European Commission

European Quality Assurance scheme for Breast Cancer Services

Scope - short version

European Commission Initiative on Breast Cancer

Quality Assurance Scheme Development Group

Healthcare Quality Team

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Joint Research Centre

SCOPE OF THE *EUROPEAN BREAST QA SCHEME*

Short version

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The scope of the **European Quality Assurance scheme (QAS) for Breast Cancer Services (BCS)** – in short, the ***European Breast QA scheme*** represents the first output in the development of the *European Breast QA scheme* and is meant to describe: 1) how the **scheme will be implemented in the European context,** according to the European legislation for accreditation; 2) the **interventions and services** that will be covered by the *European Breast QA scheme*; and 3) the **quality dimensions** that will be included. All stakeholders and individual citizens were invited to provide their feedback on the draft document. The current document presents the results following the integration of the comments received. A second call for feedback will be launched once the *European Breast QA scheme*'s requirements are available, and thus in the final version of the scheme's manual. More information about the ECIBC is available online.

1. The accreditation legal framework of the *European Breast QA scheme*

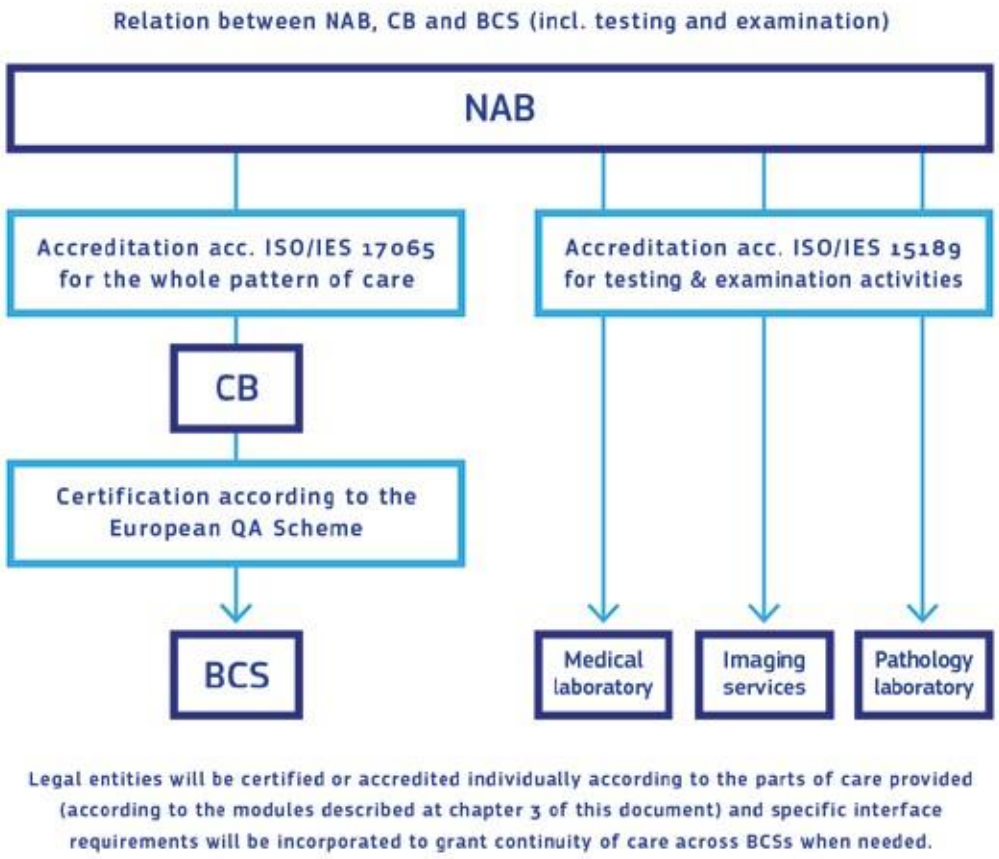
According to the European Commission Initiative on Breast Cancer (ECIBC) governance document, the voluntary European Quality Assurance scheme for Breast Cancer Services (the *European Breast QA scheme*) will be developed, piloted and, in the future, run under Regulation (EC) No 765/2008 and associated acts (hereinafter referred to as the *accreditation legal framework*).

The European co-operation for Accreditation (EA) is identified by the accreditation legal framework to manage the accreditation infrastructure within the EU, European Free Trade Association and candidate countries, as well as to coordinate and lead the European accreditation infrastructure to allow the results of conformity assessment services to be mutually recognised in all European countries.

Within ECIBC, the harmonised and peer-reviewed approach granted by the accreditation legal framework was chosen for the development and piloting of the *European Breast QA scheme*.

In order to achieve consistency in the accreditation of conformity assessment bodies, National Accreditation Bodies (NABs) use harmonised standards. Since the *European QA Breast scheme* will cover many healthcare procedures, including testing and examination activities, two main harmonised standards have been chosen: **ISO 15189:2012** (Medical laboratories –- Requirements for quality and competence) for the testing activities and **ISO/IEC 17065:2012** (Conformity assessment – Requirements for bodies certifying products, processes and services). Both standards will be directly used by the NABs: the first for accrediting testing activities (e.g. laboratories) associated to BCSs aiming to adhere to the *European Breast QA scheme*, and the second for accrediting **certification bodies** (CBs) which certify that the BCS fulfils all the specific requirements within the scheme Possible time and equivalence derogations will be covered within the scheme's owner requirements during the discussion and the QAS Development Groups approval processes.

Figure 1: Relation between NAB, CB and BCS (incl. testing and examination)



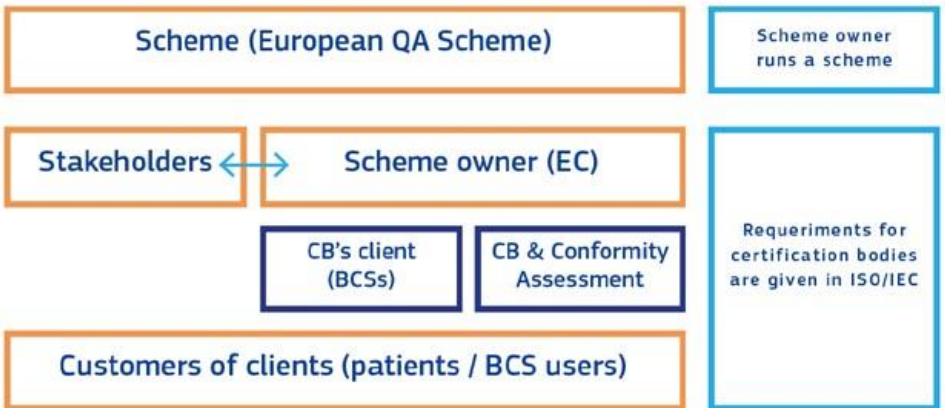
To summarise, the *European Breast QA scheme* is defined by the following two components:

The **accreditation scheme, which** is the legal and procedural framework using ISO/IEC 17065 to underpin the *European Breast QA scheme*. The accreditation framework will include:

- Requirements for accreditation of CBs by the NABs, according to ISO/IEC 17065:2012, for operating the *European Breast QA scheme*. Those requirements ensure that the CBs operate this scheme in a competent, consistent and impartial manner.
- Requirements for accreditation of testing and examination activities providers (such as medical laboratories and imaging facilities) by the NABs, according to ISO 15189:2012 or its equivalent, for providing services for breast cancer diagnosis and care.

The **certification scheme** requirements, which is the set of requirements, rules and procedures specified by the EC (scheme owner) BCS must comply with in order to be granted certification for the *European Breast QA scheme* by a CB.

Figure 2: Interactions among scheme owner, certification bodies and BCS



Two categories of requirements will be included in the certification scheme:

- 'Service/process requirements' (specific requirements): clinical and organisational Requirements as well as quality performance and results indicators which the BCS will demonstrate to fulfil in its provision of all the processes covered by the scheme, with reference to guidelines and other sets of evidence, such as best professional practices.
- 'Certification process requirements' (scheme owner requirements): audit and surveillance requirements, i.e. surveillance functions and activities; audit plans; selection of auditors and assignment criteria; decision-making mechanisms; monitoring and review of the scheme, and transparency requirements for CBs and BCSs (e.g. public availability of the list of certified BCSs, and public availability of certain key quality indicators).

For a complete overview of how the *European Breast QA scheme* is contextualised in the accreditation legal framework, the document '*First Proposal of General Requirements of a European Breast QA scheme* for BCSs', developed by EA for the ECIBC, is available on **the ECIBC website.**

The EC as scheme owner would encourage the inclusion of a trained patients' representative in the audits of the *European Breast QA scheme*. Furthermore, the feasibility of a JRC-based central database of certification/accreditation outcomes will be tested during the pilot run. In fact, as scheme owner the EC is planning to maintain a central register of certified facilities and networks – to be made publicly available on the ECIBC web hub – and a database of statistical indicators (see paragraph 4.3). A collection of indicators related to the auditors' performance will also be established.

2. Services, interventions, diseases and care processes covered

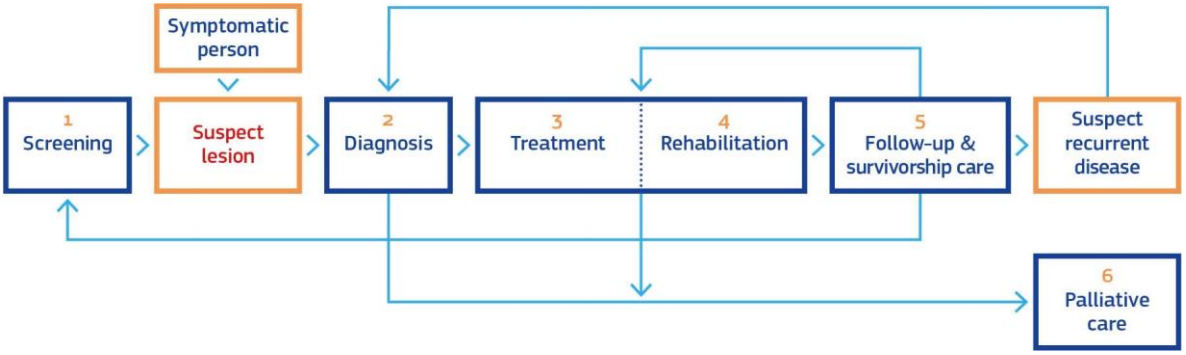
The *European Breast QA scheme* applies to BCSs (defined as all healthcare services covering, in continuum, the **full extent of breast cancer management**, from screening to follow-up, and in some cases until the end-of-life care).

Male breast cancer and other male breast diseases, such as gynecomastia, do not fall under the scope of this scheme (why? It's 1% of all breast cancers!); its blueprint may be adapted to breast cancer in male subjects in the context of a future project following the pilot run for female breast cancer.

To ensure that accreditation and certification requirements follow a patient/person- centred approach, requirements will be defined by taking into account the **care pathway** for breast cancer (and its related processes and sub-processes).

While dealing with breast cancer, persons go through different processes of care. Thereby, a general care pathway can be identified that applies to 'typical cases' of breast cancer.

Figure 3: Breast cancer care pathway



Thus, the main stages of breast cancer care can be identified as follows:

- Screening
- Diagnosis
- Treatment
- Rehabilitation
- Follow-up and survivorship care
- Palliative care

Sub-processes

For each of the care processes within the care pathway, specific sub-processes can be identified. Some of them, such as breast imaging, concern more than one care process.

Table 1a and Table 1b provide examples of sub-processes that are mapped according to the care processes, with a person's perspective in Table 1a and a system's perspective in Table 1b. Certain sub-processes, such as particular fields and types of research and training, may only be present in BCSs that are recognised as having an above-average level of expertise and act as reference centres.

Table 1b: Examples of breast cancer care sub-processes and their mapping according to processes in which they play a role: care system processes

	PROCESSES					
	SCREENING	DIAGNOSIS	TREATMENT	REHABILITATION	FOLLOW-UP & SURVIVORSHIP CARE	PALLIATIVE CARE
Team collaboration (including: multidisciplinary meeting/tumour)	x	x	x	x	x	x
Governance	x	x	x	x	x	x
Quality assurance of equipment imaging and therapy devices	x	x	x	x	x	x
Information to the public/citizens	x	x	x	x	x	x
Data management (databases and registries)	y	x	x	x	x	x
Staffing	x	x	x	x	x	x
Training/teaching for professional staff	x	x	x	x	x	x
Quality management	x	x	X	x	x	x
Quality improvement (e.g. audit) and innovation	x	x	x	x	x	x
Patient safety (e.g. medication management)	x	x	x	x	x	x
Communication provider/person	x	x	x	x	x	x
Research	x	x	x	x	x	x

A modular approach to the European context

Ideally, a conformity assessment scheme for BCSs would cover the entire care of breast cancer, including the differential diagnosis with other breast diseases. In the investigation and treatment of the disease, the patient goes through various care processes and related sub-processes along the care pathway.

These processes and sub-processes are provided by multiple professionals and – depending on the local organisation of breast care – by multiple services, too. In this context, the concept of continuity of care becomes highly relevant. The person/patient must always be involved and empowered in all processes along the pathway.

Two concepts can be used to describe the intervention of different entities and professional profiles in the breast cancer pathway: **externalisation** and **modules.**

The difference between outsourcing services and the module approach is that in the first case the coordination of care remains the responsibility of the entity contracting the external services, whilst in the second case the responsibility is transferred from one entity to the entity responsible for the subsequent care.

Table 2: Approaches to externalisation and modules

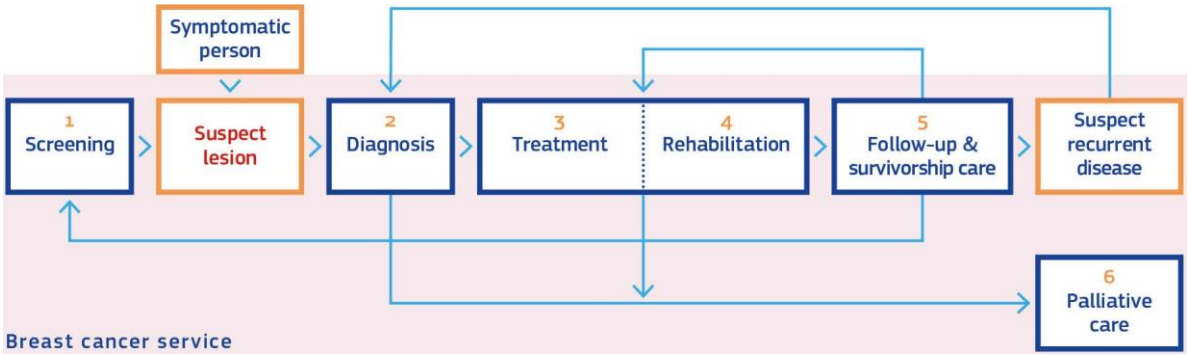
		APPROACH TO EXTERNALISATION	
		Comprehensive	Network
MODULES	One module	1A: One legal entity is responsible for the whole pathway, from screening to end-of-life care. No processes outsourced.	1B: Like 1A, although some processes or sub-processes are outsourced (e.g. some rehabilitation components, e.g. physiotherapy, sexual counselling, physical exercise).
	Two modules	2A: One legal entity is responsible for screening (e.g. regional authority) and another one (e.g. hospital) covers treatment to end-of-life care. No processes outsourced.	2B: Like 2A, although some processes or sub-processes are outsourced (e.g. some rehabilitation components, reading mammograms).
	Three modules	3A: One legal entity is responsible for screening (e.g. regional authority), another one (e.g. hospital) covers treatment to follow-up, and a third one covers end-of-life care (e.g. local authority for home care, or hospice).	3B: Like 3A, although some processes or sub-processes may be outsourced (e.g. some rehabilitation components, reading mammograms, home-based nursing).

ONE-MODULE SCENARIO (screening, breast centre and end-of-life care under the same legal responsibility)

1A: Certification of the comprehensive BCS to ISO/IEC 17065:2012 accredited *European Breast QA scheme* and accreditation of testing activities to ISO 15189:2012. Not allowed to be certified or accredited for only part of the pathway: comprehensive BCSs that provide all breast-care processes under the same legal entity but seek to obtain accreditation/ certification in a stepwise manner can use approach B on a temporary basis in order to be accredited/certified for the full list of modules in a given time frame (e.g. 3-5 years after the first certification).

1B: Certification of the comprehensive BCS to ISO/IEC 17065:2012 accredited *European Breast QA scheme* and accreditation of testing/examination activities to ISO 15189:2012. For the outsourced services/processes not coming under BCS responsibility, the BCS sets up an agreement with the external contractor which includes the need to comply with the corresponding requirements. If an outsourced process involves a testing/examination activity, the external contractor must be accredited according to EN ISO 15189:2012.

Figure 4: One module scenario

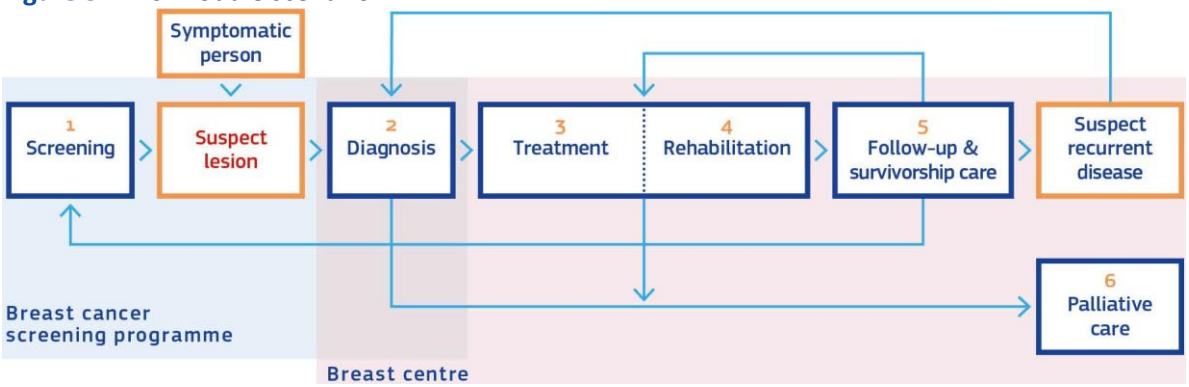


TWO-MODULE SCENARIO (screening and breast centre under different legal entities – breast centre includes end-of-life care)

2A: Certification of all the different legal entities to ISO/IEC 17065:2012 accredited *European Breast QA scheme* (group certification). The screening will be certified according to the requirements for screening programmes, and the breast centre according to the requirements for breast centres and for end-of-life care. The interface between the different entities (i.e. from screening to breast centre) must be robust, and clear criteria ('interface requirements') must be documented to establish how this is to be implemented.

2B: The same as for 1B, for externalised services.

Figure 5: Two-module scenario

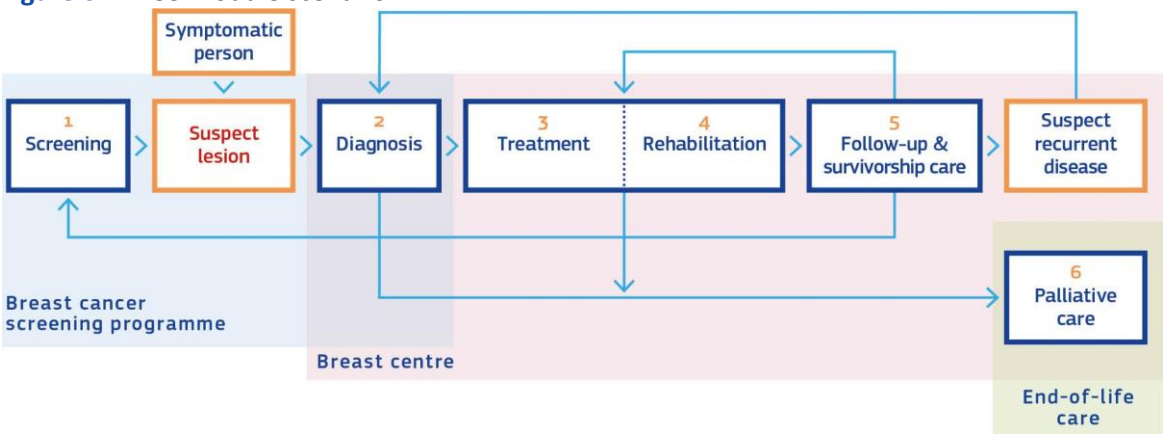


THREE-MODULE SCENARIO (screening, breast centre and end-of-life care under different legal entities – breast centre does not include end-of-life care)

3A: As for 2A and 2B, plus an 'interface requirement' included between breast centre and end-of-life care.

3B: Option 3B would allow for maximum flexibility: once the coordination of activities is provided by the screening programme, along with the breast centre and the entity responsible for end-of-life care, most of the sub-processes (e.g. genetic testing, radiation therapy, etc.) can be externalised to a contracted partner.

Figure 6: Three-module scenario



Organisation of the *European Breast QA scheme* requirements

A manual will be produced to present and explain the requirements that must be fulfilled by BCSs for certification and accreditation (of testing activities) to be granted.

The manual will specify:

- If applicable, the eligibility requirements a BCS would need to fulfil so that the accreditation/certification process could be started.
- The requirements against which the quality of the services will be judged in the accreditation/certification process, including the rationale and evidence on which they have been chosen.
- The quality domains to be addressed by process requirements (see paragraph 4.5 for the list of domains).
  Reference documents and protocols related to requirements, explaining how the respective

requirements will be fulfilled according to the specific process concerned and thus how it will be assessed (see paragraph 4.4 for referencedocuments).

- The methods for assessing whether requirements are met by BCSs, via on-site audits and other tools, according to the accreditation legal framework.
- The specific indicators, documents (e.g. guidelines) and relevant ISO certificates that will have to be fulfilled by the BCSs.

Each requirement will be univocally identified by an acronym and a number (e.g. AA1, AA2, etc.). In each requirement, identified with a statement and supported by a rationale, the criteria will be identified using a sub-heading number (e.g. AA1.1, AA1.2, etc.).

Indicators

In accordance with established practices for improving quality in European healthcare systems, the *European Breast QA scheme* will also assess whether requirements are being met by using quantitative indicators. Indicators will be associated with the requirements when the following criteria are fulfilled (NICE Healthcare Quality Standards Process Guide, Methodenpapier AQUA-Institut):

- There is significant variation in the delivery of (sub)-processes of care to persons between services and/or between Member States.
- The indicators measure key requirements for high-quality care or service provision with respect to improvements in the effectiveness, safety and experience of care.
- The performance of the (sub)-processes related to the requirements is quantitatively measurable.
- The BCS concerned has the power, within the respective country healthcare legal framework, to change the relevant care/services processes.

Indicators describe the fulfilment of a requirement by a clearly defined numerator and denominator.

Performance indicators for patients (including those related to patients' reported outcomes) and clinical outcomes will also be included.

Requirements and indicators will be mainly selected by the QASDG and oriented towards methods such as RAND/UCLA. This implies that experts within the working group will select requirements and indicators by rating them for relevance and feasibility in Delphi-like rounds.

Reference documents

The extent of conformity to the requirements by a BCS will be evaluated by means of a multi-methodological approach. The main step in such an approach will be an audit, whereby auditors will visit the service and check that the requirements are being met.

Reference documents and protocols referred to by given requirements and criteria will provide guidance both to services seeking to meet requirements and to auditors checking the fulfilment of requirements. Each document will be linked to one or more specific criteria in the manual.

The list of external documents may include, among others (but is not limited to):

- Physico-technical protocols for imaging which include quality control for equipment and the evaluation of clinical imaging quality;
- Standard operating procedures (SOPs), internationally recognised and validated methods, and ISO/CEN standards, where relevant to breast cancer;
- Proficiency tests (where available);
- Quality protocols for pathology, including the handling of specimens;
- A core set of information to be provided for informed consent (for each invasive procedure provided in the BCS and for imaging/screening if deemed relevant by the QASDG), including sample-informed consent modules and decision aids;
- Requirements for staff training and expertise (one protocol for each professional profile);
  A core set of information to be recorded in the different care processes, such as: a) databases (including record formats and characteristics); b) dischargeletter; c) imaging reports; d) medical records (inpatients and outpatients – including registration of the activities of all the professional profiles involved in care); e) pathology reports; and f) discharge/transfer towards other modules or providers. Those reference documents will take into account the need for consistency and interoperability with existing systems (e.g. electronic files on patients);
- A list of the minimum equipment that must be present in the BCS to guarantee the effective and safe provision of the service;
- Tools for collecting feedback from persons attending the BCS.

3. Quality domains

In the *European Breast QA scheme*, classification of requirements will be proposed according to the following domains:

- Clinical effectiveness
- Facilities, resources and workforce
- Personal empowerment and experience
- Safety

Finally, a synopsis of the *European Breast QA scheme*, including the manual, indicators and reference documents, is given in Figure 7.

Figure 7: Manual, indictors and reference documents