



# **Can European Standards play a role in evidence-based Quality Assurance for Breast Cancer?**

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# European Standards

(European) Standards are specifications, with which compliance is not compulsory (Quote EU-Regulation 1025/2012), i.e. they are **voluntary!**

(European) Standards can be referenced in a contract, making them compulsory for both contract parties – **otherwise** they need to agree on the technical specification for the product/service to be delivered

(European) Standards can be used in court by a court-expert as a benchmark – **otherwise** he will use other references for his opinion, which might be challenged by the counterparty

(European) Standards are

- are NOT dictated by one single party behind closed doors!
- **proposed by Stakeholders** (not only public authorities), proposal assessed in a public consultation before a resolution on approval is adopted
- **elaborated by Stakeholders** in a transparent, open, consensus driven multi-stakeholder process based on evidence and internationally recognized principles.

Once approved European Standards are implemented in 33 countries as national Standards



Transparency

Openness

Consensus driven

Based on evidence



Multi-stakeholder, e.g.:



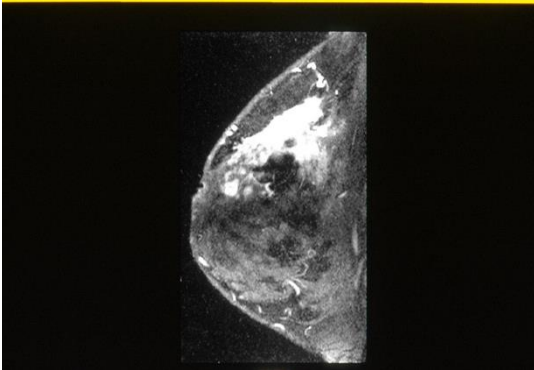
# European Standards for healthcare

Almost 400 European Standards support EU-Directives on

- Medical Devices,
- active implantable Medical Devices,
- in-vitro diagnostic Medical Devices



## Breast Imaging Technology



## Examples of European Standards used in breast cancer diagnosis and therapy:

- mammographic X-ray equipment
- Sonography
- Diagnostic monitors
- Radiation therapy, ...

# Healthcare Services

European **Standards** and other European **standardization deliverables**

- EN 15224:2012, Services in health care – Quality management systems – Requirements based on ISO 9001:2008
- EN 16224:2012, Healthcare provision by chiropractors
- CWA 16642:2013, Health Care Services - Quality Criteria for Health Checks
- EN 16372:2014, Aesthetic surgery services
- FprEN 16844:2015, Aesthetic medicine services - Non-surgical medical treatments
- EN 16686:2015, Osteopathic healthcare provision
- prEN 16872:2015, Services of Medical Doctors with additional qualification in Homeopathy (MDQH) – Requirements for health care provision by Medical Doctors with additional qualification in Homeopathy
- CEN/TR 16824:2015, Early care services for babies born with cleft lip and/or palate



# Thesis statement – Consensus driven versus evidence based



- Standards **make sense** to support quality assurance, risk mitigation, control of processes, incl. service provisions, to specify “hardware” related requirements or mutual obligations.

Standard = code of good practice, **agreement/convention** between stakeholders of healthcare services

- Standardization should **not be involved** in issues which are directly relevant to diagnosis, therapy and care, subject to evidence based medicine.

Not to standardize the **state of the art in medicine** ... but perhaps Standards refer to it (dissemination of research results), e.g. (from EN 60601-2-33:2010):

One area of concern is whether static magnetic fields are hazardous to the unborn children of exposed pregnant workers. While proving safety in an absolute sense requires an infinite number of experiments, there is no evidence in the literature to date that exposure to static magnetic fields is hazardous. An epidemiological survey [61] of MR technologists in the United States found no correlation between exposure to high static magnetic fields and spontaneous abortion rates, infertility, low birth weight, or premature delivery. Ueno studied embryonic development of frogs in 6,34 T fields and found that rapid cleavage, cell multiplication, and differentiation were unaffected [48]. Kay also investigated embryonic development of frogs in high static fields and found no adverse effects [64]. McRobbie studied pregnant mice in gradient magnetic fields and found no effects on litter number or growth rate [65].



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