EUROPEAN ACCREDITATION

SUMMARY REPORT

European voluntary quality assurance scheme for breast cancer services underpinned by accreditation and high-quality guidelines

ECIBC

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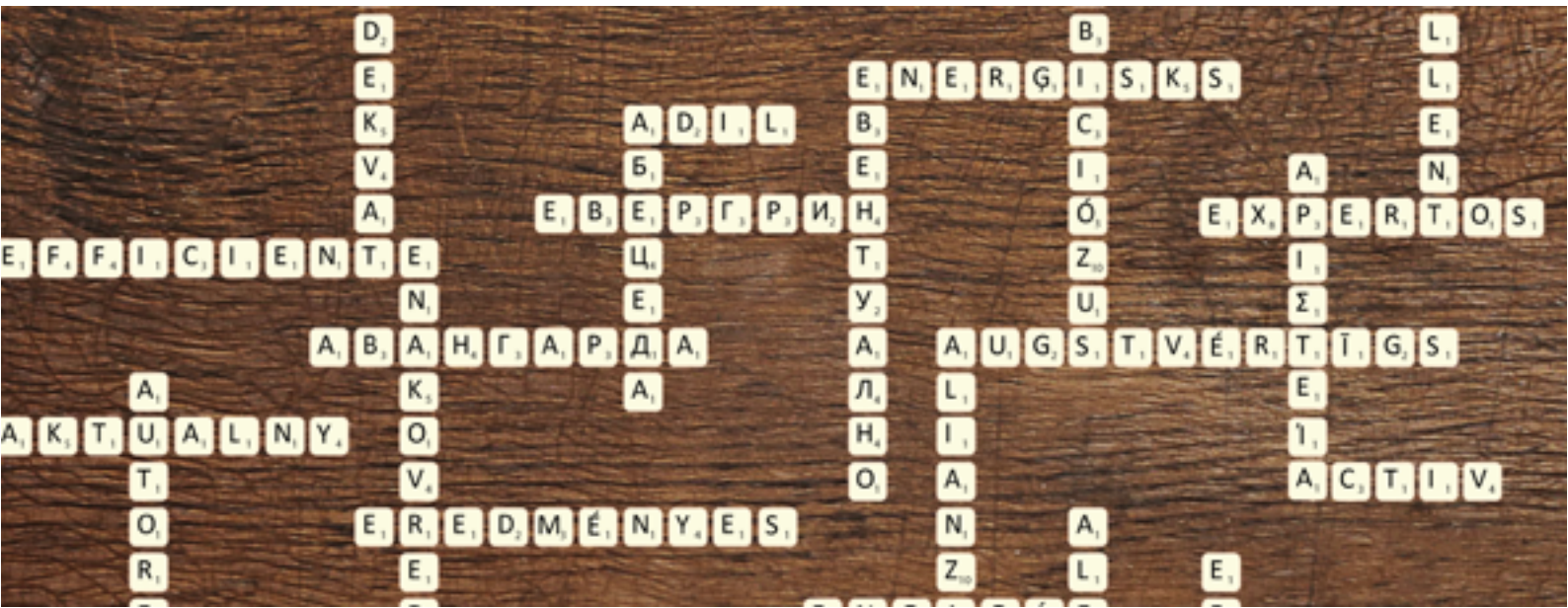
1. ABBREVIATIONS AND ACRONYMS

BCS - Breast cancer service
CAB - Conformity Assessment Body
CB - Certification Body
EA - European co-operation for Accreditation
ECIBC - European Commission Initiative on Breast Cancer
ECIS - European Cancer Information System
IEC - International Electrotechnical Commission
ISO - International Organisation for Standardisation
IT - Information technology
JRC - Joint Research Centre
MLA - Multilateral Agreement
NAB - National Accreditation Body
QA - Quality assurance
QASDG - Quality Assurance Scheme Development Group
QI - Quality indicator
QIC - Quality indicator calculator
WG - Working group



2. DEFINITIONS

Accreditation - an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity.

Certification - third-party attestation related to an object of conformity assessment, with the exception of accreditation.

Conformity assessment - demonstration that specified requirements are fulfilled.

Audit - process for obtaining relevant information about an object of conformity assessment and evaluating it objectively to determine the extent to which specified requirements are fulfilled.

NAB - National Accreditation Body – the sole body in a Member State/country that performs accreditation with authority derived from the State/government.

3. REFERENCES

EN ISO/IEC 17011:2017 - Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies

EN ISO/IEC 17065:2012 - Conformity assessment - Requirements for bodies certifying products, processes and services

EN ISO 15189:2022 - Medical laboratories - Requirements for quality and competence

EN ISO/IEC 17020:2012 - Conformity assessment - Requirements for the operation of various types of bodies performing inspection

EN ISO/IEC 17025:2017 - General requirements for the competence of testing and calibration laboratories

4. SUMMARY

The European Quality Assurance (QA) Scheme for breast cancer services has been established under the auspices of the European Commission Initiative on Breast Cancer (ECIBC)[1]. The ECIBC project was established by the European Commission's Directorate-General for Health and Food Safety, while the Commission's Joint Research Centre (JRC) oversaw the project. The owner of the European QA Scheme is the European Commission.

The European QA Scheme defines a common set of quality and safety requirements for Breast Cancer Services (BCSs) in Europe that should be followed by any entity providing BCSs to women. The fulfilment of the requirements is shown by accredited certification.

The European QA Scheme is applicable to all healthcare services covering the whole breast cancer care pathway. The breast cancer care pathway defined and covered by the scheme shows the journey followed by a patient, including possible entry and end points and the services involved. In this way is ensured that the European QA Scheme follows a patient/person-centred approach.

The requirements in the European QA Scheme are defined, where possible, by considering evidence-based recommendations from high-quality guidelines, best professional practices, and relevant legislation. The requirements are described in detail in the *Manual of the European Quality Assurance Scheme for Breast Cancer Services (the Manual for Breast Cancer Services, hereafter)*[2] and *the European QA Scheme Owner Manual (the Scheme Owner Manual, hereafter)*[2].

The requirements of the scheme are definable, measurable, and actionable. They relate directly to the maintenance, restoration, or improvement of health, and relate to one or more of the following quality domains:

- clinical effectiveness;
- safety;
- facilities, resources, and workforce;
- personal empowerment and experience.

[1] https://healthcare-quality.jrc.ec.europa.eu/en/ecibc

[2] https://healthcare-quality.jrc.ec.europa.eu/breast-quality-assurance-scheme/manuals

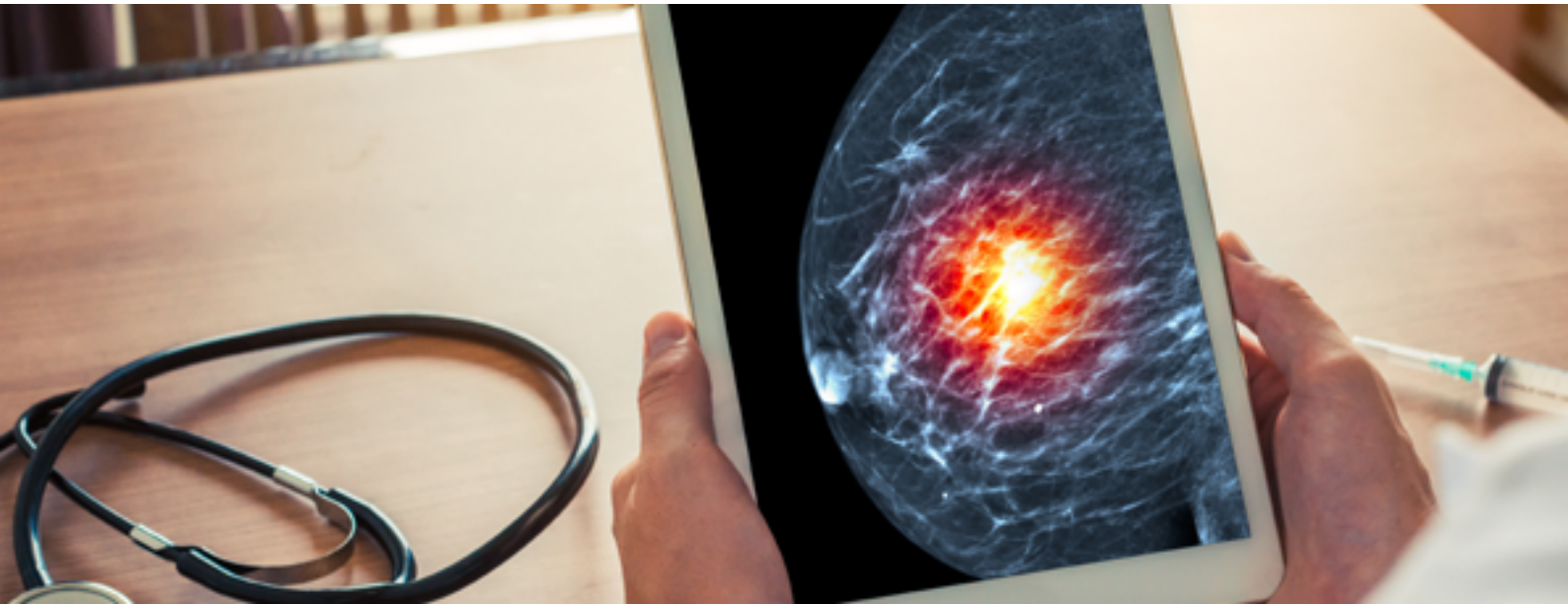
The European QA Scheme has been developed as a modular scheme, enabling different legal entities, or geographically separated services to participate according to the range of breast cancer services that they provide.

Adopting the European QA Scheme is voluntary. It is not mandatory for health services/BCSs to implement it. However, where a BCS entity does choose to implement it and wants its BCS to be certified under the scheme, then the scheme's requirements and criteria must be adhered to.

Certification is the formal recognition by an independent, impartial organisation (Certification Body, CB) that a BCS and its providers have been audited and have demonstrated that they meet all the European QA Scheme requirements. A BCS provider that adopts the European QA Scheme and achieves accredited certification can provide formal assurance that a woman using its services (for any aspect of breast cancer care) will benefit from the quality of the services, which meet the requirements of an EU-wide protocol.

Through accreditation, performed by a National Accreditation Body (NAB), a CB obtains a recognition and affirmation that it carries out its duties competently and impartially following the relevant harmonized standard (EN ISO/IEC 17065) when certifying BCSs. In addition to the harmonized standard, the scheme owner's requirements described in the Manual for Breast Cancer Services and the Scheme Owner Manual shall also be applied.

Diagnostic services, including pathology and imaging services, are part of the breast cancer services and the competence of those services can be shown by direct accreditation following the standards EN ISO 15189, EN ISO/IEC 17020, EN ISO/IEC 17025.



5. BACKGROUND, BENEFITS FOR WOMEN

Breast cancer is still the most common cancer among women in the European Union. Statistics from the European Cancer Information System (ECIS) indicated that more than 355 000 women were estimated to be diagnosed with breast cancer in 2020 (13.3% of all cancer diagnoses). Moreover, there are inconsistencies between incidence and mortality rates in some countries where mortality is higher than the European average despite a lower incidence. This may depend on many factors including quality and access to care. The European Parliament's and Council's aim is to support Member States in their efforts to fight cancer. Based on that the ECIBC started its activities in 2015 with the objectives of improving the quality of breast cancer care and reducing inequalities in care access across Europe.

The ECIBC main features include:

- the initiative is based on the latest scientific evidence available and follows an internationally recognised methodology for their activities, which also provides for full transparency and traceability;
- the activities can rely on the support of national representatives from all around Europe;
- the working groups are multidisciplinary teams including health care professionals, researchers as well as patient advocates who participate in every phase of the discussion and development of both the guidelines and the QA scheme;
- the initiative pays particular attention to patients' needs during the entire care pathway in a comprehensive manner;
- the initiative foresees the development of European breast cancer guidelines on cancer (prevention) screening and diagnosis and associated quality assurance schemes for healthcare services to facilitate the implementation of quality-ensured screening and follow-up;
- the quality assurance schemes cover the entire cancer care pathway, from prevention and screening to diagnosis, treatment, rehabilitation, management of recurrence, and palliative care;
- the European Commission supports the implementation of the ECIBC in interested countries on a voluntary basis;
- possible conflicts of interest are managed through annual and specific declarations of interest.

Two main instruments have been created to achieve the ECIBC's aims:

1. The European guidelines on breast cancer screening and diagnosis are intended to provide up-to-date, evidence-based recommendations on breast cancer screening and diagnosis. Their development is reported transparently so that they can be implemented across Europe and beyond. They offer clear, objective, and independent guidance on breast cancer screening and diagnosis to healthcare providers and women. They also guide healthcare managers and policymakers when planning, organising, and monitoring the effectiveness of screening programmes.
To complement the European guidelines for screening and diagnosis by covering the entire breast cancer pathway, the ECIBC also gathered guidelines developed by organisations worldwide. These guidelines are included in an easy-to-search catalogue and provide good practice for all breast cancer care processes after screening and diagnosis (treatment, rehabilitation, follow-up and survivorship care, and palliative care). The catalogue brings together guidelines that meet the ECIBC eligibility criteria for inclusion and is updated periodically.

2. The European QA Scheme defines a set of requirements, with which BCSs providing services ranging from screening to follow-up, and even palliative care in some cases, must comply in order to be certified under the current scheme. The certification will be made by accredited certification bodies.

To ensure the competence of the CBs certifying BCSs the European co-operation for Accreditation (EA) had been contracted by the European Commission Directorate-General JRC to deliver the accreditation aspects of the European QA Scheme. The European QA Scheme was required to fit into an accreditation framework that is compliant with the requirements of Regulation (EC) No 765/2008[3], and the standard EN ISO/IEC 17011: 2017.

Benefits for women

The European QA Scheme will benefit women. By ensuring an essential level of quality of breast cancer services with a person-centred perspective, the European QA Scheme helps reduce inequalities in healthcare delivery, empowering women and improving their quality of life and survival.

The European QA Scheme focuses on aspects that are relevant to patients and covers all the relevant care processes from screening to end-of-life care. The scheme also focuses on enhancing the outcomes of care taking into account the patient experience/satisfaction. The care pathway describes the healthcare chain and relationships across healthcare sectors, by describing the outcomes of the relevant healthcare processes involved and considering quality targets.

Particular emphasis will be placed on the requirements that are at the boundaries of care processes and sub-processes, in order to address continuity of care.

[3] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 OJ L 218, 13.08.2008, p. 30–47

6. CONCEPT OF THE SCHEME

The European QA Scheme has been developed in the project, which was established by the European Commission's Directorate-General for Health and Food Safety and the Commission's JRC oversaw the project. The owner of the European QA Scheme is the European Commission.

The main features of the ECIBC and the European QA Scheme framework:

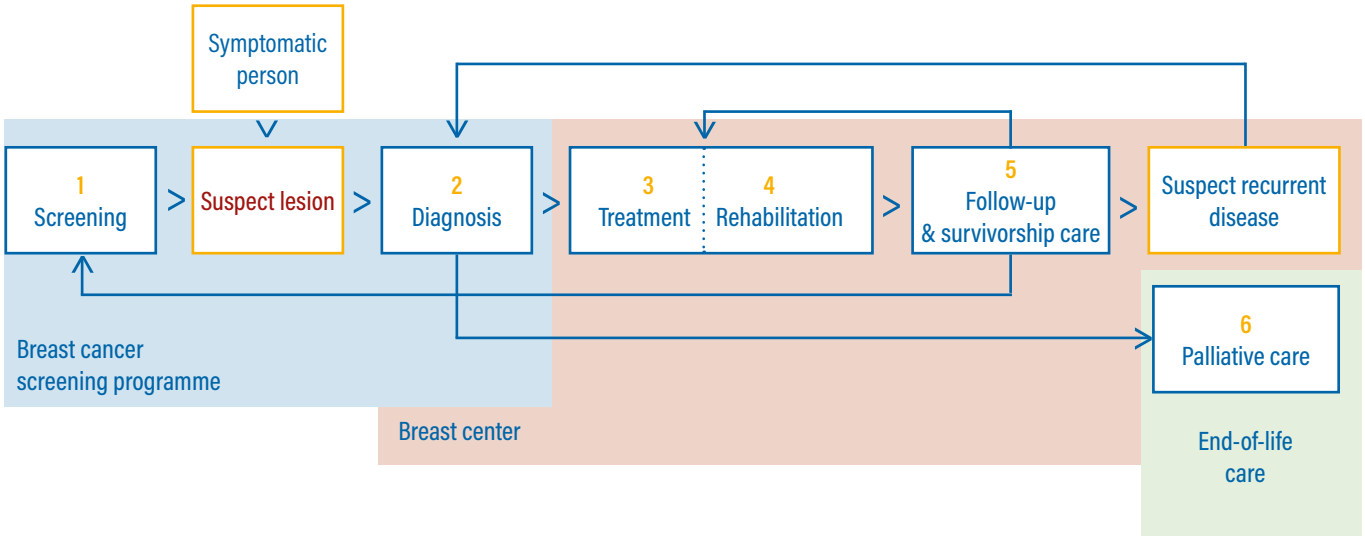
- be aligned with the report of a European survey on the organisation of BCSs in Europe published by the JRC[4];
- include, as a fundamental pillar of the European QA Scheme, quality requirements and other essential criteria, including patient safety requirements, that have been derived from strong recommendations from evidence-based clinical practice guidelines as well as other essential criteria;
- embrace all processes of care from screening through to follow-up and palliative care;
- be sufficiently modular and adaptable to accommodate the diversity of arrangements of BCSs across Europe;
- include appropriate requirements whenever deemed useful by the JRC and by the Quality Assurance Scheme Development Group (QASDG), supporting the JRC in designing the European QA Scheme and in particular for selecting the essential specific requirements, and feasible by stakeholders;
- be `future-proof' in the sense that it should be capable of adapting to future developments of the delivery and coordination of BCSs;
- identify the most appropriate international and European standards for accreditation purposes;
- ensure maximum applicability to particular arrangements pertaining to different countries by including accreditation, accredited certification, and other accredited conformity assessment activities as necessary;
- as far as possible, use the established assessment and accreditation processes and procedures of NABs.

The European QA Scheme includes a set of essential requirements that BCSs can implement to increase confidence in the quality of the care they provide for women throughout Europe. The requirements are described in the Manual for Breast Cancer Services.
The European QA Scheme is applicable to all healthcare services (including where a BCS entity is using outsourced services). To ensure that the European QA Scheme follows a patient/person- centred approach, the quality and safety requirements are defined by taking into account the complete care pathway for breast cancer from screening to follow-up and end-of-life care including all related processes and sub-processes.

The care pathway that a patient follows can be described in a flow chart (figure 1). This flow chart includes specific services and end points relevant to breast cancer care, considering the course of the disease as well as the various services involved.

[4] JRC Science and Policy Reports; Report of a European Survey on the Organisation of the Breast Cancer Care Services, 2014

Figure 1. The flowchart of breast cancer care



During the investigation and treatment of 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 services. In this context, the concept of continuity of care becomes highly relevant.

The European QA Scheme requirements for BCSs are presented in chapter 8.

Certification and the scope of certification of BCSs

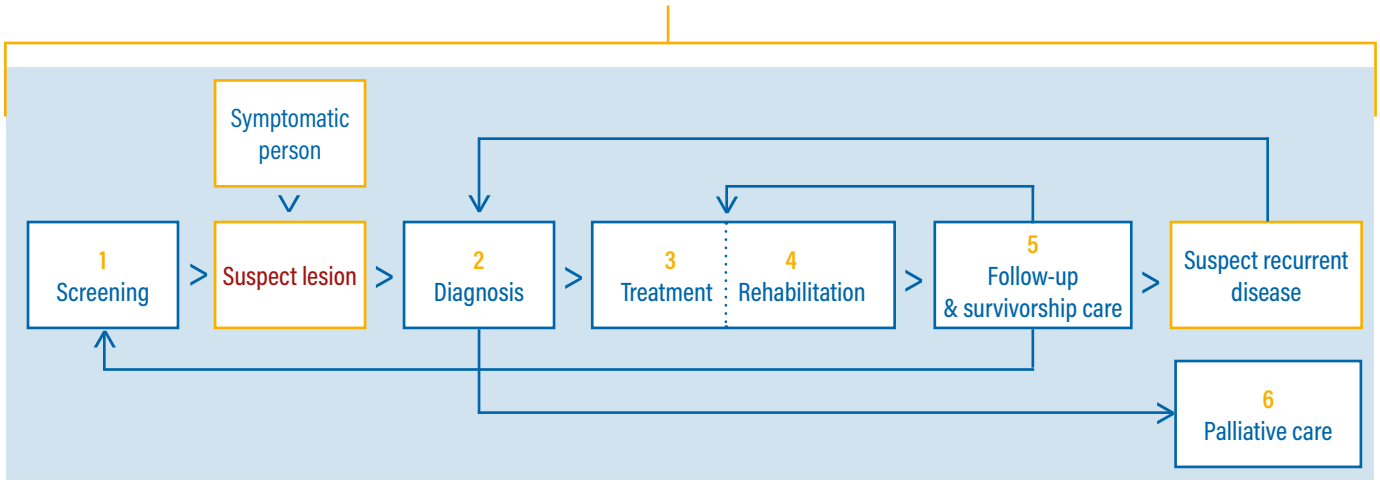
The fulfilment of the requirements of the European QA Scheme will be shown by accredited certification. Besides the accreditation criteria for CBs in the harmonized standard EN ISO/IEC 17065, the Scheme Owner Manual describes the requirements for the CBs including for the audit process and requirements for the competence of auditors.

It is acknowledged4 that different processes such as screening and diagnosis, treatment, rehabilitation, follow-up and survivorship, and end-of-life care in breast cancer care may be delivered by different entities, in the public and/or private sectors. For these reasons, the European QA Scheme has been developed as a modular scheme, enabling different legal entities or geographically separated services to participate according to the range of breast cancer services that they provide. However, it is essential to ensure that, wherever modules or processes and sub-processes within modules are delivered by different entities (even within the same overall organisation), all the entities involved in the pathway take responsibility for meeting the requirements for and coordinating the delivery ensuring the continuity of care to individuals.

A BCS entity can apply for certification for meeting the requirements of the European QA Scheme for one of the following modules:

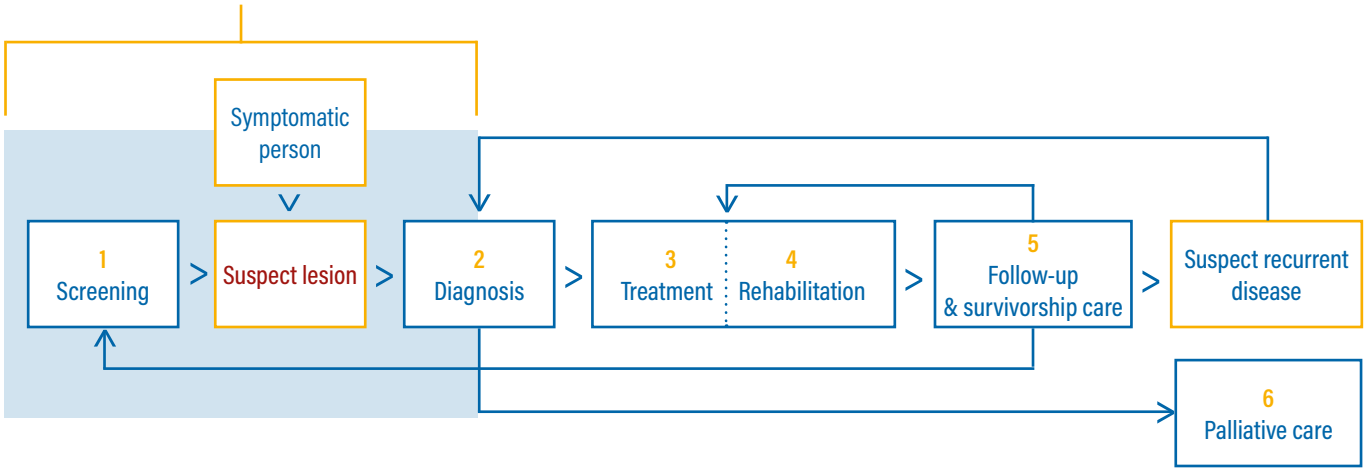
a) Certification of the entire breast cancer pathway: BCS provides all breast-care processes including outsourced services (screening, breast centre including diagnosis, treatment, rehabilitation, follow-up, survivorship care, and palliative care)

Figure 2. The flowchart of breast cancer care



b) Certification of screening programme, including outsourced services (and where applicable, diagnosis for referrals following screening)

Figure 3. Certification of screening programme (b)

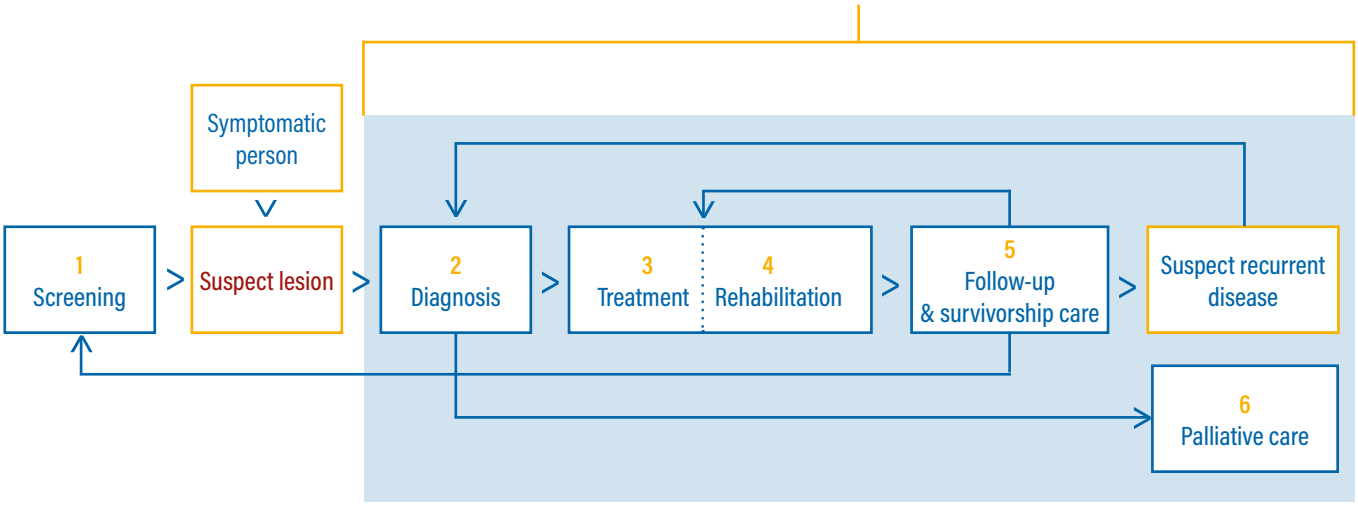


A screening programme will need to have been operating a screening service for a minimum of two years before applying for certification, in order to provide sufficient evidence of compliance with the requirements for BCSs (e.g. one complete round of screening). Screening programmes may involve one or more screening services (and, where applicable, diagnosis for referrals following screening) that are provided by outsourcing and/or operating as a `network' in different locations. In such circumstances, the legal entity that manages the overall screening programme would be the entity seeking certification.

Where a screening programme is also responsible for the diagnostic processes for referrals following screening, all the relevant European QA Scheme requirements for diagnosis must also be met, irrespective of whether these are part of the same legal entity as the screening programme or outsourced services.

c) Certification of the breast cancer care pathway without screening, including outsourced services: breast centre including diagnosis (including symptomatic women and referrals following screening), treatment, rehabilitation, follow-up, survivorship care, and palliative/end-of-life care

Figure 4. Certification of the breast cancer care pathway without screening (c)



Where a legal entity is responsible for all the processes in one of the above modules, the whole service must normally be included in the scope of certification. However, if the legal entity wishes to seek certification for separate aspects of such services initially, it may do so on a transitional basis, provided that accredited certification for the whole service is achieved within five years.

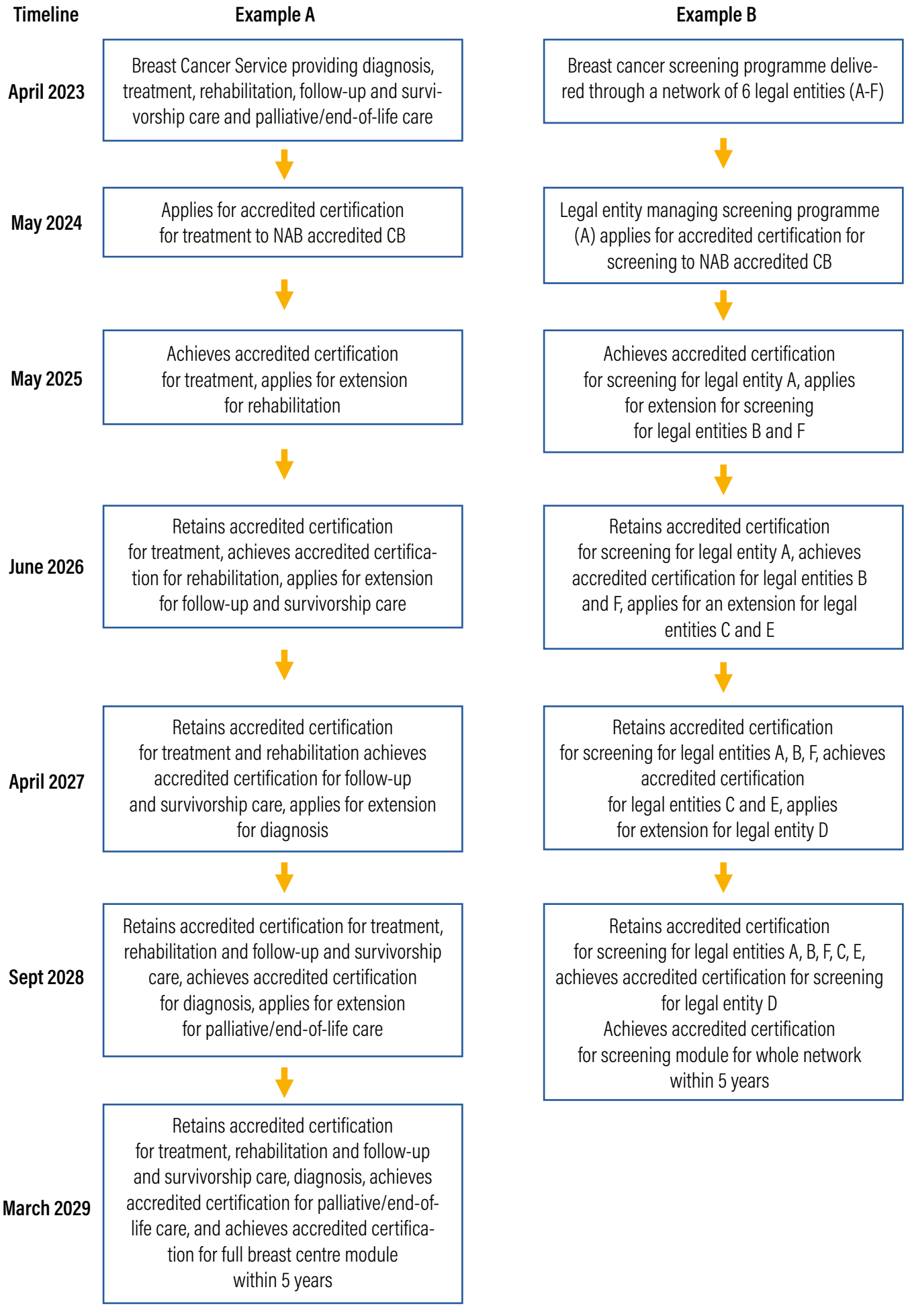
Stepwise approach to certification

It is recognised that the delivery of breast cancer services throughout Europe is very diverse, and different parts of a BCS (screening, diagnosis, treatment, rehabilitation, follow-up, survivorship care, and palliative care) may have quality assurance arrangements in place that are in different stages of development or maturity, and that may be delivered by different legal or geographically separated entities. A transitional approach is therefore proposed in recognition of the fact that, in the early stages of European QA Scheme implementation, there will be a need to accommodate this diversity of healthcare infrastructures in Europe in an inclusive way, allowing for different starting points in different countries.

It is proposed that, for a limited period of time, breast centres, screening services that operate as a network within a screening programme, and other breast cancer care services delivered through a network may seek accredited certification for their services in a stepwise approach. This recognises progression from discreet and specific BCS processes (within diverse infrastructures with different starting points) to a more coherent position with fewer variances in the delivery of BCSs in different regions and countries. It is anticipated that this may encourage national authorities and organisations delivering BCS processes to participate in this European QA Scheme, irrespective of the extent and coherence of the current provision. It is a European QA Scheme Owner requirement for the full scope of services included in the breast centre module or network to achieve accredited certification within five years of initial certification.

An example of a stepwise approach is presented in figure 5.

Figure 5. Examples of stepwise, time-limited approach to accredited certification

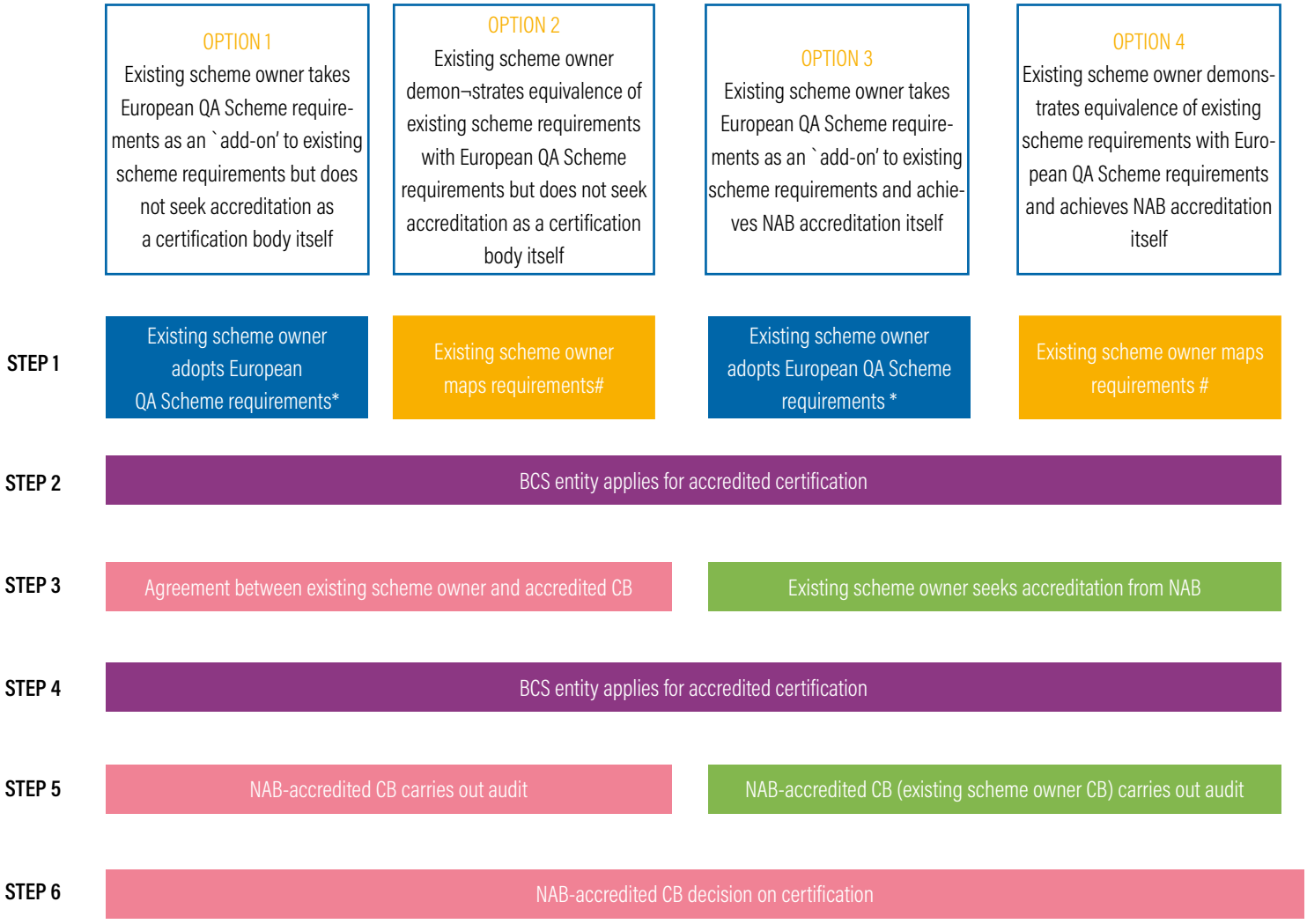


Recognition of existing cancer certification schemes operating in Europe

There are other well-established quality assurance schemes currently operating in Europe that cover the different processes of breast cancer care. In order to preserve flexibility and inclusiveness for other well-established quality assurance schemes, the European QA Scheme Owner acknowledges that BCSs that are currently certified should be able to make use of this status when seeking accredited certification for the European QA Scheme. Where a BCS entity has an existing certification, awarded by a CB that is not NAB-accredited, NAB-accredited CBs are required by the European QA Scheme Owner to take this into account in order to avoid duplication and facilitate the transition to accredited certification. For an existing certification to be eligible to be taken into account, BCS entities must be audited by a CB that has agreements with the European QA Scheme Owner and a NAB-accredited CB.

Different options are available to existing quality assurance schemes operating in Europe, and their participating BCSs, to interact with and be recognised under the European QA Scheme. Full details for each option are given in the Scheme Owner Manual. Each option has two components: 1) recognition and adoption of the European QA Scheme requirements; and 2) acceptance by NAB-accredited CBs of breast cancer service audits carried out by existing schemes.

Figure 6. Recognition by the European QA Scheme of existing (breast) cancer certification schemes operating in Europe



Networks

Networking and formalised collaboration between healthcare providers is increasingly recognised as an option for delivering cancer services. Breast cancer services may be provided by networks of organisations and specialists to enable close multidisciplinary working and/or ensure easy access to all necessary services, for example, across a geographical region. Networks may consist of multiple entities (e.g. entire institutions, parts of institutions, oncology departments, mammography facilities, etc.) belonging to different institutions that are dedicated to screening, diagnosis, treatment, rehabilitation, follow-up and survivorship care, and palliative care. The entities must have formal agreements to work together in a structured way under common governance, and to adopt uniform standards of care across the network. Coordinating patient care is the responsibility of multidisciplinary, inter-professional teams. For the European QA Scheme certification, a single legal entity would need to be responsible for ensuring that each entity within the network meets all the relevant European QA Scheme requirements, and that it has evidence from all collaborators to demonstrate that. Where these entities are legally differentiated, the services would be deemed to be outsourced.

Continuity of care

A BCS entity seeking certification is responsible for coordinating with other BCS entities to ensure the continuity of individual patient care between modules. This applies both where modules are delivered by different entities (such as departments or units) within the same overall organisation, and where modules are delivered by different legal entities. In addition, a BCS entity must take responsibility for coordinating with other BCS entities to ensure the continuity of individual patient care between processes and sub-processes within modules. This applies both where processes and sub-processes are delivered by different entities (such as departments or units) within the same overall organisation, and where these have been outsourced to different legal entities.

The specific requirements for managing continuity of care at all points in the breast cancer care pathway are clearly highlighted in a separate table on continuity of care in the *Manual for Breast Cancer Services* and with the following symbol. 

Feasibility and piloting the scheme

To ensure that the European QA Scheme is feasible and can be implemented in daily practice the feasibility of the scheme was evaluated and the implementation was tested in the pilot study.

The feasibility was evaluated using two different procedures - the feasibility evaluation made by the EA working group (EA WG) concerning certification and accreditation framework and the self-assessment procedure made by volunteer BCSs.

The feasibility evaluation of the European QA Scheme requirements and the certification process described in the *Manual for Breast Cancer Services* and the *Scheme Owner Manual* showed that it is possible to achieve the expectations of the scheme.

A pilot study was carried out to collect information about the implementation of the European QA Scheme and its feasibility in practice. The pilot was carried out with the participation of eight BCSs allowing to cover all the stages of the cancer pathway and three accredited and four non-accredited CBs. Some of the non-accredited CBs were medical societies which audit BCSs. Two NABs participated in the pilot study and witnessed the audits made by CBs. The pilot run gave useful information about how the European QA Scheme is working in practice and what should be changed and improved.

The main conclusion was that the European QA Scheme is fit for the purpose. The BCSs found it useful and a good mean to improve their quality. The CBs found the audit process possible to conduct, but there was a need for clarifications and improvements of the process. The NABs found that the scheme requirements and the audit process is possible for accreditation.

7. RIGHTS, RESPONSIBILITIES, AND LIABILITIES OF THE EUROPEAN QA SCHEME OWNER

The rights, responsibilities and liabilities for the scheme owner, CBs and BCSs are described in the *Scheme Owner Manual*.

The scheme owner takes full responsibility for:

- the objectives, content and integrity of the European QA Scheme;
- maintenance of the European QA Scheme and provision of guidance when required;
- the structure for operating and managing the European QA Scheme (which may include, for example, facilitating the exchange of experiences between BCSs and between CBs);
- documenting, maintaining and publishing the content of the European QA Scheme and ensuring relevant parties, such as CBs and BCSs, are advised of any updates;
- ensuring access to up-to-date listings of certified BCSs and accredited CBs;
- maintaining the registration process for BCSs and accredited CBs;
- ensuring that the European QA Scheme is developed and updated by individuals who are competent in both technical and conformity assessment aspects of breast cancer care;
- making and maintaining arrangements to protect the confidentiality of information provided by parties involved in the European QA Scheme;
- evaluating and managing the risks and liabilities arising from its activities;
- ensuring adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its activities;
- ensuring that it has the financial stability and resources required for it to fulfil its role in operating the European QA Scheme;
- maintaining a relationship with all relevant national authorities by keeping them updated on the European QA Scheme's current status and any developments;
- maintaining a relationship with EA by keeping it updated on the European QA Scheme's current status and any developments, in order to ensure that any relevant EA publications remain current.

In the *Scheme Owner Manual* is also described the rights, responsibilities and liabilities concerning confidentiality, use of information and document control.

The rights, responsibilities, and liabilities of CBs and BCSs are described in the next chapters of this report.

8. THE EUROPEAN QA SCHEME REQUIREMENTS FOR BREAST CANCER SERVICES

The European QA Scheme defines a set of requirements with which BCSs, providing services from screening to follow-up, and in some cases until end-of-life care, will have to comply in order to be certified under the scheme. The requirements are described in the Manual for Breast Cancer Services.

The requirements are defined, where possible, by considering evidence-based recommendations from high-quality guidelines, best professional practices, and relevant legislation. Additionally, new requirements were formulated in areas where the expert group identified a need for quality improvement. Requirements were prioritised and first rated for: 1) relevance and understandability, and then for 2) feasibility. Relevance relates to the significance of the requirements for a person-oriented care. Feasibility relates to the ability of the requirements to be implemented.

Selection criteria for the requirements

The European QA Scheme requirements have been developed in accordance with a set of principles agreed by a wide range of stakeholders and using an agreed methodology.

Details of the methodology are published on the European QA Scheme Owner's website:
https://healthcare-quality.jrc.ec.europa.eu/sites/default/files/methodologies%20docs/ECIBC_Methods_QA_scheme.pdf

The requirements and indicators were selected by the QASDG members (including breast cancer professionals and patients) in a series of structured steps. The procedure consisted of the following essential steps: collection of requirements, panel process, feasibility and pilot testing.

Definitions

Requirement: The operational definition used within the ECIBC and encompasses the meaning of a "standard" in the healthcare field: it is the level of performance required by a quality assessment scheme with respect to a certain aspect that is meaningful for breast cancer screening, diagnosis and treatment.

Statement: In the European QA Scheme each requirement comprises a statement, associated with the corresponding supporting evidence and references, which is explained in several criteria. The statement represents the overarching requirement and its general intent or principle.

Criteria, indicators: The criteria and/or indicators, and associated specifications, present measurable points by which achievement of the goal of the statement may be objectively assessed. The criteria can specify different assessment approaches: structure, process or outcomes.

Quality domain: In the scheme, the requirements are classified according to the following quality domains:

- clinical effectiveness (CEF);
- safety (SAF);
- facilities, resources and workforce (FRW);
- personal empowerment and experience (PEX).

Structure of the requirements

The requirements have been assembled in three main chapters according to their scope.

Chapter I. General requirements (GEN): cross-sectional requirements that can be applied to the entire pathway, regardless of the process involved.

Chapter II. Screening requirements (SCR): requirements addressing specific aspects of screening programmes.

Chapter III. BCS requirements: requirements dealing with specific aspects within each care process:

- Diagnosis (DGN)
  - o diagnosis (DGN)
  - o imaging (DGN-IMG)
  - o pathology (DGN-PTH)
- Treatment (TRT)
  - o treatment (TRT)
  - o surgery (TRT-SUR)
  - o systemic therapy (TRT-SYS)
  - o radiotherapy (TRT-RAD)
- Rehabilitation (RHB)
- Follow-up and survivorship care (FLW)
- Palliative care (PAL)

The distribution of requirements and measurement elements (criteria and indicators), according to the different care pathway processes, is shown in this table:

Pathway process	Number of requirements
GeneraL	20
Screening	10
Diagnosis	25
Treatment	25
Rehabilitation	2
Follow up	3
Palliative care	1
Total	86

Measurement of compliance

The compliance with the requirements in the European QA Scheme will be audited by CBs using several tools (on-site visit, interview with staff, etc.), including quantitative indicators (quality indicators). Indicators describe the fulfilment of a requirement by a clearly defined numerator and denominator. Indicators are therefore always linked to a requirement, but not every requirement will have a quantitative indicator to be measured.

The audit may focus on two different levels of performance:

a) Patient level: when the measurement is focused on the patient. In this case, the compliance with the requirement will be measured with a quantitative indicator.

b) Breast service level: the fulfilment of one or more criteria by the BCS will have to be audited using different tools and methods.

9. REQUIREMENTS FOR BCS ENTITIES

Eligibility to participate in the European QA Scheme
The eligibility to participate in the European QA Scheme is described in the *Scheme Owner Manual*.

The organisation responsible for providing the BCS must be a legal entity or a defined part of a legal entity.

The BCS entity must be willing to enter into an agreement/contract with an accredited CB (which defines the rights, responsibilities and liabilities of the parties to that agreement), and to comply with the terms and conditions of business.

The BCS provided by a legal entity must cover one of the European QA Scheme modules.

Imaging and pathology services are not eligible for stand-alone accredited certification (either separately or together) but are eligible to apply for NAB accreditation for their services.

Outsourced services that do not provide all of the processes within a module are not eligible to apply for accredited certification to the European QA Scheme as stand-alone activities/entities.

Rights, responsibilities and liabilities of BCSs
BCS entities will be required to undergo an impartial third-party audit by an accredited certification body to confirm conformance with the applicable requirements of the European QA Scheme. The BCS entity shall clearly describe the services that are provided and to be included in the certification. It is the responsibility of the BCS entity to demonstrate that its BCS complies with all the requirements of the European QA Scheme as applicable to the scope of its activities and as detailed in the Manual for Breast Cancer Services. The BCS entity shall also comply with relevant European and national legislation.

By applying for certification, BCS entities commit to complying with European QA Scheme requirements at all times, to communicating updated information and calculated QI data to the CB at the specified frequency and in the agreed format, to paying the fees associated with application, initial certification and ongoing maintenance of certification and to complying with the terms and conditions for use of the European QA Scheme certificate, mark and statement of conformity. In addition, application to a CB is taken as agreement that the CB can share specified information with the European QA Scheme Owner for the purposes of monitoring and developing the scheme's operation.

The European QA Scheme permits BCS entities to outsource processes or sub-processes of breast cancer care modules to external resources. Where a BCS entity outsources, through a legal agreement/contract, any process or sub-process of the BCS module for which it is seeking certification, the BCS entity must satisfy itself and the accredited CB that the outsourced services meet the European QA Scheme requirements.

Requirements for the management system
Besides of the requirements for the patient care the European QA Scheme also includes requirements for the management system of BCSs. These requirements cover:

- protocols and policies and a document control system;
- quality improvement policy including a quality management system;
- a patient safety system;
- a clinical information system for monitoring the quality of breast cancer care;
- a governance of data management;
- patient relevance (patient involvement);
- staff competence.

Imaging and pathology services
BCS entities that provide screening and/or diagnosis must ensure that imaging and pathology services (including outsourced services) meet all applicable European QA Scheme requirements. The following are acceptable means of demonstrating compliance:
Accreditation of imaging and pathology services for a specified scope related to BCSs, by a NAB that is signatory to the EA MLA[5] (Multilateral Agreement between national accreditation bodies (for EN ISO 15189 or EN ISO/IEC 17020 or EN ISO/IEC 17025, as required by the national authorities or NABs)). The imaging and pathology services must also demonstrate that they meet the applicable European QA Scheme requirements for imaging and pathology.

OR

Audit of screening and/or diagnosis services by an accredited CB against the relevant European QA Scheme requirements for imaging and pathology for BCSs (including management system requirements and QIs), as part of the certification process for the entire breast cancer care pathway, screening programme modules or breast cancer care pathway without screening.

CBs must adopt a `presumption of conformity' for imaging and pathology services that are accredited by a NAB that is signatory to the EA MLA. Where imaging and pathology services hold such accreditation, `presumption of conformity' by the CB means that no additional audit of the imaging and pathology service will be carried out by the CB. This is provided that the screening and/or diagnosis service has evidence of up-to-date accreditation in the form of a certificate and scope of accreditation, and evidence of compliance with the European QA Scheme requirements.

Quality indicators
Quality indicators (QIs), including both structural and process/outcome indicators, are an important tool to assist BCSs in measuring, monitoring and improving their performance. As part of the certification process compliance with European QA Scheme requirements will be verified using these quality indicators alongside other audit techniques.

The *Manual for Breast Cancer Services* contains a complete list of indicators to be computed using the quality indicators calculator tool or manually by the BCS. Compliance with requirements that do not involve quantitative measurement is expressed using an indicator with a dichotomous (yes/no) response. For both of these indicators, the desired level of fulfilment is expressed as the `Norm.'
BCS entities are required to measure their performance against the QIs and to update and submit calculated indicators for all care delivered in the previous 12 months to the CB annually using the specified data format and electronic processes.

[5] https://european-accreditation.org/mutual-recognition/the-ea-mla/

10. REQUIREMENTS FOR CBS

Eligibility to certify to the European QA Scheme

A CB must be a legal entity (or part of a legal entity), be accredited, have registered with and have entered into an agreement/contract with the European QA Scheme Owner before it can carry out audits of breast cancer services. The criterion for acceptance by the European QA Scheme Owner is that the CB is accredited for certifying to the European QA Scheme by a NAB against the requirements of the current version of standard EN ISO/IEC 17065 and that it has demonstrated compliance with the detailed requirements set out in the *Scheme Owner Manual*. The NAB must be a signatory to the EA MLA for accreditation to EN ISO/IEC 17065.

Rights, responsibilities and liabilities of CBs

The rights, responsibilities and liabilities are described more detailed in the Scheme Owner Manual. The main responsibilities are:

- by registering with the European QA Scheme Owner, a CB commits to meeting all applicable requirements of the European QA Scheme, a CB shall supply its certification services for the European QA Scheme only whilst it has a valid agreement from the European QA Scheme Owner to do so;
- a CB must achieve and maintain accreditation for certifying to the European QA Scheme from the relevant NAB and demonstrate that it complies with all the requirements of EN ISO/IEC 17065 and the European QA Scheme as applicable to the scope of its activities;
- a CB is responsible for informing the European QA Scheme Owner of all applicant BCS entities and shall inform the European QA Scheme Owner when it suspends or withdraws a certification held by a BCS entity;
- a CB is responsible for publishing or providing, on request, names and scopes of certified BCSs and the validity of certifications;
- where a CB is working with an existing scheme owner or owners, the CB is responsible for informing the European QA Scheme Owner in writing of the agreements it has in place;
- where a CB's scope of accreditation does not cover the full range of BCSs (e.g. only screening services), a CB shall ensure that the limits and scope of the accreditation shall be made clear and publicly available;
- CBs must enter into a legally enforceable agreement/contract with client BCS entities which takes account of the responsibilities of both the CB and the client.

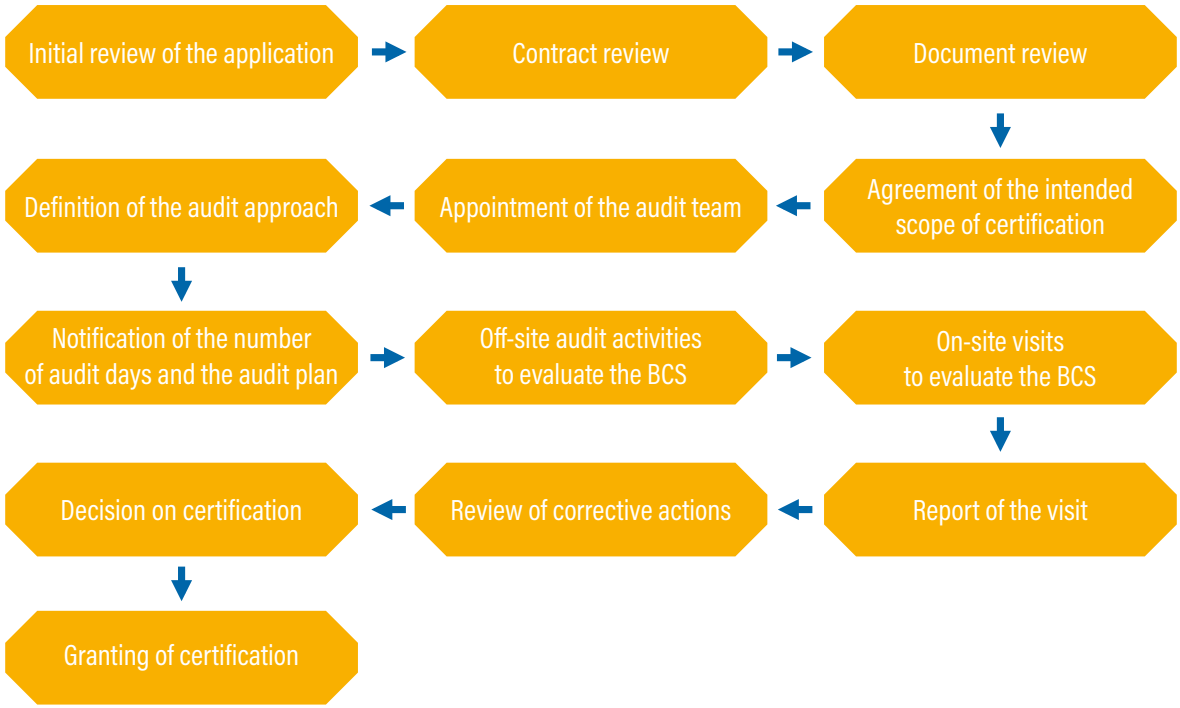
Other requirements for CB

A CB and any collaborating organisation such as an existing scheme owner must carry out its certification activities independently and impartially. In the context of the European QA Scheme a CB and its staff cannot provide consultancy services to a BCS entity and must identify and manage any risks to its impartiality arising from its activities and relationships.

Audit processes

CBs and any collaborating organisation such as an existing scheme owner must carry out their certification activities in accordance with accreditation standard EN ISO/IEC 17065 and with the European QA Scheme requirements which are described in the Scheme Owner Manual. The purpose of the audit is to verify the compliance of the BCS with the European QA Scheme requirements (which include specific quality indicators as well as general requirements).
The steps in an audit process are described in the figure 7.

Figure 7. Audit process. Details of the requirements for certification process are described in the standard EN ISO/IEC 17065 and the *Scheme Owner Manual*.



At an on-site audit, the CB audit team will:

- verify the currency, accessibility and implementation of the procedures, processes and systems as described in the documents, records and reports provided by the BCS entity;
- follow-up any queries arising from the remote audit activities carried out before the on-site visit;
- observe the delivery of the service by management and staff;
- explore the patient experience, by agreement and where appropriate and acceptable;
- provide the BCS entity with feedback on the audit findings before leaving the site.

Maintenance of certification, validity of certificate

A certificate is valid for a period of three (3) years subject to a BCS continuing to meet the requirements of the European QA Scheme and conditions for certification. In order to maintain certification, a CB will conduct surveillance activities in accordance with the procedures of a CB at least once every 12 months.

Composition of the audit team

The composition of the overall audit team (this includes both on- and off-site auditors) and the required competences will largely be determined by the scope of activities for which a BCS entity is seeking certification. In all cases, a Lead Auditor will be appointed to lead and coordinate the audit process. The requirements for the knowledge, understanding and experience of auditors for each of the breast cancer care processes (screening, diagnosis, treatment, rehabilitation, follow-up and survivorship, palliative/end-of-life care) are described in the *Scheme Owner Manual*.

The criteria for determining competence initially and on a continuing basis will be defined by each CB and will be based on the criteria for BCS practitioners specified under the European QA Scheme. In determining the composition of an audit team for a BCS audit, a CB would be expected to consider the following qualified and practising specialists for possible inclusion in the overall team:

- Physician performing breast surgery (may also be referred to as `breast surgeon')
- Radiologist (experienced in breast screening and diagnosis)
- Radiographer (experienced in breast screening and diagnosis)
- Pathologist (experienced in breast cancer diagnosis)
- Breast Care Nurse
- Specialist with expertise in patient experience, views and empowerment
- Medical Physicist
- Epidemiologist
- Patient Safety Specialist

Depending on the intended scope of certification and their individual competence, some of these individuals may form the on-site team, with others providing input remotely during the overall audit process as necessary.

In addition to the competence criteria described above, the Lead Auditor and audit team members must have a good understanding of the aims, objectives, and requirements of the European QA Scheme.

11. REQUIREMENTS FOR EA AND NABS

Role of accreditation in the scheme

The European QA Scheme is underpinned by accreditation for Conformity Assessment Bodies (CABs) performed by a NAB. EA had been contracted by the DG JRC to deliver the accreditation aspects of the European QA Scheme during the scheme development project. The European QA Scheme does not put requirements for accreditation process as the requirements are described in the standard EN ISO/IEC 17011: 2017 «Conformity assessment. Requirements for accreditation bodies accrediting conformity assessment bodies".

Feasibility evaluation and validation of the European QA Scheme

EA's task in the scheme development project was to evaluate the feasibility of the European QA Scheme concerning certification and accreditation framework and validate the scheme for accreditation purposes based on the description of the scheme and the results of the pilot study. The validation of the European QA Scheme was made according to EA's policy document for scheme validation EA-1/22 A EA Procedure and Criteria for the Evaluation of Conformity Assessment Schemes by EA Accreditation Body Members.

The conclusion of the feasibility evaluation and the validation of the scheme was that the scheme is fit for the purpose. The requirements of the scheme are clearly stated. The fulfilment of the requirements will be audited and certified by accredited CBs. The scheme owner has defined rules to manage and maintain the scheme. The final validation of the scheme will be done when the final versions of the Manual for Breast Cancer Services and the Scheme Owner Manual will be published.

Acceptance of the scheme by EA

The European QA Scheme will be accepted by EA following the procedure of the acceptance when the European Commission is the scheme owner (EA-1/22). The validation results will be reported to the Technical Management Board of EA with respect to scheme acceptance. Final decision on the implementation of the voluntary European QA Scheme will be taken by the General Assembly of EA by the recommendation of the Technical Management Board.

The cooperation with the Commission will continue when EA and NABs will implement the European QA Scheme. The contact points in EA are the Secretariat and the Technical Management Board.

12. IMPLEMENTATION OF THE SCHEME BY BCSs AND CBS

Access to the European QA Scheme
BCS entities and CBs can access and download all relevant information and documents relating to the European QA Scheme from the scheme owner's website (https://healthcare-quality.jrc.ec.europa.eu/ecibc) e.g. the Manual for Breast Cancer Services, the Scheme Owner manual, list of accredited registered CBs and list of certified services.

Access for CBs to upload information regarding the participating BCS entities will be provided at the time of registration of a CB with the European QA Scheme Owner.

Registration
The European QA Scheme Owner (EU Commission/JRC) will maintain the registration process for BCSs and accredited CBs.
To be registered a CB needs to fulfil the eligibility requirements concerning the legality (legal entity) and accreditation. A CB needs to enter agreement/contract with the scheme owner before carrying out audits of BCSs.

To be registered a BCS needs to fulfil the eligibility requirements concerning the legality (legal entity), an agreement with an accredited CB and the scope of certification. A BCS shall be certified by a NAB-accredited certification body before applying for the registration.

CBs that are authorised to certify BCSs for the European QA Scheme are listed at the European QA Scheme Owner's website. A BCS entity must apply for certification to one of these CBs.

Cooperation with the scheme owner
A CB shall appoint a contact person who has technical knowledge and understanding of the European QA Scheme and the IT platform used by the scheme. This person shall be responsible for representing a CB, be the key-user of the scheme IT platform and maintain the contacts with the European QA Scheme Owner.

A CB is responsible for:

- informing the European QA Scheme Owner of all applicant BCS entities;
- providing information to the European QA Scheme Owner and analysing and updating that information;
- updating the European QA Scheme Owner on the status of certified BCSs.

A CB is responsible for publishing or providing, on request, names and scopes of certified BCSs and the validity of certifications.

Helping tools
At the scheme owner's website are available helping tools for BCS entities like a self-assessment tool and a quality indicator calculator (QIC).

The self-assessment tool will help BCSs to determine their preparedness to comply with the requirements of the European QA Scheme and record their progress towards meeting the requirements.

QIC tool has been developed to assist BCSs in identifying the raw data that will need to be recorded in its own database and the calculations that will need to be made using this raw data in order to produce calculated QI data. Using QIC tool helps BCSs to compute indicators in a standardised manner and to measure compliance with the European QA Scheme requirements. BCSs are not obliged to use the QIC to calculate the QIs but may use alternative means of calculation.

The European QA Scheme logo and statement

The European QA Scheme Owner has developed a logo and a statement of conformity that can be used by registered CBs and BCS entities. Accredited CBs and certified BCSs will be eligible to use the European QA Scheme logo and make reference to the European QA Scheme in marketing and publicity material. Full details of the use of the logo and statement of conformity and specific requirements with regard to the form, content and use of the certificate, logo and statement of conformity are given in the Scheme Owner manual.

A BCS entity is not obliged to make use of the logo or statement of conformity of the European QA Scheme but if it does so, the use of the logo and statement of conformity must be consistent with the rules for using the logo and statement.

Confidentiality

In applying for certification, a BCS entity gives permission for the European QA Scheme Owner and a CB to use any information it has provided for internal processes and sanction procedures. All information held by the European QA Scheme Owner is available only to the European QA Scheme Owner and the CB that the BCS entity is working with. Information held by the European QA Scheme Owner will never include patient-specific information or raw data used for calculating quality indicators. The following information may be released to third parties or into the public domain by the European QA Scheme Owner and/or the CB: the name of the BCS entity, addresses of sites as applicable, unique European QA Scheme identifier, status (registered, applicant, certification status and history of certification status), scope of certification.

In registering with the European QA Scheme Owner, a CB gives permission for the European QA Scheme Owner to use information for internal processes and sanction procedures. All information held by the European QA Scheme Owner about the CB is available only to the European QA Scheme Owner and the following information may be released to third parties or into the public domain by the European QA Scheme Owner: the name and address of the CB, contact details, NAB with whom accreditation is held.

EUROPEAN ACCREDITATION

Contact:

EA Secretariat

secretariat@european-accreditation.org

http://www.european-accreditation.org

Date: 13 December 2023

ECIBC