THE EUROPEAN CO-OPERATION FOR ACCREDITATION

9th June 2016, Budapest, Hungary

European and international developments in accreditation

The network of accreditation bodies based on the EA MLA

Thomas Facklam, EA chair
1. The role of accreditation international, regional and national
2. The International and regional structure of accreditation
3. About EA
4. The transition from NAT to NAH
5. Peer evaluation of NAH
The accreditation process determines the technical competence and integrity of organisations that offer testing, examination, verification, inspection, calibration and certification services (collectively known as conformity assessment).

Accreditation operates in the public interest across all market sectors, providing a transparent and impartial assessment of these services against internationally recognised standards and other national or sectoral requirements.
# General Benefits of Accreditation

<table>
<thead>
<tr>
<th>Delivers Public Confidence</th>
<th>Minimises Product Failure or Recalls</th>
<th>Facilitates Cross Border Trade</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Despite a complex global marketplace, accreditation gives us confidence through ensuring consistently high standards in the quality of products or services purchased.</td>
<td>• Product testing carried out by a reliable independent organisation will minimise products failing or potential recalls.</td>
<td>• Accreditation is of major importance for the development of the international and regional market, as this facilitates cross border trade and eliminates barriers to trade.</td>
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</tbody>
</table>
accurate calibration, measurement and testing, performed in accordance with best practice, can
– limit errors and product failure,
– control production costs and
– contribute to an innovative environment.

essential tool for decision-making, risk management and supplier selection

provides a competitive advantage in domestic markets through access to public sector contracts, and also overseas with greater acceptance in export markets
Accreditation...

- is the preferred mechanism for identifying competent bodies to implement government policies and regulations aimed at safeguarding the public and building public confidence in activities that impact on such fields as health, welfare, security, the environment, education, and financial services

- delivers a multi-discipline solution that can be applied to support or act as an alternative to legislation.
Accreditation...

- helps to increase access to goods and services of consistent and reliable quality and safety
INTERNATIONAL NETWORK

- On a worldwide prospective two relevant organisations are:
  - ILAC
    International Laboratory Accreditation Cooperation
  - IAF
    International Accreditation Forum

- EA is a recognised region in ILAC and IAF and a signatory to their mutual arrangements

- NAH could join the IAF MLA and the ILAC MRA just based on the status of being an EA MLA signatory – once achieved
INTERNATIONAL NETWORK

ILAC
- 72 AB Full Members (all MLA signatories)
- 21 AB Associate Members
- 18 AB Affiliate Members
- 1 Regional Cooperation Body (SADCA, South Africa)
- 3 Regional Cooperations (including EA)
- 26 Stakeholder Members

IAF
- 64 AB Members and 53 MLA signatories
- 18 Associate Members
- 4 Regions (including EA)
- 4 Observers
EA MLA signatories and the accreditations they grant are internationally recognised through the **ILAC and IAF** Multilateral Agreements.

Find more information on IAF/ILAC Recognition on EA’s website:
http://www.european-accreditation.org/iaf-and-ilac
EA is an association of national accreditation bodies in Europe.

EA’s members are officially recognised by their national Governments to assess and verify conformity assessment bodies (CAB).

CAB are organisations that carry out — against international standards — evaluation services such as certification, verification, inspection, testing and calibration.

EA is responsible for harmonising accreditation within Europe, with the aim of reducing barriers to trade and protecting health, safety and the environment.
As the official guardian of the European accreditation infrastructure, EA has the overall strategic objective to safeguard the value and credibility of accredited conformity assessment services delivered by its Members and accredited conformity assessment bodies within the European market.
EA’s role in **supporting** the effective operation of the **Single Market** is recognised by

- Regulation (EC) No 765/2008
- the **General Guidelines** for cooperation and
- the **Framework Partnership Agreement** signed with the European Commission and EFTA.

In accordance with Article 14, paragraph 2 in this Regulation, an agreement has been concluded between EA and the European Commission (EC) to specify, inter alia, EA’s detailed tasks as well as funding and supervision provisions.
This agreement includes:

### General Guidelines
- **General Guidelines** for the Cooperation between the European co-operation for Accreditation and the European Commission, the European Free Trade Association and the competent national authorities.

### Framework Partnership Agreements (FPA)
- 4-year FPA sets out the financial obligations and conditions between the EC and EA.
- provide for annual operational grants and specific action grants based on EA’s annual work programmes to be approved by the EC every year.
Regulation (EC) No 765/2008 provides a legal framework for the provision of accreditation services across Europe.

The Regulation

– has been strengthening EA’s role in both voluntary and regulated sectors
– places an obligation on EU Member States to accept results issued by the conformity assessment bodies accredited by any of the EA MLA signatories
– has been strengthening the use of accreditation and the EA MLA as a basis for notification
THE EUROPEAN ACCREDITATION MODEL

- a service of general interest
- public authority
- last level of control of conformity assessment
- voluntary and mandatory fields
- mandate of the government
- full compliance with applicable rules
- accountability to stakeholders
- no predominance of any single interest group
- non-profit distributing
- no competition
COMMUNICATIONS WITH THE EUROPEAN COMMISSION

- EA is enhancing its communications with the European Commission:
  - EA is attending every meeting on accreditation held by the Expert Group on the Internal Market for Products (IMP)
  - EA is attending meetings of the EC Inter-Service Steering Group for Accreditation
  - For certain specific projects, the EA is also collaborating directly with DGs Environment, Clima, Transport, Health and Consumer Protection Agriculture.
appointed by the EC to manage the accreditation infrastructure within the EU, EFTA and candidate countries.

not-for-profit association of nationally recognised accreditation bodies

established in 1997 and registered in NL in 2000

36 full members representing 36 European economies

11 associate members

3 members have turned into a bilateral agreement with EA

permanent EA-Secretariat of 6 persons
"EA exists to coordinate and lead the European accreditation infrastructure to allow the results of conformity assessment services in one country to be accepted by Regulators and the market place in another country without further examination, for the benefit of the European community and the global economy."
Defining, harmonising and building consistency in accreditation in Europe, by ensuring common interpretation and application of the standards used by its members;

Ensuring transparency of the operations (including assessments) performed and results provided by its members;

Maintaining a multilateral agreement on mutual recognition between accreditation activities and reciprocal acceptance of accredited conformity assessment services and results;
Managing a peer evaluation system consistent with international practices;

Acting as a technical resource on matters related to the implementation and operation of the European policies on accreditation;

Cooperate with the European Commission and other European and international stakeholders;

Develop accreditation criteria and guidelines supporting harmonisation of practices;
ORIGINS OF EA

- EA was created in 1997 but its origins extend back further.

- WEMC (1973-1982)
  WECC (1976-1994)

- EAL (1994-1997)

- WELAC (1987-1994)


EA created as a legal entity on 26/06/2000
The General Assembly, the highest decision-making body of the association, supervises the management and the general course of affairs in the association and takes decisions in respect of strategy and general policies.
EA EXECUTIVE COMMITTEE (EA EX)

- EA EX holds the responsibility for implementing EA policies and the management of the association.

- Members of the EA Executive Committee (May 2015):
  
  - **Thomas Facklam,** Chairman
  - **Geir Samuelsen,** Vice-Chairman
  - **Paulo Tavares,** Chair MAC
  - **Peter Kronvall,** Chair CPC
  - **Ignacio Pina,** Chair HHC
  - **Rolf Straub,** Chair IC
  - **Kevin Belson,** Chair CC
  - **Laurent Vinson,** Chair LC
  - **Lycina, Olborska**, Additional Member
  - **Maria Papatzikou,** Additional Member
  - **Jan van der Poel,** Additional Member
  - **Emanuele Riva,** Additional Member
  - **Claudio Boffa,** Financial Oversight
  - **Jiri Ruzicka,** Financial Oversight
  - **Paul Stennett,** Financial Oversight
EA ADVISORY BOARD (EAAB)

- EAAB constitutes the primary organ within EA to ensure the effective and balanced involvement of all interested parties in European accreditation regarding policy and strategy issues.

- EAAB shall serve as the main stakeholder forum for EA to deal with issues pursuant to:
  - the requirements of Regulation (EC) 765/2008 and
  - the relevant provisions of the “General Guidelines for Co-operation between EA and the EC, EFTA and the competent national authorities”.
The EAAB's composition constitutes a **well-balanced representation** of the parties which rely on and contribute to the European accreditation system:

- Conformity Assessment Bodies
- Industry, Services and Trade
- EU Member States' National Authorities
- Consumer Associations
- Metrological Institutions
- European Commission and EFTA
- European Standardisation Organisations
- EA Representatives
Learn more about the structure of EA on our website:
http://www.european-accreditation.org/structure
EA Multilateral Agreement (EA MLA) is a signed agreement between the EA full members.

The signatories...

- recognise and accept the equivalence of the accreditation systems operated by the signing members,

- and the reliability of the conformity assessment results provided by conformity assessment bodies accredited by the signing members.
BENEFITS OF THE EA MLA

- The **MLA** creates **confidence** in, and acceptance of, accredited certifications, inspections and test reports

- MLAs **eliminate the need** for suppliers **to be certified in each country** where they sell their products or services

- The EA MLA provides a framework to realise the objective ‘**Accredited once, accepted everywhere**’.
EA Associate Members are eligible to enter into a **Bilateral Agreement (EA BLA)** 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.

The **EA BLA** has the same purpose and bilateral signatories to the EA MLA shall comply with and meet the same requirements as EA Full Members.
The scope of the EA MLA covers the following activities and standards:

- Testing (ISO/IEC 17025)
- Calibration (ISO/IEC 17025)
- Medical Laboratories (ISO 15189)
- Inspection (ISO/IEC 17020)
- Certification of management systems (ISO/IEC 17021)
- Certification of products, processes and services (ISO/IEC 17065)
- Certification of persons (ISO/IEC 17024)
- Verification of greenhouse gas emissions (ISO 14065)
EA MLA SIGNATORIES

- **EA MLA** signatories: 35 full members
- **EA BLA** signatories: 4 associate members

(June 2016)

Full list of all MLA & BLA signatories and scopes on EA’s website:
http://www.european-accreditation.org/mla-and-bla-signatories
EA and its member accreditation bodies invest significant effort and resource to maintain the integrity and robustness of the EA MLA through a peer evaluation process.

The on-site 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: internationally accepted standard for accreditation bodies
- Regulation (EC) No 765/2008
- The relevant standard for conformity assessment bodies including any additional requirements (e.g. by the EC)
EA has been informed in June 2015 that a new law on accreditation is in preparation in Hungary which will result in the termination of the existing national accreditation body NAT at the end of 2015 and a new national accreditation body will be established.

Subsequent information clarified that the new national accreditation body couldn´t be the legal successor of NAT due to the existing legal framework in Hungary.
TRANSFER FROM NAT TO NAH

At the EA MAC meeting in autumn 2015 there was no official information from Hungary available how the transfer from NAT to the new accreditation body will be carried out.

Consequently the EA MAC cancelled the EA peer evaluation of NAT planned for November 2015 as it was not clear if and how the new accreditation body would be able to follow up any findings.
End November 2015 a meeting between representatives of the government of Hungary and the EA chair took place and it was clarified that the new accreditation body will use the processes of NAT and will offer the personnel of NAT to join the new accreditation body.

With that information it was agreed on what information is needed from Hungary to be able to start the peer evaluation with the aim to have a as short as possible gap in time as signatory to the EA MLA.
TRANSFER FROM NAT TO NAH

NAT ceased to exist on 31st December 2015 and no information about the new accreditation body was available.

Consequently the EA membership of NAT was disbanded end of 2015.

The new accreditation body of Hungary NAH applied for membership in EA providing the necessary documents. Based on the positive evaluation of the documents NAH was accepted as new EA member.
NAH applied for the peer evaluation by EA and that is planned as follows:

Week 26: 27th June – 1st July

<table>
<thead>
<tr>
<th></th>
<th>Sunday 26</th>
<th>Monday 27</th>
<th>Tuesday 28</th>
<th>Wednesday 29</th>
<th>Thursday 30</th>
<th>Friday 1</th>
<th>Saturday 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>PE1</td>
<td>Arrival 13:10</td>
<td>Opening meeting Office</td>
<td>Witnessing NAT-3-0018/2015/K</td>
<td>Office (Witnessing)</td>
<td>Office</td>
<td>Office closing meeting</td>
<td>Departure</td>
</tr>
<tr>
<td>PE2</td>
<td>Arrival 13:00</td>
<td>Opening meeting Office</td>
<td>Witnessing NAT-3-0018/2015/K</td>
<td>Witnessing NAT-3-0017/2015</td>
<td>Office</td>
<td>Office closing meeting</td>
<td>Departure</td>
</tr>
<tr>
<td>PE3</td>
<td>Arrival 13:00</td>
<td>Opening meeting Office</td>
<td>Witnessing NAH-2-0329</td>
<td>Witnessing NAT-2-0204/2015</td>
<td>Office</td>
<td>Office closing meeting</td>
<td>Departure</td>
</tr>
<tr>
<td>PE4</td>
<td>Arrival 13:55</td>
<td>Opening meeting Office</td>
<td>Witnessing NAT-1-1254/2014</td>
<td>Office</td>
<td>Office</td>
<td>Office closing meeting</td>
<td>Departure</td>
</tr>
<tr>
<td>PE5</td>
<td>Arrival 12:15</td>
<td>Opening meeting Office</td>
<td>Witnessing NAT-5-0013/2014</td>
<td>Office</td>
<td>Office</td>
<td>Office closing meeting</td>
<td>Departure</td>
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<tr>
<td>PE6</td>
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<td>Witnessing NAT-10-0001/2014</td>
<td>Office</td>
<td>Office closing meeting</td>
<td>Departure</td>
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<tr>
<td>PE7</td>
<td></td>
<td>Arrival 18:05</td>
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<td>Closing meeting</td>
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EA PEER EVALUATION OF NAH

NAH applied for the peer evaluation by EA and that is planned as follows:

**Week 27: 4th July – 8th July**

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<th>Sunday 3</th>
<th>Monday 4</th>
<th>Tuesday 5</th>
<th>Wednesday 6</th>
<th>Thursday 7</th>
<th>Friday 8</th>
<th>Saturday 9</th>
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</thead>
<tbody>
<tr>
<td>PE 7</td>
<td>Arrival</td>
<td>Opening meeting</td>
<td>Office</td>
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<td>Office</td>
<td>Office closing meeting</td>
<td>Departure</td>
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<tr>
<td></td>
<td>Meeting 1800</td>
<td>Office</td>
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<tr>
<td>PE 8</td>
<td>Arrival</td>
<td>Opening meeting</td>
<td>Witnessing</td>
<td>Witnessing</td>
<td>Office</td>
<td>Office closing meeting</td>
<td>Departure</td>
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<tr>
<td></td>
<td>Meeting 1800</td>
<td>Office</td>
<td>NAT-4-0008/2015</td>
<td>NAT-4-0086/2014</td>
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<tr>
<td>PE 9</td>
<td>Arrival</td>
<td>Opening meeting</td>
<td>Witnessing</td>
<td>Witnessing</td>
<td>Office</td>
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<td>Departure</td>
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<tr>
<td></td>
<td>Meeting 1800</td>
<td>Office</td>
<td>NAT-6-0032/2015</td>
<td>NAT-6-0057/2015/K</td>
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**Week 31: 31st July – 5th August**

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<th>PE 10</th>
<th>Opening meeting</th>
<th>Witnessing</th>
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<th>Office</th>
<th>Office closing meeting</th>
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<tr>
<td></td>
<td>Arrival</td>
<td>Office</td>
<td>NAT-1-1233/2015</td>
<td>NAH-1-1699</td>
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EA PEER EVALUATION OF NAH

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<td>Meeting 1800</td>
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<tr>
<td>PE 2</td>
<td>Arrival 13:00</td>
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<td>Witnessing NAT-3-0018/2015/K</td>
<td>Witnessing NAT-3-0017/2015</td>
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<td>PE 4</td>
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</table>
After the complete peer evaluation has been carried out and all findings have been addressed satisfactorily the EA MAC will decide based on the peer evaluation report, the recommendation of the peer evaluation team and the respective task force group.

We all looking forward to get Hungary back into the network of EA MLA signatories as soon as possible.
EA Secretariat

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France

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Email: secretariat@european-accreditation.org

www.european-accreditation.org
Thanks much for your attention Questions?