



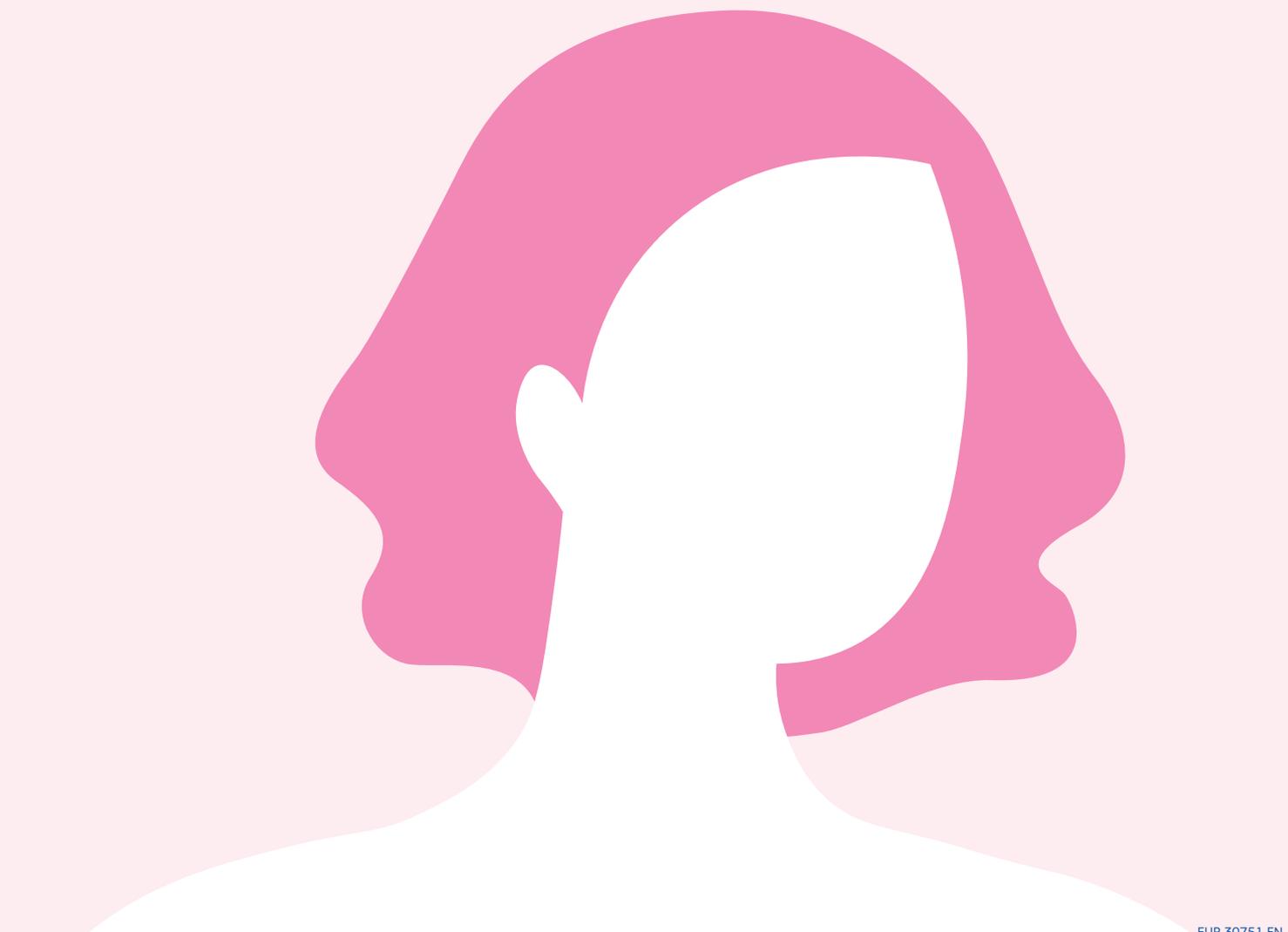
European
Commission



EUROPEAN COMMISSION
INITIATIVE ON BREAST CANCER

Scheme Owner Manual

European Quality Assurance Scheme
for Breast Cancer Services



This publication is a book by the Joint Research Centre (JRC), the European Commission's science and knowledge service. It aims to provide evidence-based scientific support to the European policymaking process. The scientific output expressed does not imply a policy position of the European Commission. Neither the European Commission nor any person acting on behalf of the Commission is responsible for the use that might be made of this publication. For information on the methodology and quality underlying the data used in this publication for which the source is neither Eurostat nor other Commission services, users should contact the referenced source. The designations employed and the presentation of material on the maps do not imply the expression of any opinion whatsoever on the part of the European Union concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.

Contact information

Name: EC Knowledge Centre on Cancer, https://knowledge4policy.ec.europa.eu/cancer_en

Address: European Commission, Joint Research Centre (JRC)
Via Enrico Fermi 2749, TP 127, 21027 Ispra (VA), Italy

E-mail: JRC-CANCER-POLICY-SUPPORT@ec.europa.eu

EU Science Hub

<https://ec.europa.eu/jrc/>

JRC125635

EUR 30751 EN

PDF ISBN 978-92-76-39196-8 ISSN 1831-9424 doi:10.2760/12969

Print ISBN 978-92-76-39195-1 ISSN 1018-5593 doi:10.2760/412838

Luxembourg: Publications Office of the European Union, 2021

© European Union, 2021



The reuse policy of the European Commission is implemented by the Commission Decision 2011/833/EU of 12 December 2011 on the reuse of Commission documents (OJ L 330, 14.12.2011, p. 39). Except otherwise noted, the reuse of this document is authorised under the Creative Commons Attribution 4.0 International (CC BY 4.0) licence (<https://creativecommons.org/licenses/by/4.0/>). This means that reuse is allowed provided appropriate credit is given and any changes are indicated. For any use or reproduction of photos or other material that is not owned by the EU, permission must be sought directly from the copyright holders.

All content © European Union, 2021

How to cite this publication: Annett JANUSCH-ROI, Luciana NEAMȚIU, Luigi CATALIOTTI, Robert MANSEL (coords.), *European Commission Initiative on Breast Cancer – Scheme Owner Manual – European Quality Assurance Scheme for Breast Cancer Services*, EUR 30751 EN, Publications Office of the European Union, Luxembourg, 2021, ISBN 978-92-76-39196-8, doi:10.2760/12969, JRC125635.



EUROPEAN COMMISSION
INITIATIVE ON BREAST CANCER

SCHEME OWNER MANUAL

European Quality Assurance Scheme
for Breast Cancer Services

Working Draft for Pilot
22 February 2021

This version of the European quality assurance scheme is provided for the purposes of piloting. It will be reissued as Version 1.0 after feedback from the pilot organisations and subsequent amendment where necessary.

AUTHORS AND CONTRIBUTORS

THE JRC TEAM COORDINATING THE PROJECT:

Annett JANUSCH-ROI, Luciana NEAMȚIU, Nadya DIMITROVA, Asli ULUTÜRK TEKIN, Elena PARMELLI, Marta GARCIA ESCRIBANO, Luciana STĂNICĂ, Gian Paolo MORGANO, Sazan PAKALIN, and Ciarán NICHOLL.

Former JRC staff: Donata LERDA, Silvia DEANDREA, Anke BRAMESFELD, Liisa PYLKKÄNEN, Nadia VILAHUR CHIARAVIGLIO, Grazia FEDERICO, Crystal FREEMAN, Jesús López ALCALDE, Massimo AMBROSIO, Giulia BOCCHI, Zuleika SAZ-PARKINSON, and Beatriz TORIGHELLI.

THE EUROPEAN COMMISSION INITIATIVE ON BREAST CANCER QUALITY ASSURANCE DEVELOPMENT GROUP (QASDG):

Kathi APOSTOLIDIS, Karen BENN († 2020), Bettina BORISCH, Hilde BOSMANS, Jennifer-Jane BRIDGES, Sara BRUCKER, Augusto CARACENI, Luigi CATALIOTTI, Saskia CLAASSEN, Alexandru ENIU, Andre GRIVEGNEE, Cary KAUFMAN, Thanos KOSMIDIS, Mechthild KRAUSE, Robert MANSEL, Jasna MESARIĆ, Ruben ORDA, Niall PHELAN, Piera POLETTI, Antonio PONTI, David RITCHIE, Vitor RODRIGUES, Elio Giovanni ROSSI, Francesco SARDANELLI, Sabine SIESLING, Giorgio STANTA, Aliko STATHOPOULOU, Tibor TOT, Luzia TRAVADO, Francisco TRESSERRA, Cary VAN LANDSVELD-VERHOEVEN, Chantal VAN ONGEVAL and Mary WOODS.

Former members of the QASDG: Jacques BERNIER, Marie CANTWELL, Daniele GENERALI, Philip POORTMANS, Vanessa KAAB-SANYAL, Charles SHAW, Simone WESSELMANN and Maggie WILCOX.

The Joint Research Centre has had the support for the development of this manual from Jane BEAUMONT within the expert contracts: CT-EX2016D278792-101-1, CT-EX2016D278792-102-1, CT-EX2016D278792-103 and CT-EX2016D278792-104-1.

ACKNOWLEDGEMENTS

Special thanks goes to the JRC Healthcare Quality team's former leader, Donata LERDA, whose commitment and dedication made the launch of the European Commission Initiative on Breast Cancer in 2015 possible. We would also like to acknowledge our other colleagues involved in defining, compiling, preparing and reviewing documents: Manuel FLORENSA-MOLIST, Sandra CALDEIRA, Nicholas NICHOLSON, Emilia RIGGI. Special thanks goes to our current and former colleagues who supported the administrative part of the project: Brigitte WESTRITSCHNIG, Cristina RADI, Jindra KONOPKOVA and Chiara MARGAGLIANO.

We would also like to thank the Directors for all their support during this period: Guy van den EEDE, Elke ANKLAM, and Krzysztof MARUSZEWSKI.

The editorial support and graphical design was completed by NOVACOMM through the framework contract PO/2016-2020/A5 SC.nr.731.

Furthermore, we would like to record our gratitude to the current and former members of [THE EUROPEAN COMMISSION INITIATIVE ON BREAST CANCER GUIDELINES DEVELOPMENT GROUP \(GDG\)](#) Mariangela AUTELITANO, Mireille BROEDERS, Xavier CASTELLS, Edoardo COLZANI, Roberto D'AMICO, Jan DANEŠ, Stephen DUFFY, Patricia FITZPATRICK, Markus FOLLMANN, Livia GIORDANO, Paolo GIORGI ROSSI, Axel GRAEWINGHOLT, Solveig HOFVIND, Lydia IOANNIDOU-MOUZAKA, Susan KNOX, Miranda LANGENDAM, Annette LEBEAU, Helen MCGARRIGLE, Lennarth NYSTRÖM, Elsa PEREZ, Cecily QUINN, Peter RABE, Holger SCHUNEMANN, Alberto TORRESIN, Ruben VAN ENGEN, Sue WARMAN († 2021), Chris DE WOLF, and Kenneth YOUNG for their involvement.

TABLE OF CONTENTS

ABBREVIATIONS AND ACRONYMS	6
1. INTRODUCTION	7
Scope of the European QA scheme: breast cancer care pathway	7
Scope, purpose and organisation of the <i>European Quality Assurance Scheme Owner Manual</i>	10
How the requirements have been developed	11
2. RECOGNITION BY THE EUROPEAN QA SCHEME OF EXISTING (BREAST) CANCER CERTIFICATION SCHEMES OPERATING IN EUROPE	12
Options for owners of existing schemes	12
Recognition for BCSs that are already certified by CBs that are not NAB accredited	14
3. EUROPEAN QA SCHEME OWNER	15
Rights, responsibilities and liabilities of the European QA scheme owner	15
Confidentiality, information use and information release	15
Document control	16
Access to the European QA scheme	16
Management of extraordinary events or circumstances affecting accredited CBs and certified BCS entities	17
Reference documents	18
4. BREAST CANCER SERVICES	19
Eligibility to participate in the European QA scheme	19
Relationship with European QA scheme owner	21
<i>Rights, responsibilities and liabilities of BCS entities</i>	21
Scope of BCS certification	22
<i>Time-limited, stepwise approach to certification</i>	22
Networks	23
Continuity of care	24
Eligibility for certification	25
Requirements for BCS entities (including all outsourced services)	26
Imaging and pathology services	28
Requirements and quality indicators	28
5. CERTIFICATION BODIES	30
Eligibility to provide certification for the European QA scheme	30
Relationship with European QA scheme owner	30
<i>Rights, responsibilities and liabilities of certification bodies</i>	30
Requirements for certification bodies	31
Audit and certification processes	32
<i>Initial application</i>	32
<i>Audit processes</i>	32
Certification process	40
Use and misuse of the European QA scheme certificate, mark and statement of conformity	44
Sanctions	44
6. ANNEXES	45
Annex 1. Recognition by the European QA scheme of existing (breast) cancer certification schemes operating in Europe	45
Annex 2. Steps towards achieving and maintaining certification for BCS entities	49
Annex 3. Time-limited stepwise approach to certification	50
Annex 4. Content of certification agreement/contract	53
Annex 5. Information to be provided by a BCS entity to a CB when applying for certification	54
Annex 6. Example of the contents of an audit report	56
Annex 7. Information to be included on a certificate	57
Annex 8. Use of the European QA scheme certificate, mark and statement of conformity	58
Annex 9. Glossary	59

ABBREVIATIONS AND ACRONYMS

BCS	Breast cancer service
CAB	Conformity assessment body
CB	Certification body
EA	European cooperation for Accreditation
ECIBC	European Commission Initiative on Breast Cancer
IAF	International Accreditation Forum
ID	IAF Informative Document
ISO	International Organisation for Standardisation
ISO/IEC	International Organisation for Standardisation/International Electrotechnical Commission
IT	Information technology
JRC	Joint Research Centre
MD	IAF Mandatory Document
NAB	National accreditation body
QA	Quality assurance
QI	Quality indicator
QIC	Quality indicator calculator

1. INTRODUCTION

The European Quality Assurance Scheme for Breast Cancer Services (the European QA scheme) has been established under the auspices of the European Commission Initiative on Breast Cancer (ECIBC) and defines a common set of quality and safety requirements for breast cancer services (BCSs) ⁽¹⁾ in Europe that should be followed by any entity providing BCSs to women (a 'BCS entity'). It covers all the relevant areas of healthcare provision for breast cancer and all breast cancer care procedures. The requirements are defined, where possible, by considering evidence-based recommendations from high-quality guidelines, best professional practices and relevant legislation. The owner of the European QA scheme is the European Commission (the 'the European QA scheme owner').

SCOPE OF THE EUROPEAN QA SCHEME: BREAST CANCER CARE PATHWAY

The European QA scheme is applicable to all healthcare services (including where a BCS entity is using outsourced services ⁽²⁾) covering the full extent of breast cancer management, from screening to follow-up and end-of-life care.

Prevention of breast cancer is not treated as a separate service within the European QA scheme. However, requirements relating to prevention have been integrated into the overall scheme requirements for breast cancer services ⁽³⁾. In this context, prevention includes the following.

- Primary prevention in the average-risk female population when the intervention is specifically targeted at breast cancer (e.g. physical activity recommendations). However, primary prevention interventions in general may be included as 'service/process requirements' in one or more of the breast cancer procedures (e.g. smoking cessation, alcohol reduction or weight-loss counselling in early diagnosis or treatment settings).
- Secondary prevention in the average-risk female population (i.e. screening mammography).
- Primary and secondary prevention, surveillance, diagnosis (including genetic testing), treatment, rehabilitation and palliative/end-of-life care for breast cancer in women at increased risk of breast cancer.
- Diagnosis and, when indicated, surgical removal of lesions that are pathologically defined as being associated with 'uncertain malignant potential'.
- Other on-malignant breast diseases when implied in a differential diagnosis of cancer.

¹ All aspects of breast cancer management, from screening through to palliative/end-of-life care, are regarded as services, irrespective of the definition of the entity that is providing the particular aspect of breast cancer management. Entities can be legally or geographically separate and can be referred to in different ways. For example: a 'unit' (such as a screening unit that is providing a breast cancer screening service), a 'department' (such as an imaging department that is providing a mammography service); a 'centre' (such as a breast centre that is providing diagnostic and treatment services); or differently described entities providing breast cancer services. See Glossary.

² An outsourced service is where a BCS entity procures a service, via an agreement/contract, from a separate legal entity or healthcare professional rather than carrying out the process or sub-process within its own organisation. The responsibility for ensuring that the outsourced service meets the relevant European QA scheme requirements, and for coordination of care, remains with the BCS entity that is procuring the service.

³ See Manual of the European QA Scheme for Breast Cancer Services (general, screening and rehabilitation).

Male breast cancer and other male breast diseases, such as gynecomastia, do not fall under the scope of this scheme. However, the scheme may be adapted to breast cancer in men in the context of a future project, following the pilot run for female breast cancer.

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, including all related processes and sub-processes. The care pathway describes the health-care chain, and relationships across healthcare sectors, by describing the outcomes of the relevant healthcare processes involved and considering quality targets. In detail, the care pathway aims to:

- present the intervention/processes for which quality should be assured in a structured way;
- present the relevant healthcare sectors involved;
- assign responsibilities for healthcare processes to healthcare providers;
- identify starting points for quality assurance;
- identify quality potential within the breast cancer care pathway.

The care pathway that a patient follows can be described in a flow chart, including specific services, end points, quality targets and quality potentials that are relevant to breast cancer care, and considering the course of the disease and the various services involved.

Although individuals with breast cancer typically go through different processes of care, it is possible to identify a general care pathway that applies to ‘typical’ cases. These care pathways are intended as a guide in the definition of requirements, and are not an exhaustive definition of all possible variations of a general pathway. This is due to the differences in local organisational settings or specific cases of breast cancer that, for one reason or another, need to follow a different pathway. The simplified general care pathway proposed for the European QA scheme is represented in Figure 1.

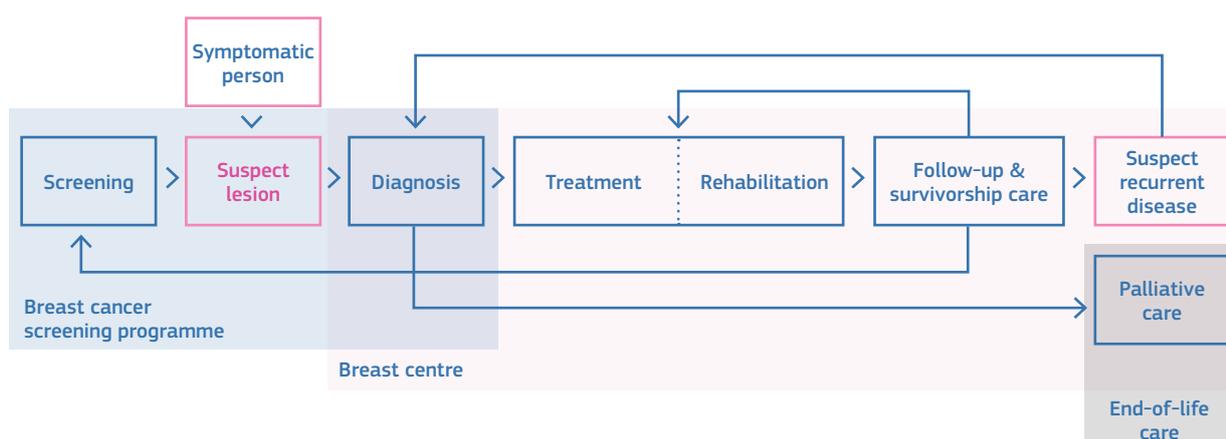


Figure 1. Breast cancer care processes

The main processes of breast cancer care can therefore be identified as: screening, diagnosis, treatment, rehabilitation, follow-up and survivorship care, and palliative care.

During investigation and treatment of the disease, the patient goes through various care processes and related sub-processes along the care pathway, provided by multiple professionals and services. The 'treatment' process itself comprises various sub-processes (e.g. surgery, radiotherapy, systemic therapy, psycho-oncological support, rehabilitation and palliative care), for both the primary treatment of breast cancer and the treatment of recurrent or metastatic disease. In this context, the concept of continuity of care becomes highly relevant. The patient must always be involved and empowered in all processes along the care pathway.

Particular emphasis should be placed on requirements that are at the boundaries of care processes and sub-processes, in order to address continuity of care. One important example of a service that crosses the boundaries of processes and sub-processes is psychosocial support resources, and their availability across all the different processes, as considered appropriate for each case.

The diversity of organisational settings for breast cancer care between countries and regions was highlighted in a survey published by the European Union in 2014 ⁽⁴⁾. It is acknowledged 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 both 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 entities involved in the pathway take responsibility for meeting the requirements for, and coordinating the delivery of, continuity of care to individuals.

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. **A pre-launch pilot will be carried out to determine the feasibility of implementing the detailed requirements described in the *Manual of the European Quality Assurance Scheme for Breast Cancer Services (Manual of the European QA Scheme for Breast Cancer Services)*. BCSs that are participating in this pilot are not required to apply for and achieve accredited certification.**

Certification is the formal recognition by an independent, impartial organisation (certification body) that a BCS and its providers have been audited ⁽⁵⁾ 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 application of all requirements deemed essential from an evidence-based perspective, and that the basic quality of the services will meet the requirements of an EU-wide protocol.

⁴ Lerda D, Deandrea S, Freeman C, Lopez Alcalde J, Neamtiu L, Nicholl C, Nicholson N, Uluturk A, Villanueva Ferragud S. Report of a European survey on the organisation of breast cancer care services. Publications Office of the European Union, 2014, ISBN 978-92-79-37303-9.

⁵ In relation to the European QA scheme, the terms 'audit', 'audited', 'auditing' and 'auditor' should be understood to include those activities that involve inspection, where 'inspection' is the examination of aspects of a BCS and determination of their conformity with the specific requirements or, on the basis of professional judgment, with the general requirements. See also Annex 9: Glossary.

SCOPE, PURPOSE AND ORGANISATION OF THE EUROPEAN QUALITY ASSURANCE SCHEME OWNER MANUAL

The scope and purpose of this manual (the *European QA Scheme Owner Manual*) is to set out the full details of how the European QA scheme is organised, managed and maintained, including the European QA scheme owner's requirements for BCSs, BCS entities and certification bodies (CBs) participating in the scheme.

The manual has 5 main sections, with 9 annexes provided in section 6.

1. Introduction

This section details the background to the European QA scheme; the breast cancer services that are within the scope of the scheme and those that are not currently included; the care processes and sub-processes that constitute the breast cancer care pathway; and the voluntary status of the European QA scheme.

2. Recognition by the European QA scheme of existing (breast) cancer certification schemes operating in Europe

This section details how existing breast cancer care certification schemes can be recognised and accepted within the European QA scheme. It sets out the key factors that need to be considered by existing schemes, CBs and the European QA scheme owner, and proposes different options for addressing these.

3. European QA scheme owner

This section describes the role of the European QA scheme owner in the operation of the European QA scheme, and its responsibilities towards the different participants in the scheme.

4. Breast cancer services

This section provides a detailed explanation of: the BCSs that are eligible to participate in the European QA scheme, including where BCSs are delivered using a network of services; the modules permitted within the scope of the scheme; the responsibilities of BCSs with respect to the European QA scheme owner and ensuring continuity of patient care; scope and eligibility for certification; the approach to certification; and an overview of the requirements that BCSs must meet.

5. Certification bodies

This section provides a detailed description of: CBs' eligibility to be involved in the European QA scheme; CBs' relationship with and responsibilities towards the European QA scheme owner; and the requirements for CBs with respect to the audit and certification processes for BCSs, including the competence of auditors.

6. Annexes

Annexes 1–8 provide further detail on different aspects of the European QA scheme's operation. **Annex 9 is a glossary** providing definitions of specific terms used in the context of the European QA scheme and this manual.

HOW THE REQUIREMENTS HAVE BEEN DEVELOPED

The European QA scheme has 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 ⁽⁶⁾.

The requirements of the QA scheme are described in this *European QA Scheme Owner Manual*, and the *Manual of the European QA Scheme for Breast Cancer Services*.

Additional resources are available to support implementation of the QA scheme:

- a **self-assessment tool** will help BCSs to determine their preparedness to comply with the QA scheme requirements, and identify what they need to do to achieve compliance;
- a **quality indicator calculator (QIC)** will help BCSs to calculate quality indicators (QIs) in a standardised way in order to measure compliance with the QA scheme.

This version of the QA scheme will be used to assess its feasibility in real settings and to pilot the certification process. A final version of the QA scheme will be prepared based on the outcomes obtained during the feasibility checks and pilot run.

To test feasibility in real settings, selected services will use the self-assessment tool to assess their compliance with the requirements. The services will also explain their compliance in a dedicated section of the self-assessment tool, and will calculate the QIs by using the QIC. For the purpose of feasibility checks, the self-assessment tool includes a feedback section for each requirement, as well as a general feedback section. The feedback, as well as the data gathered through the self-assessment tool, will be analysed and will form the basis for updating the requirements.

The BCSs involved in the feasibility checks will test both the self-assessment tool and the QI tool, and will offer feedback in a structured way (using the self-assessment tool for the modules relevant to each participating BCS)

In addition, the certification process will be checked in a pilot run with the support of the European cooperation for Accreditation (EA).

⁶ Development of the European quality assurance scheme for breast cancer services:
<https://healthcare-quality.jrc.ec.europa.eu/discover-ecibc/methodologies/quality-assurance>.

2. RECOGNITION BY THE EUROPEAN QA SCHEME OF EXISTING (BREAST) CANCER CERTIFICATION SCHEMES OPERATING IN EUROPE

The European Quality Assurance Scheme for Breast Cancer Services (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 applicable to healthcare services covering either the full extent or parts of breast cancer care (as described in section 4 of this manual), from screening to follow-up and end-of-life care. There are other well-established quality assurance schemes currently operating in Europe that cover the different processes of breast cancer care. It is important that such schemes, and the breast cancer services working to meet the requirements of those schemes, can be included in the European QA scheme. Some examples of schemes that were operating in Europe in 2015 and that included breast cancer care are provided in a European Commission survey report, published that year: *Review and analysis of external quality assessment of breast cancer services in Europe: supporting information for the development of a European quality assurance scheme for breast cancer services* (⁷). The schemes included in the report are only examples and are not intended as a definitive list.

OPTIONS FOR OWNERS OF EXISTING SCHEMES

In the first instance, existing scheme owners/CBs must meet the following requirements.

- They have established and implemented a national, European or international scheme **prior to** the formal implementation of the European QA scheme.
- They have been appointed, nominated or approved by a national, European or international body to provide a national, European or international BCS certification scheme. For example, eligible breast cancer-specific schemes are referenced in the 2015 European Commission publication *Review and analysis of external quality assessment of breast cancer services in Europe: supporting information for the development of a European quality assurance scheme for breast cancer services* (see footnote 7). There may also be other eligible schemes that are not included in this publication.

⁷ <https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/review-and-analysis-external-quality-assessment-breast-cancer-services-europe-supporting>

- All of the detailed European QA scheme requirements for BCSs set out in the *European QA Scheme Owner Manual* and the *Manual of the European QA Scheme for Breast Cancer Services* have been added to or incorporated into the existing certification scheme, or were already included.
- They have demonstrated compliance with the detailed European QA scheme requirements relevant to CBs, as set out in the *European QA Scheme Owner Manual*.
- They are impartial, competent and responsible for decisions on existing scheme certification.
- They have validated and published their requirements for quality assurance and certification.
- They ensure the confidentiality of BCS information.
- They have procedures for dealing with complaints and appeals.

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 Annex 1.

Each option has two components: 1) recognition and adoption of the European QA scheme requirements; and 2) acceptance by national accreditation body (NAB)-accredited CBs of breast cancer service audits carried out by existing schemes.

1) Recognition and adoption of the European QA scheme requirements

An existing scheme owner can adopt the European QA scheme requirements in addition to and without alteration of existing scheme requirements. Alternatively, an existing scheme owner can map its existing scheme requirements against the European QA scheme requirements, identify and cover any 'gaps', revise the existing scheme, and provide evidence that the revised scheme meets all of the European QA scheme requirements.

In both instances, the European QA scheme owner and the existing scheme owner will then enter into an agreement setting out responsibilities and liabilities for updates and changes to the existing scheme, and for communications about the scheme. Existing scheme owners must comply with the European QA scheme owner's requirements, as set out in the agreement, on: access to information systems; control; monitoring; legal, financial and administrative processes; costs; fees; and rules for privacy.

2) Acceptance by NAB-accredited CBs of breast cancer service audits carried out by existing schemes for the European QA scheme

Existing scheme owners/CBs can either enter into a legally enforceable agreement/contract with NAB-accredited CBs to provide auditing against the European QA scheme requirements, or they can independently seek accreditation from an NAB for certification for the European QA scheme (and their existing scheme if desired). Before entering into any agreement, the NAB-accredited CB must carry out a risk assessment of the existing scheme owner/CB, which will operate as an external resource for the NAB-accredited CB. The assessment will cover impartiality, competence, consistency and independence in auditing activities, and the countries where the NAB-accredited CB intends the existing scheme owner/CB to operate.

When taking into account audits carried out by existing scheme owners/CBs, NAB-accredited CBs must comply with the requirements of ISO/IEC 17065 ⁽⁸⁾. In particular, NAB-accredited CBs should ensure that the existing scheme owner/CB meets the applicable requirements of ISO/IEC 17065 described in Clause 6.2.2 on 'External resources (outsourcing)'. NAB-accredited CBs should also ensure that there is sufficient evidence that audits have been carried out by competent auditors in accordance with the European QA scheme requirements, and that they are confident that the BCSs audited by existing schemes meet the European QA scheme requirements. Where this kind of outsourcing occurs, the NAB-accredited CBs must not contract out the accredited certification review and decision process.

CBs may offer certification services outside the country or region in which they are established. NAB-accredited CBs can provide certification services for the European QA scheme for BCSs in different countries, and may enter into arrangements with a number of different existing scheme owners. They may also enter into arrangements with a number of different 'external resources', such as CBs that are not NAB accredited for certification of existing schemes, provided that all of the requirements detailed in this section (2) of the manual are met. CBs that are not NAB accredited may also provide auditing services for the European QA scheme for BCSs in different countries, and may need to enter into arrangements with one or more NAB-accredited CBs.

RECOGNITION FOR BCSS THAT ARE ALREADY CERTIFIED BY CBS THAT ARE NOT NAB ACCREDITED

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 an NAB-accredited CB.

⁸ Except where specified, the standards referred to are the current versions.

3. EUROPEAN QA SCHEME OWNER

RIGHTS, RESPONSIBILITIES AND LIABILITIES OF THE EUROPEAN QA SCHEME OWNER

The European QA 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 the European cooperation for Accreditation (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.

CONFIDENTIALITY, INFORMATION USE AND INFORMATION RELEASE

In applying for certification, the BCS entity gives permission for the European QA scheme owner and 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 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 (QIs). The European QA scheme owner and/or CB may release the following information about the BCS entity to third parties or into the public domain: name; site addresses (as applicable); unique European QA scheme identifier; status (registered/applicant, certification status and history of certification status); and scope of certification. No other information, particularly in relation to specific requirements and indicators, may be released without the written consent of the BCS entity.

In registering with the European QA scheme owner, the 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 a CB is available only to the European QA scheme owner. The European QA scheme owner may release the following information about the CB to third parties or into the public domain: name; address; contact details; and the NAB with which accreditation is held. No other information may be released without the written consent of the CB.

DOCUMENT CONTROL

The current versions of all documents relating to the European QA scheme can be downloaded free of charge from the European QA scheme owner's website. The original documents are published in English. The published versions are the only documents that can be used for certification purposes.

Documents are identified with a unique document code, date and version number. Any updates to documents are provided to all certification bodies registered with the European QA scheme owner as official communications and published on the European QA scheme owner's website. CBs are responsible for informing applicant and certified BCS entities of any changes. A summary of changes will be included in each updated document. Draft documents will be made available for consultation for 30 days before they are formally published. If no objections are received in that time, the documents will be considered accepted. There will be a lead-in period between the publication of any changes to requirements and the date they come into effect, to enable BCS entities and CBs to make any necessary changes to their processes or systems.

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 European QA scheme owner's website ⁽⁹⁾, including the *Manual of the European QA Scheme for Breast Cancer Services*, a list of certified services, a list of accredited participating CBs, and the *European QA Scheme Owner Manual*. Access to the self-assessment tool for BCS entities will be provided through the European QA scheme owner's website. CBs will be given access to upload information on participating BCS entities when they register with the European QA scheme owner.

⁹ <https://healthcare-quality.jrc.ec.europa.eu/breast-quality-assurance-scheme>

MANAGEMENT OF EXTRAORDINARY EVENTS OR CIRCUMSTANCES AFFECTING ACCREDITED CBS AND CERTIFIED BCS ENTITIES

There may be situations that prevent a CB from carrying out on-site audits of BCSs, or that affect the ability of a certified BCS entity to demonstrate that it meets all of the European QA scheme requirements. Events or circumstances that are beyond the control of the CB or the BCS entity are deemed 'extraordinary events or circumstances'. Examples include: war, strikes, riots, political instability, geopolitical tension, terrorism, crime, pandemics, flooding, earthquakes, malicious computer hacking, and other natural or man-made disasters.

In such situations, CBs and BCS entities must carry out a risk assessment to establish an appropriate course of action in response to extraordinary events, and implement an agreed plan that includes a policy and processes that safeguard business/service continuity, as well as the health and safety of personnel and patients. Alternative approaches to auditing BCSs and the delivery of breast cancer care may need to be adopted. Guidance for NABs, CBs and BCS entities on managing extraordinary events or circumstances with regard to their impact on accreditation, certification, auditing and the delivery of services can be found in the International Accreditation Forum (IAF) publication IAF ID3: *Informative Document for Management of Extraordinary Events and Circumstances Affecting ABs, CABs and Certified Organizations* ⁽¹⁰⁾.

In some instances, it may be necessary for individual BCS entities to postpone or suspend certain activities for a period of time. For example, an individual BCS entity providing a breast cancer service may need to delay chemotherapy during a localised outbreak of a highly infectious disease, as it can suppress the immune system. Such an action would clearly have an impact on the ability of a BCS to comply with some of the QI requirements of the European QA scheme, such as specified timescales between diagnosis and treatment. The period of service postponement or suspension and any associated QIs will need to be highlighted and taken into account during audits of the BCS, particularly with regard to the specified reporting interval. The CB and the BCS will need to agree how to manage the situation, for example, where there is a requirement to report continuous data for the past 12 months but it has not been possible to collect data and calculate QIs continuously due to an extraordinary event.

There may be occasions when extraordinary events or circumstances affect the delivery or operation of the **entire** European QA scheme, such as a pandemic affecting chemotherapy treatment for many BCS entities. To ensure a consistent approach across all BCSs and CBs under such circumstances, it may be necessary for the European QA scheme owner to modify some of the European QA scheme requirements for a specified period of time for all participating BCS entities affected by the extraordinary event. For example, in the case of a pandemic that results in BCSs having to delay chemotherapy for several months, the European QA scheme owner may specify that, once BCSs have reinstated this therapy, they should provide data on QIs

¹⁰ https://www.iaf.nu/upFiles/IAFID32011_Management_of_Extraordinary_Events_or_Circumstances.pdf

(e.g. timescales between diagnosis and treatment) at 6-month intervals instead of 12. Where it is deemed necessary for the European QA scheme owner to modify any of the requirements, guidance will be published on the European QA scheme owner's website.

REFERENCE DOCUMENTS

Reference documents related to the European QA scheme requirements and providing guidance to BCSs seeking to meet them are included in each individual requirement ⁽¹¹⁾, along with other literature references.

¹¹ Detailed requirements are documented in the Manual of the European QA Scheme for Breast Cancer Services.

4. BREAST CANCER SERVICES

ELIGIBILITY TO PARTICIPATE IN THE EUROPEAN QA SCHEME

Any BCS entity is eligible to participate in the scheme subject to the following requirements.

- The organisation responsible for providing the BCS must be a legal entity or a defined part of a legal entity (e.g. a breast centre that is a department within a legal entity such as a hospital).
- The BCS entity must be willing to enter into an agreement/contract with an accredited certification body (CB) ⁽¹²⁾ (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 following modules (in-house or partly outsourced with contracts/agreements):

a. Certification of the entire breast cancer care pathway: BCS that provides all breast-care processes, including outsourced services (screening, breast centre including diagnosis, treatment, rehabilitation, follow-up and survivorship care, and palliative/end-of-life care) (figure 2).

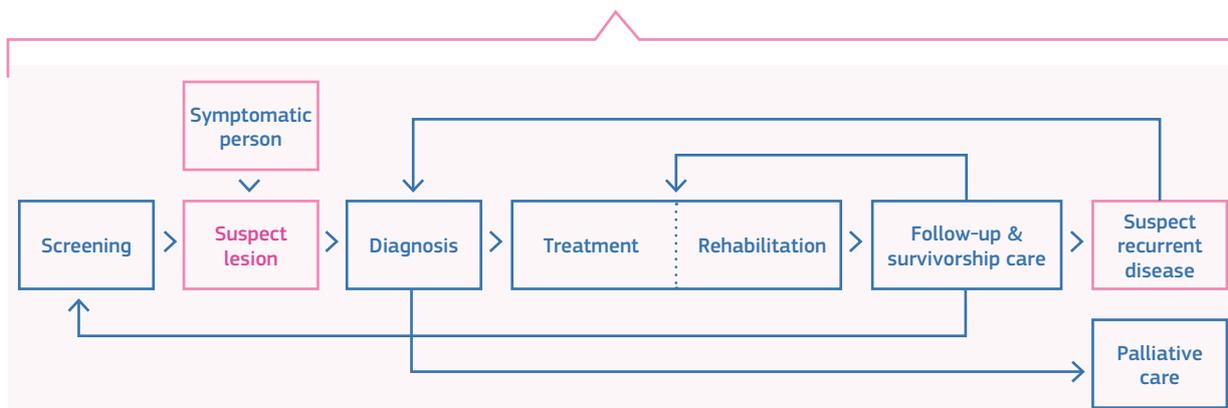


Figure 2. Certification of the entire breast cancer care pathway (a)

¹² A BCS entity may enter into an agreement/contract with an NAB-accredited CB from any country, provided that the CB meets the European QA scheme requirements. This is particularly relevant where there is no such CB within the BCS entity's country.

b. Certification of screening programme, including outsourced services (and, where applicable, diagnosis for referrals following screening) (figure 3).

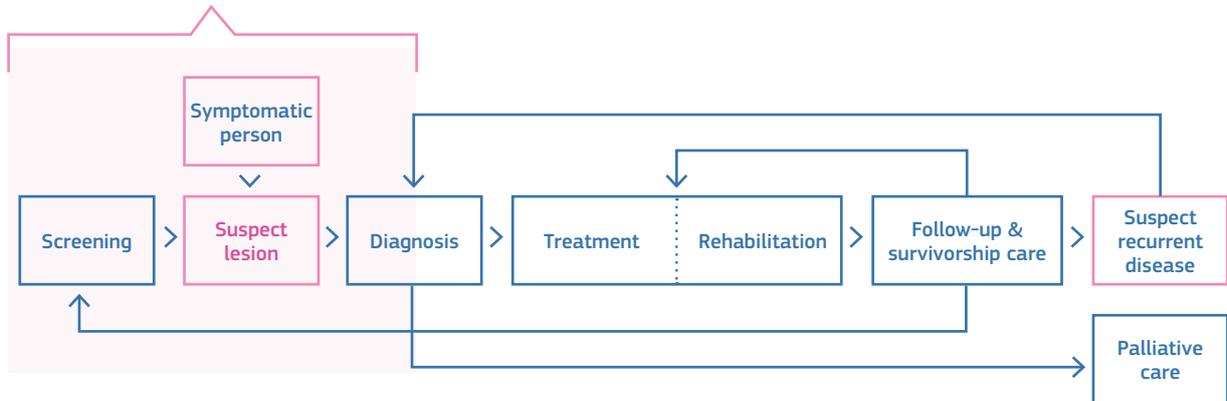


Figure 3. Certification of screening programme (b)

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 and survivorship care, and palliative care (figure 4).

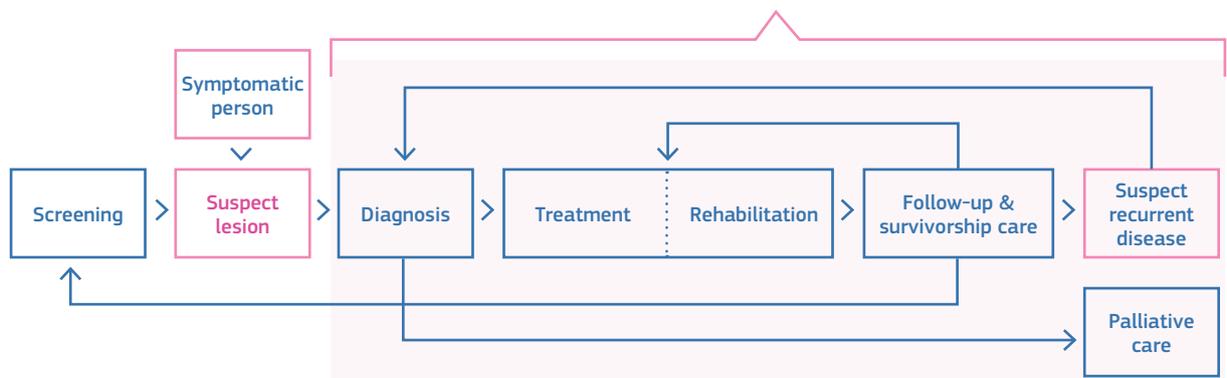


Figure 4. Certification of the breast cancer care pathway without screening (c)

RELATIONSHIP WITH EUROPEAN QA SCHEME OWNER

RIGHTS, RESPONSIBILITIES AND LIABILITIES OF BCS ENTITIES

BCS entities will be required to undergo an independent third-party evaluation by an approved CB (sometimes referred to as a 'conformity assessment body' or 'certifier') to confirm that they meet the applicable European QA scheme requirements, in order to obtain a certificate and be eligible to use the scheme's mark or statement of conformity. It is the responsibility of the BCS entity to demonstrate that its BCS complies with all of the European QA scheme requirements as applicable to the scope of its activities, and as detailed in this manual and the *Manual of the European QA Scheme for Breast Cancer Services*.

- 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 (e.g. imaging, pathology, medical oncology, etc.), the BCS entity must satisfy itself and the accredited CB that the outsourced services meet the European QA scheme requirements (see section 5, under 'Audit days and audit plan' and 'Audit techniques'). In particular, the BCS must ensure that the external resource collects performance data on applicable QIs and transfers the calculated QI data to the BCS at least every 12 months for work carried out in the previous 12 months.

No BCS entity is required by law or regulation to undergo an independent third-party evaluation. However, it should be noted that BCS entities participating in the European QA scheme are required to comply with all relevant national and European legislation.

By applying for certification, BCS entities commit to: comply with European QA scheme requirements at all times; communicate updated information and calculated QI data to the CB at the specified frequency and in the agreed format; pay the fees associated with applying, initial certification and ongoing maintenance of certification; and comply 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.

If there is any evidence of deliberate misuse by the BCS entity of the relationship between the BCS entity and the European QA scheme owner, the relationship between the BCS entity and the CB, and/or any aspect of the European QA scheme, the BCS entity will be excluded from certification for a minimum of 12 months. Any case of misuse will be publicised on the European QA scheme and CB websites.

SCOPE OF BCS CERTIFICATION

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

a. Entire breast cancer care pathway: BCS that provides all breast-care processes, including outsourced services (screening, diagnosis, treatment, rehabilitation, follow-up and survivorship care, and palliative care).

b. Screening programme, including outsourced services.

A screening programme will need to have been operating a screening service for a minimum of two (2) 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 by 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 processes are part of the same legal entity as the screening programme or outsourced services.

c. Breast cancer care pathway without screening, including outsourced services: breast centre, including diagnosis (including symptomatic women and referrals following screening), treatment, rehabilitation, follow-up and survivorship care, and palliative care.

Whichever module a BCS entity chooses, all processes and sub-processes within that module must be included in the scope of certification, even where some of those are outsourced to other entities.

A simple guide to the steps towards certification is provided in Annex 2.

TIME-LIMITED, STEPWISE APPROACH TO CERTIFICATION

The delivery of BCSs throughout Europe is very diverse, and different parts of a BCS (screening, diagnosis, treatment, rehabilitation, follow-up and survivorship care, and palliative care) may have quality assurance arrangements in place that are at 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 ⁽¹³⁾, 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 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 (5) years of initial certification.

Where a legal entity is responsible for all of 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 (5) years.

BCSs that are at an early phase of development will be able to achieve recognition of the quality of the arrangements that are already in place, on the understanding that they are expected to progress from a transitional approach to a full-module approach. Equally, entities that are already further advanced in the provision of BCSs will also be able to achieve recognition of the progress they have made, either in individual processes or the entire breast cancer pathway.

Annex 3 provides further details of a time-limited, stepwise approach to accredited certification.

NETWORKS

Networking and formalised collaboration between healthcare providers is increasingly recognised as an option for delivering cancer services ⁽¹⁴⁾. 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.

¹³ There may be different types of networks delivering breast cancer services and processes within those services (see Glossary in Annex 9).

¹⁴ European Guide on Quality Improvement in Comprehensive Cancer Control, 2017. Eds: Tit Albrecht, Régine Kiasuwa and Marc Van den Bulcke. ISBN: 978-961-7002-28-7.

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 European QA scheme certification, a single legal entity would need to be responsible for ensuring that each entity within the network meets all of 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.

The following are examples of such networks.

- Screening programmes may involve one or more screening services operating as a network in different locations.
- Chemotherapy services provided by oncology departments or centres in different hospitals under the auspices of a national or regional oncology institute.
- Palliative care services delivered through hospices, hospitals, day care facilities and home care.

CONTINUITY OF CARE

A BCS entity seeking certification is responsible for coordinating with other BCS entities to ensure 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 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 of the European QA Scheme for Breast Cancer Services* and with the following symbol. 

Examples of situations in which each BCS entity should coordinate with other BCS entities to ensure that the requirements for continuity of care are met for all patients include the following.

- A screening programme that is delivered through a network of screening services (continuity of care **within a module**).
- A screening programme that includes diagnosis for referrals following screening, where this is delivered within a network of screening services or outsourced under contract to other legal entities that provide diagnostic services (continuity of care **between processes/ sub-processes within a module**).
- A screening service that refers women to one or more breast centres (continuity of care **between modules**).

- Breast centres that accept referrals from one or more screening services (continuity of care **between modules**).
- Breast centres that outsource diagnosis, treatment, rehabilitation, follow-up and survivorship care, and/or palliative care (continuity of care **between processes/sub-processes within a module**).
- Any part of the BCS that is delivered through a network of service providers, including processes that are outsourced under contract to separate legal entities (continuity of care **between processes/sub-processes within a module**). A BCS entity that initially applies for only part of the BCS that it provides (e.g. only screening or only breast centre, when it provides both) (continuity of care **between modules**).

ELIGIBILITY FOR CERTIFICATION

In order to be eligible to apply for certification, the BCS entity must meet the following pre-requisites.

- Eligible to participate in the European QA scheme (see section 4, under ‘Eligibility to participate in the European QA scheme’).
- Self-assessed against the European QA scheme requirements for BCSs.
- Willing to enter into an agreement/contract with the CB and comply with the terms and conditions of business.
- A database that is capable of collecting performance data on applicable QIs and transferring the calculated QI data (including data from external resources) successfully to its selected CB in the agreed format, at least every 12 months. This may be outsourced, for example, to a cancer registry.
- Able to submit calculated data for each applicable QI detailed in the requirements for BCSs (including data from external resources) for all care delivered in the 12 months prior to the certification audit.

Outsourced services that do not provide all of the processes within a module (see ‘Scope of BCS certification’ section above) are not eligible to apply for accredited certification for the European QA scheme as stand-alone activities/entities. However, the different sites at which outsourced services are delivered will be identified on certification documents (see ‘Decision on certification’ in the ‘Certification process’ section, and Annex 7), so that they can be acknowledged as integral parts of the certified service, provided that they continue to demonstrate that they meet all of the relevant European QA scheme requirements. After achieving accredited certification, BCS entities are required to maintain up-to-date records of all outsourced services.

REQUIREMENTS FOR BCS ENTITIES (INCLUDING ALL OUTSOURCED SERVICES)

BCS entities must meet the European QA scheme requirements (including both structural and process/outcome indicators) for all relevant processes in order to achieve and maintain accredited certification. The methods used to select and develop the European QA scheme requirements are fully described in a European Commission publication⁽¹⁵⁾ and in the *Manual of the European QA Scheme for Breast Cancer Services*, which also sets out the requirements for BCSs in full. A web-based self-assessment tool has been developed and will be made available to BCSs, so that they can record their progress towards meeting the requirements.

The requirements against which service quality will be judged in the certification process are categorised as follows:

- General – including organisation and management (cross-sectional);
- Screening;
- Diagnosis;
- Treatment;
- Rehabilitation;
- Follow-up and survivorship care;
- Palliative (end-of-life care).

Each requirement is then categorised according to its relevance to one (or more) of the following domains:

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

BCS entities must comply with relevant European and national legislation. Although certification is not a legal compliance audit, CBs will seek evidence that arrangements are in place to ensure that:

- management and employees understand and comply with all legal requirements relevant to their responsibilities;
- all documentation, including procedures, work instructions, contracts and agreements meet legal requirements and are respected;
- any issues of legal non-compliance raised by regulatory authorities or other interested parties are addressed and resolved in a timely manner.

¹⁵ European Commission Initiative on Breast Cancer (ECIBC): methods of the voluntary European Quality Assurance Scheme for Breast Cancer Services. Selection of requirements and indicators: https://healthcare-quality.jrc.ec.europa.eu/sites/default/files/methodologies%20docs/ECIBC_Methods_QA_scheme.pdf.

In the event of a perceived conflict between the European QA scheme requirements and legal requirements, the latter take precedence.

The BCS entity must clearly describe the services that are provided and that are to be included in the certification.

The BCS entity must have a management and leadership structure with identified roles, responsibilities, authorities and interrelationships.

The BCS entity must also have a management system that is capable of meeting the European QA scheme requirements consistently, and that integrates and monitors all of its processes. The BCS entity must have policies and procedures for:

- documentation;
- control of documents;
- administrative, medical and management records, and control of those records ⁽¹⁶⁾;
- internal and external audits;
- corrective and preventive actions;
- management review;
- confidentiality and privacy;
- impartiality and integrity;
- outsourcing (e.g. how the BCS entity will satisfy itself that the organisations providing the outsourced services meet the European QA scheme requirements);
- handling of complaints;
- patient involvement, including feedback;
- patient safety;
- reports on QI results;
- quality improvement.

A BCS entity that provides evidence that it has established and maintains a management system that meets the requirements of ISO 9001 or EN 15224:2016 is accepted as meeting the European QA scheme management system requirements.

¹⁶Including (but not limited to) records of: communications and meetings; service agreements/contracts with external providers; staff qualifications; staff training and continuing competency; workbooks or worksheets; instrument printouts, and retained data and information; examination results and reports; instrument maintenance records, including internal and external calibration records; quality indicator records; incident records and action taken; accident records and action taken; risk management records; internal and external audits; non-conformities identified; corrective and preventative actions; complaints; records of quality improvement activities; records of management reviews; feedback from patients and other service users.

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 ways of demonstrating compliance;

- Accreditation of imaging and pathology services for a specified scope related to BCSs, by an NAB that is part of a mutual recognition agreement between accreditation bodies (17) (18) (for ISO 15189 or ISO standards such as ISO 17020 and ISO 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 overall BCS.

OR

- Audit and certification of screening and/or diagnosis services by a CB accredited by an NAB that is part of a mutual recognition agreement between accreditation bodies, to a specific quality-management system standard (such as ISO 9001 or equivalent), and against relevant European QA scheme requirements for imaging and pathology for BCSs (including QIs).

CBs must adopt a 'presumption of conformity' for imaging and pathology services that are accredited by an NAB that is part of a mutual recognition agreement between accreditation bodies. 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.

¹⁷ <https://european-accreditation.org/mutual-recognition/the-ea-mla/>

¹⁸ It is anticipated that EA will include the European QA scheme in the ISO 15189 peer evaluation process for NABs.

REQUIREMENTS AND QUALITY INDICATORS

Requirements and quality indicators (QIs), including both structural and process/outcome indicators, are an important tool to assist BCSs in measuring, monitoring and improving their performance. These have been developed by the Quality Assurance Scheme Development Group using a rigorous and extensive process, which is described fully in the *Manual of the European QA Scheme for Breast Cancer Services*. As part of the certification process, compliance with European QA scheme requirements will be verified using these QIs, alongside other audit techniques (see section 5, under 'Audit techniques').

Quantitative measurement of compliance with a requirement is expressed using an indicator that has a clearly defined numerator and denominator. A web-based quality indicator calculator (QIC) tool has been developed to assist BCSs in identifying the raw data that will need to be recorded in their own databases, and the calculations that will need to be made using that data in order to produce calculated QI data. BCSs are not obliged to use the QIC to calculate the QIs and may use alternative means. Raw data and individual patient information is not normally shared with CBs or the scheme owner but may be requested for data verification. For example, during audits, usually only calculated indicators should be sent to the CB performing the audit, and the QIC can be a useful means of doing this. The *Manual of the European QA Scheme for Breast Cancer Services* contains a complete list of indicators to be calculated by the BCS, either manually or using the QIC tool. Compliance with requirements that do not involve quantitative measurement is expressed using a criterion with a dichotomous (yes/no) response. For both the criteria and the indicators, the desired level of fulfilment is expressed as the 'Norm'.

BCS entities are required to measure their performance against the QIs (including the performance of external resources), 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. **Please note that a pre-launch pilot will be carried out to determine the feasibility of implementing the detailed requirements described in the *Manual of the European QA Scheme for Breast Cancer Services*. BCSs that are participating in this pilot are not required to apply the timelines specified for data collection (i.e. data collected over a period of time shorter than 12 months is acceptable for pilot purposes).**

Where a BCS does not meet the acceptable performance target for any QI, the BCS entity must inform the CB of the remedial actions being taken and the timescales for completion. **Sustained non-conformity** with any QI may result in sanctions (see 'Sanctions' in 5) being applied by the CB. Special arrangements for performance measurements against QIs may be necessary to take account of extraordinary events or circumstances (See section 3).

5. CERTIFICATION BODIES

ELIGIBILITY TO PROVIDE CERTIFICATION FOR THE EUROPEAN QA SCHEME

A CB must: be a legal entity (or part of a legal entity) ⁽¹⁹⁾; be accredited; and must have registered and entered into an agreement/contract with the European QA scheme owner before it can carry out audits of BCSs. Registration with the European QA scheme owner is initiated by making a formal written request to enter into an agreement/contract ⁽²⁰⁾. To be accepted by the European QA scheme owner, and before granting certification to any BCS, the CB must be accredited by an NAB to provide certification for the European QA scheme against the requirements of ISO/IEC 17065 ⁽²¹⁾, and must also have demonstrated that it complies with the detailed requirements set out in this manual ⁽²²⁾. The NAB must be a signatory to the European cooperation for Accreditation (EA) multilateral recognition agreement ⁽²³⁾ for accreditation to ISO/IEC 17065. The CB must provide details of where its current accreditation status, scope of accreditation, and locations covered by its accreditation can be verified (e.g. on the website of the NAB with which it is accredited).

RELATIONSHIP WITH EUROPEAN QA SCHEME OWNER

RIGHTS, RESPONSIBILITIES AND LIABILITIES OF CERTIFICATION BODIES

- By registering with the European QA scheme owner, a CB commits to meet all applicable European QA scheme requirements (e.g. applying any changes to the European QA scheme requirements within a specified timescale) and to comply with the terms and conditions for use of the European QA scheme certificate, mark and statement of conformity.
- A CB will provide certification services for the European QA scheme only while it has a valid agreement from the European QA scheme owner to do so.
- A CB must achieve and maintain accreditation to provide certification for the European QA scheme from the relevant NAB. It is also responsible for demonstrating to the NAB that it complies with all of the ISO/IEC 17065 and European QA scheme requirements that apply to the scope of its activities, and as detailed in this manual.
- 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 BCSs; reporting

¹⁹ A governmental certification body is considered to be a legal entity on the basis of its governmental status.

²⁰ Contact details can be found on the European QA scheme owner's website.

²¹ ISO/IEC 17065: Conformity assessment – requirements for bodies certifying products, processes and services.

²² A certification body that has applied for accreditation to certifying BCSs for the European QA scheme requirements may, however, carry out audits of BCSs before being granted accreditation.

²³ <https://european-accreditation.org/mutual-recognition/the-ea-mla/>

incidents of misuse of the European QA scheme certificate, mark and statement of conformity to the European QA scheme owner; and collecting any fees associated with the certification process.

- A CB is responsible for publishing or providing, on request, the names and scope of certified BCSs, and the validity of certifications.
- The European QA scheme permits outsourcing of auditing activities by a CB. Where a CB is working with an existing scheme owner or owners (see section 2) as an external resource, the CB is responsible for informing the European QA scheme owner, in writing, of the agreements it has in place for outsourcing any auditing activities.
- A CB that outsources any auditing activities is responsible for demonstrating that the external resource has been assessed and subsequently monitored, and meets the applicable requirements for the outsourced activities.
- A CB is responsible for obtaining a BCS's agreement to use external resources before those external resources are deployed.
- Where a CB's scope of accreditation does not cover the full range of BCSs (e.g. screening services only), the CB must ensure that the limits and scope of the accreditation are clear and publicly available, and that certification services outside the scope of the accreditation are distinguished from those that are accredited.
- A CB must inform the European QA scheme owner in writing about changes in its accreditation status (e.g. suspension or withdrawal) within three (3) working days of the change in status, detailing its action plans and the circumstances leading to this.
- A CB must inform the European QA scheme owner within three (3) working days when it suspends or withdraws a certification held by a BCS entity, and when it reinstates a suspended or withdrawn certification.
- CBs must enter into a legally enforceable agreement/contract with client BCS entities that includes the content set out in Annex 4, and that takes account of the responsibilities of both the CB and the client.

REQUIREMENTS FOR CERTIFICATION BODIES

A CB must be accepted by the European QA scheme owner as described under 'Eligibility to provide certification for the European QA scheme' (above).

A CB must appoint a contact person who has technical knowledge and understanding of the European QA scheme and the IT platform that the scheme uses. This person will be responsible for representing a CB, being the key user of the scheme's IT platform, and maintaining contact with the European QA scheme owner.

A CB and any collaborating organisation, such as an existing scheme owner (see section 2), must carry out their 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 that arise from its activities and relationships (including those of its staff).

CBs and any collaborating organisation, such as an existing scheme owner (see section 2), must carry out their certification activities in accordance with the audit and certification processes described in its manual. All records relating to activities carried out for the European QA scheme must be kept for a period of time that is compliant with national legal requirements and, where relevant, NAB requirements.

CBs are required to manage the competence of personnel involved in the certification process in accordance with the requirements of ISO 17065, clause 6.1.2.

AUDIT AND CERTIFICATION PROCESSES

INITIAL APPLICATION

CBs that are authorised to certify BCSs for the European QA scheme are listed on the European QA scheme website ⁽²⁴⁾. A BCS entity must apply for certification to one of these CBs. Please note that CBs may offer certification services outside the country or region in which they are established. CBs will make available:

- online application facilities that include the detailed information listed in Annex 5;
- certification agreements/contracts that include the responsibilities of both the CB and BCS entity, as well as the terms and conditions of the agreement/contract in accordance with the details listed in Annex 4.

Information about the certification processes, rules and procedures will be maintained and made available by each CB.

At the time of application, BCS entities are required to submit to their selected CB calculated data on their performance measures for all relevant QIs (including those related to external partners), using the standard agreed process and format ⁽²⁵⁾.

AUDIT PROCESSES

Audit and certification processes can be used by the BCS both as an educational opportunity and to improve its performance. The processes will include the following steps by the CB:

- initial review of the application;
- contract review;
- document review;

²⁴ There is a list of CBs on the European QA scheme website: <https://healthcare-quality.jrc.ec.europa.eu/breast-quality-assurance-scheme>.

²⁵ <https://healthcare-quality.jrc.ec.europa.eu/breast-quality-assurance-scheme>.

- agreement of the intended scope of certification;
- appointment of the audit team;
- definition of the audit approach;
- notification of the number of audit days (both on- and off-site) and the audit plan;
- off-site audit activities (e.g. examination of written and/or electronic information, telephone discussions/interviews) to evaluate the BCS ⁽²⁶⁾;
- on-site visits to evaluate the BCS;
- report of visit;
- review of corrective actions (if any);
- decision on certification;
- granting of certification.

The purpose of the audit is to verify the BCS's compliance with the European QA scheme requirements, including specific QIs.

Composition of audit team

The composition of the overall audit team (including both on- and off-site auditors), and the required competences, will largely be determined by the scope of activities for which the BCS entity is seeking certification. In all cases, a lead auditor will be appointed to coordinate the audit process.

The following competences will be required within the overall audit team for each of the breast cancer care processes.

Screening

Knowledge, understanding and experience of:

- providing a breast cancer screening programme;
- screening performance evaluation;
- imaging modalities used to assess suspicious findings in first-level screening mammography (additional mammographic views or tomosynthesis, ultrasound, etc.);
- percutaneous breast biopsy;
- patient safety;
- the patient experience of breast cancer screening;
- the European QA scheme requirements;
- the relationships between screening and other breast cancer care processes.

²⁶ Where CBs and any collaborating organisation, such as an existing scheme owner, use ICT for off-site audit activities, they must ensure that they comply with the IAF publication IAF MD4: IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes.

Diagnosis

Knowledge, understanding and experience of:

- diagnostic imaging;
- percutaneous breast biopsy;
- cytology and histopathology of breast lesions;
- patient safety;
- breast cancer nursing care;
- the patient experience of breast cancer diagnosis;
- the European QA scheme requirements;
- the relationships between diagnosis and other breast cancer care processes.

Treatment

Knowledge, understanding and experience of:

- image-guided pre-surgical localisation of breast lesions;
- breast cancer surgery;
- radiation therapy;
- medical oncology;
- clinical genetics;
- nuclear medicine;
- patient safety;
- breast cancer nursing care;
- the patient experience of breast cancer treatment;
- the European QA scheme requirements;
- the relationships between treatment and other breast cancer care processes.

Rehabilitation

Knowledge, understanding and experience of:

- physiotherapy;
- patient safety;
- breast cancer nursing care;
- the patient experience of breast cancer rehabilitation;
- the European QA scheme requirements;
- the relationships between rehabilitation and other breast cancer care processes.

Follow-up and survivorship care

Knowledge, understanding and experience of:

- follow-up, including periodical imaging surveillance or re-inclusion in a screening programme;
- survivorship care;
- patient safety;
- breast cancer nursing care;
- the patient experience of breast cancer follow-up and survivorship care;
- the European QA scheme requirements;
- the relationships between follow-up and survivorship care and other breast cancer care processes.

Palliative/end-of-life care

Knowledge and understanding of:

- palliative/end-of-life care;
- the patient and relatives' experience of palliative/end-of-life care;
- the European QA scheme requirements;
- the relationships between palliative/end-of-life care and other breast cancer care processes.

Where a BCS entity provides integrated or overlapping breast cancer care processes (e.g. both screening and diagnostic processes), the audit team will need to include the knowledge, understanding and experience requirements for each process.

In addition, the lead auditor and audit team members must have a good understanding of the aims, objectives and requirements of the European QA scheme.

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 ⁽²⁷⁾. When deciding on the composition of an audit team for a BCS audit, a CB is expected to consider these qualified and practising specialists for 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.

²⁷ See GEN-20 Training in the Manual of the European QA Scheme for Breast Cancer Services: <https://healthcare-quality.jrc.ec.europa.eu/breast-quality-assurance-scheme/manuals>.

As a minimum, proof of professional competence, such as a revalidation certificate or similar, must be available for each auditor. Depending on the intended scope of certification and their individual competence, some of these individuals may also form the on-site team, with others providing input remotely during the overall audit process as necessary. In addition to their professional competence, CBs are required to provide evidence that auditors demonstrate: integrity and independence; fairness; due professional care; confidentiality; an evidence- and risk-based approach; acceptable behaviour during audits; good auditing techniques; and appropriate technical knowledge.

A CB will be expected to record the rationale and process for appointing the audit team for each audit undertaken. A BCS entity will be informed of the proposed audit team in advance and will be given the opportunity to put forward any valid objections it may have with regard to individual team members. During the certification cycle, the CB may decide to vary the composition of the on-site team of auditors by appointing individuals from the overall audit team in rotation.

Audit days and audit plan

The number of person days required to audit the BCS will depend on: the scope of activities; the size and complexity of the BCS; the number and geographical location of sites where the BCS is provided; any outsourcing being undertaken; the extent of compliance with the European QA scheme requirements; and any other aspect of the BCS that is relevant to the provision of breast cancer care.

Information provided by the applicant BCS in the online application will be used to determine the extent of the audit. This would usually be done following discussion with the BCS. A CB must be able to provide an acceptable rationale for the number of person days for every audit activity. In advance of any audit activity being undertaken, a CB will provide information to a BCS entity about: the number of person days that will be needed; the proposed plan for carrying out the audit; any key members of staff needed during on-site visits; and any processes, services, meetings, documents, results and reports that the BCS entity will need to make available to the audit team, including information from remote sites, outsourced services and other collaborators where relevant.

As far as possible, different auditors will be assigned to audit different aspects of the BCS's activities both remotely and through on-site visits, in order to avoid duplication of effort. The CB will be responsible for ensuring that each auditor is aware of the extent and limit of their assigned role.

For on-site visits, it is the BCS entity's responsibility to ensure that all members of the audit team are given access to all of the activities, areas and staff indicated in the audit plan. A team of auditors would normally attend the on-site audit at the same time, but, depending on circumstances, it may be necessary for different audit team members to attend on separate dates or at different times.

During the pilot process only, the number of person days for each BCS audit will be as follows.

a. Screening: 1–3 person days for on-site auditing plus 1–2 person-days for remote auditing.

b. Breast centres (including palliative/end-of-life care): 1–3 person days for on-site auditing plus 1–2 person days for remote auditing.

c. Both screening and breast centres (including palliative/end-of-life care): 2–5 person days for on-site auditing plus 2–3 person-days for remote auditing.

The number of on-site and remote person days will be reviewed following feedback from the pilot process. Where CBs and any collaborating organisation, such as an existing scheme owner, use ICT for remote auditing, they must ensure that they comply with IAF MD4: *IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes*.

Audit techniques

The main purpose of a certification audit is to confirm that the BCS meets all of the applicable European QA scheme requirements, as part of the wider BCS improvement process. Auditors will therefore be seeking evidence that demonstrates that the BCS complies with all of the applicable requirements. Exceptional and excellent practices will be highlighted.

The audit techniques used by CBs to determine whether a BCS meets the European QA scheme requirements will include, but are not limited to:

- examining documents, records and reports;
- on-site visits (preparatory, initial and follow-up audits), including remote sites where applicable;
- observing service delivery;
- interviewing staff;
- interacting with patient representatives, where applicable;
- observing multidisciplinary meetings.

During the audit process CBs will examine:

- the design of the BCS, including risk assessment, patient safety, preventative planning and contingency arrangements;
- functions, processes, sites and outputs;
- the management system;
- outsourced activities (acceptance of accredited services, certified services, etc.);
- documentation, processes, procedures, records and reports;
- arrangements for measuring performance against European QA scheme QIs;
- arrangements for submitting and updating calculated QI data to the CB;
- resources (personnel, facilities, equipment and technology);
- patient experience, including any feedback from patients;
- other information as necessary.

Many of the European QA scheme requirements detailed in the *Manual of the European QA Scheme for Breast Cancer Services* include guidance on where evidence of compliance might be found ('Data source'). However, other sources of evidence may also be acceptable. Checklists of audit activities for auditors are available as downloadable documents from the ECIBC website⁽²⁸⁾.

Where feasible, auditors may carry out some audit activities remotely before conducting an on-site audit, including the following.

- Examining documents, records and reports relating to:
 - the design of the BCS, including risk assessment, preventive planning and contingency arrangements;
 - functions, processes, sites and outputs;
 - the management system;
 - patient safety measures;
 - outsourced activities (acceptance of accredited services, certified services, etc.);
 - arrangements for measuring performance against the European QA scheme QIs;
 - arrangements for submitting and updating calculated QI data to the CB;
 - resources (personnel, facilities, equipment and technology);
 - patient involvement processes.

- Conduct telephone interviews with staff.

²⁸ <https://healthcare-quality.jrc.ec.europa.eu/breast-quality-assurance-scheme>

During an on-site audit, the CB's on-site 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 on any queries arising from the remote audit activities carried out before the on-site visit;
- observe 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.

The CB will provide a written report on the findings of the audit process no later than 15 working days after the on-site audit is concluded. The report will address all of the applicable European QA scheme requirements and any contractual requirements specified by the European QA scheme owner or CB. An example of the content of an audit report can be found in Annex 6.

The audit report will highlight exceptional, excellent and exemplary practices within the breast cancer service, as well as any improvements to the processes and sub-processes that have been introduced.

Where the audit team identifies that the BCS is not conforming to all of the European QA scheme requirements, non-conformities will be raised in reference to the specific requirement and categorised according to the nature of the non-conformity. Where a non-conformity arises due to regional or national legislation, the regional or national legislation will normally take precedence. For example, if national or regional legislation specifies that women aged 40–75 must be invited for mammography screening, this must be implemented, rather than the lower European QA scheme requirement of 50–69 ⁽²⁹⁾. However if the regional or national legislation specifies a lower acceptable limit than the European QA scheme, the European QA scheme takes precedence. For example, if national or regional legislation specifies that only women aged 55–65 will be invited for mammography screening, this would be a non-conformity, because the European QA scheme requirement is that women aged 50–69 must be invited for mammography screening. An action plan describing the actions that the BCS entity will take to address non-conformities will be agreed and a time frame set for the actions to be completed.

Exceptional practices, non-conformities and recommended actions

Exceptional practices identified by auditors may include examples from any of the processes or sub-processes where the BCS is delivering, for example, outstanding care to patients, excellent training and support for staff, first-class facilities or any other outstanding aspect of the service. Improvements to processes and sub-processes are also included in this reporting category.

Non-conformities will be categorised as follows:

²⁹ Requirement SCR-4 in the Manual of the European QA Scheme for Breast Cancer Services.

- **Minor:** any non-conformity that does not in itself adversely affect the performance of the overall service. It is expected that minor non-conformities **will normally be resolved within four (4) weeks** of the audit and the BCS entity will provide documentary evidence of the actions taken.
- **Major:** any non-conformity that could result in failure or reduced operability of the service, and that could put patients at risk. Depending on the specific nature of the non-conformity, any actions taken must **normally be resolved within three (3) months** of the audit and **will normally be verified through an additional visit to the BCS entity**. In some circumstances, it may be necessary to require actions to be taken within a shorter timescale, or to suspend or partially suspend certification until the non-conformities have been adequately addressed.
- **Contractual.** Any non-conformity relating to contractual requirements of the European QA scheme owner and/or the CB.

In addition, a CB may identify recommended actions for the BCS entity that do not in themselves constitute non-conformity with the European QA scheme requirements, but that could lead to improvements in the BCS if implemented.

CERTIFICATION PROCESS

Decision on certification

After confirmation by members of the audit team that **all non-conformities have been satisfactorily addressed and resolved**, the report and other information relating to the certification process will be reviewed by an authorised, competent and independent decision maker within a CB. The BCS will be granted certification for a defined scope of activities if the decision maker is satisfied that there is sufficient evidence that: the BCS has been audited by a competent audit team; the audit was comprehensive enough to be confident that the BCS complies with the European QA scheme requirements and any certification requirements; and that **all identified non-conformities are confirmed to have been addressed and resolved**. A certificate detailing the certified services will be issued, and must reflect the scope of certification and the sites/legal entities covered by the certification (where applicable).

Every site covered by the certification must be mentioned on the main certificate, and every site is entitled to get its own sub-certificate. Where certification documents are issued for different sites, they must make clear:

- that the BCS certification is for the organisation as a whole;
- which specific activities performed by that specific site/legal entity are covered by the certification;
- that there is a traceable link to the main certificate (e.g. a code);
- that the validity of the sub-certificate depends on the validity of the main certificate.

Under no circumstances can certification documents be issued solely in the name of a site/legal entity, or suggest that the service delivered by this site/legal entity is itself certified. Nor may the certification documents include a declaration of conformity with the European QA scheme for the individual site processes/activities. The BCS certified is the whole service offered by the **overall** BCS entity.

The information to be included on a certificate is given in Annex 7. The CB will also give the BCS entity access to the mark that may be used on stationery, marketing and publicity material, pricing quotes, reports, certificates, websites and brochures.

Within four (4) weeks after the certification decision, the CB shall provide a copy of the certificate to the European QA scheme owner, along with the BCS's calculated QI data for QI performance measures in the agreed format, and will continue to update this data at the agreed frequency.

Complaints and appeals against certification decision

Where a BCS entity is dissatisfied with any aspect of a CB's service (except a decision on certification), it should submit a complaint using the CB's documented process. If the BCS entity does not consider the CB to have resolved its complaint satisfactorily, it can refer the complaint to the NAB with which the CB holds accreditation. A complaint about the detailed content of the European QA scheme should be made to the European QA scheme owner.

Where a BCS entity is dissatisfied with a CB's decision on certification, it should submit an appeal using the CB's documented process. A BCS can only make an appeal in relation to a certification decision that affects it directly. If the BCS entity does not consider the CB to have resolved its appeal satisfactorily, it can refer the appeal to the NAB with which the CB holds accreditation.

Scope of certification

The BCS can be certified for the European QA scheme requirements for modules:

- a. **Entire breast cancer care pathway:** all breast-care processes, including outsourced services (screening, diagnosis, treatment, rehabilitation, follow-up and survivorship care, and palliative care).
- b. **Screening programme, including outsourced services** (and, where applicable, diagnosis for referrals following screening).
- c. **Breast cancer care pathway without screening, including outsourced services:** breast centre, including diagnosis (including symptomatic women and referrals following screening), treatment, rehabilitation, follow-up and survivorship care, and palliative care.

Granting and maintenance of certification, and validity of certificate

A certificate is valid for a period of three (3) years, subject to a BCS continuing to meet the European QA scheme requirements and conditions for certification. BCSs can maintain certification by undergoing surveillance and recertification audit visits, and by continuing to meet the European QA scheme requirements and conditions for certification. In addition, a BCS entity must maintain up-to-date records of key personnel and workforce, outsourced services, and remote sites and premises, and must inform the CB within four (4) weeks of any significant changes. Significant changes are any alterations that have the potential to have an adverse effect on the provision of breast cancer care or compliance with the European QA scheme requirements. This includes, but is not limited to, changes to outsourced services, replacement of key personnel, reduction in workforce numbers and structural changes to facilities.

Surveillance and recertification frequency and procedures

In order to maintain certification, certified BCSs will undergo surveillance by, and in accordance with the procedures of, their accredited CB at least once every 12 months. The BCS entity will be required to provide:

- information on any changes that have occurred, including changes to the organisational structure, management, management system, staff, facilities, equipment, calibration, processes, outsourced services, outcome of internal or external audits, complaints investigated and patient satisfaction;
- details of QI performance measures over the preceding 12 months.

The surveillance may not necessarily cover all of the elements examined in the initial audit, but auditors will sample selected elements of the service to confirm continuing compliance with the European QA scheme requirements. All relevant QIs will be reviewed annually. The surveillance plan will take into account: improvements and exceptional practices that have been identified; the nature of any non-conformities raised during the previous audits; any changes that have taken place in the BCS since the previous audit; compliance with QIs; and any complaints received about the BCS. Certification will only be valid if the BCS continues to meet the specified European QA scheme requirements and conditions for certification.

The first surveillance activity will take place within 12 months of the initial audit (not the certification decision), and recertification activities will take place within a time frame that ensures that the audit process is completed before the certificate expires, in accordance with the procedures of the accredited CBs.

All of the European QA scheme requirements will be reaudited at least once in the three (3) year certification period. Following successful demonstration that the BCS meets all of the relevant European QA scheme requirements, the CB will issue a further certificate that is valid for a period of three (3) years, subject to the BCS continuing to meet the European QA scheme requirements and conditions for certification during that period.

Extension of certification scope

Where a BCS has been certified for a limited scope of activities (see the 'Scope of BCS certification' section), the BCS entity may apply to the relevant CB to extend the scope of its certified activities, using the CB's application form and process. The process for extending the scope is normally similar to the initial process of applying for certification, with the audit focusing on the additional scope of activities. Scope extension audits may also be conducted in conjunction with surveillance or recertification audits.

Reduction of certification scope

If circumstances change and a BCS entity no longer provides certain elements of the service (e.g. where a certified screening service and breast centre are separated into independent legal entities), it may wish to reduce the scope of its certification. It may do so by applying to the relevant CB, provided that the scope is still in accordance with the European QA scheme, as detailed in the 'Scope of BCS certification' section.

Withdrawal of certification

A BCS entity may withdraw from certification for the European QA scheme by giving the relevant CB formal written notice of its intention to withdraw. The BCS entity must also inform the European QA scheme owner of its withdrawal from certification.

Suspension of certification

If a BCS entity is unable to demonstrate that it meets the European QA scheme requirements and conditions for certification within the specified time frames, a CB may suspend certification for a specified period of time, normally not exceeding six (6) months. Sustained non-conformity in achieving any QI norm may result in suspension or termination of certification. During a period of suspension, the BCS entity must discontinue the use of marketing and promotional materials that refer to certification and the European QA scheme, or that include the European QA scheme mark.

Termination of certification

If a BCS entity continues to be unable to demonstrate that it meets the European QA scheme requirements and conditions for certification beyond the six (6)-month suspension period, a CB may terminate the certification.

A CB may also terminate a BCS's certification if the entity is found to be operating illegally or without integrity.

On termination of certification, the BCS entity must: discontinue the use of marketing and promotional materials that refer to certification and the European QA scheme, or that include the scheme mark; return all certification documents to the CB; and inform the European QA scheme owner of the termination of its certificate.

USE AND MISUSE OF THE EUROPEAN QA SCHEME CERTIFICATE, MARK AND STATEMENT OF CONFORMITY

The European QA scheme owner has developed a mark and statement of conformity that can be used by accredited CBs and BCS entities that achieve and maintain accredited certification for their services. Accredited CBs and certified BCSs will be eligible to use the European QA scheme mark and refer to the European QA scheme in marketing and publicity material. Full details of the use of the mark and statement of conformity, and specific requirements for the format, content and use of the certificate, mark and statement of conformity are given in Annex 8.

If deliberate misuse of the certificate, mark and/or statement of conformity is detected and confirmed, the European QA scheme owner may impose sanctions against a CB or a BCS entity, which may include legal action. CBs may also suspend certification if deliberate misuse of the certificate, mark and/or statement of conformity by a BCS entity is detected and confirmed.

SANCTIONS

A CB may impose the following sanctions where a BCS entity is found not to be complying with the European QA scheme requirements, including contractual requirements:

- full suspension of certification scope;
- termination of certification;

The CB may also publish its reasons for imposing sanctions.

Where different sites/legal entities are included in the certification (e.g. networks), certification documentation may be withdrawn in its entirety if any of the sites does not meet the necessary requirements for maintaining certification.

The European QA scheme owner may impose the following sanctions where a BCS or CB is found not to be complying with the European QA scheme requirements, including contractual requirements:

- legal action;
- publication of the details of misuse of the certificate, mark or statement of conformity;

The scheme owner may also publish its reasons for imposing sanctions.

6. ANNEXES

ANNEX 1. RECOGNITION BY THE EUROPEAN QA SCHEME OF EXISTING (BREAST) CANCER CERTIFICATION SCHEMES OPERATING IN EUROPE

Options for owners of existing schemes

There are two components to each option, both of which must be addressed by existing quality-assurance scheme owners and any accredited CBs with which they collaborate. These are a) recognition and adoption of the European QA scheme requirements; and b) acceptance of existing scheme audits of BCSs for the European QA scheme.

OPTION 1: Existing scheme owner takes the European QA scheme requirements as an 'add-on' to existing scheme requirements, but does not seek accreditation as a CB itself.

a) Recognition and adoption of the European QA scheme requirements.

- The existing scheme owner adopts the European QA scheme requirements **in addition to** and without alteration of existing scheme requirements.
- The European QA scheme owner and existing scheme owner enter into an agreement setting out responsibilities and liabilities for updates and changes to the existing scheme, and communications about it. Existing scheme owners must comply with the relevant requirements set out by the European QA scheme owner in the agreement with regard to: access to information systems; control; monitoring; legal, financial and administrative approaches; costs; fees; and rules for privacy.

Recognition and adoption of European QA scheme requirements by an existing scheme **is initiated by the existing scheme owner** requesting to enter into an agreement with the European QA scheme owner, **but is the overall responsibility of the European QA scheme owner.**

PLUS:

b) Acceptance of existing scheme audits of BCSs for the European QA scheme.

- Existing scheme owners enter into a legally enforceable agreement/contract with NAB-accredited CBs as an external resource, to provide auditing against the European QA scheme requirements.
- NAB-accredited CBs ensure that existing scheme owners/partners meet all of the relevant requirements of the European QA scheme and ISO/IEC 17065, in order to satisfy the NAB accreditation requirements.

- BCSs that are certified by an existing non-accredited scheme apply for accredited certification to the accredited CB with which their existing scheme has an agreement/contract.
- Accredited CB notifies the existing scheme that it should carry out the audit process for the European QA scheme.
- The existing scheme carries out the audit in accordance with the agreement/contract with the accredited CB and submits its report to the accredited CB.
- The accredited CB reviews the audit report and related activities, and makes a decision on accredited certification.

Acceptance of existing scheme audits of BCSs is **initiated by the existing scheme owner** requesting cooperation with a NAB-accredited CB to provide auditing services for the European QA scheme requirements. However, **it is the overall responsibility of the NAB-accredited CB** (through the accreditation process).

Please note that NAB-accredited CBs may initiate an approach to existing scheme owners if they are considering including the European QA scheme within their scope of accreditation.

OPTION 2: Existing scheme owner demonstrates the equivalence of existing scheme requirements with the European QA scheme requirements, but does not seek accreditation as a certification body itself.

a) Recognition of the equivalence of existing scheme requirements with European QA scheme requirements.

- The existing scheme owner maps its scheme requirements against those of the European QA scheme, identifies and fills any gaps that exist, revises the existing scheme (where necessary) and provides evidence to demonstrate that its scheme meets all the European QA scheme requirements.
- The European QA scheme owner or a designated body reviews the mapping evidence and recognises other schemes as being equivalent, or requiring additions/clarifications.
- The European QA scheme owner and existing scheme owner enter into an agreement setting out responsibilities and liabilities for updates and changes to the existing scheme, and communications about it. Existing scheme owners must comply with the relevant European QA scheme requirements set out in the agreement with regard to: access to information systems; control; monitoring; legal, financial and administrative approaches; costs; fees; and rules for privacy.

Recognition of the equivalence of existing scheme requirements with European QA scheme requirements is **initiated by the existing scheme owner** requesting recognition of equivalence from the European QA scheme owner. However, **it is the overall responsibility of the European QA scheme owner** to confirm the equivalence of existing scheme requirements with European QA scheme requirements.

PLUS:

b) Acceptance of existing scheme audits of BCSs for the European QA scheme, as in Option 1 b).

OPTION 3: Existing scheme owner takes the European QA scheme requirements as an 'add-on' to existing scheme requirements and achieves NAB accreditation itself.

a) Recognition of adoption of European QA scheme requirements, as in Option 1 a).

PLUS:

b) Acceptance of existing scheme audits of BCSs for the European QA scheme.

- Existing scheme owners seek accreditation from an NAB for certification for the European QA scheme (and their existing scheme if desired).
- BCSs apply for accredited certification for their existing scheme and/or the European QA scheme.

Acceptance of existing scheme audits of BCSs for the European QA scheme is **initiated by the existing scheme owner** requesting accreditation for certification for the European QA scheme. However, **overall responsibility is with the NAB (through the accreditation process)**.

OPTION 4: Existing scheme owner demonstrates the equivalence of existing scheme requirements with the European QA scheme requirements and achieves NAB accreditation itself.

a) Recognition of the equivalence of existing scheme requirements with the European QA scheme requirements, as in Option 2 a).

PLUS:

b) Acceptance of existing scheme audits of BCSs for the European QA scheme, as in Option 3 b).

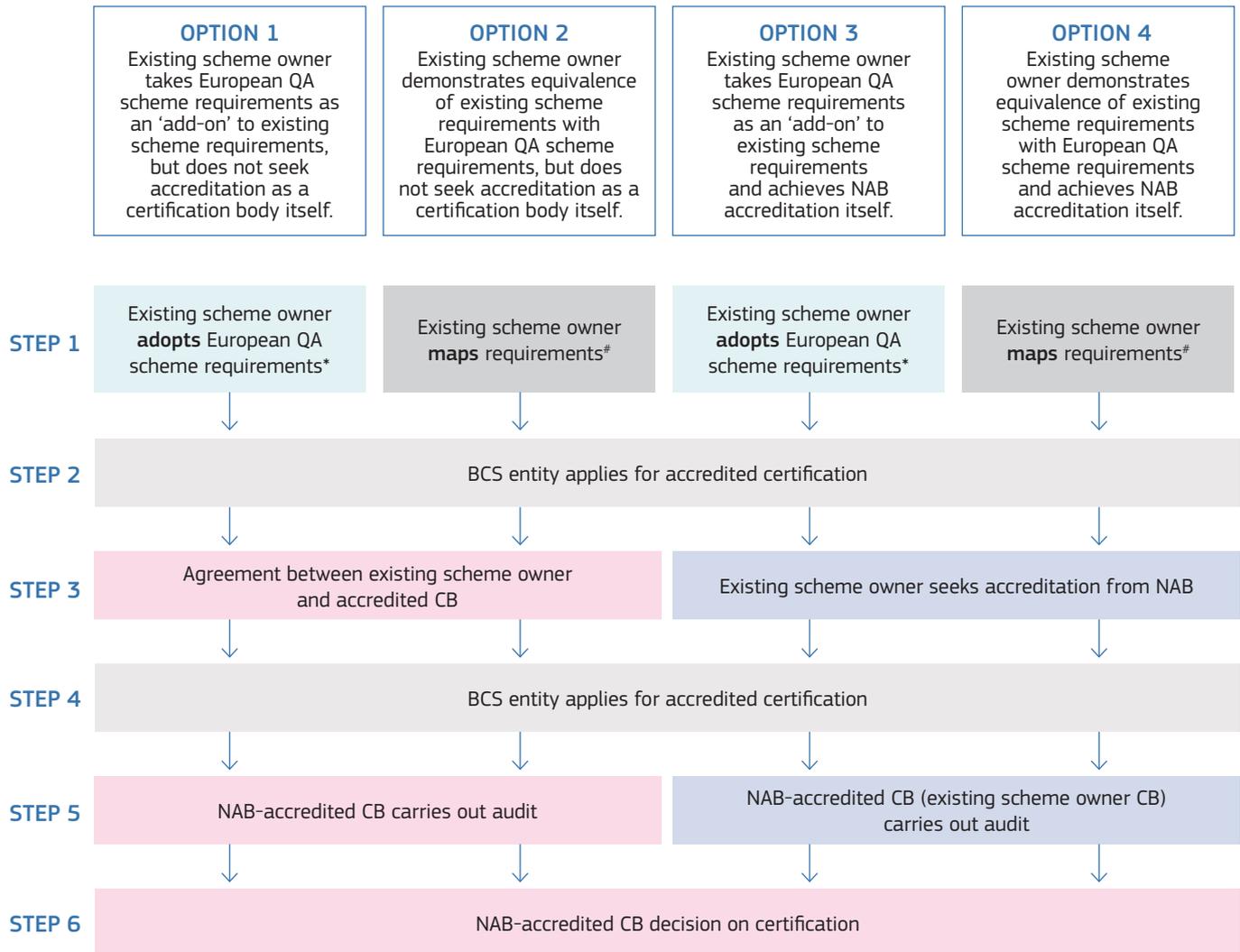


Figure 5. Recognition by the European QA scheme of existing (breast) cancer certification schemes operating in Europe

* An existing scheme owner can adopt the European QA scheme requirements **in addition to and without alteration** of existing scheme requirements.

An existing scheme owner can map its existing scheme requirements against the European QA scheme requirements, identify and fill any gaps, revise the existing scheme and provide evidence that the revised scheme meets all of the European QA scheme requirements.

ANNEX 2. STEPS TOWARDS ACHIEVING AND MAINTAINING CERTIFICATION FOR BCS ENTITIES

1. Download the *Manual of the European QA Scheme for Breast Cancer Services* from the European QA scheme website.
2. Carry out a self-assessment of compliance with applicable European QA scheme requirements, including quality indicators (QIs), using the web-based tools (self-assessment and QI calculator) provided on the European QA scheme website, and take action to address any non-conformities.
3. Select one of the approved CBs listed on the European QA scheme website (see also section 5 'Certification bodies' of this manual) and contact it to obtain the application documentation.
4. Submit an application for certification, including the application form and all specified information.
5. Sign agreement/contract with the CB, including agreement to pay all fees associated with the certification process.
6. Accept the proposed audit team and plan.
7. Participate in the certification audit, including visit(s) to the BCS facilities.
8. Address any non-conformities to demonstrate compliance with the European QA scheme requirements.
9. The certificate issued is valid for three (3) years, for a specified certification scope.
10. Participate in annual surveillance activities.
11. Participate in recertification activities before the certificate expires.

ANNEX 3. TIME-LIMITED STEPWISE APPROACH TO CERTIFICATION

Stepwise approach

During the transitional stage, BCS entities may apply for, and achieve, accredited certification for limited aspects of BCSs, such as individual processes within the breast centre modules of breast cancer care. Screening services and other services operating as a network, and breast centres, may adopt a time-limited, stepwise approach to achieving accredited certification for different entities in a network and/or different processes within modules. They must commit to achieving accredited certification for all entities and/or processes in a module within five (5) years of starting the certification process.

The BCS entity that manages a screening programme, or other services operating as a network, can initially apply for accredited certification for one or more of the collaborating entities and/or locations within the network.

Breast centres can initially apply for accredited certification for the following reduced scopes.

1. Diagnosis (includes imaging and pathology) services for breast cancer. Please note that 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.
2. Treatment services for breast cancer.
3. Rehabilitation services for breast cancer.
4. Follow-up and survivorship care for breast cancer.
5. Palliative/end-of-life care for breast cancer.
6. Any combination of breast centre services (1–5) for breast cancer.

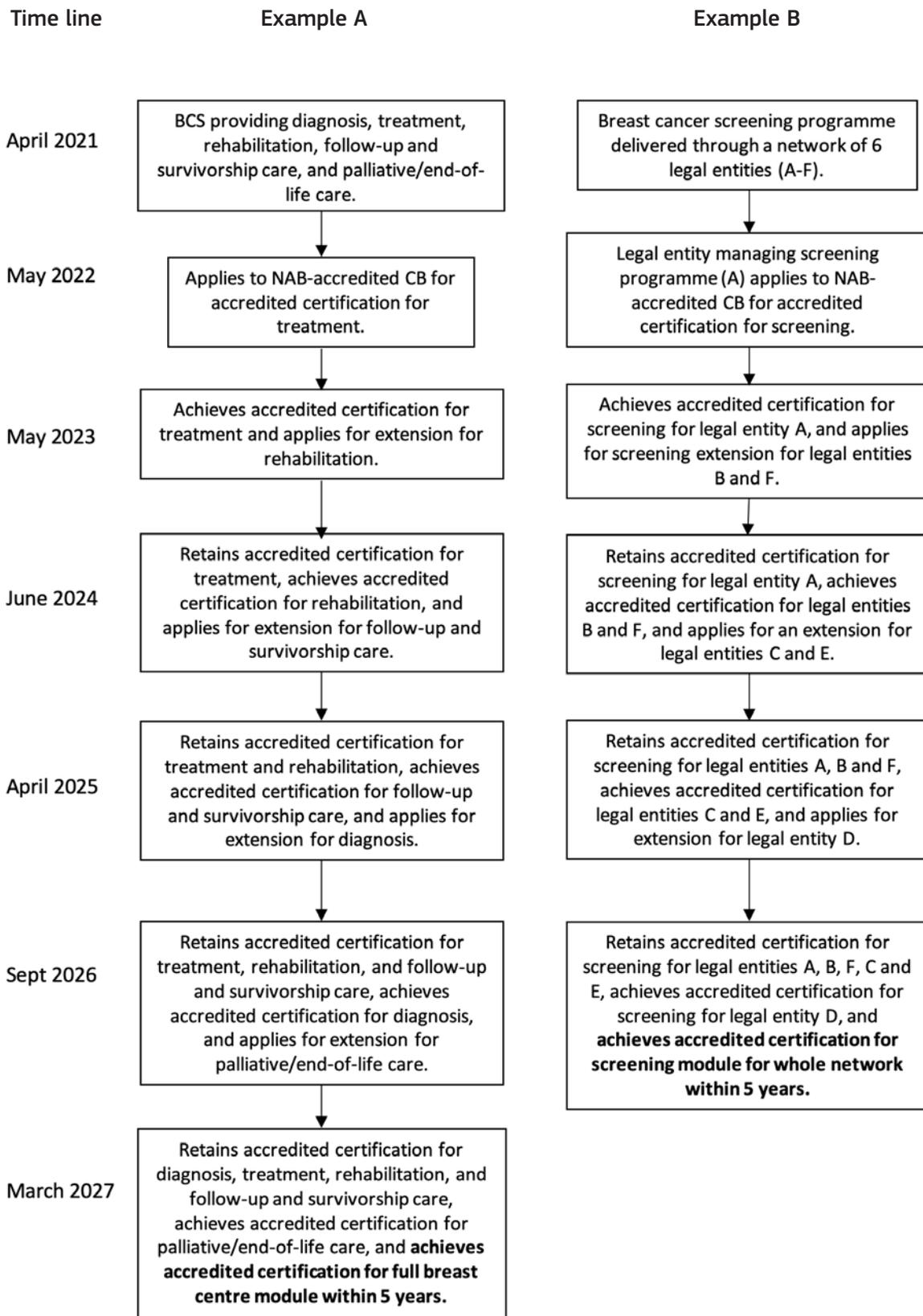
If a BCS entity does not initially apply for accredited certification for all of the breast cancer care processes in the module (a, b, or c in section 4) that it has chosen, the criteria for managing continuity of care between the different processes must be clear, robust and documented in order to explain how this will be implemented. This includes where one or more processes are outsourced ⁽³⁰⁾.

³⁰ See definition in Glossary (Annex 9).

The requirements for BCSs are detailed in the *European QA Scheme Owner Manual* and the *Manual of the European QA Scheme for Breast Cancer Services*. Irrespective of whether a full module approach or a stepwise approach is followed, all BCSs and their entities must meet all the relevant requirements in order to achieve accredited certification for a specified, limited scope. The audit and certification processes described in the *European QA Scheme Owner Manual* will also apply to both the full module approach and the stepwise approach.

BCS entities may apply for stepwise extensions to their scope of accredited certification over a period of five (5) years, until all entities in a network and/or all processes within a module have been included in the accredited scope of certification. If a BCS does not achieve accredited certification for all entities in a network and/or processes within each module (described in section '1. Introduction' of the *European QA Scheme Owner Manual*), within the specified time period of five (5) years, accredited certification will be withdrawn from the BCS.

Examples of a time-limited, stepwise approach to accredited certification



ANNEX 4. CONTENT OF CERTIFICATION AGREEMENT/CONTRACT

- Background circumstances of the agreement/contract.
- Names, addresses and authorised representatives of the parties (CB and BCS entity) to the agreement/contract.
- Definitions of terms.
- Services to be provided.
- Rights, responsibilities and liabilities of the parties to the agreement/contract (e.g. requirement for BCS entity to inform the CB of any significant changes to its personnel, workforce, facilities, outsourced services, etc.).
- Rules governing the use of certificates, mark and statements of conformity.
- Surveillance of certification.
- Suspension and withdrawal of certification.
- Complaints.
- Appeals.
- Use of subcontractors.
- Changes by the BCS entity.
- Changes to the scheme and specified requirements.
- Transfer of certification.
- Fees and charges.
- Ownership of information/data.
- Intellectual property:
 - owned by the CB;
 - ownership of pre-existing material;
 - third-party material;
 - moral rights;
 - ownership of certification documentation and marks of conformity.
- Insurance and liability.
- Termination.
- Force majeure.
- Survival and severability.
- Dispute resolution.
- Alteration of the agreement/contract.
- Serving notice under the agreement/contract.
- Governing law and jurisdiction.

Please note that CB agreements must include, as a minimum, all of the requirements of ISO 17065:2012, clause 4.1.2.2.

ANNEX 5. INFORMATION TO BE PROVIDED BY A BCS ENTITY TO A CB WHEN APPLYING FOR CERTIFICATION

- Date of application.
- Legal name and full postal address of registered office of the applicant BCS entity.
- Unique European QA scheme identifier assigned by European QA scheme owner.
- Contact details:
 - name of legal representative who is authorised to sign on the organisation's behalf;
 - name of the BCS's clinical director;
 - name of representative to whom all administrative enquiries should be addressed;
 - business addresses, telephone numbers and email addresses of the above individuals.
- Sites at which services are provided:
 - places (where services are managed and delivered);
 - name and title of person responsible for managing service at each site;
 - business address and contact details for each site.
- Description of services provided at each site, e.g.:
 - screening and diagnosis for referrals following screening;
 - breast centre, including:
 - diagnosis (including symptomatic women and referrals following screening);
 - treatment;
 - rehabilitation;
 - follow-up and survivorship care;
 - palliative/end-of-life care.
- Description of processes provided at each site, e.g.:
 - screening provision;
 - breast imaging and guided imaging interventions;
 - nuclear medicine;
 - breast pathology (cytology, histology, prognostics and genomics);
 - genetic evaluation (risk assessment) and testing;
 - laboratory testing;
 - breast surgery;
 - breast reconstructive surgery;
 - medical oncology;
 - radiation oncology;
 - other medical treatments;
 - fertility preservation;
 - complementary and integrative medicine;
 - breast care nursing (including community-based nursing and district nursing);
 - rehabilitation modules and interventions (physiotherapy, psychotherapy, sexual counselling, neurocognitive therapy, physical exercise, nutrition and management of lymphoedema);
 - symptom control;
 - supportive care;
 - psycho-oncology (including screening for distress);
 - social service counselling;
 - reintegration (e.g. going back to work);

- patient/person involvement and empowerment (e.g. communication of diagnosis and treatment plan, patient information, patient navigation provided by a health professional, shared decision making and self-management);
- primary prevention and health promotion;
- research;
- continuity of care;
- data management;
- patient safety;
- quality improvement.
- Standard(s) to which the BCS is to be certified (number, title and year of issue).
- Organisational structure including numbers of breast surgeons, breast radiologists, breast medical oncologists, breast radiation oncologists, breast pathologists, breast nurses and other professionals.
- Names, qualifications and background of individuals providing care.
- Details of any current quality-assurance recognition, certification or accreditation held, including name of scheme(s) and standard(s).
- Details of any partner organisations providing BCSs, including names of schemes and standards of any current quality-assurance recognition, certification or accreditation held by each partner organisation.
- Services provided by partner organisations:
 - screening and diagnosis for referrals following screening;
 - breast centre, including:
 - diagnosis (including symptomatic women and referrals following screening);
 - treatment;
 - rehabilitation;
 - follow-up and survivorship care;
 - palliative/end-of-life care.
- Calculated data on performance measures for all QIs relevant to the scope of activities for all sites.
- Declaration of willingness to abide by the requirements of the certification agreement/contract:
 - signature;
 - name of authorised person;
 - date.

ANNEX 6. EXAMPLE OF THE CONTENTS OF AN AUDIT REPORT

- Name of CB.
- Names of CB auditors.
- Name of European QA scheme.
- Date of audit.
- Calculated data for QI measures.
- Completed, detailed checklist of all applicable requirements.
- Exceptional practices.
- Non-conformities.
- Recommendations.
- Action-plan due date.
- Completion-of-actions due date.

ANNEX 7. INFORMATION TO BE INCLUDED ON A CERTIFICATE

- Certificate number or other unique identification.
- Name of European QA scheme (under which the certificate is issued).
- Name and address of CB.
- Name and address of BCS entity and European QA scheme unique identifier.
- Name and address of all sites, reflecting the overall BCS entity to which the certification documents relate. When temporary sites are shown on the certification documents, they will be identified as temporary.
- Statement of conformity, including:
 - the scope of certification (the scope will make it clear when the certified activities are performed by different sites/legal entities, but if those activities only include a sub-set of the overall BCS entity's scope, the certificate will include the sites/legal entities' sub-scopes);
 - description of the service.
- European QA scheme requirements and other normative document(s) (including dates of publication) that the BCS fulfils.
- How the BCS is provided (e.g. online or at physical sites).
- Geographical location(s) of BCS sites, if applicable.
- Reference to the CB's accreditation status, if applicable.
- Certificate's term or date of expiry (where applicable).
- Certificate's date of issue.
- Means by which the certificate's authenticity can be verified (e.g. status published on CB website).
- Name, title and signature (or defined authorisation) of individual at CB who is responsible for the certificate.

ANNEX 8. USE OF THE EUROPEAN QA SCHEME CERTIFICATE, MARK AND STATEMENT OF CONFORMITY

Use of certificate

A BCS entity may display the certificate issued by a CB and bearing the European QA scheme mark only on internal walls and surfaces of buildings belonging to the BCS entity.

Statement of conformity (reference to accredited certification)

A BCS entity may make reference to its accredited certification on stationery, marketing and publicity materials, pricing quotes, reports, certificates, exhibition stands and brochures using the following wording only:

‘Breast cancer service [unique identifier] certified for the European QA scheme for [screening], [breast centre] and [palliative/end-of-life care] services.

Use of the European QA scheme mark or statement of conformity by a BCS entity

A BCS entity is not obliged to use the European QA scheme’s mark or statement of conformity, but, if it does, its use must be consistent with the following.

The mark and statement of conformity:

- must always be associated with the unique identifier issued to the BCS entity by the European QA scheme owner, and the name or mark of the certified BCS;
- may be used on stationery, marketing and publicity materials, pricing quotes, reports, certificates, exhibition stands and brochures;
- may be used on websites, provided that the extent and limitations of the BCS’s certification are clearly described;
- must be displayed only in the appropriate format, size and colour, or the appropriate wording specified by the European QA scheme owner;
- must not be used in any way that might be misleading about the status of a certified BCS (e.g. the mark and statement of conformity may not be used on any stationery, marketing and publicity materials, pricing quotes, reports, certificates, exhibition stands, websites and brochures relating solely to activities that are not included in the scope of certification);
- must not be used on reports or certificates issued by organisations to which services such as pathology or imaging have been outsourced;
- must not be used on stationery, marketing and publicity materials, pricing quotes, reports, certificates, exhibition stands, websites and brochures by a BCS entity whose certification has been suspended or terminated;
- must not be used by a BCS entity that has withdrawn from certification;
- must not be displayed on the exterior of any buildings, on flags or on vehicles.

ANNEX 9. GLOSSARY

Accreditation

The term 'accreditation' can mean different things in different contexts. A description of some of these different contexts is given in the 2015 European Commission publication *Review and analysis of external quality assessment of breast cancer services in Europe: supporting information for the development of a European quality assurance scheme for breast cancer services* (see footnote 7).

Accreditation certificate

In the context of the European legal framework on accreditation: a formal document or set of documents stating that accreditation has been granted for the defined scope (ISO/IEC 17011:2017).

Accreditation mark

In the context of the European legal framework on accreditation: a mark issued by an accreditation body to be used by accredited CBs to indicate an entity's direct conformity with a set of requirements (ISO/IEC 17011:2017).

Agreement

A document describing the processes and procedures that discreet entities (such as geographically separate locations of the same legal entity) agree to implement.

Audit

Systematic, independent and documented process for obtaining evidence and assessing it objectively to determine the extent to which specified requirements are fulfilled (ISO 19011:2018). In relation to the European QA scheme, the general terms 'audit', 'audited', 'auditing' and 'auditor' should be understood to include those activities that involve inspection, where 'inspection' is the examination of aspects of a BCS and determination of their conformity with the specific requirements or, on the basis of professional judgment, with the general requirements.

Auditor

A person qualified to carry out audits for or on behalf of a certification body

Audit team

All personnel who are involved in auditing a BCS, whether in an on-site visit to the BCS or by carrying out other off-site auditing activities (e.g. individuals with specialist expertise who may be consulted on limited aspects of a BCS's activities).

Appeal

Request for reconsideration of a decision made on a lodged complaint.

Breast cancer service

Comprises all healthcare services covering the full extent of breast cancer management, from screening to follow-up, and in some cases end-of-life care. These services may provide primary care, as well as a range of high-specialty services including, but not limited to, screening, diagnostic imaging, pathology, surgery, radiation and medical oncology.

BCS entity

The body that has legal responsibility for the breast cancer service.

Breast centre

A BCS entity that is responsible for providing diagnosis, treatment, rehabilitation, follow-up and survivorship, and palliative/end-of-life care. Some of these activities may be outsourced, but the breast cancer care must be coordinated and provided by a multidisciplinary team of specialists.

Certification

Process by which accredited certification bodies, based on an audit, provide written assurance that breast cancer services and entities conform to the scheme's requirements.

Certification body

Organisation that is a legal entity or part of a legal entity providing audit and certification services.

Certification decision

Granting, continuing, expanding or reducing the scope of, or suspending, restoring, withdrawing or refusing certification by a certification body.

Competence

Demonstrated ability to apply knowledge and skills to achieve intended results.

Complaint

A legal document that is an expression of dissatisfaction not constituting an appeal.

Conformity assessment body

Body that performs conformity assessment activities and that can be the object of accreditation (ISO/IEC 17011:2017).

Continuity of care

The degree to which a series of discrete healthcare events is experienced as coherent, connected and consistent with the patient's medical needs and personal context.

Contract

A legally binding agreement that sets out terms and conditions, including financial remuneration, between different entities.

Exceptional practice

Exceptional practices are where the BCS is delivering outstanding care to patients, excellent training and support for staff, first-class facilities and environment, or any other outstanding aspect of the service. Also includes any improvements made to BCS processes and sub-processes.

External resources

Different entities or healthcare professionals used by an NAB-accredited CB to audit processes or sub-processes. See also 'outsourcing'.

Extraordinary event or circumstance

An event or circumstance that is beyond the control of the certification body or entity providing a breast cancer service, such as: war, strikes, riots, political instability, geopolitical tension, terrorism, crime, pandemics, flooding, earthquakes, malicious computer hacking, and other natural or man-made disasters.

Formal assurance

Assurance that exists when BCS entities achieve accredited certification from certification bodies that have been accredited to international standard ISO/IEC 17065 by a national accreditation body that is a signatory to a multilateral agreement of the European cooperation for Accreditation (EA).

Lead auditor

An individual that leads and coordinates the audit team's activity.

Management system

Set of interrelated or interacting elements to establish policy and objectives and to achieve those objectives, used to direct and control an organisation with regard to quality and safety management.

Module

A module is a distinct process or aggregation of processes (e.g. screening and diagnosis, diagnosis, treatment, follow-up, rehabilitation, palliative/end-of life care, and the complete care pathway) that fall under the responsibility of a single entity.

National accreditation body

In the context of the European legal framework on accreditation: an authoritative body that performs accreditation (ISO/IEC 17011:2017).

Networks

Arrangement whereby different legal entities or geographical locations of the same legal entity work together in cooperation to deliver the entire breast cancer service, or discreet processes (such as treatment, surgery or diagnosis) within the breast cancer service. Please note that where networks involve different legal entities, each legal entity takes individual responsibility (e.g. for financial arrangements), but all entities cooperate through the terms of the agreement/contract to ensure continuity of patient care.

Non-conformity

Deviation from specified requirements related to the breast cancer service or to certification requirements defined by the certification body.

Non-conformity – contractual

Any non-conformity relating to contractual requirements of the European QA scheme owner and/or the CB.

Non-conformity – major

Non-conformity that could result in the failure of the service, reduced operability of the service, and that could put patients at risk. Clearance of a major non-conformity will normally require an additional on-site visit to a BCS entity.

Non-conformity – minor

Non-conformity that does not in itself adversely affect the performance of the overall service.

Off-site audit activities

Activities such as document examination, telephone interviews, examination of electronic records and other activities that may be carried out remotely by one or more auditors during the audit process before, during and/or after an on-site visit.

On-site audit team

Auditors who attend the premises of a BCS entity with the aim of auditing and verifying the compliance of the BCS with the European QA scheme requirements.

On-site visits

Attendance by an auditor or team of auditors at the BCS entity's site(s) to carry out audit activities to verify the BCS's compliance with the requirements (including QIs) of the European QA scheme.

Outsourcing

A process or sub-process is defined as outsourced when an entity that is responsible for the coordination of breast cancer care procures that process or sub-process via a legally binding agreement/contract with a different entity or healthcare professional (also known as 'external resources').

Patient safety

Pursuit of the reduction and mitigation of unsafe acts within the healthcare system, as well as the use of best practices shown to lead to optimal patient outcomes.

Process

Set of interrelated or interacting activities that result in an outcome

Quality

Degree to which a set of inherent characteristics of a service meets requirements.

Quality assurance

The systematic monitoring and evaluation of the various aspects of a service to ensure that standards of quality are being met.

Quality improvement

Implementation of changes that will deliver person-centred care that is better, safer, more effective and more efficient, using a range of specific tools and methods.

Quality indicator

A means of demonstrating that a requirement is being met. Indicators are always linked to a requirement, but not every requirement will have a quantitative indicator to be measured. A quantitative indicator is expressed using a clearly defined numerator and denominator.

Quality potential

Quality potentials correspond to known or anticipated deficits in the quality of care for a specific disease, indication or intervention. They correspond to processes in the care pathway for which under-, over- or inadequate treatment has been reported, meaning that treatment is not being provided at the required quality. Quality potentials are therefore starting points for implementing measures to improve the quality of care.

Quality target

Defined parameters within the context of a quality assurance scheme that signify high-quality healthcare and relate to healthcare being effective, safe and patient-centred.

Recommended action

An action that the certification body recommends the BCS entity should take, but which does not constitute non-conformity with the European QA scheme requirements and is regarded as an improvement in practices.

Records

Records contain information from a particular point in time, stating results achieved or providing evidence of activities performed. Records can be in any format or medium, providing they are readily accessible and protected from unauthorised alteration.

Requirement

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. In the European QA scheme, a requirement consists of the statement, criteria and reference documents.

Risk

Effect of uncertainty on objectives (ISO 31000:2018).

Scope

Extent and boundaries of the audit, certification, accreditation or scheme activity (ISO 19011:2018).

Screening programme

Legal entity managing a screening process in which the procedures are specified (e.g. standard operating procedures) and a team at national, regional or local level is responsible for implementing the policy (i.e. for coordinating the delivery of screening services, maintaining the required quality, and reporting on performance and results).

Screening service

Entity performing mammography tests and working under an agreement/contract for a screening programme.

Service

Provision of an aspect or aspects of breast cancer care to a patient by an entity, which may be a legal entity or a clearly defined part of a legal entity, such as a unit, department or centre.

Standard

Normative document containing a set of requirements against which something can be measured, judged or evaluated.

GETTING IN TOUCH WITH THE EU

In person

All over the European Union there are hundreds of Europe Direct information centres. You can find the address of the centre nearest you at: https://europa.eu/european-union/contact_en.

On the phone or by email

Europe Direct is a service that answers your questions about the European Union. You can contact this service:

- by freephone: 00 800 6 7 8 9 10 11 (certain operators may charge for these calls),
- at the following standard number: +32 22999696, or
- by electronic mail via: https://europa.eu/european-union/contact_en.

FINDING INFORMATION ABOUT THE EU

Online

Information about the European Union in all the official languages of the EU is available on the Europa website at: https://europa.eu/european-union/index_en.

EU publications

You can download or order free and priced EU publications from EU Bookshop at: <https://publications.europa.eu/en/publications>. Multiple copies of free publications may be obtained by contacting Europe Direct or your local information centre (see https://europa.eu/european-union/contact_en).

The European Commission's science and knowledge service Joint Research Centre

JRC Mission

As the science and knowledge service of the European Commission, the Joint Research Centre's mission is to support EU policies with independent evidence throughout the whole policy cycle.



EU Science Hub
ec.europa.eu/jrc



@EU_ScienceHub



EU Science Hub - Joint Research Centre



EU Science, Research and Innovation



EU Science Hub

