



# **EA MLA REPORT 2018**



## **CONTENTS**

FOREWORD3
1 - INTRODUCTION
2 - THE EA MLA
3 - SCOPE OF THE EA MLA
4 - SIGNATORIES OF THE EA MLA
5 - OPERATION OF THE EA MLA COUNCIL
6 - EA PEER EVALUATION PROCESS AND ACTIVITIES 12
7 - EA PEER EVALUATORS14
8 - IMPROVEMENT OF THE EA MLA
AND PEER EVALUATION PROCESS
9 - COOPERATION WITH IAF/ILAC : IAF/ILAC PEER EVALUATION OF EA19
ANNEX 1 - Full Member signatories to the EA MLA
ANNEX 2 - Associate Member signatories to the EA MLA

### **FOREWORD**



The EA Multilateral Agreement (MLA), signed so far by 42 EA Members, carried on growing and extending during 2018, when, notably, EA welcomed a new EA BLA signatory – our special congratulations to BSCA, the national accreditation body of Belarus.

Since 2017, EA has been working to pave the way for expanding the scope of the EA MLA for reference materials producers (RMP) according to ISO 17034. The first peer evaluations started in 2018 when the first two EA Members have been successfully

evaluated for accreditation in the RMP field. Those two NABs will effectively become EA MLA signatories for RMP as soon as the EA MLA is launched for this scope in May 2019, provided that at least three members are successfully peer-evaluated by that date at the EA MLA Council (MAC) meeting.

The most striking development in 2018 is certainly the way how EA has succeeded in reinforcing the pool of EA peer evaluators to consolidate the peer evaluation process, which remains under constant improvement. EA's organisation of several training activities, such as newcomer training sessions, has considerably improved evaluator resources: by end of 2018, the total number of EA evaluators has risen by 29% in comparison with 2017. Despite a constant number of peer evaluations performed in comparison with 2017, the total number of man-days allocated to these peer evaluations rose by nearly 30% compared to the previous year - which shows the significant increase in the total number of EA MLA scopes peer-evaluated in 2018.

EA has also increased its recognition of MLA scopes in IAF (International Accreditation Forum) and ILAC (International Laboratory Accreditation Cooperation) in 2018. EA's application to ILAC for extending the MRA signatory status to the scope "Reference Material Producers – ISO 17034" has notably been accepted by the ILAC Arrangement Management Committee. The decisions on EA's peer evaluation by IAF/ILAC for extension of its MLA/ MRA signatory status to accreditation of greenhouse gas (GHG) verification and validation bodies (ISO 14065) and proficiency testing providers (ISO/IEC 17043) have also been made in favour of both extensions in May 2018.

Moreover 2018 is a remarkable year since, after a major training effort performed in December 2017, we started to do peer evaluations against the revised ISO/IEC 17011: *Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies.* 

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, made the progress achieved in 2018 possible. I am very grateful for their outstanding contribution to maintaining 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.

Paulo Tavares (IPAC)
Chair of the EA Multilateral Agreement Council

### 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 2017 to further develop the coverage of the EA MLA and to strengthen the operation of the EA peer evaluation system, including management of EA 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 and market surveillance relating to the marketing of products and repealing Regulation (EEC) 339/93', EA has been recognised by the European Commission (EC) 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 cooperation 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, and to 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 is under negotiation with EFTA and should be signed in early 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 onsite 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 intensifies its efforts dedicated to training of new peer evaluators. Two newcomer training sessions were organised in June 2018 to support further development of EA's pool of evaluators.

### 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 EA signatories of the EA MLA with the aim of establishing mutual confidence in the respective accreditation systems and in their accredited attestations of conformity. EA Associate Members shall comply with the same requirements as Full Members when signing the EA Multilateral Agreement. 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. 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.



### 3 - SCOPE OF THE EA MLA

### The EA MLA covers the following activities and standards:

Scopes of accreditation covered by the EA MLA on 31 December 2018

Accreditation of	Scope/Activity (Level 2)	Standards (Level 3)
Laboratories	3	EN ISO/IEC 17025 EN ISO 15189 EN ISO/IEC 17025
Certification Bodies	Certification of Persons	EN ISO/IEC 17065 EN ISO/IEC 17024 EN ISO/IEC 17021
GHG Validation and Verification Bodies	Validation and Verification	EN ISO 14065
Inspection Bodies	Inspection	EN ISO/IEC 17020
Proficiency Testing Providers (PTP)	Proficiency Testing	EN ISO/IEC 17043

## During 2018, EA Members delivered more than 35.200 accreditations under the scopes for which they have signed the EA MLA, distributed as follows:

Numbers of accreditation certificates issued under the EA MLA in 2018

Type of accreditation	2018
Calibration	3.094
Testing	18.530
Medical Examinations	3.896
Products Certification	1.896
Management Systems Certification	1.367
Persons Certification	644
GHG Validation & Verification	142
Inspection	5.528
Proficiency Testing Providers (PTP)	179
TOTAL	35.276

It is worth noting that in 2018, EA Members delivered 57 accreditations according to ISO 17034 in the field of reference materials producers (RMP), for which the EA MLA will be launched in May 2019 provided that at least three members are successfully peer-evaluated by that date.

### 4 - SIGNATORIES OF THE EA MLA

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 accreditation bodies' compliance with the requirements laid down in:

- Regulation (EC) No 765/2008;
- 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 2018) is given in Annexes 1 and 2. For the latest information, please visit the EA website.

#### 1 - EA FULL MEMBERS

Out of 36 EA 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 2017, with a slight increase in the number of signatories for inspection, management systems certification and proficiency testing providers.

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

Type of accreditation	2010	2011	2012	2013	2014	2015	2016	2017	2018
Calibration	27	28	32	32	33	32	33	33	33
Testing	28	31	33	33	33	33	34	34	34
Medical Examinations*	-	-	-	-	-	31	31	31	31
Inspection	27	29	31	32	33	32	32	33	34
Management Systems Certification	28	29	29	29	30	29	30	30	32
Products Certification	29	29	31	31	31	31	31	31	31
Persons Certification	26	26	26	27	28	27	28	28	28
GHG Validation and Verification	-	-	-	9	25	24	25	24	24
Proficiency Testing Providers	-	-	-	-	-	-	-	15	16

<sup>\*</sup> Number of EA Member signatories to the scope of medical examinations has been explicitly recorded since 2015 only.

### 4 - SIGNATORIES OF THE EA MLA

### 2 - EA ASSOCIATE MEMBERS

Out of 14 EA Associate Members, 8 have signed the EA MLA. BSCA, the national accreditation body of Belarus, has become an EA BLA signatory in October 2018.

The number of Associate Member signatories for each scope of the EA Multilateral Agreement remains stable compared to 2017, with the only increase due to BSCA's signatory status.

Numbers of EA Associate Member signatories to the EA MLA through a bilateral agreement

Type of accreditation		2011	2012	2013	2014	2015	2016	2017	2018
Calibration	8	2	4	4	4	4	4	7	8
Testing	8	2	4	4	4	4	4	7	8
Medical Examinations*	-	-	-	-	-	1	1	2	2
Inspection	4	2	2	2	4	4	4	7	7
Management Systems Certification	3	1	2	1	2	2	2	3	4
Products Certification	1	0	0	0	0	1	1	3	4
Persons Certification	2	1	1	1	1	1	1	2	3

<sup>\*</sup> Number of EA Member signatories to the scope of medical examinations has been explicitly recorded since 2015 only.



Map of EA MLA and BLA signatories in December 2018

### 5 - OPERATION OF THE EA 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) and Bilateral Agreement (BLA) of EA.

### **EA MLA Council (MAC)**

The MAC is composed of one representative from each EA Full Member and Associate Member, one observer from the EA Advisory Board and one observer from the European Commission. Since 2016, all EA MLA/BLA signatories have the voting right within the EA MAC on peer evaluations and MLA signatory status.

In 2018, the EA MAC was chaired by Paulo Tavares from IPAC (Portugal) and vice-chaired by Daniela Ionescu from RENAR (Romania) until after the summer. The election of a new Vice-Chair for the end of the current term, i.e. until end of 2019, is still processed within the EA MAC.

In 2018, the EA MAC held two meetings on 25-26 April in Belgrade, Serbia, and on 3-4 October in Budapest, Hungary, where the decisions mentioned hereafter were made.



### **EA 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 harmonization of the peer evaluations and operations of the MAC, including meetings.

In 2018, the MAC MG held two face-to-face meetings the day before MAC meetings, i.e. on 24 April in Belgrade, Serbia and on 2 October in Budapest, Hungary. In addition, the MAC MG had 6 web meetings in 2018.

### 5 - OPERATION OF THE EA MLA COUNCIL

#### **EA 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 Ionescu from RENAR (Romania) has replaced Lydie Mauger as the EA MAC Secretary in September 2018. Previously Daniela was the EA MAC Vice-Chair as well as an EA evaluator for products certification and GHG validation and verification. She worked in RENAR, the Romanian NAB, as Director of Quality Management and International Relations as well as Lead Assessor for products certification and GHG validation and verification. She will now be responsible for managing the EA MAC Secretariat.



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

### **Decisions made by the EA MAC**

#### **Decisions in April 2018:**

DAkkS, the German NAB, became an EA MLA signatory in the field of proficiency testing providers (PTP), thus increasing to 16 the number of signatories of the EA MLA for PTP accreditation (ISO/IEC 17043) which was launched in April 2017.

DPA, the Albanian NAB, while remaining an EA MLA signatory for testing, became a signatory to the EA MLA in the fields of inspection and management systems certification.

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

EAK, the Estonian NAB, remained an EA MLA signatory in the fields of calibration, testing, medical examinations, inspection, products certification, management systems certification, persons certification and GHG Validation & Verification.

### 5 - OPERATION OF THE EA MLA COUNCIL

IPAC, the Portuguese NAB, remained an EA MLA signatory in the fields of calibration, testing, medical examinations, inspection, products certification, management systems certification, persons certification and GHG Validation & Verification.

BATA, the NAB in Bosnia and Herzegovina, remained an EA BLA signatory in the fields of calibration, testing and inspection.

#### **Decisions in October 2018:**

IARNM (former IARM), the NAB of the Republic of North Macedonia, while remaining an EA MLA signatory for calibration, testing, medical examinations, inspection and products certification, became a signatory to the EA MLA in the field of management systems certification.

BSCA, the Belarusian NAB, became an EA BLA signatory in the fields of calibration, testing, as well as management systems, products and persons certification.

BAS, the Bulgarian NAB, remained an EA MLA signatory in the fields of calibration, testing, medical examinations, inspection, products certification, management systems certification, persons certification and GHG validation & verification.

CYS-CYSAB, the Cyprus NAB, remained an EA MLA signatory in the fields of calibration, testing, medical examinations and inspection.

LATAK, the Latvian NAB, remained an EA MLA signatory in the fields of calibration, testing, medical examinations, inspection, products certification, management systems certification, persons certification and GHG validation & verification.

RvA, the Dutch NAB, remained an EA MLA signatory in the fields of calibration, testing, medical examinations, proficiency testing providers, inspection, products certification, management systems certification, persons certification and GHG validation & verification.

Moreover, RvA and UKAS, the UK NAB, became the first two EA Members having been successfully evaluated for accreditation in the field of reference materials producers (RMP) according to ISO 17034. RvA and UKAS will effectively become EA MLA signatories for RMP as soon as the EA MLA is launched for this scope during the MAC meeting in May 2019, provided that at least three members are successfully peer-evaluated by that date.

### 6 - EA PEER EVALUATION PROCESS AND ACTIVITIES

The reliability of the EA 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 EA peer evaluation process is carried out in accordance with EA-2/02 M:2018: *EA Procedure for the Evaluation of a National Accreditation Body*, which has been revised in May 2018 in order to align it with IAF/ILAC-A2:01/2018: *IAF-ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Requirements and Procedures for Evaluation of a Single Accreditation Body*.

The national accreditation body applies for MLA signatory status, specifying the scope (testing, calibration, etc.) 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 onsite 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 EA website.

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

#### 2 - PEER EVALUATION ACTIVITIES

A total of 18 peer evaluations were performed during 2018, consisting of:

- 1 initial evaluation for PTP accreditation: EGAC (Egypt):
- 1 extension evaluation to RMP accreditation: UKAS (United Kingdom);
- 6 re-evaluations with scope extension to RMP accreditation: RvA (The Netherlands), CAI (Czech Republic),
   DAkkS (Germany), INAB (Ireland), ENAC (Spain), ACCREDIA (Italy);
- 2 re-evaluations with scope extension to PTP accreditation: NAH (Hungary), SNAS (Slovakia);
- 1 re-evaluation with scope extension to medical examinations: SA (Slovenia);
- 1 re-evaluation with scope extensions to medical examinations and management systems certification: GAC (Georgia);
- 3 re-evaluations: ISRAC (Israel), BELAC (Belgium), TUNAC (Tunisia);
- second part of 3 re-evaluations: NAB-MALTA (Malta), LATAK (Latvia), BAS (Bulgaria).

### 6 - EA PEER EVALUATION PROCESS AND ACTIVITIES

In total, 14 evaluation reports were reviewed during the April and October EA MAC meetings, consisting of:

- 1 for initial evaluation;
- 6 for re-evaluation:
- 1 for re-evaluation with extension of MLA signatory status to management systems certification;
- 1 for re-evaluation with extension of MLA signatory status to products certification;
- 1 for re-evaluation with extension of MLA signatory status to management systems certification, inspection and persons certification;
- 1 for re-evaluation with extension of MLA signatory status to RMP;
- 1 for extension of MLA signatory status to RMP;
- 1 for extension of MLA signatory status to PTP;
- 1 for extraordinary evaluation.

#### EA peer evaluation activities

	2010	2011	2012	2013	2014	2015	2016	2017	2018
Total numbers of evaluations performed <sup>1</sup>	13	19	12	11	13	10	19	18	18
Total numbers of reports discussed <sup>2</sup>	14	14	12	34	27	10	9	21	14
Total man-days for evaluation	455	750	754	673	807	583	1.138	1.080	1.393
Extraordinary evaluations on site	3	3	3	0	2	0	1	2	0
Suspension	2	0	0	0	1	0	0	0	0

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

In 2018, the evaluation teams reported a total of 84 non-conformities, 139 concerns and 81 comments. By the end of 2018, the peer evaluation of 14 NABs was in progress to be completed in 2019, when 13 other NABs are planned to be peer-evaluated.

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

### 7 - EA PEER EVALUATORS

EA peer evaluators are highly qualified and experienced 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 IAF or ILAC levels.

#### 1 - NUMBER OF EVALUATORS

In 2018, 43 evaluators have been authorized for the first time and 32 evaluators have been re-approved for a period of three years, i.e. acknowledged for having all technical competences to perform EA peer evaluations under specific accreditation scopes.

Regarding evaluators' upgrading based on their performance during peer evaluations, 4 evaluators were upgraded as team leaders, 10 others as deputy team leaders and 13 others as team members.

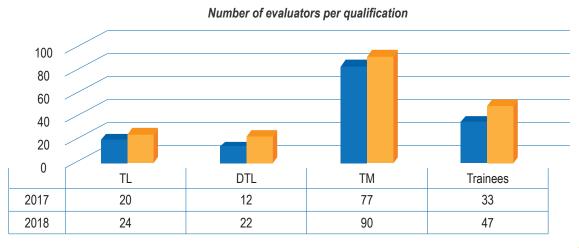
### Number of evaluators per qualification

By end of December 2018, a total number of 183 evaluators (4 observers excluded) are authorized to perform peer evaluations on behalf of EA, breaking down as follows:

- 47 Trainee Team Members (+ 42% compared to 2017)
- 90 Team Members (TMs) (+ 17% compared to 2017)
- 22 Deputy Team Leaders (DTLs) (+ 83% compared to 2017)
- 24 Team Leaders (TLs) (+ 20% compared to 2017)

It is worth stressing that the total number of EA evaluators has risen by 29% in comparison with 2017. This shows how EA succeeded to increase its pool of evaluators by organising several training activities, such as newcomer training sessions which have considerably improved the evaluator resources.

The MAC Secretariat appointed a total of 114 evaluators (15 team leaders and 99 team members, among which 23 trainees) who spent 1.393 man-days to carry out the 18 peer evaluations totalized in 2018. It is worth stressing that the total number of man-days allocated to the peer evaluations rose by nearly 30% compared to the previous year.



2017

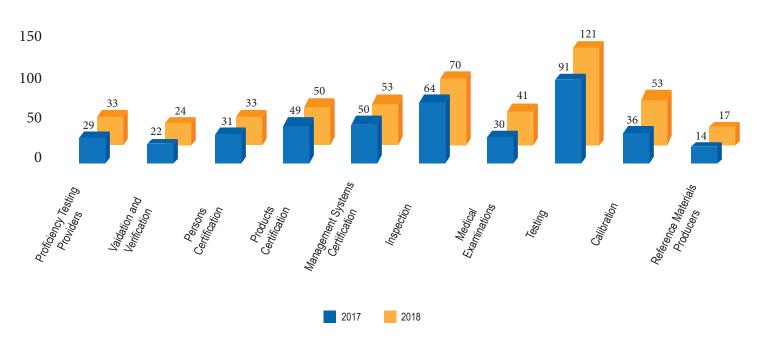
2018

### 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.

#### Number of evaluators per scope



### Number of evaluators per NAB

In December 2017, 14 NABs were identified as having few or none 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. One year later, 8 out of the 14 NABs have improved their situation: 1 NAB which did not contributed to evaluations so far has now 4 evaluators, 2 other NABs have doubled their numbers of evaluators, and 5 others have gained one additional evaluator.

15

### 7 - EA PEER EVALUATORS

#### 2 - TRAINING OF PEER EVALUATORS

The issue of evaluator resource is still a priority issue on the MAC agenda. In order to support the further development of EA's pool of evaluators for a busy peer evaluation program, the 2018 training plan has been reinforced and several training activities as mentioned below took place in 2018.

### **Newcomer training sessions**

The MAC Secretariat organised two newcomer training sessions dedicated to potential new evaluators on 4-6 June 2018 in the RvA offices in Utrecht, The Netherlands, and on 19-21 June 2018 in Lillestrøm, Norway. Hosted by the Dutch (RvA) and Norwegian (NA) NABs, the trainings were co-convened by Paulo Tavares (IPAC, Portugal), Chair of the MLA Council, together with Ed Wieles (RvA, The Netherlands) and Varpu Rantanen (FINAS, Finland), both highly experienced and esteemed Team Leaders. 44 participants from 29 EA NABs have been provided with insight in the processes supporting the peer evaluation system. Nine of them were immediately qualified as Team Members, while 34 others should at first become trainee Team Members.

Those two newcomer training sessions have significantly increased the number of new evaluators: many trainee Team Members have now to be assigned to peer evaluations in 2019, and perhaps 2020. Therefore, there will be no newcomer training in 2019 in order to invite at first the new evaluators to join EA peer evaluations.

### Refresher training sessions

A refresher training session focusing on greenhouse gas (GHG) validation and verification as well as management systems certification was organised by the EA MLA Council on 10-11 December 2018. The training hosted by the EA Secretariat was led by Niels-Christian Dalstrup (DANAK, Denmark) and Phil Shaw (UKAS, UK); Daniela lonescu attended the training as the MAC Secretary. 25 participants from different EA NABs discussed some aspects of ISO/IEC 17011: 2017 in combination with ISO/IEC 17021-1, such as competence of NABs' personnel, scope of accreditation, evidence of CBs' competence management systems, witnessing of management systems, reporting/records of CABs' effective fulfilment of requirements, and the IAF Mandatory Documents to be applied, especially IAF MD 20: Generic Competence for AB Assessors: Application to ISO/IEC 17011. Regarding GHG validation and verification, discussions mainly concerned how NABs confirm (record) to demonstrate that verification bodies satisfy with Regulation (EU) 600/2012, how they demonstrate a representative sampling of verifiers staff's competence and performance, and how they demonstrate witnessing of a representative part of scopes.

Two refresher training sessions will be organised in 2019. The first one aimed at Team Leaders and Deputy Team Leaders will be held on 18-19 June 2019 in Brussels. Hosted by the Belgian NAB BELAC, the training will be led again by Paulo Tavares, Ed Wieles and Varpu Rantanen. The second refresher training session, mainly dedicated to proficiency testing providers (PTP) and persons certification, is planned to take place in December 2019.

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

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

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

### IT project for EA evaluators' and peer evaluations' management

EA has been considering the development of an IT tool for an improved management of peer evaluations and peer evaluators. The analyses of different options and related benefits will be concluded in spring 2019.

### MAC project on reengineering the peer evaluation system

The EA peer evaluation process is under continuous review. Regulation (EC) No 765/2008 reinforces the role of EA and its peer evaluation role in both voluntary and regulated sectors. EA shall support and harmonize the implementation of stringent rules to achieve consistency throughout Europe, as well as greater transparency and acceptability to all, 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 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 progressing in 2018. The 9 Task Force Groups appointed in 2017 to support the reengineering of EA peer evaluation system presented their proposals resulting from the final recommendations of the EA MAC Management Group (MG) at the MAC meeting in April 2018. Due to the complexity of the project, the MAC MG decided at their last meeting in October to meet in the beginning of 2019 and consolidate the document on re-engineering, based on the TFGs' final reports. The document will be presented at the MAC meeting to be held in May 2019.

#### 2 - DEVELOPMENT OF THE EA MLA

Following the line started in 2017, the landmark in the EA MLA development in 2018 still consisted in paving the way for the launch of the accreditation scope for reference materials producers (RMP) expected in May 2019.

In May 2017, the EA General Assembly has approved to expand the scope of the EA MLA for reference materials producers (RMP) as new level 2 conformity assessment activity using ISO 17034 as a new level 3 normative document (EA Resolution 2017 (39) 18) and, acting upon the recommendation from the EA Multilateral Agreement Council, has approved the launching of the EA MLA for reference materials producers (ISO 17034) during the MAC meeting in spring 2019, provided that at least three members are successfully peer-evaluated by that date (EA Resolution 2017 (39) 19). Subsequently, in October 2017, the EA MAC has endorsed a formal document that supports harmonisation of practical issues in peer evaluations intended for the launch of EA MLA for reference materials producers (ISO 17034).

In 2018, the first peer evaluations for extension to the field of reference materials producers have been starting; two NABs have already been successfully evaluated.

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

#### 3 - MANAGEMENT OF TRANSITIONS OF STANDARDS

EA's process for the management of transitions of standards and IAF/ILAC documents was finalized in 2017 with the completion of a full set of rules.

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

The revised internationally-accepted standard 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.

As requested by the IAF/ILAC transition plan, EA has established specific implementation dispositions, which were included in the document "ISO/IEC 17011:2017 Transition plan" approved by the EA MAC on 26 April 2018 in Belgrade.

12 NABs were peer evaluated in 2018 against the requirements of the new ISO/IEC 17011:2017. In October 2018, one EA MLA signatory was confirmed to have successfully made the transition from ISO/IEC 17011:2004 to ISO/IEC 17011:2017.

The decisions regarding the other 41 EA MLA signatories for demonstrating compliance with the requirements of new ISO/IEC 17011 (either by peer evaluation or document review) are to be made prior to November 2020.

It is worth noting that the EA Horizontal Harmonisation Committee organised a workshop dedicated to ISO/IEC 17011 on 7 March 2018 in Brussels, Belgium when 72 participants could familiarise with the changes made to the standard between 2004 and 2017 versions. The EA evaluators, mainly Team Leaders and Deputy Team Leaders, had already been trained in December 2017 for the new ISO/IEC 17011:2017.

#### 4 - PEER EVALUATIONS WITH POTENTIAL SECURITY RISKS FOR EVALUATORS

A task force group within the EA MAC was established in 2017 to make proposals upon which the legal aspects related to EA's responsibilities towards evaluators' security and safety when they are assigned for peer evaluations in higher-risk third countries should be analysed.

In the light of recommendations by the EA legal adviser, and after joint consideration with the EA Executive Committee, the EA MLA Council endorsed in October 2018 a new work item proposal for the revision of EA-2/02: *EA Procedure for the Evaluation of a National Accreditation Body* in order to include provisions related to the respective responsibilities of EA and NABs for the peer evaluators carrying out peer evaluations in (third) countries.

### 9 - COOPERATION WITH IAF/ILAC: PEER EVALUATION

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 MRA SIGNATORY STATUS TO RMP

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

The scope extension has been covered by ILAC in the evaluation of EA in 2018 – see Section 9, point 4 hereafter.

## 2 - EXTENSION OF EA'S MLA/MRA SIGNATORY STATUS TO GHG VALIDATION & VERIFICATION AND PROFICIENCY TESTING PROVIDERS

Following the successful evaluation performed in 2017, in which the EA Secretariat and 2 EA NABs participated for on-site and witnessing activities, and a positive review of the evaluation report identifying non-critical findings, the formal decision on EA's peer evaluation by IAF/ILAC for extension of its MLA/MRA signatory status to accreditation of greenhouse gas (GHG) verification and validation bodies (ISO 14065) and proficiency testing providers (ISO/IEC 17043) has been finally made, based on IAF and ILAC ballots, in favour of both extensions in May 2018.

Further to ILAC's formal decision in May 2018 to extend EA's MRA status to proficiency testing providers, the effective recognition of EA for this field of accreditation will come into force after a second regional accreditation group in ILAC is successfully evaluated for the PTP scope.

## 3 - RENEWED EXTENSION OF EA'S MLA SIGNATORY STATUS TO IAF MLA SUB-SCOPES

According to the new IAF procedure for the evaluation of Accreditation Bodies and Regional Cooperation Bodies, EA's application for the extension of its IAF MLA signatory status to the following management system sub-scopes:

- Information Security Management System (ISMS);
- Food Safety Management System (FSMS);
- Medical Devices Quality Management Systems (MDMS);
- Energy Management Systems (EnMS);

was approved in April 2018 at the Frankfurt meeting of the IAF MLA Management Committee, and accordingly EA recognized for these sub-scopes.

In October 2018, EA has also been recognized by IAF for the sub-scopes FAMI-QS (The Quality and Safety System for Speciality Feed Ingredients asbl) under management systems certification, and "IPC Management System Auditors Certification Scheme" under persons certification.

### 9 - COOPERATION WITH IAF/ILAC: PEER EVALUATION

#### 4 - FULL RE-EVALUATION OF EA BY IAF/ILAC

The full re-evaluation of EA by IAF and ILAC, which includes the scope extension for RMP, started with witnessing activities in INAB, the Irish NAB, and ACCREDIA, the Italian NAB, respectively in September and November 2018. The IAF/ILAC team carried on with the re-evaluation by visiting the EA Secretariat in Paris on 3-4 December 2018. The re-evaluation will end in May 2019 when the decision-making process of the EA MLA Council will finally be evaluated during its next meeting. The outcome of EA's re-evaluation is expected in autumn 2019.

During the re-evaluation activities in 2018, only 1 concern has been raised by the IAF/ILAC evaluation team.

# ANNEX 1 - EA MULTILATERAL AGREEMENT SIGNATORIES (31 DECEMBER 2018)

	CALIBRATION LABORATORIES	TESTING LABORATORIES	MEDICAL LABORATORIES	CERTIFICATION BODIES - PRODUCTS	CERTIFICATION BODIES - PERSONS	CERTIFICATION BODIES - MANAGEMENT SYSTEMS	VALIDATION & VERIFICATION BODIES	INSPECTION BODIES	PROFICIENCY TESTING PROVIDERS
ALBANIA - <b>DPA</b>		V				0		0	
AUSTRIA - AA	V	V	V	V	V	V		<b>√</b>	
BELGIUM - BELAC	V	V	V	V	V	√	V	<b>√</b>	V
BULGARIA – BAS	V	V	V	V	<b>√</b>	√	V		
CROATIA - HAA	V	√	V	√	√	√	√	√	
CYPRUS - CYS	V	√	V					√	
CZECH REPUBLIC - CAI	V	√	V	√	√	√	V	<b>V</b>	V
DENMARK - DANAK	V	V	V	V	√	√	V	√	V
ESTONIA - EAK	V	V	V	V	V	√	V	V	
FINLAND - FINAS	V	V	V	√	√	√	√	√	V
FRANCE - COFRAC	V	√	V	√	√	√	√	√	V
FYROM - IARNM	V	√	V	√		O		√	
GERMANY - DAkkS	V	√	V	√	√	√	√	√	0
GREECE - ESYD	V	<b>√</b>	V	<b>√</b>	√	√	<b>√</b>	<b>√</b>	√
HUNGARY – <b>NAH</b>	V	V	V	<b>√</b>	√	√	<b>√</b>	<b>√</b>	
IRELAND - INAB	V	<b>√</b>	V	<b>√</b>		√		<b>√</b>	
ITALY - ACCREDIA	V	V	V	V	√	√	<b>√</b>	<b>√</b>	V
LATVIA - <b>LATAK</b>	V	V	V	V	√	√	<b>V</b>	√	
LITHUANIA - <b>LA</b>	V	V	V	√	√	√		√	
LUXEMBURG - OLAS	V	√	V	√		√		√	
MALTA – NAB-MALTA	V	V						√	
NETHERLANDS - RvA	V	V	V	V	V	V	V	V	V
NORWAY - NA	V	√	V	√	√	√	√	√	V
POLAND - PCA	V	V	V	√	√	√	<b>√</b>	√	V
PORTUGAL - IPAC	V	V	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$		
ROMANIA - RENAR	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$		$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$
SERBIA - ATS	<b>V</b>	√	√	√	√	√		√	
SLOVAKIA - SNAS	V	√	V	√		√	√	√	
SLOVENIA - SA	V	V		√	√	√	<b>√</b>	√	
SPAIN - ENAC	V	√	V	V	<b>√</b>	<b>√</b>			V
SWEDEN - SWEDAC	V	√	V	V	√	<b>√</b>	<b>√</b>	√	V
SWITZERLAND - SAS	V	<b>√</b>	V	V	<b>√</b>	<b>√</b>		√	
TURKEY – TURKAK	V	V	V	V	<b>√</b>	<b>√</b>		√	
UNITED KINGDOM - UKAS	V	V	V	V	V	V	V	V	V

# ANNEX 2 - EA BILATERAL AGREEMENT SIGNATORIES (31 DECEMBER 2018)

	CALIBRATION LABORATORIES	TESTING LABORATORIES	MEDICAL LABORATORIES	CERTIFICATION BODIES - PRODUCTS	CERTIFICATION BODIES - PERSONS	CERTIFICATION BODIES - MANAGEMENT SYSTEMS	VALIDATION & VERIFICATION BODIES	INSPECTION BODIES	PROFICIENCY TESTING PROVIDERS
ALGERIA - ALGERAC	V	V						√	
BELARUS - BSCA	O	0		0	0	O			
BOSNIA & HERZEGOVINA - BATA	V	V						V	
GEORGIA - GAC	√	√		V	$\sqrt{}$			V	
ISRAEL - ISRAC	√	√	V					√	
REPUBLIC OF MOLDOVA - MOLDAC	V	V	V	V		$\sqrt{}$		V	
UKRAINE – <b>NAAU</b>	V	V		$\sqrt{}$	V	$\sqrt{}$		√	
TUNISIA - TUNAC	V	V				√		√	

<sup>☐</sup> Signatory in 2018







#### 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
www.european-accreditation.org - secretariat@european-accreditation.org



