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EUROPEAN COMMISSION
INITIATIVE ON BREAST CANCER

Manual for Certification Bodies

European Quality Assurance Scheme
for Breast Cancer Services



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European Quality Assurance Scheme
for Breast Cancer Services

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is provided for the purposes of piloting.

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ABBREVIATIONS AND ACRONYMS

BCS	Breast cancer service
CAB	Conformity assessment body
CB	Certification body
EA	European co-operation for Accreditation
ECIBC	European Commission Initiative on Breast Cancer
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

ABSTRACT

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) in Europe that should be followed by any entity providing BCSs to women.

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

Adopting the European QA scheme is voluntary: it is not mandatory for health services/BCSs to implement it.

This manual intends to facilitate the process for piloting of the certification body audit process of BCSs for the European QA scheme and to provide guidance to certification bodies on:

- the requirements for BCSs and where the full details are documented,
- the audit processes that must be used for BCSs,
- how to report the results of the audits,
- who to report the audit to.

After the certification pilot has been completed, the European QA scheme will be updated.

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 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.

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 certification pilot is being carried out to determine the practicability of auditing BCSs against 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 formally to apply for and achieve certification by an accredited certification body.***

SCOPE, PURPOSE AND ORGANISATION OF THE CB MANUAL

The scope and purpose of this manual is to facilitate the process for piloting of the certification body audit process of BCSs for the European QA scheme and to provide guidance to certification bodies on:

- the requirements for BCSs and where the full details are documented
- the audit processes that must be used for BCSs
- how to report the results of the audits
- who to report the audit to

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.

After the certification pilot has been completed, this manual will be reconsidered in the context of the results and conclusions of the pilot as well as other scheme documents such as the *European QA Scheme Owner Manual*³ and the *Manual of the European QA Scheme for Breast Cancer Services*.

This manual also sets out and explains the requirements that must be fulfilled by certification bodies (CBs) in order to be accepted by the Scheme Owner for certifying BCSs in accordance with the requirements of the European QA scheme.⁴

This manual has 5 main sections, with 4 annexes provided in section 6.

1. Introduction

This section provides a very brief background to the European QA scheme, the care processes that constitute the breast cancer care pathway and the voluntary status of the European QA scheme. A more detailed description of the scope of the European QA scheme with respect to the breast cancer care pathway is provided in section 1 of the *European QA Scheme Owner Manual*.

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

This section briefly describes 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. Full details can be found in section 2 and Annex 1 of the *European QA Scheme Owner Manual*.

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. Further information on this can be found in section 3 of the *European QA Scheme Owner Manual*.

4. Breast cancer services

This section provides an 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; 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 1–3 provide further detail on different aspects of the European QA scheme's operation relevant to CBs.

³ <https://healthcare-quality.jrc.ec.europa.eu/breast-quality-assurance-scheme/manuals>

⁴ Manual of the European QA Scheme for Breast Cancer Services.

Annex 4 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.⁵

The requirements of the QA scheme are described in the *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.

The current version of the QA scheme is being used to assess its feasibility in real settings and to pilot the certification audit process. A final version of the QA scheme will be prepared based on the outcomes obtained during the feasibility checks and the certification pilot which is being run with the support of the European cooperation for Accreditation (EA).

⁵ *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.

OPTIONS FOR OWNERS OF EXISTING SCHEMES

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 section 2 and Annex 1 of the *European QA Scheme Owner Manual*.

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.

For the purposes of the certification pilot, it might be necessary for any existing scheme owners that are participating in the pilot to enter into legal 'collaborative arrangements' with the European QA scheme owner rather than to have a formal contractual agreement as described in section 2 of the European QA Scheme Owner Manual. A legal 'collaborative arrangement' (rather than a formal contractual agreement) might also be necessary between an existing scheme owner and an accredited certification body for acceptance of the breast cancer service audits carried out by existing schemes.

If an accredited CB is intending to use an existing scheme owner/CB as an external resource, the accredited CB must carry out a risk assessment of the existing scheme owner/CB. The risk assessment will cover impartiality, competence, consistency and independence in auditing activities, and the countries where the accredited CB intends the existing scheme owner/CB to operate.

If an accredited CB takes into account audits that have been carried out by existing scheme owners/CBs, the accredited CB must 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)'. 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.

CBs may offer certification services outside the country or region in which they are established. 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. If accredited CBs enter into arrangements with these 'external resources', such as CBs that are not accredited for certification of existing schemes, CBs need to ensure that all of the requirements detailed in section 2 of the *European QA Scheme Owner Manual* are met. If there are CBs that are not accredited providing auditing services for the European QA scheme for BCSs in different countries, they need to enter into arrangements with one or more 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, 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 accredited CB.

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

By participating in the certification pilot, the BCS entity gives permission for the European QA scheme owner and CB to use any information it has provided for internal processes and 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.

By participating in the certification pilot, the CB gives permission for the European QA scheme owner to use information for internal processes and 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.

Further information regarding document control, access to the European QA scheme, management of extraordinary events or circumstances affecting accredited CBs and certified BCS entities, and reference documents is detailed in section 3 of the *European QA Scheme Owner Manual*.

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)⁶ (which defines the rights, responsibilities and liabilities of the parties to that agreement), and to comply with the terms and conditions of business.
- *For the purposes of the certification pilot, it might be necessary for any BCS entity participating in the pilot to enter into legal 'collaborative arrangements' with an accredited CB rather than to have a formal contractual agreement as described in section 4 of the European QA Scheme Owner Manual.*
- 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 1).

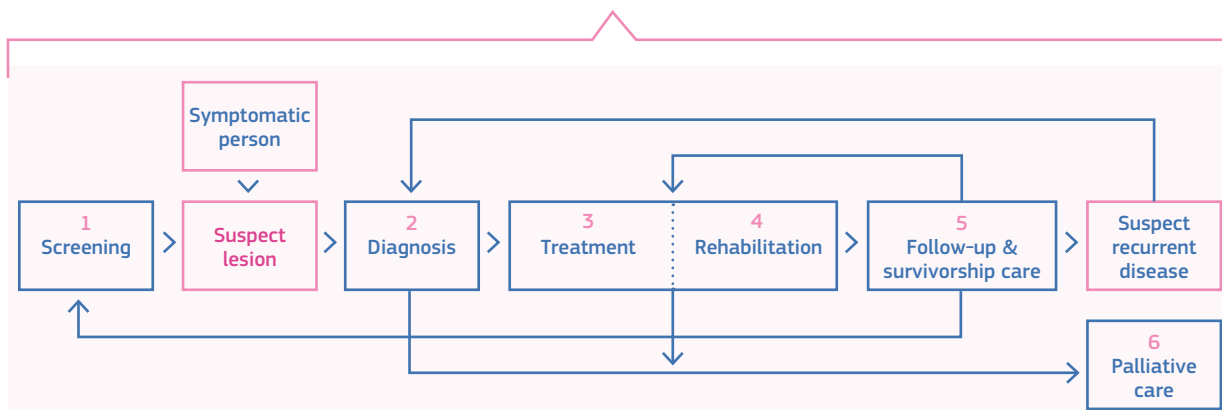


Figure 1. Certification of the entire breast cancer care pathway (a)

⁶ A BCS entity may enter into an agreement/contract with an 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 2).

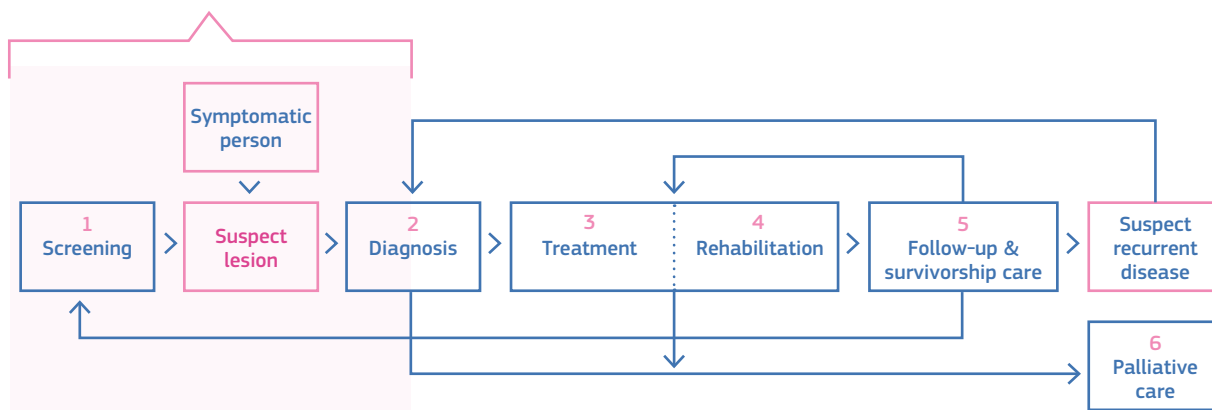


Figure 2. Certification of screening programme (b)

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 3).

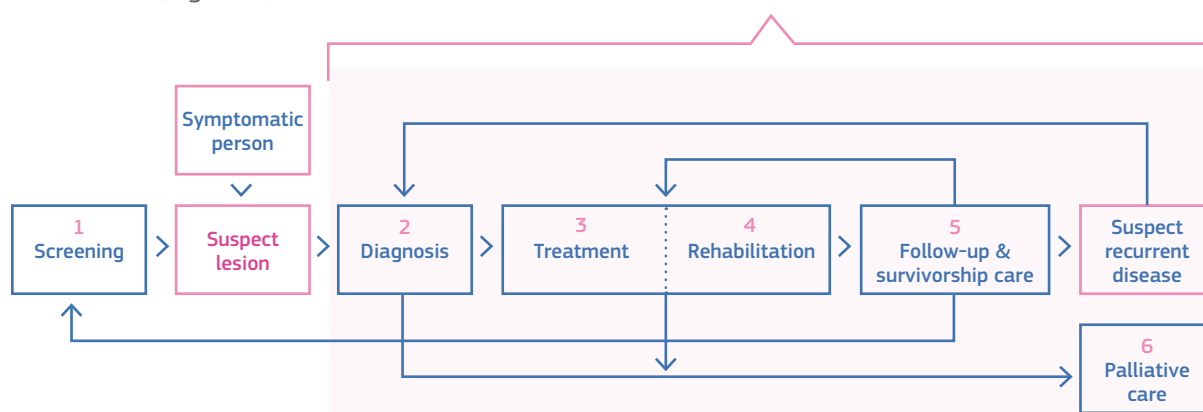


Figure 3. Certification of the breast cancer care pathway without screening (c)

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 *European QA Scheme Owner 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. 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.

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 of the *European QA Scheme Owner Manual*.

NETWORKS

Networking and formalised collaboration between healthcare providers is increasingly recognised as an option for delivering cancer services.⁷ Breast cancer services may be provided by networks of organisations and specialists to enable close multidisciplinary working and/or ensure easy access to all necessary services, for example, across a geographical region. Networks may consist of multiple entities (e.g. entire institutions, parts of institutions, oncology departments, mammography facilities, etc.) belonging to different institutions that are dedicated to screening, diagnosis, treatment, rehabilitation, follow-up and survivorship care, and palliative care.


The entities must have formal agreements to work together in a structured way under common governance, and to adopt uniform standards of care across the network. Coordinating patient care is the responsibility of multidisciplinary, inter-professional teams. For 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. 

⁷ *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.

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 this section '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. ***For the purposes of the certification pilot, a BCS will need to have a database that is capable of collecting any available performance data on applicable QIs (data collected over a period of time shorter than 12 months is acceptable for pilot purposes) and transferring the calculated QI data to their pilot CB.***
- 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. ***For the purposes of the certification pilot, a BCS will need to submit any available calculated QI data for applicable QIs (data collected over a period of time shorter than 12 months is acceptable for pilot purposes).***

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 section 5 ‘Certification process’ and Annex 7 in the *European QA Scheme Owner Manual*), 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 publication⁸ 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 detailed in the *Manual of the European QA Scheme for Breast Cancer Services*.

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.

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.

⁸ *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.

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;⁹
- 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 in the form of a certificate issued by a certification body accredited to ISO 17021-1 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.

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^{10, 11} (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

⁹ Including (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.

¹⁰ <https://european-accreditation.org/mutual-recognition/the-ea-mla/>

¹¹ It is anticipated that EA will include the European QA scheme in the ISO 15189 peer evaluation process for NABs.

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

OR

- Audit and certification of screening and/or diagnosis services, to a specific quality-management system standard (such as ISO 9001 or EN15224 by a CB accredited for ISO 17021-1), and audit and certification against relevant European QA scheme requirements for imaging and pathology for BCSs (including QIs) as part of the certification process for the entire breast cancer care pathway, screening programme modules or breast cancer care pathway without screening.

CBs must adopt a 'presumption of conformity' for imaging and pathology services that are accredited by 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 dependent on the screening and/or diagnosis service providing 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.

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 pilot audit 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 in the certification pilot, participating BCSs 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).**

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);¹² 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.¹³

For the purposes of the certification pilot, it might be necessary for any accredited CBs that are participating in the pilot to enter into legal ‘collaborative arrangements’ with the European QA scheme owner rather than to have a formal contractual agreement as described in section 5 of the European QA Scheme Owner Manual.

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 17065,¹⁴ and must also have demonstrated that it complies with the detailed requirements set out in the *European QA Scheme Owner Manual*.¹⁵ The NAB must be a signatory to the European cooperation for Accreditation (EA) multilateral recognition agreement¹⁶ 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).

No certificates will be issued for the European QA scheme during the pilot phase of the scheme. CBs do not therefore need to have achieved accreditation for certifying BCSs against the European QA scheme requirements prior to participation in the pilot. Once the European QA scheme has been finalised and published, CBs will be able to seek accreditation for certifying, and BCSs will be able to seek accredited certification, for the scheme.

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).
- 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.

¹² A governmental certification body is considered to be a legal entity on the basis of its governmental status.

¹³ Contact details can be found on the European QA scheme owner's website.

¹⁴ ISO/IEC 17065: Conformity assessment – requirements for bodies certifying products, processes and services.

¹⁵ 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.

¹⁶ <https://european-accreditation.org/mutual-recognition/the-ea-mla/>

- A CB must achieve and maintain accreditation to provide certification for the European QA scheme from the relevant NAB. ***For the purposes of the certification pilot, any accredited CBs that are participating in the pilot will not be required to have applied for or achieved accreditation for the European QA scheme.*** 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 the *European QA Scheme Owner 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; and updating the European QA scheme owner on the status of BCSs.
- 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 of the *European QA Scheme Owner Manual*) 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.
- For the purposes of the pilot, a CB that is intending to seek accreditation in the future for certifying to the European QA scheme should be clear about the extent and limitations of its intended scope of accreditation, for example if it is intending to offer certification for screening services only.

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 of this manual), must carry out their certification activities in accordance with the audit and certification processes described below. All records relating to activities carried out for the European QA scheme pilot exercise must be managed in accordance with any requirements specified in

the collaborative arrangement with the scheme owner. For example, reports of audits will be provided to the BCS and will also be submitted to the European Scheme Owner to provide the feedback that will enable review and revision of the European QA Scheme, as necessary.

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

AUDIT AND CERTIFICATION PROCESSES

INITIAL APPLICATION

CBs that are authorised to certify BCSs for the European QA scheme will be listed on the European QA scheme website.¹⁷ 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 of the *European QA Scheme Owner Manual*;
- 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 of the *European QA Scheme Owner Manual*.

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.¹⁸

AUDIT PROCESSES

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

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

¹⁷ There is a list of CBs on the European QA scheme website: <https://healthcare-quality.jrc.ec.europa.eu/breast-quality-assurance-scheme>.

¹⁸ Link/cross-reference to agreed process and format.

- off-site audit activities (e.g. examination of written and/or electronic information, telephone discussions/interviews) to evaluate the BCS;¹⁹
- on-site visits to evaluate the BCS;
- report of visit.

The purpose of the audit is to verify the BCS's compliance with the European QA scheme requirements, including specific QIs. ***For the purposes of the pilot, the process will end after the audit has been completed.***

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.

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.

¹⁹ 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*.

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.²⁰ 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.

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

During the certification 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.

²⁰ 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>.

- 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 certification 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. ***For the purposes of the pilot, CB auditors must use the checklist applicable to the BCS being audited.***

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.

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 3.

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 50–69.²¹ However if the regional or national legislation specifies a lower acceptable limit than the European QA scheme, the European QA scheme takes precedence.

²¹ Requirement SCR-4 in the *Manual of the European QA Scheme for Breast Cancer Services*.

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 resolve any non-conformities will be agreed and a time frame set for the actions to be completed. *For the purposes of the pilot, CBs will need to agree that the intended action plan, if implemented, would be expected to resolve any non-conformities raised but they will not need to confirm that actions have actually been taken by the BCS within a specific timeframe because no certificates will be issued at the end of the pilot.*

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:

- **Minor:** any non-conformity that does not in itself put patients at risk or adversely affect the performance of the overall service. *Except for the pilot exercise*, the BCS entity will need to 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. *Except for the pilot exercise*, the BCS entity will need to provide documentary evidence of the actions taken and the CB will need to verify the action taken for example through an additional visit to the BCS entity.
- **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

For the purposes of the pilot, the process will end after the audit has been completed. Full details of the certification process which will be followed after the European QA scheme has been launched are described in the European QA Scheme Owner Manual.

Reports of audits will be provided to the BCS and will also be submitted to the European Scheme Owner to provide the feedback that will enable review and revision of the European QA scheme, as necessary.

6. ANNEXES

ANNEX 1. 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 2. 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 3. 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 4. 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 of the *European QA Scheme Owner Manual*).

The meaning of accreditation as used in the European QA scheme is: Accreditation - third-party attestation related to a conformity assessment body, conveying formal demonstration of its competence, impartiality and consistent operation in performing specific conformity assessment activities.

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 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 a certification body 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 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 programme, entire cancer care pathway, breast cancer care pathway without screening) 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 certification body.

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). According to QA scheme requirements, the certification scopes of BCSs can be:

- screening programme,
- entire cancer care pathway,
- breast cancer care pathway without screening

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.

Sub-process

Part or parts of an overall module (e.g. screening, diagnosis, imaging, pathology, treatment, follow-up, rehabilitation, palliative/end-of life care).

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