



EUROPEAN ACCREDITATION LEGAL FRAMEWORK

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Ed Wieles

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- European model on Accreditation
- Requirements for Accreditation bodies
- Harmonised standards for accreditation
- EA, Peer evaluations and the MLA

THE ACCREDITATION STRUCTURE BEFORE 2010

- Private and public accreditation bodies;
- No legal status for part of the ABs;
- Multiple accreditation bodies in a country;
- Cross border activities in EU;
- No formal requirement to be peer evaluated;
- No formal recognition of EA.

SINCE 2010: REGULATION (EC)765/2008

- Accreditation body shall have public authority;
- One National Accreditation Body per member state;
- Not-profit-distributing & no competition;
- Accountability to stakeholders;
- Signatory of the EA-MLA;
- Applicable for voluntary and mandatory fields.

OBJECTIVES OF REGULATION (EC) 765/2008

- To give more confidence in the work of the conformity assessment bodies such as laboratories, inspection- and certification bodies;
- To realise a level playing field for the conformity assessment bodies;
- To facilitate trade by the acceptance of products and services in EU-region based on a “tested once, accepted everywhere” principle.

THE EUROPEAN CO-OPERATION FOR ACCREDITATION - EA

- EA is an **association of national accreditation bodies** in Europe;
- EA Members are officially recognised by their national governments to accredit **conformity assessment bodies (CABs)**;
- EA is responsible for harmonising accreditation within Europe;
- EA manages a peer evaluation system.

FACTS & FIGURES FOR EA

- **36 Full Members (34 MLA signatories)** - EU and EFTA and candidate countries;
- **12 Associate Members** (potential candidate members or covered by the EU Neighbourhood policy), 4 Members have turned into a **Bilateral Agreement** with EA;
- **Peer evaluation** system:
 - average appr. 15 peer evaluations/year
 - appr. 700 man-days/year.

STATISTICS ON ACCREDITATIONS UNDER EA-MLA

- 3.044 Calibration laboratories
- 17.859 Testing laboratories
- 2.966 Medical laboratories (ISO 15189)
- 1.606 Product Certification bodies
- 1.218 Management System Certification bodies
- 433 Person Certification bodies
- 4.948 Inspection bodies
- 160 Proficiency Testing Providers
- 40 Reference Material Producers
- 135 EU ETS Verification bodies

REQUIREMENTS FOR ACCREDITATION BODIES

- ISO/IEC 17011: Competence, structure, impartiality, process, information;
- EA-MLA: Cooperation, participation in technical work, peer evaluations, use documents endorsed by EA;
- IAF-MLA and ILAC-MRA;
- National requirements (for example administrative law);
- Scheme requirements.

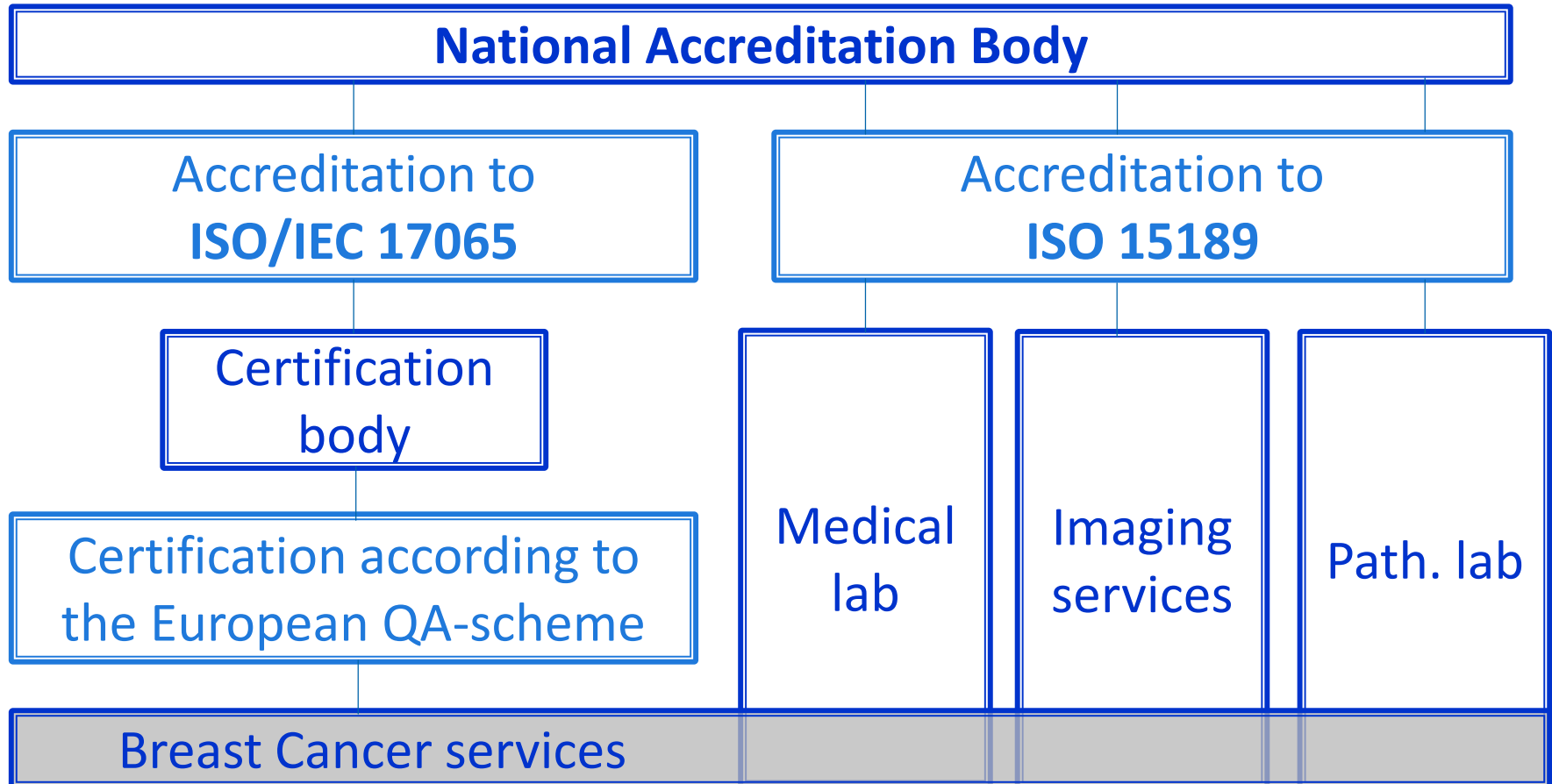
NEW LEGAL REQUIREMENTS SINCE 2010

- Regulation (EC)765/2008:
 - Public authority, one NAB,
 - no competition, not-for-profit,
 - peer evaluated;
- Use harmonised standards:
 - No “accreditation light”,
 - No activities that may compete with accreditation.

HARMONISED STANDARDS

- European commission asks CEN/CENELEC to investigate and confirm that a standard may be used to demonstrate that products, services, or processes comply with relevant EU legislation;
- Standards may be EN (derived from ISO or IEC standards) or ETSI standards;
- For example: Accreditation to EN-ISO/IEC 17065 confirms that a certification body complies with requirements in EU directives.

HARMONISED STANDARDS IN BCS



MULTILATERAL AGREEMENTS BETWEEN ABS

- Condition to sign the multilateral agreement: a positive result of a peer evaluation;
- Signatories of the MLA recognise and accept:
 - The **equivalence** of the accreditation systems operated by the signatories;
 - The **reliability** of the conformity assessment results (e.g. a report or certificate) provided by CABs accredited by the signatories for the relevant scope.

EXPECTATION ONE MAY HAVE ABOUT EA-MLA

- Results of laboratories and certification bodies accepted all over EA-region;
- EA supports the development of multinational schemes to contribute to harmonisation;
- Stakeholders such as industry, (health care) service providers, CABs and EU represented in EA;
- Experiences and expertise are shared between ABs.

ACHIEVEMENTS OF SYSTEM

- EA-MLA contributes to harmonised application of standards;
- EA peer evaluations are good learning experiences for evaluated AB and evaluators;
- Working in technical committees supports common understanding of requirements;
- EA provides possibilities for benchmarking;
- NABs are represented in EU through EA.

CHALLENGES FOR THE SYSTEM

- Developing appropriate accreditation services for new markets, regulators;
- Maintain sufficient resources for peer evaluations: means a significant burden for the smaller ABs;
- Stakeholders not always understand the system:
 - differences between certification and accreditation?

EA STRATEGY

- Based on the values: Harmonised, Competent, Responsible, Confidence;
- Objectives:
 1. Good governance to deliver consistent and sustainable results;
 2. Close cooperation with regulators and stakeholders to strengthen accreditation at the European and international level;
 3. Continue to develop accreditation to support innovation and growth in existing and new areas.

THANK YOU

