The added value of accreditation for testing, inspection and certification activities.

(and research?)

Paolo Bianco - ACCREDIA

Accreditation: third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

Conformity assessment body (CAB): body that performs conformity assessment services (e.g. laboratory, certification body, inspection body)

The accreditation can avoid the second party audits/ reviews, as the customers and end-users trust the third party evaluation of the competence of the conformity assessment body.

In the voluntary sector, many lines of industry have, both within an economy as well as globally, set up systems for conformity assessment and approval, aiming at achieving a minimum technical level, enabling comparability, and also ensuring competition on equal terms.

In the regulatory sector, government authorities implement laws covering the approval of products (including services) for reasons of safety, health, environmental protection, fraud prevention or market fairness.
EU policy (Regulation 765/2008) has promoted the accreditation for notification purposes (CE Marking).

Regulation 765/2008

1. A national accreditation body shall, when requested by a conformity assessment body, evaluate whether that conformity assessment body is competent to carry out a specific conformity assessment activity. Where it is found to be competent, the national accreditation body shall issue an accreditation certificate to that effect.

Regulation 765/2008

2. When a Member State decides not to use accreditation, it shall provide the Commission and the other Member States with all the documentary evidence necessary for the verification of the competence of the conformity assessment bodies it selects for the implementation of the Community harmonisation legislation in question.
3. National accreditation bodies shall monitor the conformity assessment bodies to which they have issued an accreditation certificate.

Regulation 765/2008

Principle of non-competition

1. National accreditation bodies shall not compete with conformity assessment bodies.
2. National accreditation bodies shall not compete with other national accreditation bodies.
3. National accreditation bodies shall be permitted to operate across national borders, within the territory of another Member State, either at the request of a conformity assessment body in the circumstances set out in Article 7(1), or, if they are asked to do so by a national accreditation body in accordance with Article 7(3), in cooperation with the national accreditation body of that Member State.

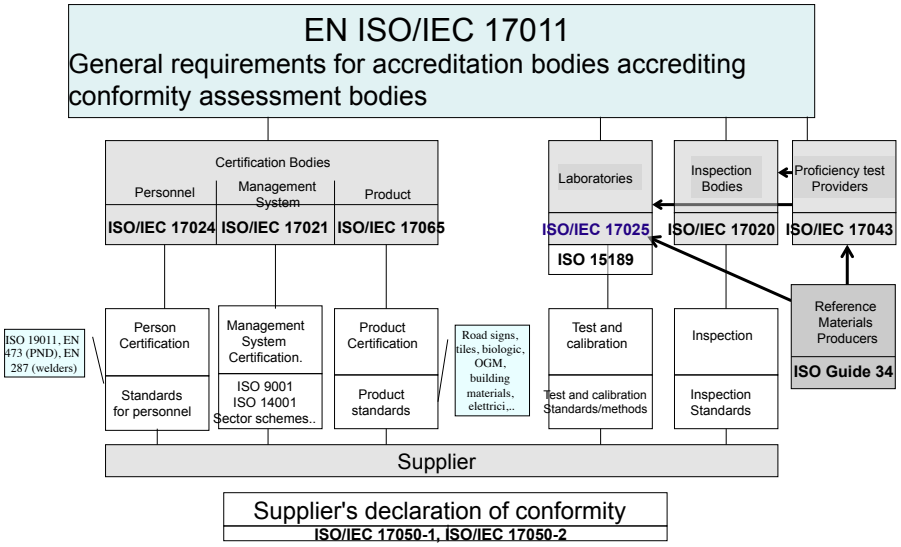
Regulation 882/2004

1. The competent authority shall designate laboratories that may carry out the analysis of samples taken during official controls.
2. However, competent authorities may only designate laboratories that operate and are assessed and accredited in accordance with the following European standards:

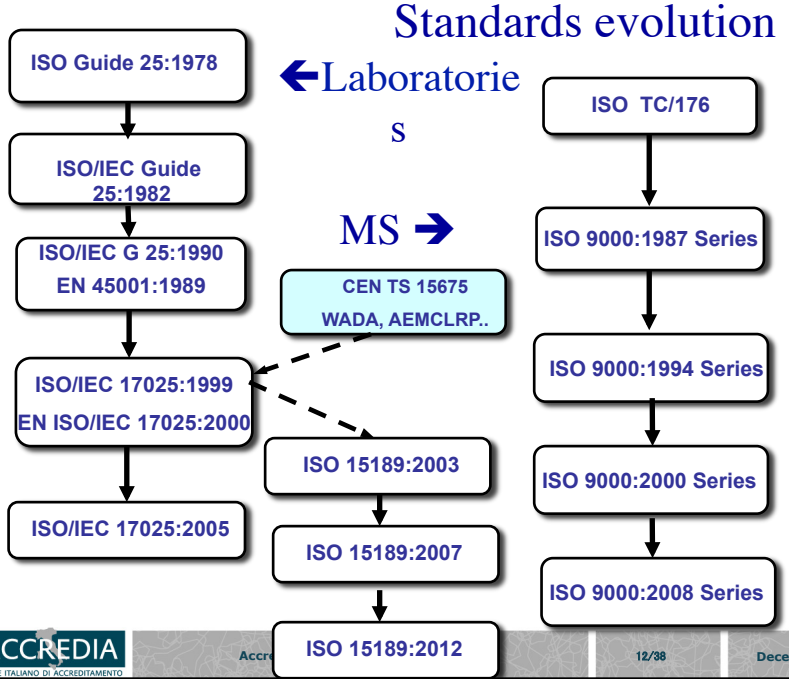
(a) EN ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories;

(b) EN ISO/IEC 17011 General requirements for accreditation bodies accrediting conformity assessment bodies.

Conformity evaluation standards



Standards evolution



Standards for laboratories

- ISO/IEC 17025. General requirements for the competence of testing and calibration laboratories.
- ISO 15189. Medical laboratories -- Particular requirements for quality and competence.
- UNI EN ISO 22870. Point-of-care testing (POCT) -- Requirements for quality and competence.
- CEN TS 15675. Air quality. Measurement of stationary source emissions. Application of EN ISO/IEC 17025:2005 to periodic measurements.
- Other Sector standards (WADA, AEMCRLP, Bluetooth, EPA energy saving, etc.)

ISO/IEC 17025

4 MANAGEMENT REQUIREMENTS

4.1 Organization
4.2 Management system
4.3 Document control
4.4 Review of requests, tenders and contracts
4.5 Subcontracting of tests and calibrations
4.6 Purchasing services and supplies
4.7 Service to the customer
4.8 Complaints
4.9 Control of nonconforming testing and/or calibration work
4.10 Improvement
4.11 Corrective action
4.12 Preventive action
4.13 Control of records
4.14 Internal audits
4.15 Management reviews

ISO/IEC 17025

5 TECHNICAL REQUIREMENTS

5.1 General
5.2 Personnel
5.3 Accommodation and environmental conditions
5.4 Test and calibration methods and method validation
5.5 Equipment
5.6 Measurement traceability
5.7 Sampling
5.8 Handling of test and calibration items
5.9 Assuring the quality of test and calibration results
5.10 Reporting the results

Mutual recognition

- Who is entitled to accredit?
- The international organizations (EA, ILAC, IAF), by means of the peer-evaluation process, verify the conformity of the Accreditation body to the ISO/IEC 17011 requirements.
- The national recognition (Regulation 765/2008, DM 22-12-2009 in Italy) is subject to the peer evaluation organized by the European Cooperation for Accreditation (EA).

The European co-operation for Accreditation

- A not-for-profit association registered in the Netherlands in June 2000.
- 33 Full Members representing 33 European economies.
- 13 Contracts of Cooperation signed with non EU / EFTA AB's Out of these contracts, 4 have turned into a bilateral agreement with EA.
- EA is an active Member of ILAC (International laboratory Accreditation Cooperation) and IAF (International Accreditation Forum) as a recognised regional cooperation.

Purpose of EA

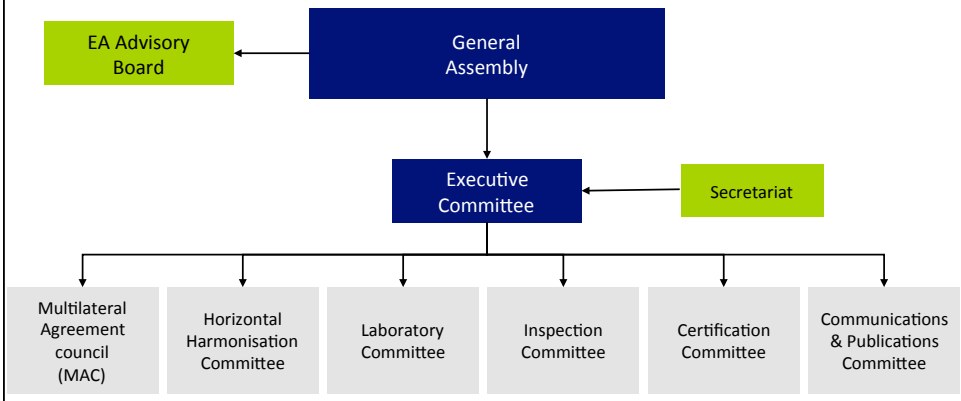
The European co-operation for Accreditation (EA) is the Association of the national accreditation bodies that provide accreditation for the following conformity assessment activities:

- Calibration
- Testing
- Inspection
- Certification of quality, environmental management systems
- Certification of products
- Certification of persons
- Verification bodies & verifiers (EMAS, EU/ETS, ETV)

Purpose of EA (2)

- Provide Europe with an effective, reliable accreditation infrastructure
- Develop accreditation criteria and guidelines supporting harmonisation of practices
- Operate a sound, robust, reliable peer evaluation process
- Ensure equivalence of accreditation and equal reliability of accredited results
- Cooperate with the European Commission and other European, international stakeholders

EA Organizational structure



EA MLA Signatories

- Multilateral Agreements (MLAs) create confidence in, and acceptance of, accredited certifications, inspections and test reports, eliminating the need for suppliers to be certified in each country where they sell their products or services. EA's role in supporting the effective operation of the Single Market is recognized by Regulation 765/2008, the Guidelines for cooperation and Framework Partnership agreement signed with the European Commission and EFTA.

EA MLA Signatories

33 Full Member accreditation bodies have signed the EA MLA, out of which 26 have signed for all accreditation activities covered by the EA MLA.

Austria	France	Luxembourg	Slovenia
Belgium	Germany	Malta	Spain
Bulgaria	Hungary	Netherlands	Sweden
Croatia	Greece	Norway	Switzerland
Czech Rep.	Ireland	Poland	Turkey
Denmark	Italy	Portugal	United Kingdom
Estonia	Latvia	Romania	Cyprus
Finland	Lithuania	Slovakia	FYROM
			Serbia

Full details of the scope for MLA Signatories can be found on the EA website

EA & MLA Members November 2012

Calibration ; testing ; products, management systems certification and persons certification ; inspection

Calibration ; testing ; products and management systems certification; inspection

Calibration; testing; products and management systems certification

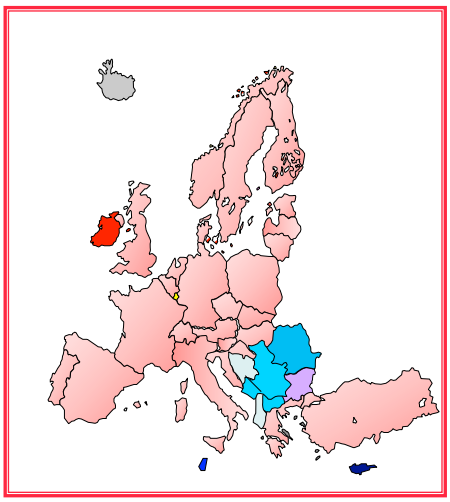
Products, Persons and management system certification, Inspection

Testing ; products, management systems certification ; inspection

Testing

Full members non signatories

Contracts of Cooperation (European countries)

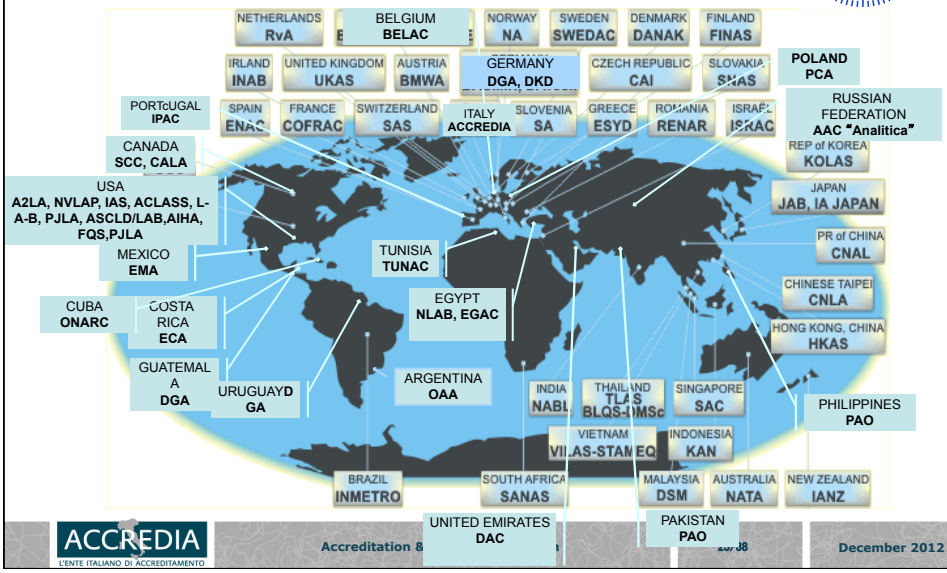


Mutual Recognition

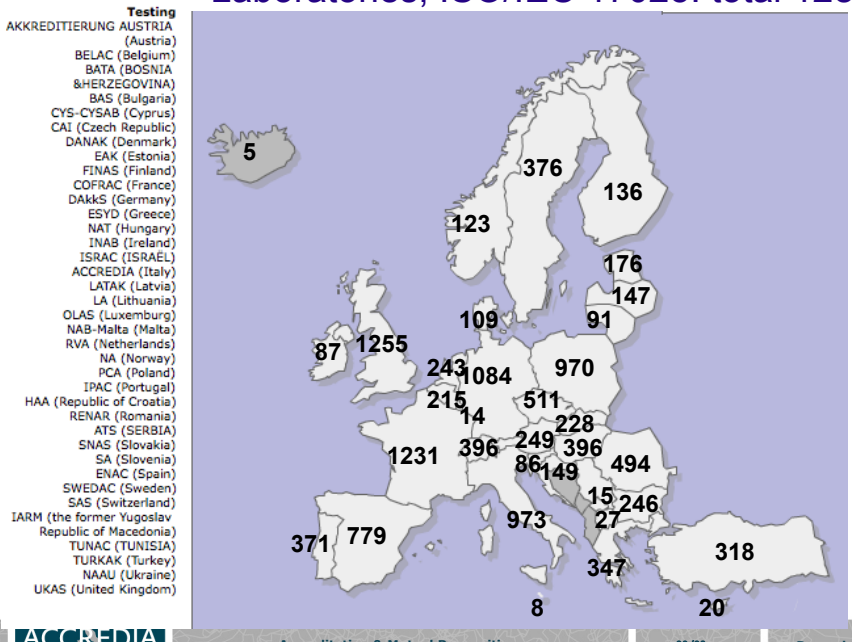
- **EA: European Cooperation for Accreditation.**
  - 33 European members (EU, EFTA, EU candidates).
  - 14 non European members with contract of cooperation.
  - 37 Abs are signatories of the Mutual Recognition Agreement or the bilateral agreement (with different scopes as testing, calibration, inspection, certification: QMS, personnel, EMS, product,...).
- **ILAC: International Laboratory Accreditation Cooperation.**
  - 78 full members (ILAC MRA signatories) from 65 economies
  - 18 Associated members
  - 20 Affiliates, 25 Stakeholders
- **IAF: International Accreditation Forum:**
  - 63 members
  - 46 signatories MLA for QMS
  - 41 signatories MLA for EMS
  - 38 signatories MLA for product certification.

ILAC arrangement

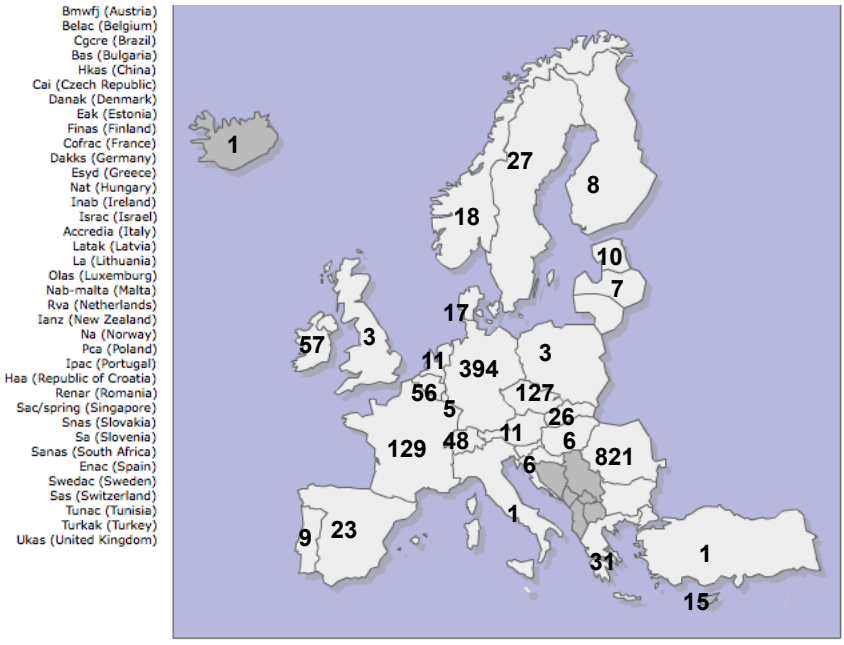
78 ABs from 65 Economies (November 2012)



Laboratories, ISO/IEC 17025: total 12833



Medical Laboratories, ISO 15189: total 1871



Accreditation vs certification

Some laboratories hold an ISO 9001 certification for their management system; but **only** the accreditation attests the technical competence.

The confusion between certification and accreditation is a well known problem, so that ISO, ILAC and IAF have issued a joint communiqué (2005, revised in 2008) in order to clarify that the accreditation covers **also** the ISO 9001 requirements. That means that accreditation is needed, not certification.

Joint IAF - ILAC - ISO Communiqué

A laboratory's fulfilment of the requirements of ISO/IEC 17025:2005 means the laboratory meets both the technical competence requirements and management system requirements that are necessary for it to consistently deliver technically valid test results and calibrations.

The management system requirements in ISO/IEC 17025:2005 (Section 4) are written in language relevant to laboratory operations and meet the principles of ISO 9001:2008 “Quality Management Systems Requirements” and are aligned with its pertinent requirements.

Accreditation vs certification

Mandatory requirement: ISO/IEC17021 - 8.4.2.

A certification body shall not permit its marks to be applied to laboratory test, calibration or inspection reports, as such reports are deemed to be products in this context.

Research laboratories

At the September LC Meeting in Oslo there was a presentation from the SERIES Project on the seismic engineering laboratories, with the aim of showing the goals of the project, including accreditation/qualification.

It was noted that a document from RvA (RvA-T31) already addressed the accreditation of research and development, based on the flexible scope approach.

Research laboratories

Referring to ISO/IEC 17025 requirements, personnel competence (5.2), environmental conditions (5.3) methods planning and validation (5.4) and review of the research planning are needed.

The research laboratories shall also comply with the standard requirements relating to equipment (5.5), traceability (5.6),sampling (5.7) and handling of the test items (5.8), quality assurance of the tests.

The research report could be different from a test report, but should comply as far as measurements are involved.


Thank you for your attention