

Requirements for the accreditation in the European Quality Assurance Scheme for Breast Cancer Services

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Webinar for NABs 28/04/2022



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Presentation

- The tasks and the role of EA WG BCS
- Accreditation in the QA scheme
- EA process to accept and implement the QA scheme
- Preparation to accredit CBs according to the QA scheme in the future
- Accreditation of certification bodies
- The pilot run, the role of accreditation in the pilot
- How laboratory accreditation is involved in the scheme

The tasks and the role of EA WG BCS

Appointed in 2014

Project Manager Accredia (2014-2021),
FINAS (2021-)

Members DANAK, ENAC, IARM (2014-
2017), DAkks (2020-), Accredia (2021-)

EA project task force/steering group
ESYD, SAS, UKAS

The tasks and the role of EA WG BCS

Terms of reference:

- The purpose of the EA BCS WG is to **advise** the EA Executive Committee through the EA BCS STG for Breast Cancer Services on accreditation matters related to the development and operation of **accreditation activities in the breast cancer services sector** and to **implement the project within EA.**



The tasks and the role of EA WG BCS

Terms of reference continue:

- In particular, to respond to the requirements of the **European Commission/JRC for advice on specific technical issues** including:
 - The formulation and review of specific technical criteria to **facilitate** effective and consistent **application of EA NABs accreditation activities** when assessing conformity assessment bodies in the field of accreditation **for the European scheme for breast cancer services**;
 - **The acceptability of existing processes and procedures** for different elements of breast cancer services **as a basis for accrediting** conformity assessment bodies (e.g. laboratories, certification bodies, etc.);
 - **The provision of information** relating to breast cancer services that may have an important impact upon NABs' services;
 - The need for the establishment of specialist task forces.

The tasks and the role of EA WG BCS

- Roadmap for the contract with the European Accreditation

DELIVERY DATE	ACTIVITIES/TASKS	OUTPUT
May 2022	Contract Progress Meeting JRC – EA	
May 2022	Support in organisation and conduction of training courses for auditees and assessors / auditors related to the accreditation (for CABs)/ certification process (for BCSs) (part of Task 4: The pilot run)	Deliverable 4.6 - Support to the JRC for the organisation and conduction of training courses for auditees and assessors / auditors related to the accreditation (for CABs)/ certification process (BCSs) (contractor must provide advice on criteria for the selection of trainers and subjects to be covered, and must be available to provide training for the parts related to the legal aspects, etc.).
Jul 2022 – Dec 2022 (6 months)	Pilot run (part of Task 4: The pilot run)	Deliverable 4.7 - Coordination of the pilot run. The contractor must coordinate concerned NABs and CABs, provide a unique contact point available round-the clock for all people involved, etc. Deliverable 4.8 – Continuous monitoring for the pilot run, including coordination of the activity of the NAB.
Oct 2022	Contract Progress Meeting JRC – EA	

The tasks and the role of EA WG BCS

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How EA WG BCS has supported the JRC:

Feasibility report

- QA scheme is generally compliant with the requirements of the relevant accreditation standards and certification scheme framework

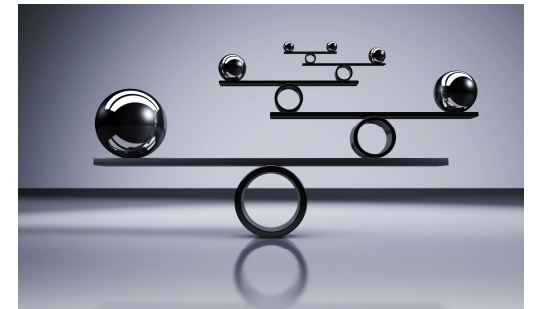
Guiding material

Support to organize the pilot run

- Help to find the participants to the pilot run
- Presentation about the accreditation requirements in the training courses for participants
- Monitoring the pilot run

Accreditation in the QA scheme

- Object - Increase the confidence in the quality of the breast cancer care
- Quality chain
 - Breast cancer services → certification bodies → accreditation bodies
- Accreditation of certification bodies according to EN ISO/IEC 17065
- Accreditation of diagnostic services according to EN ISO 15189 or EN ISO/IEC 17025 or EN ISO/IEC 17020 (pathology)



EA process to accept and implement the QA scheme

- **EA-1/22**
- Where the EC requests EA to **evaluate the scheme**, this will be undertaken by EA as a membership body
- **Responsibility** for progressing such a request will lie with **the Executive or TMB** once established
- Involve the **input of a task force** competent in the area of the scheme that shall report directly to the Executive committee or Technical Management Board once established, but which will take **the technical decision** with respect to scheme acceptance.
- **Final decision** on the implementation of the scheme shall be taken by **the GA**

Preparation to accredit CBs according to the QA scheme in the future

Competence of NAB

- Knowledge of the scheme requirements
 - Requirements for certification bodies
 - Requirements for breast cancer services
- A need for technical assessors/experts
 - Possible European expert pool
 - → training needs

Co-operation with scheme owner

- Information exchange

Support from EA BCS WG

Accreditation of certification bodies

- Special issues to be noticed:
 - Competence requirements and availability of auditors/experts
 - Remote audits
 - Already existing schemes, co-operation with accredited CB
 - Scope of certification, modules
 - Continuity of care, networks

The pilot run, the role of accreditation in the pilot

- Voluntary BCSs, CBs and NABs (Accredia, ENAC)
- Participating CBs already accredited
- Assessment process without decision making, as the scheme is in the pilot phase
- Assessment focusing on the implementation of the scheme and competence of auditors, witnessing included
- Output of the pilot assessment = report
- EA WG BCS will observe the assessments and certification audits
- Financial support possible from the project budget
- Same time the parallel 'pilot' for non-accredited CBs



How laboratory accreditation is involved in the scheme

Scheme Owner Manual:

- CBs are required to adopt a 'presumption of conformity' for those imaging and pathology services that are accredited by a NAB that is part of a mutual recognition agreement between accreditation bodies. Where imaging and pathology services hold such **accreditation, 'presumption of conformity' by the CB means that no additional audit of the imaging and pathology service** will be carried out by the CB. This is provided that the screening and/or diagnosis service has evidence of up-to-date accreditation in the form of a certificate and **scope of accreditation, and evidence of compliance with the European QA scheme requirements.**

Thank you for your attention!

Questions?

