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## **FOREWORD**



Thomas Facklam, EA Chairman

#### Dear all,

2016 has been a busy year for the EA Multilateral Agreement Council (MAC) with no less than 19 peer evaluations (PE) planned and completed for a total of 1138 mandays of evaluation, and the starting of the evaluations for the new scope of accreditation of proficiency testing providers with positive results which should allow the launch of the Multilateral Agreement (MLA) in April 2017 as decided by the EA General Assembly.

At the end of 2016, we are proud to serve 36 Full Members, 13 Associate Members, 38 signatories to the MLA including through a bilateral agreement. During the year, we have relied on 101 assigned team members and 12 trainees, 34 MAC Members appointed in the Task Force Groups for the review of PE reports and 11 MAC Management Group members being involved with the MAC Chair (Paulo Tavares) and Vice Chair (Daniela Ionescu) and the Secretariat in the daily operations of the system. Think that more than 34600 accreditations had been delivered by EA-member national accreditation bodies (NABs) at the end of 2016.

Those are just a few numbers to illustrate why and how the EA MLA has been successful.

We have started to put efforts into a number of actions to enhance and facilitate the work done by our evaluators, such as developing a new IT project to facilitate online exchanges for peer evaluation, monitoring of the process, and to strengthen interactions with stakeholders like the U.S. Nuclear Energy Institute and the U.S. Nuclear Regulatory Commission. An observer from the EA Advisory Board now attends the MAC meetings regularly and gives us valuable feedback supporting continuous improvement of our practices. Moreover, the results of the survey made in 2016 give us guidelines for re-engineering our peer evaluation system and guaranteeing a continuous improvement of our process. As a result of the peer review of EA, ILAC and IAF have renewed their confidence in EA and its members in October 2016 by deciding to maintain EA in their MLAIMRA respectively for testing, medical testing, calibration, inspection, management systems and products certification, and extension for certification of persons.

I would like to sincerely thank all members of the Multilateral Agreement Council, the EA evaluators and the Secretariat of EA for all the energy dedicated and work done during this year to improve our organization and give sense to our main objective: "Accredited once, accepted everywhere".

EA is at a turn of its history. I trust that we have everything in hand to make another success of the next years.

## 1 - INTRODUCTION

The EA Multilateral Agreement (EA MLA) report contains information on the signatories to the EA MLA as well as an overview of the key activities completed in 2016 to further develop the coverage of the MLA and to strengthen the operation of the EA peer evaluation system, including management of EA evaluators.

The main objective of the peer evaluation activities is to evaluate the on-going compliance of national accreditation bodies 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 to operate the peer evaluation system of national accreditation bodies.

The recognition of EA is confirmed in 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;* these guidelines were initially signed by the parties on 1 April 2009. A new Framework Partnership Agreement (FPA) was signed on 24 June 2014 for the period 2014-2017 and negotiations have started for the next period 2018-2021. 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 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 on-site evaluations is to verify the accreditation body signatories' continuing compliance with the internationally-agreed criteria for accreditation bodies and with provisions set out in Regulation (EC) No 765/2008.

Maintaining a sound and reliable evaluation system also requires that EA intensifies its efforts for the training of new evaluator resources. In 2016, one newcomer session was organised for 28 participants and another session has already been planned in 2017.

## 2 - THE EA MLA

The MLA is an agreement signed between national accreditation bodies – Full and Associate Members of EA – 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 the 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 the EA MLA signatories and their accredited conformity assessment bodies.

The EA MLA is providing 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.

As in 2015, EA has been maintaining close relationships with several Directorates-General (DGs) and services of the European Commission during 2016, notably:

- DG Internal Market, Industry, Entrepreneurship and SMEs (GROW). Discussions about the Construction Product Regulation, EA's support to EC in the discussions on the Transatlantic Trade Investment Partnership (TTIP) with the US.
- DG Environment (ENV). Discussion about Environmental Technology Verification, revised ETV general verification protocol and its implementation in accreditation.
   Discussion on new standard ISO 14034:2016 Environment management - ETV.
- DG Climate Action (CLIMA). Discussions on Delegated Act regarding Regulation on the monitoring, reporting and verification of carbon dioxide emissions from maritime transport.
- DG Mobility and Transport (MOVE). Discussions about Railway sector and Interoperability of the railway system within the Community, elaboration of an accreditation scheme for railways Notifies Bodies under the auspices of the European Railway Agency (ERA).
- DG Justice (JUST). Discussions on General Data Protection Regulation.
- Joint Research Centre (JRC) on Breast Cancer Services. Project put on hold in mid-2016.
- EGNOS (European Geostationary Navigation Overlay Service) scheme. EA supports DG GROW in the elaboration of the scheme.

# EA SUPPORTS GROUND-BREAKING TRADE ACCORD BETWEEN CANADA AND THE EUROPEAN UNION

On 10 June 2016, EA and the Standards Council of Canada (SCC) signed a bilateral cooperation agreement aimed to support the Canada and European Union (EU) Comprehensive Economic and Trade Agreement (CETA).

The Canada and EU CETA is a high quality agreement that reinforces Canada's fundamental relationship with the European Union. The CETA covers all aspects of Canada's broad trading relationship with the EU, including goods, services, investment, government procurement and regulatory cooperation. It will provide Canada's access to the world's largest market with more than 500 million people in 28 countries, and a combined GDP of \$20 trillion.

The bilateral cooperation agreement (BCA) signed on 10 June 2016 by EA and the Standards Council of Canada (SCC) will enable the implementation of the Conformity Assessment Protocol provided for in the CETA agreement, allowing for the mutual acceptance by Canada and the EU of test results and product certifications delivered by each other's recognized bodies. This will help facilitate trade and open doors for EU and Canadian companies.

The EA-SCC agreement "will be essential to supporting the Government of Canada's trade agenda and opening up tremendous opportunities for Canadian companies who wish to grow and expand into the European market", asserts John Walter, SCC Chief Executive Officer.

Indeed differing regulations and standards between countries can cause delays and restrict market access for industry. Such a mutual recognition of accreditation bodies through the CETA Conformity Assessment Protocol will help to address these issues by allowing conformity assessment bodies in Canada and the EU to be recognized in certain areas through one mutually-accepted accreditation.

For Andreas Steinhorst, the EA Executive Secretary, the EA-SCC cooperation agreement should be welcomed as "a key element for the implementation of CETA and its protocol on the mutual acceptance of the results of conformity assessment. The agreement is going to support the elimination of import duties and technical obstacles to trade, saving European exporters around  $\in$ 500 million a year. Furthermore, it will strengthen the consumers' trust in marketed products".

This major cooperation agreement signed by EA demonstrates again the importance of the role played by accreditation which proves a crucial milestone in trade agreements and free movement of goods and services at a global level.

A pilot projet to start in 2017 will involve EA Members to look into practices for the assessment notified bodies. It will focus on the ATEX (Hazardous locations, in Canada) directive. Two experts from EA and SCC will witness accreditation assessments by a national accreditation body in Europe and in Canada. The project will be monitored at the EA level through a steering group appointed among the Executive Committee members.

#### For further information about:

- the CETA: ec.europa.eu
- the EA-SCC protocol: www.international.gc.ca



**Picture:** John Walter, SCC Chief Executive Officer, with Andreas Steinhorst, EA Executive Secretary, signing the SCC-EA bilateral cooperation agreement.

#### THE 2016 EA-ERA COOPERATION PROJECT SUCCESSFULLY ACHIEVED

EA successfully fulfilled its cooperation role with the European Railway Agency (ERA, which has been replaced by the European Union Agency for Railways) to improve the consistent assessment of conformity assessment bodies regarding the Interoperability Directive (IOD).

The main objective was to develop a detailed set of requirements, in particular the technical requirements, needed to be fulfilled by notified bodies in order to improve and harmonize the general level of performance of EU notified bodies under Directive 2008/57/EC and to increase trust in the work performed by notified bodies.

The accreditation scheme developed is divided into two parts: a first one produces general references and information on legal requirements for notified bodies, scheme owner, the NAB assessment teams, accreditation information etc., and a second one provides sectorial requirements to apply when accrediting CABs for the purpose of notification under the IOD.

This successful outcome is a very good example of fruitful cooperation between EA and the European Commission and its agencies. It enhances confidence for future cooperation projects with the European Commission and its DGs and agencies.



# 3 - SCOPE OF THE EA MLA

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

Accreditation of	Scope/Activity (Level 2)	Standards (Level 3)
Laboratories	Testing and Medical Examinations  Calibration	ISO/IEC 17025 ISO 15189 ISO/IEC 17025
Certification bodies	Certification of products Certification of persons Certification of management systems	ISO/IEC 17065 ISO/IEC 17024 ISO/IEC 17021
Verification bodies	Verification of greenhouse gas emissions	ISO 14065
Inspection bodies	Inspection	ISO/IEC 17020
Proficiency Testing Providers (PTP)	Proficiency Testing	ISO/IEC 17043

Figure 1: Scopes of accreditation covered by the EA MLA on 31/12/2016.

In Resolution 2012(30)16 adopted in November 2012(30)16, the EA General Assembly decided to extend the EA MLA to a new scope for the accreditation of Proficiency Testing Providers. The first evaluations for PTP took place in 2016, through either regular (8) or extension (5) evaluations.

# At the end of 2016, EA Members had delivered more than 34623 accreditations, distributed as follows:

Type of accreditation	2016
Calibration	3253
Testing	18733
Medical examinations	3410
Product certification	1742
MS certification	1365
Persons certification	484
Inspection	5204
Proficiency Testing Providers (PTP)	176
Reference Materials Producers (RMP)*	44
GHG Verification	133
Eco-Management and Audit Scheme (EMAS)	79
Total	34623

**Figure 2:** Numbers of accreditations in 2016.

<sup>\*</sup> Not yet covered by the EA MLA.

# 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:

- ISO/IEC 17011, the internationally-accepted standard for accreditation bodies;
- Regulation (EC) No 765/2008;
- the relevant standard for conformity assessment bodies including any additional requirements, e.g. those set out by the European Commission in relevant sector-based legislation.

A list of EA MLA signatories (on 31 December 2016) is given in Annex 1. For the latest information, please visit the EA website.

The number of Full Member signatories for each scope of the EA Multilateral Agreement remains stable compared to 2015.

Full Member signatories to the EA MLA	2010	2011	2012	2013	2014	2015	2016
Calibration	27	28	32	32	33	32	33
Testing	28	31	33	33	33	33	34
Inspection	27	29	31	32	33	32	32
Management Systems	28	29	29	29	30	29	30
Products	28	29	31	31	31	31	31
Persons	26	26	26	27	28	27	28
GHG Verification	0	0	0	9	25	24	25

Figure 3: Numbers of EA Full Member signatories to the EA MLA.

Associate Member signatories to the EA MLA	2010	2011	2012	2013	2014	2015	2016
Calibration	8	2	4	4	4	4	4
Testing	8	2	4	4	4	4	4
Inspection	4	2	2	2	4	4	4
Management Systems	3	1	2	1	2	2	2
Products	1	0	0	0	0	1	1
Persons	2	1	1	1	1	1	1

Figure 4: Numbers of EA Associate Member signatories to the EA MLA through a bilateral agreement.

Figures no 5-11 show the number of the EA MLA signatories by scope between 2009 and 2016.

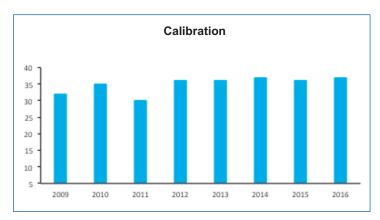


Figure 5: Numbers of EA MLA Signatories - Calibration

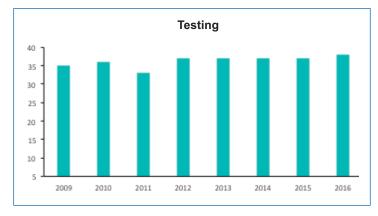


Figure 6: Numbers of EA MLA Signatories - Testing

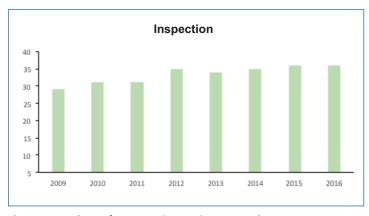


Figure 7: Numbers of EA MLA Signatories - Inspection

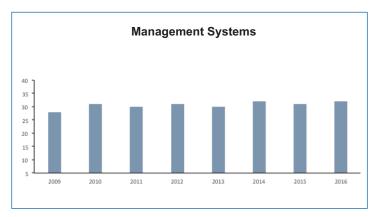


Figure 8: Numbers of EA MLA Signatories - Management Systems

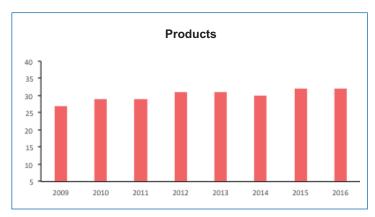


Figure 9: Numbers of EA MLA Signatories - Products

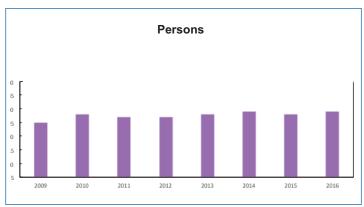


Figure 10: Numbers of EA MLA Signatories - Persons

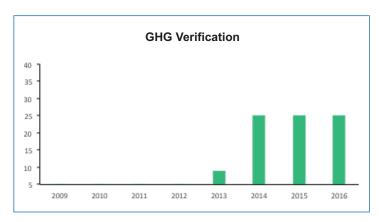


Figure 11: Numbers of EA MLA Signatories - GHG Verification

# 5 - DECISIONS BY THE EA MLA COUNCIL ON PEER EVALUATION ACTIVITIES

The EA MLA Council (MAC) 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 Agreements (BLAs) of EA.

The MAC is composed of one representative from each EA Full Member, one observer from the EA Advisory Board representing the Member States and one observer from the European Commission. By decision made in April 2015, the MAC changed its voting rules to allow all MLA signatories to vote. The MAC terms of reference and EA Articles of Association have been amended accordingly. It means that Associate Members having signed a BLA have a voting right, on an equal basis with the Full Members having signed the MLA.

In 2016, the MAC held two meetings on 20-21 April in Riga, Latvia and 5-6 October in Skopje, the Former Yugoslav Republic of Macedonia.

**Nineteen (19)** national accreditation bodies were peer evaluated during 2016, distributed as follows:

- 1 pre evaluation
- 2 initial evaluations
- 5 initial evaluations for extension of MLA signatory status to PTP accreditation
- 8 re-evaluations with extension of MLA signatory status to PTP accreditation
- 2 re-evaluations
- 1 extraordinary evaluation as part of a complaint investigation process

In total, nine (9) evaluation reports were reviewed during the April and October MAC meetings, distributed as follows:

- 5 for re-evaluations
- 2 for initial evaluation
- 2 for initial evaluation for extension of MLA signatory status to PTP accreditation



**Picture:** EA MAC meeting on 20-21 April 2016 in Riga, Latvia.



**Picture:** EA MAC meeting on 5-6 October 2016 in Skopje, the Former Yugoslav Republic of Macedonia.

# 6 - PEER EVALUATION PROCESS

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 being further strengthened to accommodate the specific needs of regulatory fields in order to raise the reassurance of sector-based stakeholders and regulators that the accreditation bodies' technical competence is thoroughly assessed.

Year	2010	2011	2012	2013	2014	2015	2016
Total numbers of evaluations performed <sup>1</sup>	13	19	12	11	13	10	19
Total numbers of reports discussed <sup>2</sup>	14	14	12	34	27	10	9
Total man-days for evaluation	455	750	754	673	807	583	1138
Additional information required	10	7	2	2	2	2	6
Extraordinary evaluations on site	3	3	3	0	2	0	1
No conditions imposed	3	6	7	6	5	6	4
Decision deferred	3	0	2	0	1	1	2
Suspension	2	0	0	0	1	0	0

Figure 12: Results of EA peer evaluation process.

In 2016, the evaluation teams reported a total of 74 non-conformities, 61 concerns and 49 comments.

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

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

# 7 - DEVELOPMENT OF THE EA MLA

The peer evaluations for the new PTP scope took place according to the plan: 13 evaluations for PTP were completed during the year, 5 as extension and 8 during routine re-evaluations.

Actions also started in 2016 to further extend the EA MLA to cover Refence Materials Producers (RMP). Evaluations should start by beginning of 2018, after the relevant training and approval of team members are completed. A train-thetrainer harmonisation session should take place on 30 and 31 May 2017 in Milan, hosted by ACCREDIA (Italy). The workshop will be targeted at NAB assessors and potential team members for RMP.



**EA WorkShop on** Accreditation of RMPs against ISO 17034 Milan, 30th and 31st May 2017

Dear Colleagues,

ACCREDIA is pleased to welcome you to the EA Workshop on Accreditation of Reference Material Producers against ISO 17034, in Milan.

Date: 30th and 31st May 2017.

Information about the venue, schedule of the meetings, accommodation and transportation are available in the pages below.

The ACCREDIA reference person who is going to attend the meeting is Giulia Suriani

(g.suriani@accredia.it).
Looking forward to meeting you in Milan.

#### **ACCREDIA**



30<sup>th</sup> and 31<sup>st</sup> May 2017 Date:

ACCREDIA - Certification and Inspection Department Venue:

Via Tonale, 26 00125 MILAN

ITALY Tel. +39 02 210**0**961 Fax +39 02 20119637 E-mail: milano@accredia.it Web: www.accredia.it

# 8 - MONITORING AND IMPROVEMENT OF ACTIVITIES

#### • Approval and re-approval of evaluators

In 2016, 13 Team Members (TMs)/Team Leaders (TLs) had to be re-approved. The result of the process was as follows:

- 3 evaluators were re-approved directly because they met the 3 criteria defined, 1 was re-approved subject to attending an EA training;
- 4 evaluators were approved for a new scope;
- 3 evaluators were not approved as TM for new scopes because they act as TLs mainly;
- the MAC MG could not make a decision for 2 evaluators in the absence of updated information in their CVs.

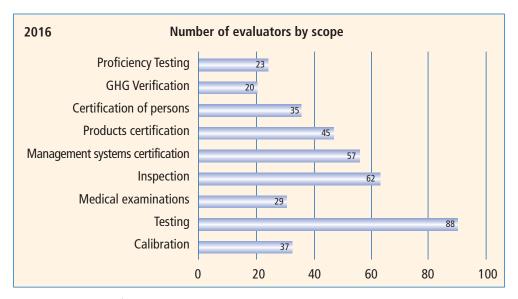


Figure 13: Numbers of evaluators by scope.

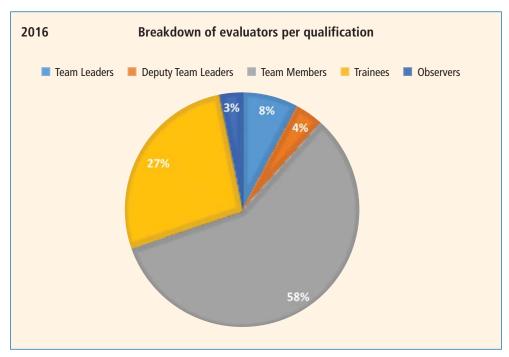


Figure 14: Breakdown of evaluators per qualification (based on a total of 129 evaluators).

#### • Change in MAC Management Group (MG) and Secretariat team



On 21 April 2016, **Cecilie Laake** from NA was elected a new MAC MG Member during the Multilateral Agreement Council meeting held in Riga, Latvia.



Starting from mid-October 2016, the new MAC Secretary is **Lydie Mauger**. Lydie has been involved in the peer evaluation operations for two years and took over all the tasks and responsibilities previously given to Martine Blum.



In mid-September, Marine Thiebaud, who was in charge of EA evaluators, left EA. Further to the comprehensive restructuring undertaken by the Executive Secretary in 2016, the relevant tasks and responsibilities have been transferred and centralised in the Secretariat at the administration level. **Sandy Adonel** will be entrusted with them as of 2017.

#### Improving daily operations

#### Several measures have been implemented to improve the MAC operations.

Concerning meetings, a complete list of all decisions submitted to the Council as a result of the discussions is now projected at the end of meetings for approval. A debrief session of the Management Group is planned after each plenary to review all actions and distribute responsibilities, identify routes for improvement and potential issues for future meetings.

At the operational level, it is an established practice that, for each peer evaluation, one MG member is appointed to monitor the process in cooperation with the Secretary. The role of the appointed MAC MG has been highlighted and the list of appointments is now made available on a continuous basis.

The template for a CV of evaluator trainee was updated to include PTP accreditation as a new scope of the EA MLA. The privacy and confidentiality statements were also updated.

# The IT project for the management of EA evaluators and peer evaluations continued in 2016.

The IT supplier was selected and the Secretariat could start the specification phase with three workshops held in December 2016. The MAC Secretary and the project manager participated. The three workshops were dedicated to the management of EA evaluator resources (administrative data, approval and reapproval process, training, etc.). Management of the PE process will be considered in a next stage in early 2017.

This new IT tool is designed to be used by all the persons involved in the system and peer evaluations i.e in addition to the Secretariat and the MAC Management Group members, team members, team leaders and deputy team leaders, NABs under evaluation, trainers, all with dedicated access rights. The future system will give users access to PE records, documents, templates and forms in a more friendly and convenient way. Data on peer evaluations will be stored to facilitate sharing and consultation by those involved in the process.

The next series of workshops of the development/specification phase will deal with the process itself; the objective is to give the Secretariat better tools to reinforce and facilitate monitoring and follow-up.

In the mid-term, the project team will take actions to involve a small team from the MAC or MAC Management Group from the NABs to test the tool before the launching of the online system, planned by end 2017.

It is worth emphasizing that this IT project is fully aligned with the MAC project on re-engineering of the PE process. Both will be jointly developed to support the successful introduction of the new approach in EA peer evaluations.





In response to a finding by the ILAC/IAF team, the EA Articles of Association were reviewed, as well as the EA Rules of Procedure in order to allow Bilateral Agreement signatories to have a voting right in the MAC for decisions related to signatories. The MAC terms of reference were also revised to reflect the change.

The process for the management of transitions of standards and ILAC/IAF documents has been established and documented. The template for surveys of members was improved and a process for dealing with the results by seeking further information or action from the members where relevant is being documented. The complete set of rules will be completed in 2017 and eventually published as a supplement to EA-2/02 EA Procedure for the evaluation of a National Accreditation Body.

Likewise, the process for dealing with changes notified by members was improved. Classification of changes by degree of criticality as well as a template to be used for review and decision during MAC meetings were discussed with the MG. This should also be completed and published as another supplement to EA-2/02. In practice, changes are notified to the Secretariat for review, first by the MG who prepares a recommendation on any needed action from the NAB to be then approved by the MAC. A table, which describes the changes and the recommendation by the MG, is compiled for presentation at the MAC meeting.

**A list of publications for use by EA evaluators** is now given in EA-INF/01 *List of EA publications and international documents.* 

Started in 2014, the **benchmarking table** is now regularly reviewed and improved by the MG. The table gives, on an anonymous basis, a list of findings resulting from EA evaluations. The MG agreed that, after each MAC meeting, MG members would be appointed to review the reports and update the table. It has been recognised indeed that the table would also be a valuable training tool at the NAB level.

#### • MAC project on re-engineering of the peer evaluation system

The MAC re-engineering project is progressing. In October 2016, the MAC Chair, Paulo Tavares, made a presentation of the results of the extensive survey carried out within the MAC. The objective of the survey, which was followed by a workshop session held in April 2016 in Riga, was to collect MAC Members' and evaluators' feedback on how to improve the EA peer evaluation process. MAC Members will be invited to discuss proposals to be prepared by the MAC Management Group in advance of the spring 2017 MAC meeting.



Picture: Peer evaluation re-engineering project - Report to MAC MG (October 2016).

#### Training and knowledge-sharing

In order to support further development of the EA pool of evaluators, the MAC organised a newcomer training in June 2016 and decided to have an additional session in June 2017. The session will complete a 2017 training plan, which already covers refresher activities to be performed during two distinct workshops.

#### In 2016:

- A training workshop on ISO/IEC 17043 was held in February in Staines-upon-Thames, England; 23 participants attended.
- A training workshop for newcomer/potential evaluators was held in June in Utrecht, Netherlands; 28 participants attended.
- A refresher training on ISO/IEC 17020 & ISO/IEC 17065 for team members was held in December in Paris, France; 15 participants attended.

In addition, a presentation was made for the MAC at its April meeting on PTP, by the Convenor of the Laboratory Committee TFG dealing with harmonisation issues for PTP and RMP. The TFG set up the training workshop for ISO/IEC 17043 and is involved in the preparation of a similar workshop on EN ISO 17034 for RMP to be held in May 2017.

#### Interaction with Stakeholders

In 2016, contacts were made through ILAC with the U.S. Nuclear Energy Institute (NEI) and the U.S. Nuclear Regulatory Commission (NRC). The purpose is to allow observers from NEI and NRC to watch an EA peer evaluation in a confidence-building approach. The MAC approved the principles of such a witnessing while emphasizing that the ILAC MRA gives the relevant confidence to stakeholders and should be referred to accordingly. The MAC decided that a set of rules should be developed to address such requests in general. It was also agreed that as a first requirement, the agreement of the NAB under peer evaluation would be necessary before planning further any activities with observers.

#### Policy for inter-laboratory comparisons (ILCs)

How to consider the results of highlighted inter-comparisons for confirming the effectiveness of the EA MLA was a major issue for discussion in EA in 2016. The Laboratory Committee, the MAC, the Executive Committee and the EA General Assembly were involved and the following position was eventually endorsed:

- the value of proficiency testing and other inter-comparisons for laboratories and, to some extent, inspection bodies was recognized for several critical activities such as method validation and quality control;
- there is no evidence that the effectiveness of the EA MLA can be monitored by the so-called highlighted ILCs;
- IAF/ILAC-A1 is not requiring regional groups to initiate or highlight specific proficiency testing activities (or other kinds of ILCs) as one of the technical activities referred to in order to support the demonstration of equivalence within the Regional Group and between Regional Groups;
- those highlighted ILCs shall not be taken into account under the framework of the peer evaluation process.

The Laboratory Committee and the Horizontal Harmonisation Committee will consider the consequences of the new EA policy during 2017, in the light of the on-going ILC plan and the future of the two WGs ILC for testing and calibration. EA-1/06, the document setting out the requirements for the EA MLA signatories, will be revised to reflect the decision made.

#### Market feedback - Complaints and appeals

Complaints provide a valuable mechanism for receiving feedback relating to the effectiveness of the MLA. This often confirms that the MLA is working efficiently and that the process in place is suitably robust. This can also provide information likely to improve areas of the MLA.

In 2016, EA received and managed five new complaints. All five complaints were closed by end 2016. Out of these five complaints, two originated in IAF. Two other complaints having started before 2016 remain open at end 2016.

One appeal against a MAC decision was received, managed and closed in 2016 according to the EA procedure.

#### Relations with ILAC/IAF – ILAC/IAF peer evaluation of EA

The re-evaluation of EA by ILAC and IAF started in 2014 with three observations of EA peer evaluation teams and the audit of the EA Secretariat in Paris. It ended up in 2015 with observing an additional peer evaluation and the decision-making process at a MAC meeting. The evaluation team was led by Roxanne Robinson (A2LA, USA).

At their annual meeting in October 2016 in New Delhi, ILAC and IAF agreed to renew their confidence to EA and its members by confirming EA's signatory status for testing, medical testing, calibration, inspection, management systems and products certification, and extension for certification of persons.



In 2017, EA will be peer evaluated by ILAC/IAF for extension of its MLA/MRA signatory status to accreditation of greenhouse gas verifiers and proficiency testing providers. The relevant on-site and witnessing activities will be completed before summer 2017. In parallel, the application process for IAF management systems sub-scopes has been reopened. The full re-evaluation of EA by ILAC/IAF should normally be planned in 2018.

# ANNEX 1 FULL MEMBER SIGNATORIES TO THE EA MLA – 31 DECEMBER 2016

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

<sup>\*</sup> Signatory for testing laboratories only; not signatory for medical laboratories.

# ANNEX 2 EA BILATERAL AGREEMENT SIGNATORIES

	CALIBRATION LABORATORIES	TESTING and MEDICAL EXAMINATIONS	CERTIFICATION BODIES - PRODUCTS	CERTIFICATION BODIES - PERSONS	CERTIFICATION BODIES - MANAGEMENT SYSTEMS	VERIFICATION BODIES	INSPECTION BODIES
BOSNIA&HERZEGOVINA - BATA	V	√ *					√
ISRAEL - <b>ISRAC</b>	√	√					√
UKRAINE - <b>NAAU</b>	√	√ *	√	√	√		√
TUNISIA - TUNAC	√	√ *			√		√

<sup>\*</sup> Signatory for testing examinations only; not signatory for medical examinations.









