Maria Papatzikou (ESYD)
Chair of the EA Multilateral Agreement Council

1 - INTRODUCTION

This report provides information on the signatories to the EA MLA, as well as an overview of the key activities completed in 2022 to further develop the coverage of the 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 Regulation (EC) No 765/2008 and 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 strengthen the position of accreditation, national 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 30 August 2022, the fourth Framework Partnership Agreement (FPA) was signed with the European Commission for the period 2023-2026. A similar agreement was signed with EFTA on 16 November 2022.

Following article 11 of Regulation (EC) No 765/2008, a national authority shall recognise the equivalence of services delivered by a national accreditation body from the European Economic Area (EEA) which has successfully undergone peer evaluation by EA. Accordingly, a national authority shall accept the reports and certificates issued by a conformity assessment body accredited by the national accreditation bodies from the EEA that are EA MLA signatories.

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 – Members of EA which are successfully peer evaluated – to recognise and accept the equivalence of the accreditation systems and the reliability of the conformity assessment results.

EA 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. All of those EA Members that are signatories of the EA MLA aim to establish mutual confidence in the respective accreditation systems and in their accredited attestations of conformity.

Therefore, the marketplace can have confidence in activities of the 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.

Map of MLA signatories in December 2022



3 - SCOPE OF THE MLA

The EA MLA covers the following activities and standards:

Accreditation of	Scope/Activity (Level 2)	Standards (Level 3)
Laboratories	Testing and Medical Examinations	EN ISO/IEC 17025
	Calibration	EN ISO 15189
		EN ISO/IEC 17025
Certification Bodies	Certification of Products	EN ISO/IEC 17065
	Certification of Persons	EN ISO/IEC 17024
	Certification of Management Systems	EN ISO/IEC 17021-1
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 Provision	EN ISO/IEC 17043
Reference Material Producers (RMP)	Reference Material Production	EN ISO 17034
Biobanks	Biobanking	EN ISO 20387

During 2022, EA Members delivered about 37,600 accreditations under the scopes for which they have signed the EA MLA, representing a 2% increase compared to 2021.

Numbers of accreditation certificates issued under the EA MLA

Type of accreditation	2020	2021	2022
Calibration	3,214	3,277	3,374
Testing	18,555	18,651	18,962
Medical Examinations	3,891	3,831	3,903
Products Certification	2,000	2,062	2,113
Management Systems Certification	1,441	1,436	1,553
Persons Certification	741	812	842
Validation & Verification	155	146	144
Inspection	6,055	6,252	6,396
Proficiency Testing Provision (PTP)	209	226	244
Reference Material Production (RMP)	50	72	74
TOTAL	36,311	36,765	37,605

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 set out by the European Commission in relevant sector-based legislations as well as those covered in relevant EA and IAF/ILAC documents.

A list of EA MLA signatories and scopes (on 2 January 2023) is annexed to this report. For the latest information, please visit the [EA website](#).

Out of 49 EA Members, 44 have signed the MLA.

The individual EA Multilateral Agreement Signatories are listed by MLA scope in [EA-INF/03: Signatories to the EA Multilateral Agreements](#).

The numbers of member signatories for each scope of the EA Multilateral Agreement remain identical to those registered in 2021, with the exception of a slight increase in the numbers of signatories for medical examinations, product certification and inspection.

Numbers of member signatories to the MLA by scope

Type of accreditation	2020	2021	2022
Calibration	41	41	41
Testing	42	42	42
Medical Examinations	37	37	38
Inspection	42	42	43
Management Systems Certification	36	36	36
Products Certification	36	36	37
Persons Certification	32	33	33
Validation and Verification	25	25	25
Proficiency Testing Provision	20	20	20
Reference Material Production	8	12	12

5 - OPERATION OF THE MLA COUNCIL

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) of EA.

MLA Council (MAC)

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

Maria Papatzikou from ESYD (Greece) was the chair of the MAC for the term 2021-22. She has been re-elected at the General Assembly in May 2022 to carry on chairing the MAC until the end of 2024.

Karine Vincent from COFRAC (France) vice-chaired the MAC in 2022.

The MAC held its 46th meeting remotely on 6-7 April 2022, and its 47th meeting on 4-5 October 2022 in Turin, Italy.

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.

Secretariat

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



Daniela Ionescu is the MAC Secretary.



Sandy Adonel is responsible at the Secretariat for the training and monitoring of EA evaluators.

5 - OPERATION OF THE MLA COUNCIL

Decisions made by the MAC

Upon decisions made by the MAC in 2022:

ATS, the Serbian National Accreditation Body (NAB), became an EA MLA signatory in the field of proficiency testing provision (EN ISO/IEC 17043).

Furthermore, ATS remained an EA MLA signatory in the fields of calibration (EN ISO/IEC 17025), testing (EN ISO/IEC 17025) including medical examinations (EN ISO 15189), inspection (EN ISO/IEC 17020), certification of management systems (EN ISO/IEC 17021-1), certification of products (EN ISO/IEC 17065) and certification of persons (EN ISO/IEC 17024).

BAS, the Bulgarian NAB, remained an EA 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 (EN ISO 14065).

Afterwards the EA MLA status of BAS, the Bulgarian NAB, for validation and verification has been updated to ISO/IEC 17029 following the successful transition to EN ISO/IEC 17029 (level 3) + EN ISO 14065:2020 (level 4).

BATA, the Bosnia and Herzegovina NAB, became an EA MLA signatory in the fields of medical examinations and certification of products.

Furthermore, BATA remained an EA MLA signatory in the fields of calibration, testing and inspection.

CYS-CYSAB, the Cypriot NAB, remained an EA MLA signatory in the field of calibration and testing including medical examinations.

EGAC, the Egyptian NAB, remained an EA MLA signatory in the field of proficiency testing provision.

The EA MLA status of ENAC, the Spanish NAB, for validation and verification has been updated to ISO/IEC 17029 following the successful transition to EN ISO/IEC 17029 (level 3) + EN ISO 14065:2020 (level 4).

IARNM, the North Macedonian NAB, remained an EA MLA signatory in the fields of calibration, testing including medical examinations, inspection, certification of management systems and certification of products.

ISAC, the Icelandic NAB, became an EA MLA signatory in the field of inspection.

ISRAC, the Israeli NAB, remained an EA MLA signatory in the fields of calibration, testing including medical examinations, and inspection.



5 - OPERATION OF THE MLA COUNCIL

NAAU, the Ukrainian NAB, remained an EA MLA signatory in the fields of calibration, testing including medical examinations, inspection, certification of persons, certification of products and certification of management systems.

NAB-MALTA, the Maltese NAB, remained an EA MLA signatory in the fields of calibration, testing and inspection.

RENAR, the Romanian NAB, remained an EA MLA signatory in the fields of calibration, testing including medical examinations, inspection, proficiency testing provision, certification of management systems, certification of products, certification of persons, and validation and verification.

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

SWEDAC, the Swedish NAB, remained an EA MLA signatory in the field of calibration, testing including medical examinations, inspection, certification of management systems, certification of products, certification of persons, validation and verification, and proficiency testing provision.

Afterwards the EA MLA status of SWEDAC for validation and verification has been updated to ISO/IEC 17029 following the successful transition to EN ISO/IEC 17029 (level 3) + EN ISO 14065:2020 (level 4).

The EA MLA status of TURKAK, the Turkish NAB, for validation and verification has been updated to ISO/IEC 17029 following the successful transition to EN ISO/IEC 17029 (level 3) + EN ISO 14065:2020 (level 4).

UKAS, the United Kingdom NAB, remained an EA MLA signatory in the fields of calibration, testing including medical examinations, inspection, proficiency testing provision, certification of management systems, certification of products, certification of persons, validation and verification, and reference material production.



6 - PEER-EVALUATION PROCESS AND ACTIVITIES

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 [EA-2/02 M:2022 EA Procedure for the evaluation of a National Accreditation Body](#).

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

The 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. 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. 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 2022, the MAC had scheduled 14 peer evaluations, out of which 13 were performed by the end of December 2022 as follows:

- 9 re-evaluations: BELAC (Belgium), CAI (Czech Republic), DAkkS (Germany), ENAC (Spain), INAB (Ireland), ISRAC (Israel), NAH (Hungary), SA (Slovenia) and SNAS (Slovakia);
- 1 re-evaluation with extension for medical examinations and products certification: TUNAC (Tunisia);
- 1 re-evaluation with extension for PTP: GAC (Georgia);
- 2 initial evaluations: ATCG (Montenegro) and ISAC (Iceland).

At its meeting in October 2022, the MAC reconfirmed the EA MLA signatory status of NAAU, the Ukrainian NAB, whose full re-evaluation, anticipated in 2022, will finally be carried out in May 2023 as originally planned.

Since the pandemic has become alleviated and NABs in most European countries have decided to restart performing on-site assessments again, the MAC restarted on-site peer evaluations in 2022. Due to the lifting of COVID-19 pandemic restrictions, the EA MAC has decided that all peer evaluations will be carried out on-site as from 1 January 2023. In case of extraordinary circumstances preventing the peer-evaluation team from going on-site, the MAC Management Group will consider the specific situation and decide accordingly.

6 - PEER-EVALUATION PROCESS AND ACTIVITIES

EA peer-evaluation activities

	2019	2020	2021	2022
Total numbers of evaluations performed ¹	16	7	25	13
Total numbers of reports discussed ²	17	31 ³	13	15
Total man-days for evaluation	935	335	1,764	1,070
Extraordinary evaluations on site	3	0	2	0
Suspension	0	0	1	0

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

² Reports of evaluations, but not necessarily conducted in the specific year.

³ 31 reports, out of which 18 related to transition to EN ISO/IEC 17011:2017.

The total number of evaluations performed in 2022 was reduced by half in comparison to 2021, when the postponements from 2020 had a major impact on the programme of peer evaluations. As a consequence, the total number of man-days allocated to the peer evaluations performed in 2022 went down compared to 2021. The figures in 2022 have been regaining a similar level as before the pandemic years.

The evaluation teams reported a total of 127 non-conformities for those peer evaluations carried out in 2022.



7 - EA 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 Secretariat. They can be mandated for peer evaluation at the ILAC or IAF levels.

1 - NUMBER OF EVALUATORS

By end of December 2022, a total number of 177 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.

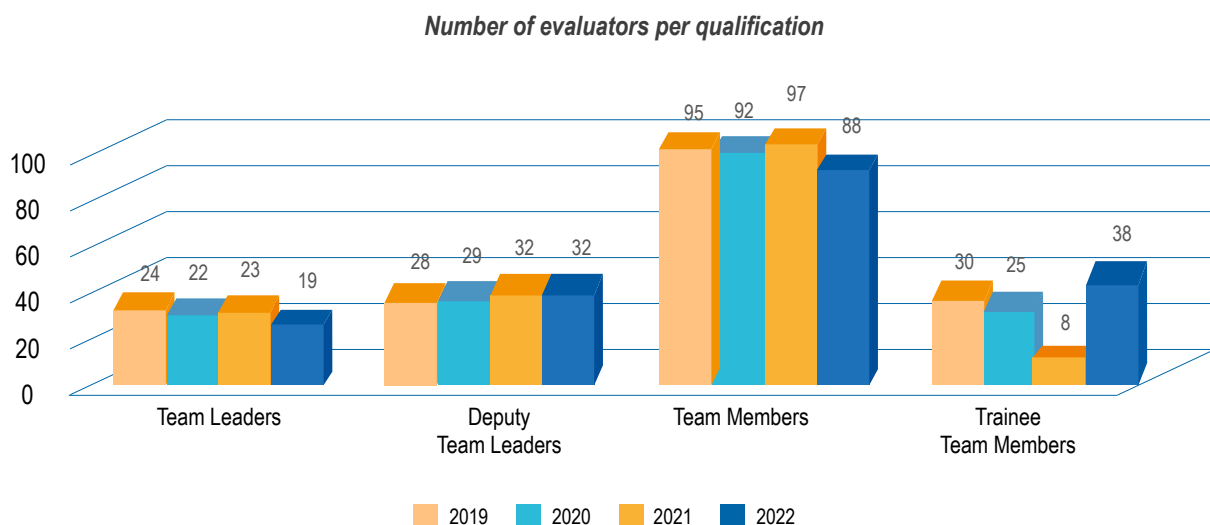
In 2022, 50 evaluators have been re-approved for a period of three years.

Number of evaluators per qualification

By end of December 2022, the 177 authorised evaluators are broken down as follows:

- 38 Trainee Team Members
- 88 Team Members (TMs)
- 32 Deputy Team Leaders (DTLs)
- 19 Team Leaders (TLs)

The pair of newcomer training sessions organised in 2022 (see Section VII.2 below) to make up for the lack of such trainings since 2020, and the need to compensate the end of participation of a large number of evaluators for various reasons, have led to a surge in the number of Trainee Team Members, thus restoring the total number of evaluators (increased by 11% compared to 2021) registered before the pandemic crisis.

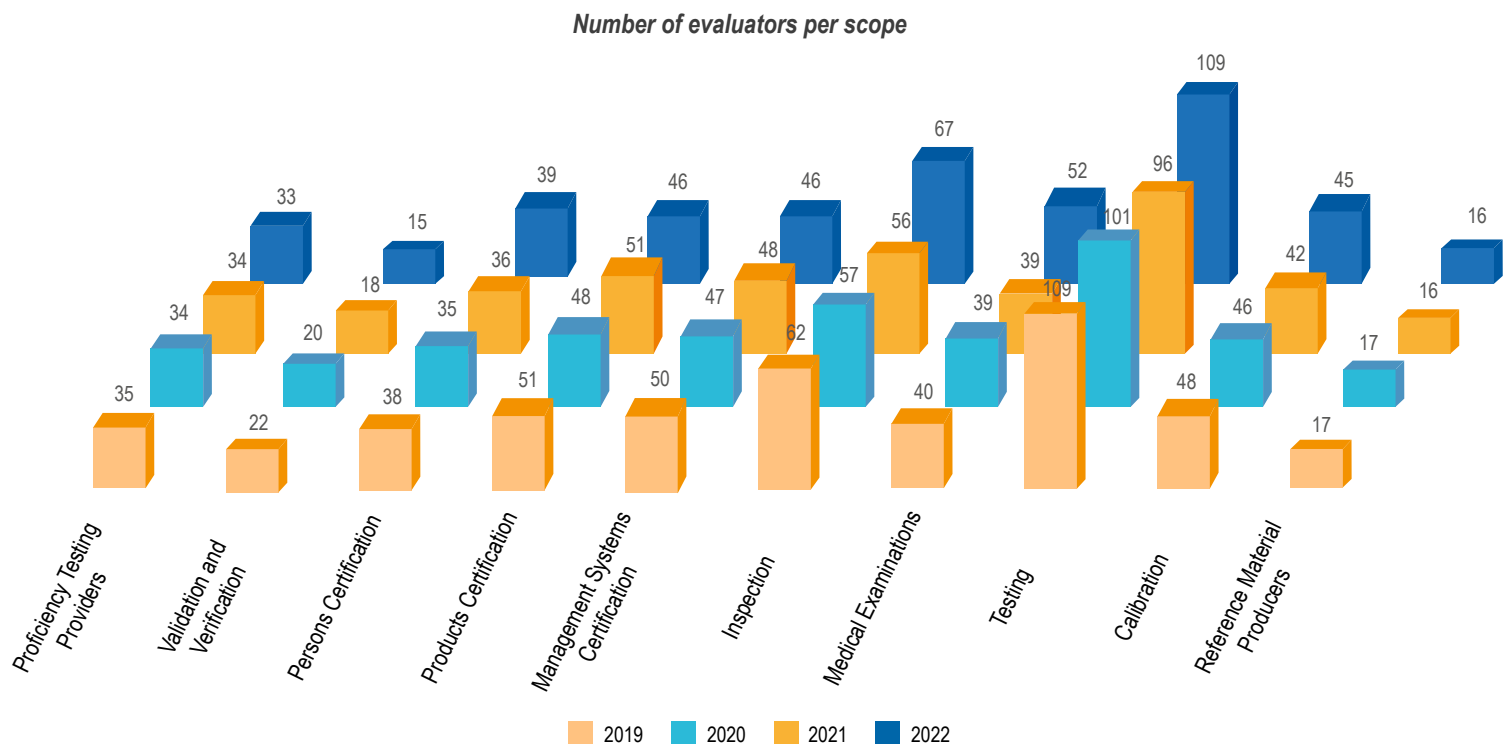


7 - EA PEER EVALUATORS

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 evaluators in 2022, i.e. 23% of the total number of competent evaluators. The following scopes gathering the highest numbers of evaluators are inspection (14%) and medical examinations (11%), the latter having caught up the leading pack in 2022. The next scopes are product certification and management systems (10%), closely followed by calibration (10%).



Number of evaluators per NAB

The two newcomer training sessions held in 2022 (see Section VII.2 below) have allowed to select new evaluators, several of whom belong to a few NABs which had no evaluator in the previous years. Moreover, although the number of evaluators has decreased in some NABs, a large number of the latter gain one or several evaluators; five of them have even doubled the number of their evaluators since January 2022.

7 - EA PEER EVALUATORS

2 - TRAINING OF PEER EVALUATORS

In 2022, 5 trainings were specifically organised for EA evaluators, i.e. 2 newcomer training sessions as well as 3 refresher trainings dedicated to Team Members.

Newcomer training sessions

The issue of evaluator resources is still a priority issue on the MAC agenda, all the more since there had been no newcomer training session since 2018. Even if many new evaluators and trainee team members had been assigned to peer evaluations in 2019, the absence of any newcomer training session owing to the pandemic situation since 2020 and the departure of a number of evaluators resulted in a progressive decrease in the number of peer evaluators, which should be increased in 2022.

To make up lost pandemic time, a pair of newcomer training sessions has thus taken place in 2022. The first one, still held remotely from 1 to 3 March, gathered 25 participants from 20 NABs. The second newcomer training session took place face-to-face from 18 to 20 October 2022 in Brussels, Belgium, where 27 participants from 19 NABs could get together.

Both newcomer training sessions in 2022 have permitted EA to gain a total of 46 new peer evaluators, 12 of whom could be directly assigned as Team Members and 34 of whom were first assigned as Trainee Team Members.

In order to further improve the situation, the MAC Management Group has decided to organise an additional newcomer training session at the end of 2023 before the one normally planned in 2024.

Refresher training sessions

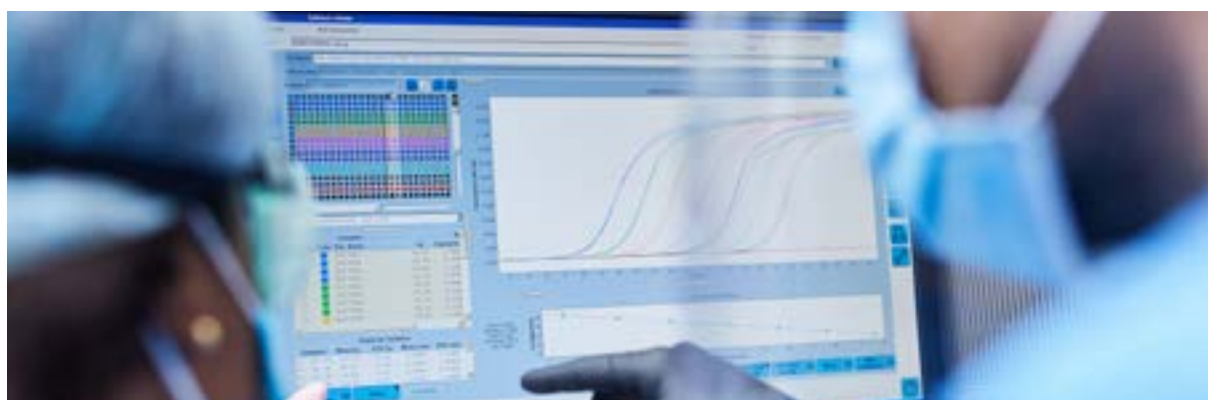
Three refresher training sessions were organised remotely in 2022.

The first session held on 28-29 June 2022 was dedicated to calibration and reference material production (RMP). 27 Team Members from 17 NABs took part in the training programme.

The second refresher training session organised on 15-16 November 2022 and attended by 29 Team Members from 20 NABs focused on testing, medical examinations and proficiency testing provision (PTP).

The last refresher training session gathered 23 Team Members from 18 NABs on 28-30 November 2022 in a programme dedicated to management systems certification, persons certification and validation and verification.

Because the sanitary situation is getting much better, the MAG Management Group has agreed that refresher trainings will alternate physical and remote sessions from now onwards. As a result, all refresher training sessions will be held on-site in 2023.



8 - IMPROVEMENT OF THE MLA AND PEER-EVALUATION PROCESS

1 - IMPROVING THE PEER-EVALUATION PROCESS

The peer-evaluation process is under ongoing review by the MAC, peer evaluators and EA internal auditors.

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 accreditation 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 entering its final stage in 2022. The revision of EA-2/02: *EA Procedure for the Evaluation of a National Accreditation Body* has been achieved together with the adoption of the following five supplements to EA-2/02, which have all been published:

- [EA-2/02 S1: Description of Competence Criteria of the EA Secretariat Personnel Involved in the Management of the Peer-Evaluation Process:](#)
- [EA-2/02 S2: Circumstances and Process of Involving EA Technical Committees in Peer-Evaluation Issues:](#)
- [EA-2/02 S3: Risk-Based Approach for the Planning of a Peer Evaluation of a National Accreditation Body:](#)
- [EA-2/02 S4: Procedure for Remote Peer Evaluations during the COVID-19 Pandemic:](#)
- [EA-2/02 S5: Multilateral Agreement Council Procedure for Making the EA MLA Decisions by Online Ballot, In-Between Meetings.](#)

Furthermore, the MAC decided in October 2022 to revise EA-2/02 S4 in order to make it applicable to other extraordinary circumstances than the COVID pandemic.

Besides, the revision of the MAC Terms of Reference to include the role and responsibilities of the Secretariat and to clarify the Task Force Group's and the Secretariat's roles, the rules on the performance of witnessing in advance of the peer-evaluation visit, as well as the rules on assignment of Team Leaders and Team Members to peer evaluations, has been finalised, approved and published on the EA website.

Only two issues in the reengineering project remain to be finalised in 2023, i.e. the competence of evaluators and the feedback mechanisms for any lessons learned during peer evaluations.

2 - DEVELOPMENT OF THE MLA

Launching of the EA MLA for EN ISO/IEC 17029

EA adopted in November 2021 the IAF Resolution 2021-22 related to the transition to a single Validation & Verification MLA under ISO/IEC 17029:2019 *Conformity assessment — General principles and requirements for validation and verification bodies* besides the EN ISO 14065:2013 *Greenhouse gases — Requirements for greenhouse gas validation and verification bodies for use in accreditation or other forms of recognition*.

8 - IMPROVEMENT OF THE MLA AND PEER-EVALUATION PROCESS

For this purpose, the MAC approved in April 2022 the roadmap towards an EA MLA according to EN ISO/IEC 17029 and the transition plan to EN ISO/IEC 17029:2019 + EN ISO 14065:2020. The actions foreseen in the transition plan, including the training of peer evaluators and decision-makers, have been completed.

At its meeting in autumn 2022, the MAC decided to start the peer evaluations in the field of validation and verification against EN ISO/IEC 17029 on 5 October 2022.

Furthermore, the MAC decided to launch the EA MLA for validation and verification bodies (EN ISO/IEC 17029) based on at least one successful transition to EN ISO/IEC 17029 (level 3) and EN ISO 14065:2020 (level 4), declared by a NAB, or at least one successful peer evaluation of a NAB against EN ISO/IEC 17029.

The first four signatories by end of 2022 are BAS, the Bulgarian NAB, ENAC, the Spanish NAB, SWEDAC, the Swedish NAB, and TURKAK, the Turkish NAB.

Extension of the EA MLA to biobanking

In 2022, EA has completed the process of extending its MLA to include biobanking, which had been initiated in 2021 with the approval of a roadmap identifying the actions to be undertaken, such as the revision of EA documents to include the biobanking activity and the harmonised standard into the EA MLA and training of peer evaluators.

The international standard ISO 20387: *General requirements for biobanking*, published in 2018, specifies general requirements for the competence, impartiality and consistent operation of biobanks, including quality control requirements to ensure biological material and data collections of appropriate quality. Many EA NABs are offering accreditation to biobanking facilities since accreditation is the best means to demonstrate the competence of biobanks.

A training course on biobanking was held remotely on 13 and 25 October 2022 under the auspices of the EA Laboratory Committee.

On 23 November 2022, the EA General Assembly has decided to expand with immediate effect the EA MLA for biobanking as a level 2 conformity assessment activity using EN ISO 20387 *Biotechnology — Biobanking — General Requirements for Biobanking* as a new level 3 normative document.

A last decision has still to be made by the MAC in April 2023 to define the prerequisites for the launch of the MLA on biobanking. In the meantime, the MAC has made those arrangements needed to start with the peer evaluations of EA NABs, including the training of the MAC members, who are the decision-makers.

3 - INCREASED VISIBILITY OF THE MLA

According to the *EA Strategy 2025*, EA has been working on having an EA MLA mark for the purpose of identifying MLA signatories and their accredited CABs. After EA Members selected their preferred option for the MLA mark at the General Assembly in November 2019, the Executive Board, still called Executive Committee at that time, 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.

The formal registration as a collective mark of the EU was completed in June 2022. The process for registering the EU mark as an international mark is progressing for those 16 EA MLA signatories which are not EU Members. The General Assembly on 23 November 2022 reconfirmed that, as agreed in November 2019, the EA MLA mark shall not be used until it is registered in the countries of all EA MLA signatories.

The application of the MLA mark should remain voluntary for NABs signatories of the EA MLA, which will be entitled

8 - IMPROVEMENT OF THE MLA AND PEER-EVALUATION PROCESS

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 signatories.

4 - MANAGEMENT OF TRANSITIONS OF STANDARDS AND IAF/ILAC DOCUMENTS

The MAC has strengthened its process for ensuring continuing compliance with the MLAs transitions.

The transition periods of the following six standards and documents having come to an end in late 2021 or in 2022, the MAC carried out surveys on each transition to monitor EA members' compliance with the requirements during 2022:

- ILAC P15:05/2020 *Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies* (survey launched at the end of 2021);
- ISO 14064-1:2018 *Greenhouse gases — Part 1: Specification with guidance at the organization level for quantification and reporting of greenhouse gas emissions and removals*;
- ISO 22000:2018 *Food safety management systems — Requirements for any organization in the food chain*;
- ISO 50001:2018 *Energy management systems — Requirements with guidance for use*;
- ISO/IEC 27006:2015 AMD 1:2020 *Information technology — Security techniques — Requirements for bodies providing audit and certification of information security management systems — Amendment 1*;
- ISO/IEC 20000-1:2018 *Information technology — Service management — Part 1: Service management system requirements*.

The feedback received from each survey indicated that all members completed the transition within the agreed timeframe.

9 - COOPERATION WITH IAF/ILAC: PEER EVALUATION OF EA

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

In 2022, EA applied to IAF to update its IAF MLA for validation and verification to ISO/IEC 17029. EA's application is in progress at IAF level.

2 - FULL RE-EVALUATION OF EA BY IAF/ILAC

The re-evaluation of EA by IAF/ILAC started in early September 2022 with the evaluation of the EA Secretariat and continued with the evaluation of the scopes of medical examinations, inspection, persons certification as well as validation and verification in 3 NABs.

Furthermore, IAF/ILAC evaluated the MAC decision-making process when they participated remotely in the MAC meeting held on 4-5 October in Turin, Italy.

The final IAF/ILAC decision on the re-evaluation of EA is awaited in 2023.



ANNEX - MULTILATERAL AGREEMENT SIGNATORIES (2 JANUARY 2023)

	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		√		√		√	√			
ALGERIA - ALGE- RAC	√	√		√						
AUSTRIA - AA	√	√	√	√	√	√	√	√		
BELARUS - BSCA	√	√	√	√	√	√	√		√	
BELGIUM - BELAC	√	√	√	√	√	√	√	√	√	√
BOSNIA & HERZEGOVINA - BATA	√	√	☐	√	☐					
BULGARIA - BAS	√	√	√	√	√	√	√	√		
CROATIA - HAA	√	√	√	√	√	√	√	√		
CYPRUS - CYS	√	√	√	√	√					
CZECH REPUBLIC - CAI	√	√	√	√	√	√	√	√	√	√
DENMARK - DANAK	√	√	√	√	√	√	√	√	√	√
EGYPT - EGAC									√	
ESTONIA - EAK	√	√	√	√	√	√	√	√		
FINLAND - FINAS	√	√	√	√	√	√	√	√	√	
FRANCE - COFRAC	√	√	√	√	√	√	√	√	√	√
GEORGIA - GAC	√	√	√	√	√		√			
GERMANY - DAKkS	√	√	√	√	√	√	√	√	√	√
GREECE - ESYD	√	√	√	√	√	√	√	√	√	
HUNGARY - NAH	√	√	√	√	√	√	√	√	√	
ICELAND - ISAC				☐						
IRELAND - INAB	√	√	√	√	√	√	√			√
ISRAEL - ISRAC	√	√	√	√						
ITALY - ACCREDIA	√	√	√	√	√	√	√	√	√	√
LATVIA - LATAK	√	√	√	√	√	√	√	√		
LITHUANIA - LA	√	√	√	√	√	√	√			
LUXEMBURG - OLAS	√	√	√	√	√	√				
MALTA - NAB-MALTA	√	√		√						
NORWAY - NA	√	√	√	√	√	√	√	√	√	
POLAND - PCA	√	√	√	√	√	√	√	√	√	√
PORTUGAL - IPAC	√	√	√	√	√	√	√	√		
REPUBLIC OF MOLDOVA - MOL- DAC	√	√	√	√	√	√				
REPUBLIC OF NOR- TH MACEDONIA - IARNM	√	√	√	√	√	√				
ROMANIA - RENAR	√	√	√	√	√	√	√	√	√	

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	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
SERBIA - ATS	√	√	√	√	√	√	√			
SLOVAKIA - SNAS	√	√	√	√	√	√	√	√	√	
SLOVENIA - SA	√	√	√	√	√	√	√	√		
SPAIN - ENAC	√	√	√	√	√	√	√	√	√	√
SWEDEN – SWEDAC	√	√	√	√	√	√	√	√	√	
SWITZERLAND - SAS	√	√	√	√	√	√	√			
NETHERLANDS - RvA	√	√	√	√	√	√	√	√	√	√
TURKEY – TURKAK	√	√	√	√	√	√	√	√	√	√
UKRAINE – NAAU	√	√	√	√	√	√	√			
UNITED KING- DOM - UKAS	√	√	√	√	√	√	√	√	√	√
TUNISIA - TUNAC	√	√		√		√				

 *Signatory in 2022*



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