



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

Dr Andreas Steinhorst, EA
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Why Accreditation in the Health Care sector?



Michael Bührke_pixelio.de



Dieter Schütz_pixelio.de



Ch. Herzau-Weisel_pixelio.de



Bernd Kasper_pixelio.de



Thorben Wengert_pixelio.de



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**).



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WHAT IS ACCREDITATION?

- 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**.



Health & Consumer Protection
Directorate-General

**European guidelines for quality assurance in breast
cancer screening and diagnosis** *Fourth Edition*

Editors
N. Perry
M. Broeders

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.



BENEFITS FOR CONSUMERS/PATIENTS

Accreditation...

- Helps to increase access to services of **consistent and reliable quality and safety.**



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BENEFITS FOR GOVERNMENTS AND REGULATORS

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.



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REGULATION (EC) NO 765/2008

- 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

EA: ROLE IN EUROPE

*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.*

ABOUT EA

- 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**.

EA: BASIC FACTS

- **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

EA'S MISSION (1)

- 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;

EA'S MISSION (2)

- **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**;

ACCREDITATION IN THE HEALTH CARE SECTOR

- 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.



Rainer Sturm_pixello.de

EUROPEAN CO-OPERATION FOR ACCREDITATION

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EA and accreditation?
Visit our website and consult
our promotional materials:
[http://www.european-
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CONTACT

EA Secretariat

75 avenue Parmentier
FR - 75544 Paris Cedex 11
France

Phone: + 33 (0)1 40 21 24 -62

Email: secretariat@european-accreditation.org

www.european-accreditation.org