EA European Accreditation support to the European Commission – Regulation (EC) No 765/2008 - NLF

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Why Accreditation in the Health Care sector?
WHAT IS ACCREDITATION?

- The **accreditation process** determines the technical competence and integrity of organisations that offer **examination**, testing, 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**.
WHAT IS ACCREDITATION?

- Accreditation of certification bodies based on international standards and agreed additional requirements.

- Accreditation of medical laboratories based on ISO 15189 and if relevant additional requirements.
Accreditation...

- Helps to increase access to services of consistent and reliable quality and safety.
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, environment, education, and financial services.
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
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 is an association of national accreditation bodies in Europe.

EA Members are officially recognised by their national governments to assess and verify conformity assessment bodies (CABs).

CABs are organisations that carry out — against international standards — assessment 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.
36 Full Members representing 36 European economies

12 Associate Members

3 Members have turned into a Bilateral Agreement with EA

Permanent EA Secretariat composed of 6 persons
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;
EA supports the project on a European voluntary Quality Assurance scheme for Breast Cancer Services underpinned by Accreditation and high-quality Guidelines.

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.
You want to learn more about EA and accreditation? Visit our website and consult our promotional materials:
http://www.european-accreditation.org/promotional-information
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