BREAST DIAGNOSTIC SERVICES CERTIFICATION PROCEDURE

**Application form**

**Mandatory entry requirements**
1. The Breast Diagnostic Unit has a critical mass of 2000 mammograms/annual
2. The Breast Diagnostic Unit has a Clinical Director
3. The Breast Diagnostic Unit has a formal data recording system (including image results, assessment processes and outcomes)

**Contractual documents**
- Agreement
- Certification Rules and Regulation
- Regulation for the use of certification logo
- Privacy

BCCert send the questionnaire to be filled in prior the audit

STAGE 1 - OFFSITE
EXPERT INVOLVED: physicist

STAGE 2 - ONSITE
EXPERTS INVOLVED in the AUDIT TEAM: visit manager, pathologist, radiologist, radiographer, physicist (in specific cases)

NC (Non Conformities): inability to comply with a mandatory requirement
R (Recommendations): non satisfaction of a recommended requirement

Centre proposal for Corrective Actions

Evidence documents for NC (Showing compliance)

CERTIFICATION DECISIONER EVALUATION

Satisfactory NO
- Back to the centre for a new proposal to be sent
- Back to the centre for additional documents to be sent
- POSITIVE = Certificate and LOGO
- POSITIVE+ADDITIONAL REQUESTS = Certificate and LOGO

Feasibility NO
- Request for additional information

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EXPERTS INVOLVED in the AUDIT TEAM: radiologist, radiographer

Centre proposal for Corrective Actions
Evidence documents for NC (Showing compliance)

REVIEW

Back to the centre for a new proposal to be sent
Back to the centre for additional documents to be sent
POSITIVE = Certification can continue
POSITIVE + ADDITIONAL REQUESTS = Certification can continue but Certification Decisioners can ask for additional information to be provided or, if necessary, for an extra audit

Satisfactory NO

YEAR 2 - 2nd SURVEILLANCE AUDIT ONSITE

EXPERTS INVOLVED in the AUDIT TEAM: visit manager, radiologist, radiographer

NC (Non Conformities): inability to comply with a mandatory requirement
R (Recommendations): non satisfaction of a recommended requirement

Centre proposal for Corrective Actions
Evidence documents for NC (Showing compliance)

REVIEW

Back to the centre for a new proposal to be sent
Back to the centre for additional documents to be sent
POSITIVE = Certification can continue
POSITIVE + ADDITIONAL REQUESTS = Certification can continue but Certification Decisioners can ask for additional information to be provided or, if necessary, for an extra audit

Satisfactory NO
3rd SURVEILLANCE AUDIT

EXPERTS INVOLVED: visit manager

NC (Non Conformities): inability to comply with a mandatory requirement
R (Recommendations): non satisfaction of a recommended requirement

- Centre proposal for Corrective Actions
  - Satisfactory NO
    - Back to the centre for a new proposal to be sent
  - Evidence documents for NC (Showing compliance)
    - Satisfactory NO
      - Back to the centre for additional documents to be sent
      - POSITIVE = Certification can continue

REVIEW

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

RENEWAL AUDIT

For detailed procedure, see INITIAL AUDIT

YEAR 3 - 3rd SURVEILLANCE AUDIT OFFSITE

YEAR 4 - RENEWAL AUDIT