



START PROCEDURE

Breast Centres Certification - Italcert scheme in partnership with BCCert



Application form

Mandatory entry requirements

1. the Breast Centre has a database validated by **Eusoma** (validation not older than 2 years)
2. the Breast Centre has a critical mass of 150 newly diagnosed cases of primary breast cancer (at all ages and stages) coming under its care each year
3. the Breast Centre has a Clinical Director

Satisfactory NO

The Certification procedure cannot start

Satisfactory YES

Contractual Documents

- Agreement
- Certification Rules and Regulation
- Regulation for the Use of Certification Logo
- Privacy

BCCert will send details to login the online questionnaire to be filled in prior the audit

Feasibility NO

Request for additional information or adjustments

Feasibility YES

BCCert will send date proposal for the Initial audit and the audit plan

INITIAL AUDIT

AUDIT REPORT

AUDIT TEAM

Highly specialised European auditors

- Lead Auditor
- Breast Surgeon
- Breast Radiologist
- Breast Pathologist
- Breast Care Nurse

AUDIT SCHEDULE

- Evaluation of Breast Centres documents
- Meeting with the Breast Centre
- Auditors divide to separate tasks
- MDT meeting observed by the Audit team
- Meeting of the Audit team and feed back to the Breast Centre

In case of a multisite Breast Centre, additional auditors must be foreseen depending on Breast Centre complexity and structure.

NC (Non conformities) = inability to comply with a mandatory requirement

R (Recommendations) = non satisfaction of a NON mandatory requirement

BREAST CENTRE PROPOSAL FOR CORRECTIVE ACTIONS

Satisfactory NO

Back to the Breast Centre for a new proposal to be sent

Satisfactory YES

EVIDENCE DOCUMENTS for NC (showing compliance)

Satisfactory NO

Back to the Breast Centre for additional documents to be sent

Satisfactory YES

CERTIFICATION DECISIONERS EVALUATION

POSITIVE = CERTIFICATE and LOGO

POSITIVE + ADDITIONAL REQUESTS = Certificate and LOGO but Certification Decisioners can ask for additional information to be provided or, if necessary, for an extra audit

YEAR 1 - INITIAL AUDIT

YEAR 2

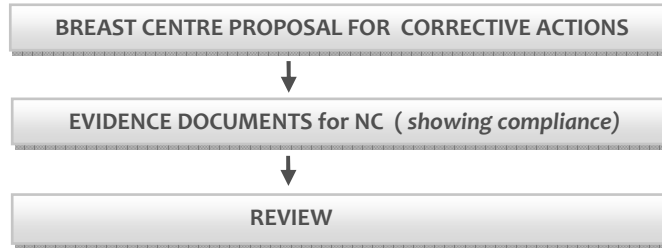


AUDIT TEAM

- Lead Auditor
- One auditor among the following : Breast Surgeon, Breast Radiologist or Breast Pathologist

In case of a multisite Breast Centre, additional auditors must be foreseen depending on Breast Centre complexity and structure.

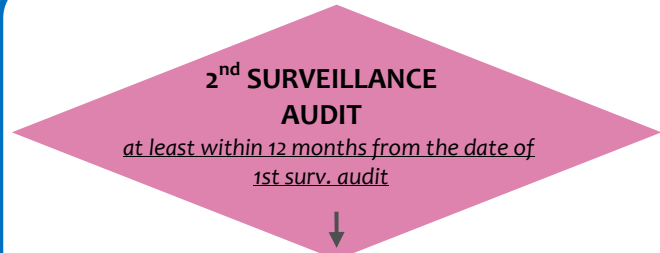
**NC (Non conformities)
R (Recommendations)**



POSITIVE = certification can continue

POSITIVE + ADDITIONAL REQUESTS = Certification can continue but the Breast Centre can be asked to provide additional information or, if necessary, an extra audit can be requested

YEAR 3

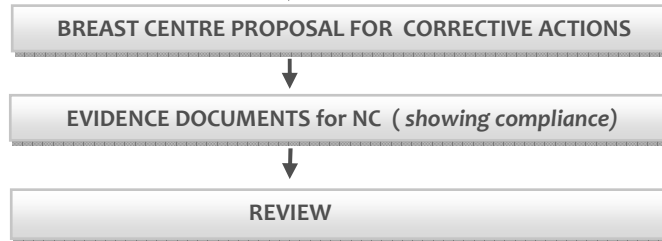


AUDIT TEAM

- Lead Auditor
- One auditor among the following : Breast Surgeon, Breast Radiologist or Breast Pathologist

In case of a multisite Breast Centre, additional auditors must be foreseen depending on Breast Centre complexity and structure.

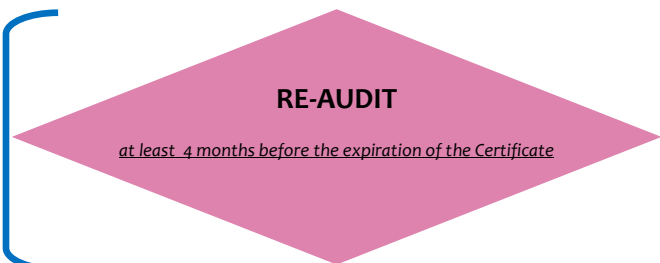
**NC (Non conformities)
R (Recommendations)**



POSITIVE = certification can continue

POSITIVE + ADDITIONAL REQUESTS = Certification can continue but the Breast Centre can be asked to provide additional information or, if necessary, an extra audit can be requested

YEAR 4 RE-AUDIT



For the detailed procedure see Initial audit