

EA MLA Annual Report 2015



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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 2015 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 peer evaluation activities is to evaluate the ongoing 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 conformity assessment bodies 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 (Regulation No 765/2008), 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 that was



signed by the parties on 1 April 2009. A second Framework Partnership Agreement (FPA) was signed on 24 June 2014 for the period 2014-2017. 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 these 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.





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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, test, inspection and calibration certificates and reports issued by accredited conformity assessment bodies.

EA multilateral agreement.

EA Associate Members¹ 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 MLA signatories² 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 provides the European market with a network of conformity assessment bodies that are competent within their scope of accreditation to issue equivalent, 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.

- Associate Members are from those countries/economies identified by the EU or EFTA as a potential candidate country/economy for EU or EFTA membership, or identified by the EU in the European Commission Neighbourhood Policy as a country/economy of particular importance.
- 2) In this report, the term "EA MLA Signatories" covers those accreditation bodies – either Full Members or Associate Members of EA – that have signed the EA MLA Agreement.







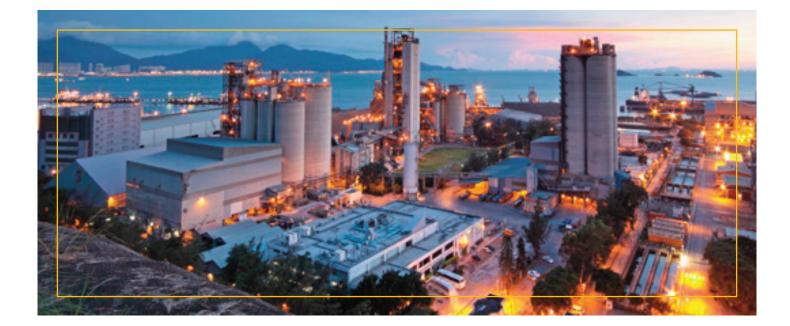
The EA MLA covers the following activities and standards:

| 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 |
| Validation and Verification bodies | Validation and Verification of greenhouse gas emissions | ISO 14065 |
| Inspection bodies | Inspection | ISO/IEC 17020 |
| Proficiency Testing Providers | Proficiency Testing | ISO/IEC 17043 |

Figure 1: Scopes of accreditation covered by the EA MLA.

y EA Resolution 2012(30)16 adopted in November 2012, the General Assembly decided to extend the EA MLA to a new scope for accreditation of proficiency testing providers (PTP).

The first evaluations for PTP are planned to take place in 2016, through either regular (8) or extension (5) evaluations.



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 in relevant sector-based legislation by the European Commission.

A list of EA MLA signatories (on the date of 31 December 2015) is attached in Annexes 1 and 2.



For the latest information, please visit the EA website.

During 2015, one accreditation body applied for extension of activities covered by the EA MLA and subsequently signed the EA MLA: IARM, Macedonia, for medical testing according to ISO 15189. A number of applications for accreditation of proficiency testing providers were also received. 13 peer evaluations could be planned in 2016.





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

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

Figure 2: Number of EA Full Member signatories to the EA MLA.

* Out of 36 Full Members, 32 have signed for all or part of the MLA. On 31 December 2015, NAT, Hungary, ceased its operations. As a consequence, the Hungarian NAB stopped its EA and EA MLA membership. Furthermore, DPA, Albania, has changed its status from Associate to Full Member of EA as a result of Albania being identified as a candidate country in the EU. DPA could sign the MLA for testing as a Full member.

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

Figure 3: Number of EA Associate Member signatories to the EA MLA through a bilateral agreement.

n 2015, NAAU, Ukraine, extended its bilateral agreement signatory status to cover product certification.

Out of twelve Associate Members, four have signed

the MLA through a bilateral agreement for more than one scope. GAC, Georgia and MOLDAC, Moldova have been pre-evaluated; peer-evaluations will follow in 2016.



Figures 4-10 show the number of the EA MLA signatories by scope between 2010 and 2015.

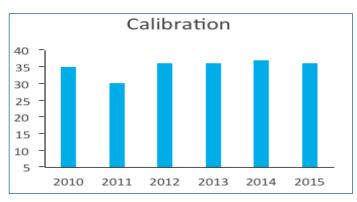


Figure 4: Number of EA MLA Signatories - Calibration

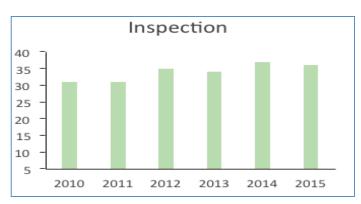


Figure 6: Number of EA MLA Signatories - Inspection

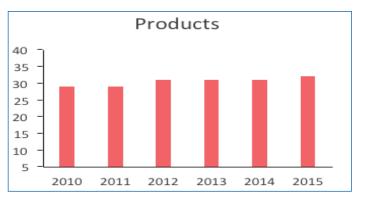


Figure 8: Number of EA MLA Signatories - Products

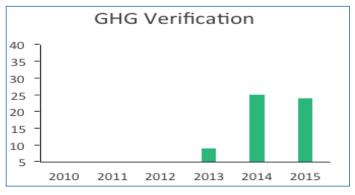


Figure 10: Number of EA MLA Signatories – GHG Verification

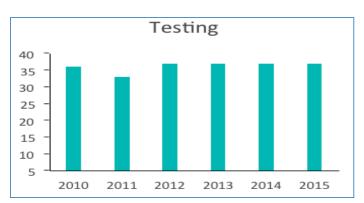


Figure 5: Number of EA MLA Signatories - Testing



Figure 7: Number of EA MLA Signatories – Management systems

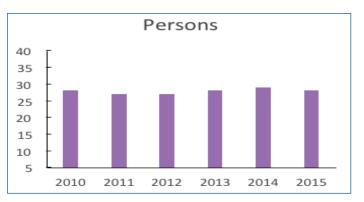


Figure 9: Number of EA MLA Signatories - Persons



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 (BLA) 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. In October 2015, the MAC decided to recommend the EA General Assembly to change its voting rules to allow all MLA signatories to vote. It means that Associate Members having signed a BLA would have a voting right, on an equal basis with Full Members signatories to the MLA. The provision will be implemented as soon as the EA Articles of Association have been revised and published.

In 2015, the MAC held two meetings on 22-23 April in Istanbul, Turkey and 1-2 October in Berlin, Germany.



Ten national accreditation bodies were peerevaluated during 2015. In total, ten evaluation reports were reviewed during the April and October MAC meetings.

The peer-evaluation of NAT, Hungary, was cancelled by decision of the MAC, based on the information notified to EA in summer 2015 according to which NAT operations would stop on 31 December 2015. As a result, NAT membership and MLA signatory status were cancelled.

These reports related to:

- ★ re-evaluation (7 reports)
- ★ initial evaluation (1 report)
- ★ pre peer-evaluation (2 reports)





The EA peer evaluation process is under continuous review. Regulation (EC) No 765/2008 reinforces the role of EA and its peer evaluation activity in both voluntary and regulated sectors.

EA shall support and harmonize the implementation of more stringent rules to achieve consistency throughout Europe, as well as greater transparency and acceptability of accredited results by all, including national authorities.

The peer evaluation process is being further strengthened to fully accommodate the specific



needs of regulatory sectors, with a view to raise the reassurance of sector-based stakeholders and regulators that the accreditation bodies' technical competence is thoroughly assessed.

The peer evaluation process is ongoing and extensive. The following table gives an analysis of the outcome of the peer evaluations from 2010 to 2015:

| Year | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 |
|--|------|------|------|------|------|------|
| Total number of evaluations performed ¹ | 13 | 19 | 12 | 11 | 13 | 10 |
| Total number of reports discussed ² | 14 | 14 | 12 | 34 | 27 | 10 |
| Total man-days of evaluation effort | 455 | 750 | 754 | 673 | 807 | 583 |
| Additional info required | 10 | 7 | 2 | 2 | 2 | 2 |
| Extraordinary evaluations on site | 3 | 3 | 3 | 0 | 2 | 0 |
| No conditions imposed | 3 | 6 | 7 | 6 | 5 | 6 |
| Decision deferred | 3 | 0 | 2 | 0 | 1 | 1 |
| Suspension | 2 | 0 | 0 | 0 | 1 | 0 |

¹ Evaluations, initial, 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.

In 2015, the evaluation teams reported a total of 32 non-conformities, 95 concerns and 56 comments.

At its meeting in October 2014, the MAC approved a proposed road map to develop the MLA for the inclusion of ISO/IEC 17043 for accreditation in the field of proficiency testing providers (PTP) as a new Level 2 activity. Basically, the MAC agreed that the peer evaluation process as set out in EA-2/02: EA Policy and Procedures for the Multilateral Agreement would apply in full.

n consultation with the EA Laboratory Committee (LC) and in light of similar discussions in the other regions, it was also stated that specific guidance was not necessary.

In accordance with the road map, harmonization training activities will take place in February 2016; they will target both NAB assessors and EA evaluators already qualified for testing / calibration, or potential evaluators to be used for this field.

The prepared peer evaluation plan provides that a total of 8 regular and 5 extension peer-evaluations



will cover PTP activities in accordance with EA-2/02. The peer evaluations of applicant EA NABs for signing the EA MLA for PTP accreditation will begin in April 2016. The first decisions on signatures of the EA MLA for PTP accreditation are expected to be made by the EA MAC in April 2017.

The development of the EA MLA for inclusion of accreditation of reference material producers is also progressing. ISO 17034, the applicable standard for accreditation in the field is almost ready for publication.



EA has been maintaining close relationships with several DGs and services of the European Commission (EC) during 2015:

- DG Internal Market, Industry, Entrepreneurship and SMEs (GROW)
- ★ DG Environment (ENV)
- ★ DG Climate Action (CLIMA)
- ★ DG Mobility and Transport (MOVE) / ERA
- DG Agriculture and Rural Development (AGRI)
- ★ Joint Research Centre (JRC)

Furthermore EA contributed directly to several projects initiated by the EC

Regulation (EU) No 1257/2013 on ship recycling, contribution to the guidelines on independent verifiers

EA commented the proposed guidelines on independent verifiers. These guidelines are related to Article 15(4) of the Ship Recycling Regulation, which introduces a two-step inspection and verification regime for facilities located in third countries willing to recycle EU flag ships.

Directive 2008/57/EC on Interoperability of the rail system within the Community, elaboration of an accreditation scheme for railways Notified Bodies (NoBos) under the auspice of the European Railway Agency (ERA)

In March 2014, the European Commission Directorate-General for Mobility and Transport (DG MOVE) asked the European Railway Agency (ERA) to provide a formal advice, in collaboration with EA, on an accreditation scheme for notified bodies under the Interoperability Directive 2008/57/EC (IOD).

The final aim was to improve the quality of work performed by the notified bodies (NoBos) in the railway sector.

ERA launched the project "Accreditation scheme for notified bodies under the IOD" and invited EA for cooperation. The accreditation scheme shall notably cover the technical as well as organisational and operational capacities necessary for NoBos to properly perform their duties. The project work was performed through an ad-hoc task force gathering together ERA's internal project team, EA, EU railway NoBos and the Intergovernmental Organisation for International Carriage by Rail (OTIF). Susana Huerta Vela (ENAC) and Martins Ozolins (LATAK) were appointed as EA representatives, as well as Inge-Lise Clausen (DANAK) and Curt-Peter Askolin (SWEDAC) as their deputies. This ad-hoc task force met four times from February to December 2015.

The TFG successfully elaborated the draft accreditation scheme for notified bodies under the IOD, which was published together with the final report end of 2015. The final accreditation scheme for notified bodies under the IOD was published in early 2016 by ERA.

Furthermore, EA had close cooperation with ERA in 2015 regarding Regulation (EC) 402/2013 on the common safety methods (CSM) for risk assessment. In 2015, ERA and EA started to work on the organization of a workshop for NABs and national authorities in order to explain what Regulation (EC) 402/2013 requires to be done with respect to the check of competence of the CSM assessment body and what particularities are needed for the railway domain. The workshop will be held in 2016 in Valenciennes, France.

Proposed Regulation setting up a Union system for supply chain due diligence self-certification of responsible importers of tin, tantalum and tungsten, their ores, and gold originating in conflict affected and high-risk areas

The proposed Regulation setting up a Union system for supply chain due diligence self-certification of responsible importers of tin, tantalum and tungsten, their ores, and gold originating in conflict affected and high-risk areas is still under preparation.

Proposed Regulation on organic production and labelling of organic products

EA, through WG Food of the Certification Committee has been cooperating with DG AGRI on matters relating to these regulations and a specific contact point has been established. A Task Force has been appointed within the WG Food to contribute to the development of the regulation and ensure related EA documentation is suitable and up to date. Discussions and activities are ongoing. The specific application document (EA-3/12) is still implemented in consultation with DG AGRI. Proposed Regulation on the monitoring, reporting and verification of carbon dioxide emissions from maritime transport

The Regulation EU 2015/757 on monitoring, reporting and verification of emissions of CO2 from maritime transport was published at the end of April 2015 and entered into force on 1 July 2015.

In Articles 15 and 16, the Commission is empowered to adopt delegated acts to further specify rules for verification activities and methods for accreditation of verifiers.

During the first half year of 2015, there was communication between DG CLIMATE ACTION (DG CLIMA) and EA related to the Regulation and the planned work for developing delegated acts to further specify the rules for verification and accreditation in the Regulation.

The work about elaborating the basis for the delegated acts is done within two sub-groups under the European Sustainable Shipping Forum (ESSF) - one sub-group on Shipping MRV Monitoring and one for Shipping MRV Verification and Accreditation. EA nominated Niels Christian Dalstrup, DANAK, to represent EA in the second sub-group and to take on the task as one of two rapporteurs. This was confirmed in the first meeting of the Sub-group on 7 July 2015, where Katharine Palmer (Lloyds Register) and Niels Christian Dalstrup (EA) were approved and appointed rapporteurs for verification and accreditation respectively.

A second meeting took place on 28 October 2015 and three more meetings have been planned in 2015-2016.

Directive 2014/47/EU on the technical roadside inspection of the roadworthiness of commercial vehicles circulating in the Union and repealing Directive 2000/30/EC; application of article 14 and annex V of Directive 2014/45/EU on periodic roadworthiness tests for motor vehicles and their trailers and repealing Directive 2009/40/EC

Discussions in the EA IC Technical Network (TN) Car Inspection started on Directive 2014/47/EU (Roadside Inspections) to check how every Member State is planning the RSI. Other discussions are progressing on the role of NABs in application of Directive 2014/45/EU annex V, related to the supervision of vehicle inspection bodies.

Ongoing implementation of the Joint Research Centre (JRC) – EA project on Breast Cancer Services

The EC initiated a project to develop an EU quality assurance (QA) scheme for breast cancer services (BCS) which aims at ensuring that there is a process whereby all BCS, irrespective of the country and organizational framework within which they are provided, can demonstrate that they meet an agreed standard and that patients and commissioners of services can have a high degree of confidence in all the processes directly related to breast cancer healthcare at all stages of BCS.

This scheme, which will be based on a revision of the European Quality Assurance Guidelines for Breast Cancer Screening and Diagnosis, is to be underpinned by accreditation in accordance with Regulation (EC) 765/2008. All aspects of BCS including diagnosis, surgery, treatment, nursing care and palliative care will be covered by the QA scheme; the main focus will be the quality of care and experience of the patient.

EA's mission, based on a service contract with the European Commission / JRC, is to provide comprehensive guidance for the scheme's different stakeholders, i.e. national authorities, professional bodies, national accreditation bodies (NABs) and conformity assessment bodies (CABs). Managing a well-established process for the production and publication of application, technical, advisory and guidance documents, EA will provide generic publications describing the accreditation framework, toolkit, processes and procedures for accreditation. The project, suspended in November 2014, continued in September 2015.

Completion of the action "Implementation of accreditation and peer evaluation of NABs according to EN ISO 14065 and Commission Regulation EU No 6002/2012" (25 February 2015)

The project was successfully completed within the contractual deadline at the end of February 2015. The final report was presented and accepted by the EC DG Climate Action.

The peer evaluation program was achieved in accordance with the project plan with 25 EA member NABs having signed the EA MLA for GHG verification. Access to data concerning accredited verifiers is possible from the EA homepage.

Enhancement of the cooperation with the European Commission, DG Environment, regarding EU-ETV (Environmental Technology Verification)

EA established a regular contact with DG ENV regarding EU-ETV. The following issues were discussed in 2015:

- ★ Revision of the General Verification Protocol
- Draft ISO 14034 "Environmental Management Environmental Technology Verification"

Completion of the service contract "Approximation of the EU and RF Accreditation System"

European exporters and Russian importers face difficulties in mutual trade due to application of different conformity assessment standards and requirements. Started in January 2013, the 3-year cooperation project between EA and RusAccreditation called "Approximation of EA and Russian Federation accreditation systems", aimed to support increasing trade between the European Union (EU) and Russian Federation (RF) through modernising and aligning Russia's technical regulation system and related infrastructure of standardisation, conformity assessment, accreditation, market surveillance to the EU system. A centralized independent accreditation system without competition should be established to enable the Russian accreditation system to join the European and international multilateral recognition agreements.

For this purpose, the EU signed a services contract with EA. EA provided experts to firstly evaluate the situation in Russia by analysing the legislative framework and technical processes of the Russian management and accreditation systems through performing evaluation of Russian conformity assessment bodies; then issue recommendations on how to improve the legal basis and technical elements of the Russian accreditation system in order for it to comply with European and international standards and requirements. Besides, EA experts set up and managed awareness-raising events to promote the new approach and training activities for assessors to support the implementation of the modified system. The project was successfully concluded in December 2015.

At the international level also, Regulators rely on the EA MLA

On 11 March 2015, EA had a meeting with DG GROW, with the U.S. Mission for the EU in order to explain and to promote the European Accreditation Infrastructure. The U.S. Mission for the EU is involved in the negotiation about the Transatlantic Trade and Investment Partnership (TTIP).

EA has also established close contact with the U.S. Food Drug Administration (FDA), in particular regarding the new U.S. Food Safety Modernisation Act (FSMA). Two meetings between EA and the FDA took place in 2015 in Brussels.

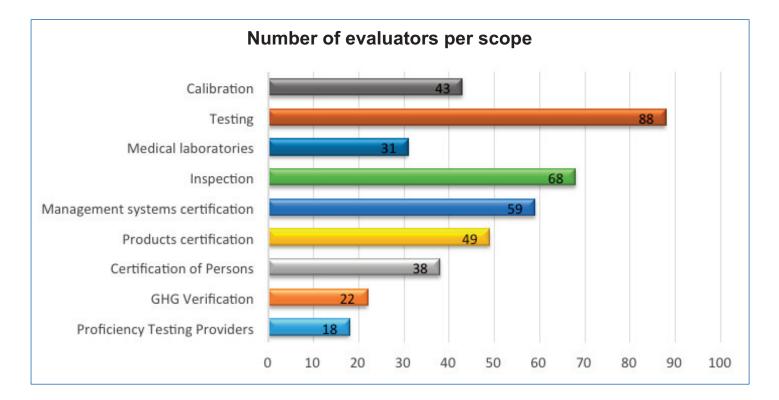
The Comprehensive Economic and Trade Agreement between the EU and Canada under discussion

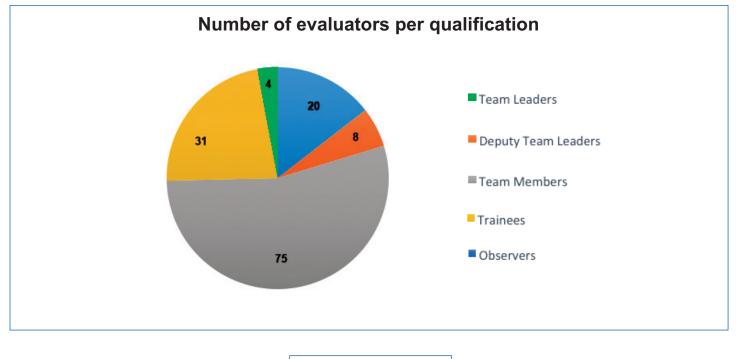
The Comprehensive Economic and Trade Agreement (CETA) is a negotiated EU – Canada treaty. Part of CETA is the protocol about mutual acceptance of the results of conformity assessment in order to facilitate trade and benefit industry generally. According to the protocol, a cooperation arrangement between the European and Canadian accreditation systems should be put in place. Based on mutually agreed terms of reference issued in September 2015, in agreement with the Standardization Council of Canada (SCC), EA established a TFG in charge of preparing the Bilateral Cooperation Agreement as requested in the protocol.



Approval and re-approval of evaluators

process for EA evaluator re-approval was established based on the re-approval rules applied in 2014 and on data received through the online survey conducted during summer 2014 and continuous update of the MAC database. This resulted in the extension of the scopes of competence for several evaluators and a much better overview of the areas where new resources are needed. Re-approval will be performed based on a new online survey to be run in early 2016 with a view to complete evaluators' CVs. The template for the online survey has been changed to allow collecting more detailed information on the evaluators' competence for both the MLA main fields and sub-fields. This is meant to improve the overall competence of evaluation teams.





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8 Monitoring and improvement of activities (continued)

MAC Management and Secretariat team

In 2015, EA elected a new Chair of the MAC. Paulo Tavares, IPAC, took over from Nicole Vanlaethem, BELAC. The MAC elected a new Vice Chair: Daniela Ionescu from RENAR, and 4 new members of the Management Group (MG): Rozsa Ring (NAT, Hungary – Rozsa had to step down when NAT terminated its activities on 31 December 2015), Norman Brunner (AA, Austria), Jiri Ruzicka (CAI, Czech Republic) and Claudio Boffa (NAB Malta).

The MAC Secretariat team is now composed of 3 persons: Martine Blum is the MAC Secretary; Lydie Mauger is responsible for the management and planning of peer evaluations; Marine Thiebaud is responsible for evaluator resource management and evaluator training.

In addition, the EA Executive Secretary, Andreas Steinhorst, plays a key role in the processes for reviewing applications or appointing evaluation teams; he also brings the necessary technical support into the daily operations and ensures the liaison with the ILAC MRA and IAF MLA mirror committees.

Improving daily operations

In October 2015, the MAC endorsed the final draft of EA-2/02-S1 Selection, Training and Monitoring of Evaluators to be submitted to EA comments before voting by the EA General Assembly. The EA ballot was successful and the document approved. The set of requirements for management of EA evaluators has been published as a separate supplement in January 2016.

In order to reflect the current operational practices and streamline the peer evaluation process, the following tasks have been transferred to the EA Secretariat:

★ Assigning individual team leaders, deputy team leaders and team members to evaluation teams according to the proposals resulting from the application review by the team leader, and in compliance with the peer evaluation programme;



- Monitoring the budget for peer evaluations and training activities;
- Establishing Task Force Groups (TFGs) in charge of reviewing evaluation reports and providing written reports to support MAC members in their decision-making;
- Preparing annual reports on delivered man days per NAB for both EA and international (IAF, ILAC, Regional Bodies) evaluations and budgets for man-days to be delivered by EA Members;
- Maintaining the database of team leaders, deputy team leaders and team members for the peer evaluation process;
- Re-approving team leaders and team members for their continued use as evaluators for the evaluation process - based on stipulated criteria and giving them feedback on their performance;
- Liaising with the ILAC MRA and IAF MLA Management Committees.

As a consequence of the transfer of responsibilities, the WG Training was disbanded and the terms of reference of the MAC MG were revised.

Reinforcing the process for dealing with notification of changes in EA NABs

The MG developed a process for dealing with notification of changes reported by MAC members. The process provides that, in addition to informing the MAC of a change, the MAC member shall provide an impact analysis report. The process is being documented but practices have already been streamlined, an impact analysis being now systematically asked and analysed in advance of MAC meetings. The new process has been introduced in the revised version of EA-2/02. The Secretariat created a template for reporting and supporting decision making at MAC meetings.

Improving the peer evaluation management system and documentation

Improvement of the management and operations of the EA MAC and peer evaluation system is also based on clear, updated and practical documentation. Indeed a great effort was dedicated to the review and alignment of the MAC document system. Furthermore EA-2/02, the top-level process document, was subject to an extensive review by the MAC Secretariat and MG. For clarity purposes, it was decided to split EA-2/02 and create a supplement covering the process and procedures for *Selection, Training and Monitoring of Evaluators.* (See above).

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 peer-evaluations, started in 2013, continued in 2015. Online services will be developed for more friendly access and use of documents and templates and management of data by all involved in the system. The target date is end of 2016 for the implementation of the IT tool. At the end of 2014, a complete set of specifications was ready. Potential suppliers have been consulted in the course of 2015, two of which have been selected for further consultation and for a decision to be made by July 2016.

Training and knowledge-sharing

In 2015:

 A training workshop for newcomer/potential evaluators was held in June 2015 in Paris, France; 25 participants attended.

- ★ A refresher training on ISO/IEC 17025 & ISO 15189 for Team members was held in November 2015 in Brussels, Belgium; 20 participants attended.
- A refresher training seminar for Team Leaders and Deputy Team Leaders was held in December 2015 in Brussels, Belgium; 15 participants attended.

A new policy for the planning of MAC training activities was established based on the results of the extensive 2014 and 2015 evaluator resource survey. This policy aims at ensuring regular and systematic refresher trainings for team members and team leaders, and enhanced focus on the horizontal issues of peer evaluation such as evaluation techniques, risks, documentation and statistical information. How to deal with purely technical issues and understanding/application of the standards for harmonization purposes remains the responsibility of EA technical committees.

The following two-year cycle was approved and has already been initiated:

- Year 1: two refresher trainings (laboratories, certification or inspection)
- Year 2: one newcomer training and one team leader training

ILAC/IAF peer evaluation

The re-evaluation of EA by ILAC and IAF started in 2014 with 3 observations of EA peer evaluation teams and the audit of the EA Secretariat in Paris. It ended up in 2015 with the observation of an additional peer evaluation and the decision making process at a MAC meeting. The evaluation team was led by Roxanne Robinson (A2LA, USA).

| Evaluation | Number of Non-conformities | Number of concerns | Number of comments | TOTAL |
|-------------------------|-------------------------------|-----------------------|--------------------|-------|
| Secretariat | 2 | 1 | 3 | 6 |
| AB1 Observation | 0 | 6 | 3 | 9 |
| AB2 Observation | 0 | 2 | 4 | 6 |
| AB3 Observation | 1 | 1 | 0 | 2 |
| Decision Making Process | 0 | 3 | 1 | 4 |
| AB4 Observation | 2 | 1 | 1 | 4 |
| TOTAL | 5 | 14 | 12 | 21 |

The table below summarizes the findings arising from the evaluation:

The findings concern mainly the following processes:

- Adoption of ILAC/IAF documents and monitoring of transition periods
- ★ Witnessing planning, including sampling
- ★ Evaluator training

The MAC MG reviewed the findings, provided a root analysis and drafted the final answers to ILAC/IAF. In order to close the findings in relation to the adoption of ILAC/IAF documents, EA-2/02 and EA-1/14 Procedure for development and approval of EA documents and the adoption of ILAC/IAF documents have to be revised. Revision is ongoing and the corrective actions are expected to be closed by mid-2016. Moreover, the transition periods for new or revised standards and new or revised ILAC/IAF mandatory documents are now monitored on a continuous basis by the EA Secretariat. Surveys are performed under the aegis of the technical committees concerned, before and after the deadline for transition. After the deadline, the MAC Secretariat checks proper implementation by EA Members for the MAC to consider any necessary action in case of non compliance.

The corrective actions related to the training have been addressed during the last Team Leaders and Deputy Team Leader Refresher Training in November 2015 and the findings are now closed. The ongoing actions are subject to continuous monitoring by the Secretariat.

Continuous monitoring of peer evaluations

Regularly, at least once a month, a review of the annual peer evaluation plan is made by the Secretariat. The objective is threefold:

- Ensure that the process develops within the required time frame;
- ★ Identify issues and difficulties sufficiently in advance for action to be taken as necessary;
- ★ Support a smooth decision-making in the MAC.

Benchmarking table

The Secretariat prepared a benchmarking table which is a compilation of issues that arose during peer evaluations. The MAC found the material to be relevant for consideration and use at the NAB level. It is based on findings from peer evaluations reviewed during the October 2014 and 2015 MAC meetings, reflected in an anonymous way. Annex 1 Full Member signatories to the EA MLA – 31 December 2015

| | CALIBRATION LABORATORIES | TESTING and MEDICAL LABORATORIES | CERTIFICATION BODIES - PRODUCTS | CERTIFICATION BODIES - PERSONS | CERTIFICATION BODIES - MANAGEMENT SYSTEMS | VERIFICATION BODIES | INSPECTION BODIES |
|-----------------------------|-----------------------------|--|---------------------------------------|--------------------------------------|--|------------------------|----------------------|
| Albania – Dpa | | √ ** | | | | | |
| AUSTRIA – AA | | \checkmark | \checkmark | \checkmark | | | \checkmark |
| BELGIUM – BELAC | | \checkmark | \checkmark | \checkmark | | \checkmark | \checkmark |
| BULGARIA – BAS | | \checkmark | | \checkmark | | \checkmark | |
| CROATIA – HAA | | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark |
| CYPRUS – CYS-CYSAB | | \checkmark | | | | | \checkmark |
| CZECH REPUBLIC – CAI | | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark |
| DENMARK – DANAK | | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark |
| ESTONIA – EAK | | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark |
| FINLAND – FINAS | | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark |
| FRANCE – COFRAC | | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark |
| FYROM – IARM | | \checkmark | \checkmark | | | | \checkmark |
| GERMANY – DAkkS | | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark |
| GREECE – ESYD | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark |
| HUNGARY – NAT termir | nated its act | ivities on 31 | December | 2015. | | | |
| IRELAND – INAB | \checkmark | \checkmark | \checkmark | | \checkmark | \checkmark | \checkmark |
| ITALY – ACCREDIA | | \checkmark | \checkmark | \checkmark | | | \checkmark |
| Latvia – Latak | | \checkmark | \checkmark | \checkmark | | \checkmark | \checkmark |
| LITHUANIA – LA | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark | | \checkmark |
| LUXEMBURG - OLAS | | \checkmark | \checkmark | | | | \checkmark |
| Malta – Nab-Malta | | $\sqrt{**}$ | | | | | \checkmark |
| NETHERLANDS – RvA | | \checkmark | \checkmark | \checkmark | | \checkmark | \checkmark |
| Norway – Na | | \checkmark | \checkmark | \checkmark | | \checkmark | \checkmark |
| POLAND – PCA | | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark |
| Portugal - Ipac | | \checkmark | \checkmark | \checkmark | | \checkmark | \checkmark |
| Romania – Renar | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark |
| SERBIA – ATS | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark | | \checkmark |

** Not signatory for medical laboratories according to ISO 15189.

Annex 1 Full Member signatories to the EA MLA – 31 December 2015 (continued)

| | CALIBRATION LABORATORIES | TESTING and MEDICAL LABORATORIES | CERTIFICATION BODIES - PRODUCTS | CERTIFICATION BODIES - PERSONS | CERTIFICATION BODIES - MANAGEMENT SYSTEMS | VERIFICATION BODIES | INSPECTION BODIES |
|---------------------------------|-----------------------------|--|---------------------------------------|--------------------------------------|--|------------------------|----------------------|
| SLOVAKIA – SNAS | \checkmark | \checkmark | | \checkmark | \checkmark | \checkmark | \checkmark |
| SLOVENIA – SA | \checkmark | √ ** | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark |
| SPAIN – ENAC | \checkmark | | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark |
| SWEDEN – SWEDAC | \checkmark | | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark |
| SWITZERLAND – SAS | \checkmark | | \checkmark | \checkmark | \checkmark | | \checkmark |
| TURKEY – TURKAK | | | \checkmark | \checkmark | \checkmark | | \checkmark |
| UNITED KINGDOM – UKAS | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark |

** Not signatory for medical laboratories according to ISO 15189.

Annex 2 Associate Member signatories to the EA MLA – 31 December 2015

| | CALIBRATION LABORATORIES | TESTING and MEDICAL LABORATORIES | CERTIFICATION BODIES - PRODUCTS | CERTIFICATION BODIES - PERSONS | CERTIFICATION BODIES - MANAGEMENT SYSTEMS | VERIFICATION BODIES | INSPECTION BODIES |
|---------------------------------------|-----------------------------|--|---------------------------------------|--------------------------------------|--|------------------------|----------------------|
| BOSNIA & HERZEGOVINA – BATA | | $\sqrt{**}$ | | | | | \checkmark |
| ISRAEL – ISRAC | \checkmark | | | | | | |
| UKRAINE – NAAU | \checkmark | $\sqrt{**}$ | \checkmark | \checkmark | | | \checkmark |
| TUNISIA – TUNAC | | $\sqrt{**}$ | | | | | \checkmark |

** Not signatory for medical laboratories according to ISO 15189.





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