



EUROPEAN QA-SCHEME FOR BREAST CANCER SERVICES

The Selection of Standards and
other points of attention

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DEVELOPMENT OF A QA-SCHEME UNDERPINNED BY ACCREDITATION

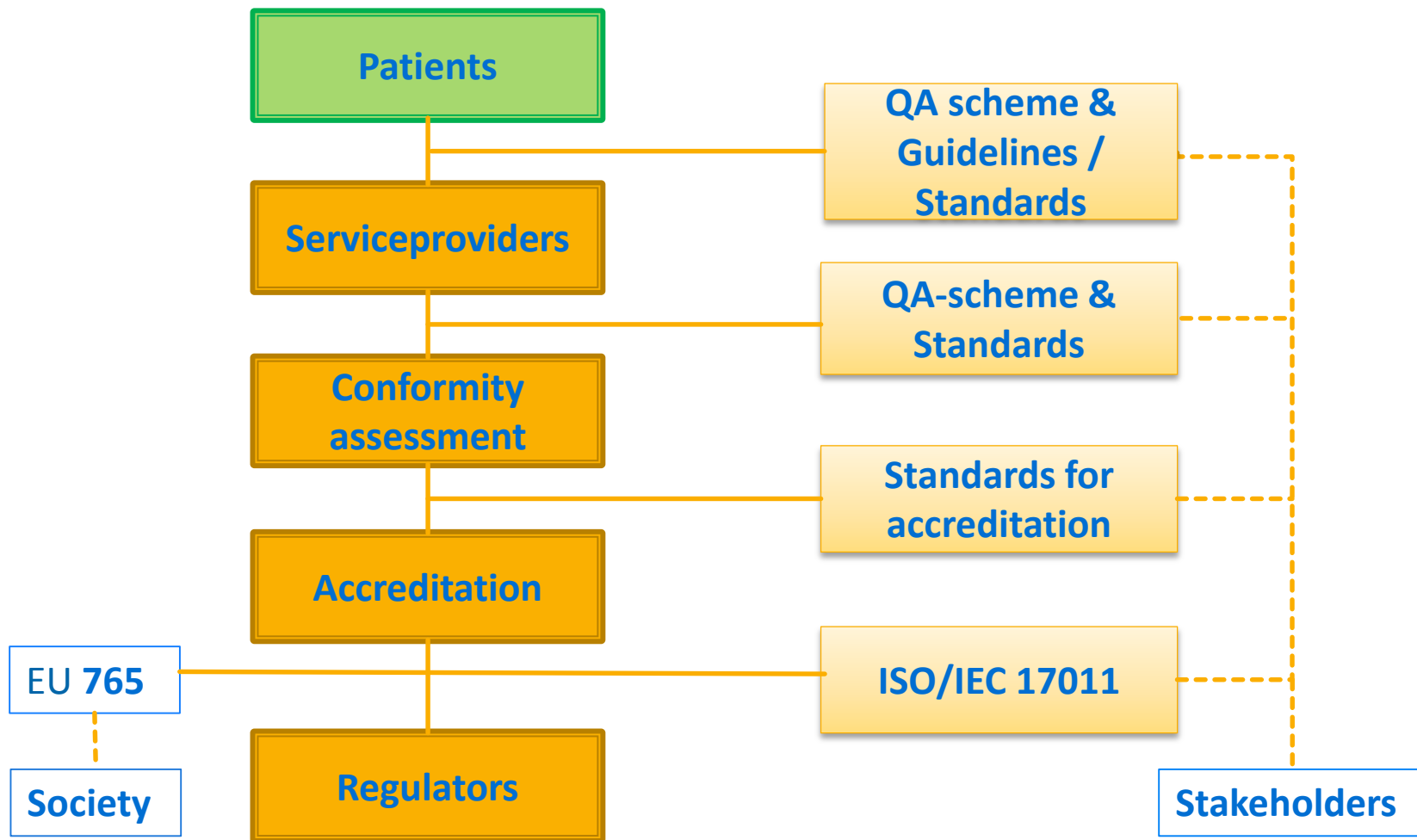
- Participation of **Stakeholders**
- Based on **Science**
- Making use of **Standards** and consensus Guidelines

In order to achieve.....

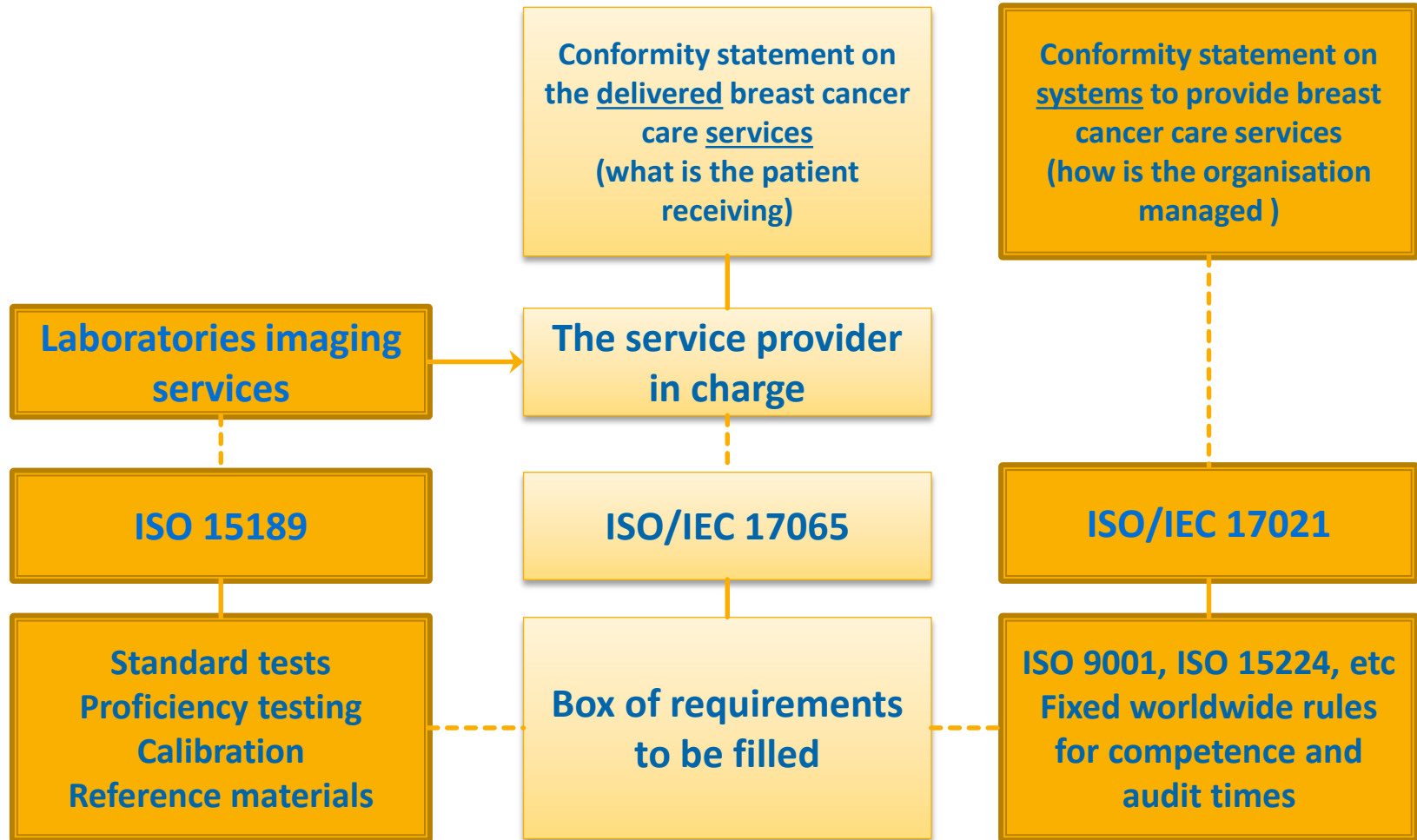
QA-SCHEME – THE ULTIMATE GOAL

- Patient centered , a quality assurance scheme that defines outputs and outcomes for the patient and thus reduces the burden of cancer
- Harmonised minimum quality level of delivery of Breast Cancer Services across borders in the EU and thus reduces health inequalities in Europe
- Continuous improvement through evaluations

UNDERPINNED BY ACCREDITATION IN LINE WITH EU 2008/765



DETERMINING THE STANDARDS FOR ACCREDITATION



FILLING THE EMPTY BOX?

The QA-Scheme should answer at least:

- What is to be certified
- How should be certified
- Who should be involved
- How to validate the scheme

BUILDING A PROCESS CERTIFICATION SCHEME

Conformity assessment functions and activities ^a within product certification schemes		Types of product certification schemes ^b							
		1a	1b	2	3	4	5	6	N ^{c,d}
I	Selection, including planning and preparation activities, specification of requirements, e.g. normative documents, and sampling, as applicable	x	x	x	x	x	x	x	x
II	Determination of characteristics, as applicable, by: a) testing b) inspection c) design appraisal d) assessment of services or processes e) other determination activities, e.g. verification	x	x	x	x	x	x	x	x
III	Review Examining the evidence of conformity obtained during the determination stage to establish whether the specified requirements have been met	x	x	x	x	x	x	x	x
IV	Decision on certification Granting, maintaining, extending, reducing, suspending, withdrawing certification	x	x	x	x	x	x	x	x
V	Attestation, licensing								
VI	Surveillance, as applicable (see 5.3.4 to 5.3.8), by:								

^a Where applicable, the activities can be coupled with initial audit and surveillance audit of the applicant's management system (an example is given in ISO/IEC Guide 53) or initial assessment of the production process. The order in which the assessments are performed may vary and will be defined within the scheme.

^b An often used and well-tried model for a product certification scheme is described in ISO/IEC Guide 28; it is a product certification scheme corresponding to scheme type 5.

^c A product certification scheme includes at least the activities I, II, III, IV and V a).

^d The symbol N has been added to show an undefined number of possible other schemes, which can be based on different activities.

EXAMPLES OF BUILDING BLOCKS

- Define the required service characteristics: what will be the outputs to be achieved by the service provider?
- How can these be ascertained/evaluated?
- How can the process used to evaluate the outputs be validated?
- What competence of auditors is required?
- Is Peer Review a possibility in some areas? Under which conditions? With what type of output? In accordance with ISO 17040?
- Requirements for laboratories, imaging services . No real options other than ISO 15189/17025. The preferred one seems to be 15189, as it was designed by the profession itself to include the professional expertise to judge, interpret the results in the context of the diagnosis and foreseen treatment (if any) for the patient.
- Requirements to the management system for the chain/path of care, just any or ISO 15224/9001

HOW TO STRENGTHEN ISO 15189 FOR USE IN THE QA-SCHEME

The scheme may define

- Testing methods, standards
- Calibration requirements
- Validation methods
- Round robin tests
- Reference materials, etc, etc

In order to harmonize and benchmark results from laboratories and their interpretation by the professionals in the light of treatment of the patient

HOW GOOD IS THE CARE DELIVERED UNDER A QA-SCHEME?

The quality of the BC-service is determined by the quality of the Guidelines and Standards prescribed by the scheme

The variability is inherent in the guidelines and standards, and can be reduced by parameters in the QA-scheme like evaluation frequency, sampling, assessor/auditor/inspector competence

The harmonisation across borders and the variability in the work of conformity assessment bodies is enhanced by accreditation.

JUSITFIED CONFIDENCE IN COMPETENCE AND QUALITY?

- That is the primary goal for conformity assessment and accreditation.
- We are happy to work with the results of the Guidelines group and the QA-Scheme Development Group in the ECIBC and JRC

The patient can go anywhere in Europe and be confident she is taken care of in a good and competent manner based on evidenced practices

THANK YOU

