European Quality Assurance Scheme for Breast Cancer Services:
Implementation and practical aspects for the National Accreditation Bodies

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Once the feasibility study has been completed, and the pilot has been done, it is likely that there will be changes to the requirements for Breast Cancer Services and the requirements for the Certification Bodies.

Accreditation for certification for the QA scheme should be similar to any other `service certification' under ISO/IEC 17065.

European Commission

ECIBC

EUROPEAN COMMISSION
INITIATIVE ON BREAST CANCER

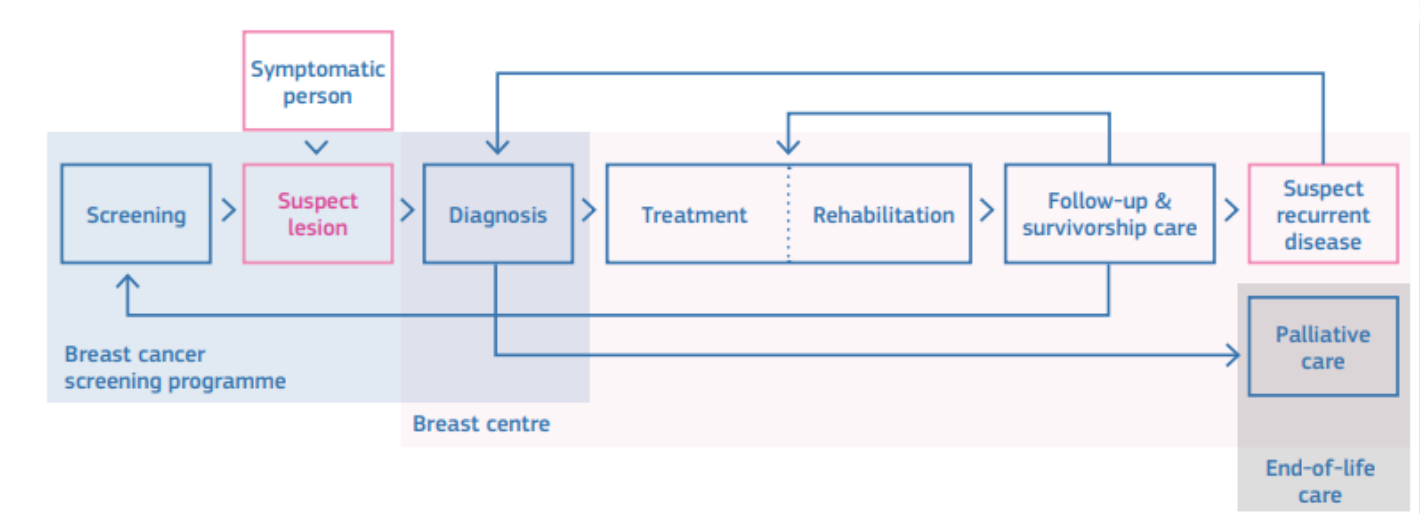
- *The QA scheme is 'service certification' of breast cancer services, and it covers all the **relevant areas** of healthcare provision for breast cancer and all breast cancer care **procedures**.*

The '*European QA scheme*' will be underpinned by the legal and procedure framework, described in EU Regulation 765/2008, using ISO/IEC 17065:2012. This standard was chosen, as granting the necessary flexibility, both in terms of the **clinical contents** and of **healthcare systems diversity**.

- *Adopting the 'European QA scheme' is voluntary, so 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.*

- *The organization of services varies both within and between countries and might include networks of organisations/entities, outsourcing and other arrangements for delivering services.*

However, the '*European QA scheme*' is applicable to all healthcare services covering part or the full extent of breast cancer management, **from screening to follow-up and end-of-life care (3 modules)**.



The simplified general care pathway proposed for the European QA scheme

The '*European QA scheme*' permits BCS entities to outsource processes or sub-processes of breast cancer care modules to external resources. Nevertheless, the responsibility for ensuring that the outsourced service, for which the BCS is seeking certification, meets the relevant '*European QA scheme*' requirements, remains with the **BCS entity that is procuring the service**.

- *The scheme does not require accreditation of **anatomical pathology laboratories** or **imaging services**, but some of these may already hold (or decide to seek) accreditation for relevant activities.*

Therefore, there are some specified options in the '*European QA scheme*' for **acceptance** of anatomical pathology laboratories and imaging services by CBs, including the case of **Accreditation** of anatomical pathology laboratories or imaging services by a NAB (MLA signatory), which also demonstrate that they meet the applicable '*European QA scheme*' requirements for imaging and pathology.

In such cases, no additional audit of the imaging and pathology service will be carried out by the CB, providing there is an up-to-date accreditation and evidence of compliance with the scheme requirements, as well.

Please note that for the '*European QA Scheme*':

- **mammography services** and **pathology services** are not eligible for stand-alone accredited certification. These services are only eligible for accredited certification as part of an application from an organised screening programme;
- however, **mammography services** and **pathology services** may already hold, and are eligible to apply for, NAB accreditation for their services.

- A **CB, to be eligible** to carry out audits of BCSs for the QA Scheme, must:

- be a legal entity (or part of a legal entity);
- be accredited by a NAB (MLA signatory), against the requirements of ISO/IEC 17065 for the '*European QA scheme*'; and
- have registered and entered into an agreement/contract with the European QA scheme owner.

A CB, to be accepted by the '*European QA scheme*' owner, must provide where:

- details of its current accreditation status;
- its 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).

Please note that for the '*European QA Scheme*' it is not possible for a CB to have accreditation for a scope that only covers separate processes within a module.

- ***Comprehensive checklists*** *have been developed for* ***auditors*** *to use. At this stage it is not mandatory for the CBs to use them but, if they don't, they need to demonstrate that what they are using is just as comprehensive.*

Example of an auditor's checklist for Pathology for 1 requirement is following….

AUDITOR CHECKLISTS

DIAGNOSIS PATHOLOGY REQUIREMENTS

AUDITOR CHECKLIST

Name of BCS Entity:	
Unique BCS Entity Identifier:	
Networked services:	Yes ☐ No ☐
	For each audited entity/location within a network, please use additional relevant supplementary checklists
Outsourced services:	Yes ☐ No ☐
	For each outsourced service that is audited, please use additional relevant supplementary checklists
Name of Auditor:	Date of audit:

Abbreviations: NA = Not Applicable NC = Not Checked

Note: This checklist must only be used in conjunction with the *Manual for Breast Cancer Services* which includes, in detail, all of the requirements that must be met and all of the norms which must be achieved.

Some requirements are highlighted with this symbol for continuity of care: .

DGN-PTH-1: Time from receipt of specimen to issuing of result for non-surgical biopsies and surgical specimens

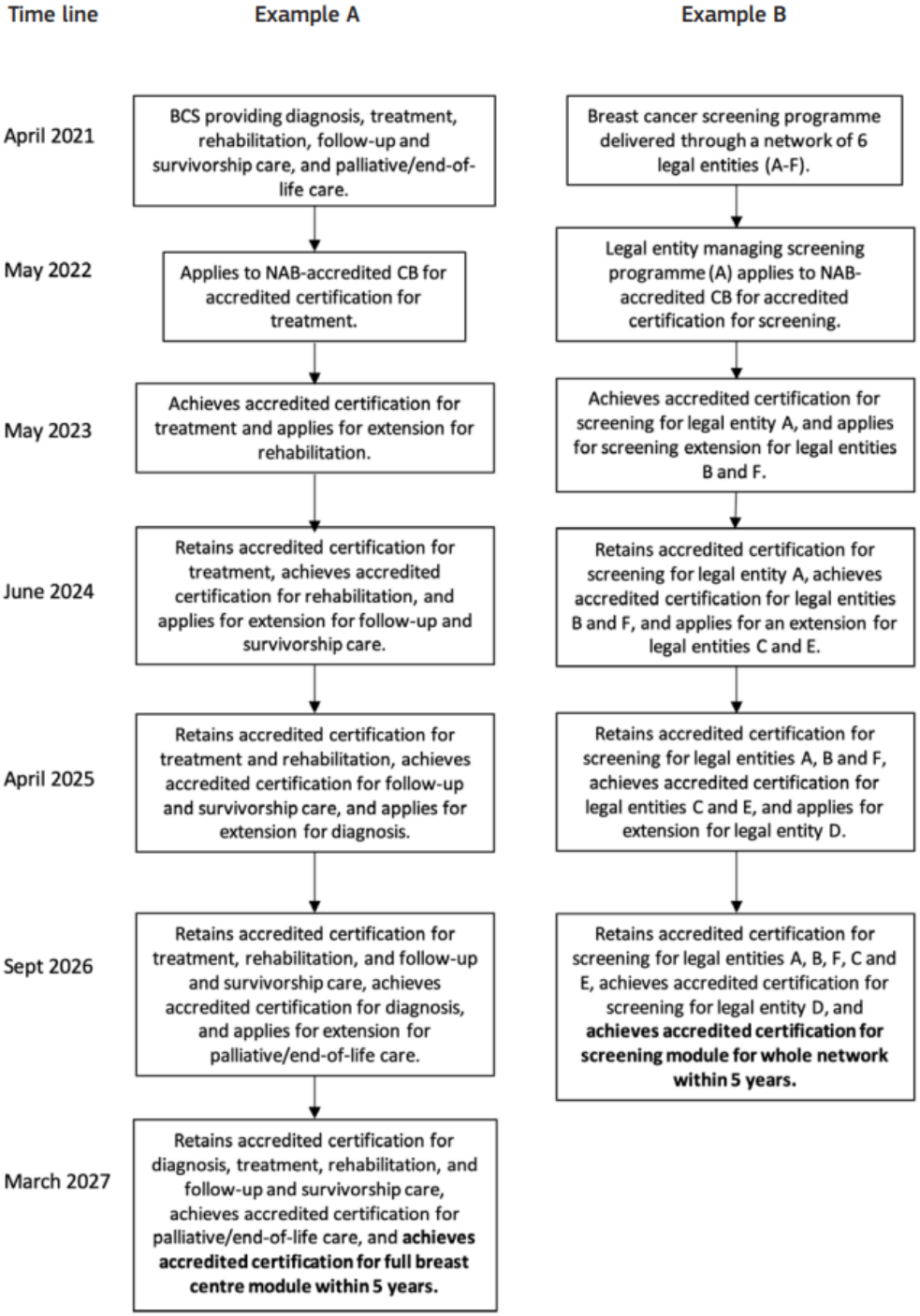
Statement
The maximum time from receipt of a breast specimen by the pathology service to the release of the pathology results, including immunohistochemistry (IHC), must be 5 working days for non-surgical biopsies and 10 working days for surgical specimens.

Compliance criterion	Evidence to be checked	Yes / No / NA / NC	Norm achieved? Yes / No
DGN-PTH-1.1 Each pathology service has a procedure for identifying cases that remain unreported for longer than anticipated, and has a documented system to manage and report those cases.	Procedure for identifying and managing cases that are not reported within the anticipated time.		
DGN-PTH-1.2 Proportion of pathology results from non-surgical biopsies released from the pathology service within 5 working days (7 calendar days) after receipt of the breast specimen by the pathology service.	Documented protocol for collection of data and calculation of indicator.		
	Raw data and calculated indicators.		
	Pathology reports.		
	Records/reports of dates of specimen receipt and release of pathology results from non-surgical biopsies.		
DGN-PTH-1.3 Proportion of pathology results from surgical specimens released from the pathology service within 10 working days (14 calendar days) after receipt of the breast specimen by the pathology service.	Documented protocol for collection of data and calculation of indicator.		
	Raw data and calculated indicators.		
	Pathology reports.		
	Records/reports of dates of specimen receipt and release of pathology results from surgical specimens		

Notes:

- *There will be a **transitional stage** when certification can be achieved in a **step-wise manner** (over a period of 5 years), for individual processes within the three modules, and, also, for different entities within a network.*

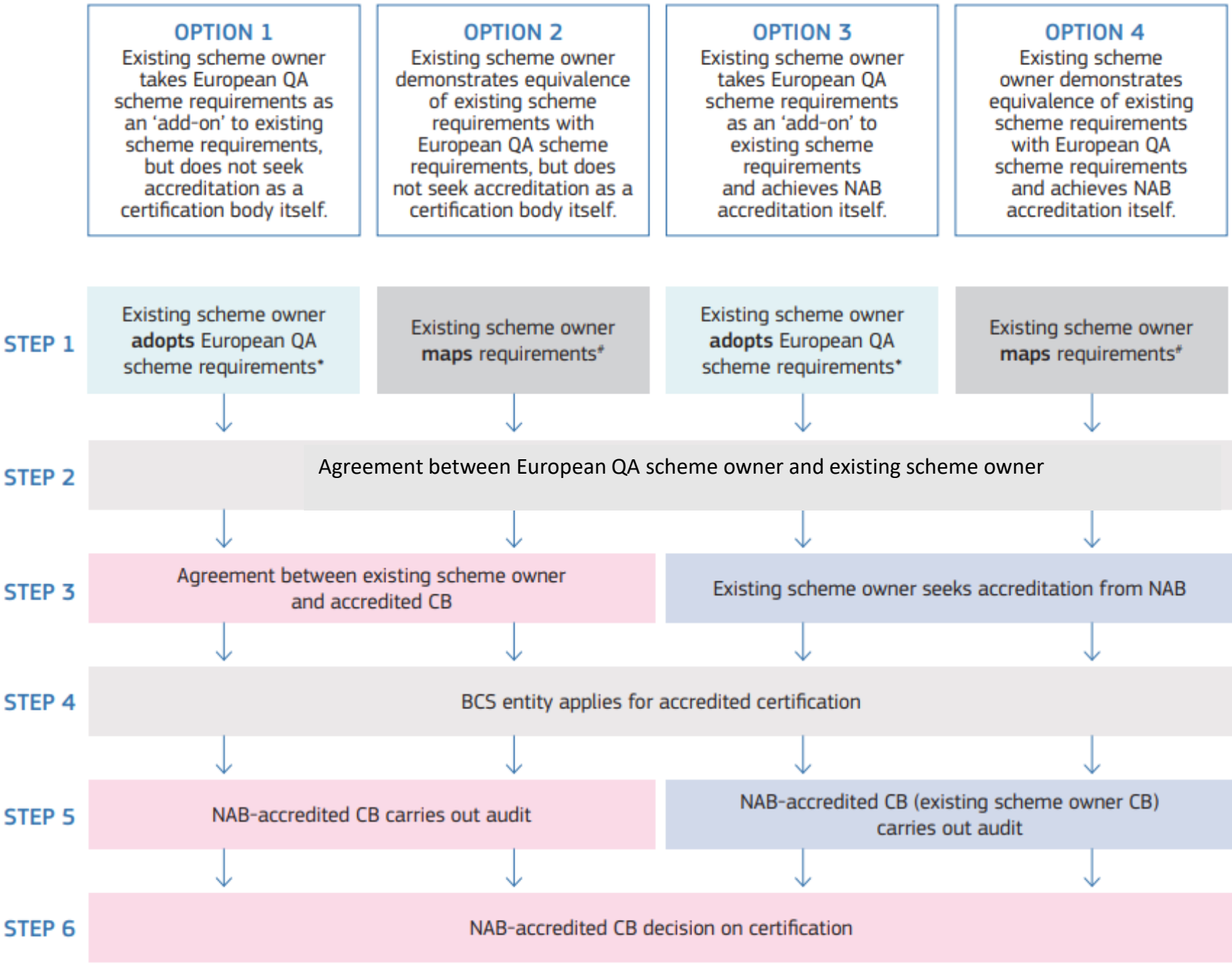
Examples of a time-limited, stepwise approach to accredited certification are following (for a single legal entity and network)…


Time line
Example A
Example B
April 2021
BCS providing diagnosis, treatment, rehabilitation, follow-up and survivorship care, and palliative/end-of-life care.
Breast cancer screening programme delivered through a network of 6 legal entities (A-F).
May 2022
Applies to NAB-accredited CB for accredited certification for treatment.
Legal entity managing screening programme (A) applies to NAB-accredited CB for accredited certification for screening.
May 2023
Achieves accredited certification for treatment and applies for extension for rehabilitation.
Achieves accredited certification for screening for legal entity A, and applies for screening extension for legal entities B and F.
June 2024
Retains accredited certification for treatment, achieves accredited certification for rehabilitation, and applies for extension for follow-up and survivorship care.
Retains accredited certification for screening for legal entity A, achieves accredited certification for legal entities B and F, and applies for an extension for legal entities C and E.
April 2025
Retains accredited certification for treatment and rehabilitation, achieves accredited certification for follow-up and survivorship care, and applies for extension for diagnosis.
Retains accredited certification for screening for legal entities A, B and F, achieves accredited certification for legal entities C and E, and applies for extension for legal entity D.
Sept 2026
Retains accredited certification for treatment, rehabilitation, and follow-up and survivorship care, achieves accredited certification for diagnosis, and applies for extension for palliative/end-of-life care.
Retains accredited certification for screening for legal entities A, B, F, C and E, achieves accredited certification for screening for legal entity D, and achieves accredited certification for screening module for whole network within 5 years.
March 2027
Retains accredited certification for diagnosis, treatment, rehabilitation, and follow-up and survivorship care, achieves accredited certification for palliative/end-of-life care, and achieves accredited certification for full breast centre module within 5 years.

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

- *The scheme allows CBs that are accredited (or applicant) for the 'European QA Scheme' to cooperate with non-accredited CBs (who **may already be operating a certification scheme for breast cancer services**) and to accept their audits, but the accredited CBs must demonstrate that such arrangements meet ISO/IEC 17065 requirements.*
- *The scheme also expects accredited CBs to `take account' of certifications granted to breast cancer services by the non-accredited CBs that they cooperate with, but they must still comply with ISO/IEC 17065.*
- *Existing scheme owners may decide to seek accreditation from NABs but must demonstrate that they meet the QA Scheme requirements*.

A Table with the different options for recognition is following…


OPTION 1
Existing scheme owner takes European QA scheme requirements as an 'add-on' to existing scheme requirements, but does not seek accreditation as a certification body itself.
OPTION 2
Existing scheme owner demonstrates equivalence of existing scheme requirements with European QA scheme requirements, but does not seek accreditation as a certification body itself.
OPTION 3
Existing scheme owner takes European QA scheme requirements as an 'add-on' to existing scheme requirements and achieves NAB accreditation itself.
OPTION 4
Existing scheme owner demonstrates equivalence of existing scheme requirements with European QA scheme requirements and achieves NAB accreditation itself.
STEP 1
Existing scheme owner **adopts** European QA scheme requirements*
Existing scheme owner **maps** requirements#
Existing scheme owner **adopts** European QA scheme requirements*
Existing scheme owner **maps** requirements#
STEP 2
Agreement between European QA scheme owner and existing scheme owner
STEP 3
Agreement between existing scheme owner and accredited CB
Existing scheme owner seeks accreditation from NAB
STEP 4
BCS entity applies for accredited certification
STEP 5
NAB-accredited CB carries out audit
NAB-accredited CB (existing scheme owner CB) carries out audit
STEP 6
NAB-accredited CB decision on certification

*As **Continuity of care*** is an extremely important element in the ‘European QA scheme’

a BCS entity seeking certification is responsible for coordinating with other BCS entities to ensure continuity of individual patient care between modules

and

CBs must ensure that they audit the BCSs procedures and practices for this, particularly when different BCS entities are working together to deliver different processes within and between modules covering the overall breast cancer care pathway.

Thank you for your attention!