

# BREAST DIAGNOSTIC SERVICES CERTIFICATION PROCEDURE



ITALCERT Scheme, in partnership with BCCERT



## 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)

Satisfactory NO

Certification procedure cannot start

### 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

Feasibility NO

Request for additional information

BCCert send a date proposal for the initial audit

INITIAL  
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)

AUDIT  
REPORT

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

CERTIFICATION DECISIONER EVALUATION

POSITIVE = Certificate and LOGO

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

YEAR 0 - AUDIT STAGE 1 OFFSITE and AUDIT STAGE 2 ONSITE

YEAR 1- 1st SURVEILLANCE AUDIT OFFSITE



EXPERTS INVOLVED: visit manager

AUDIT REPORT

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

REVIEW

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

YEAR 2- 2nd SURVEILLANCE AUDIT ONSITE



EXPERTS INVOLVED in the AUDIT TEAM: radiologist, radiographer

AUDIT REPORT

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

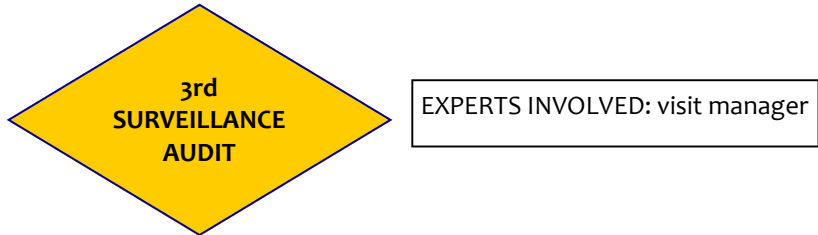
Back to the centre for additional documents to be sent

REVIEW

POSITIVE = Certification can continue

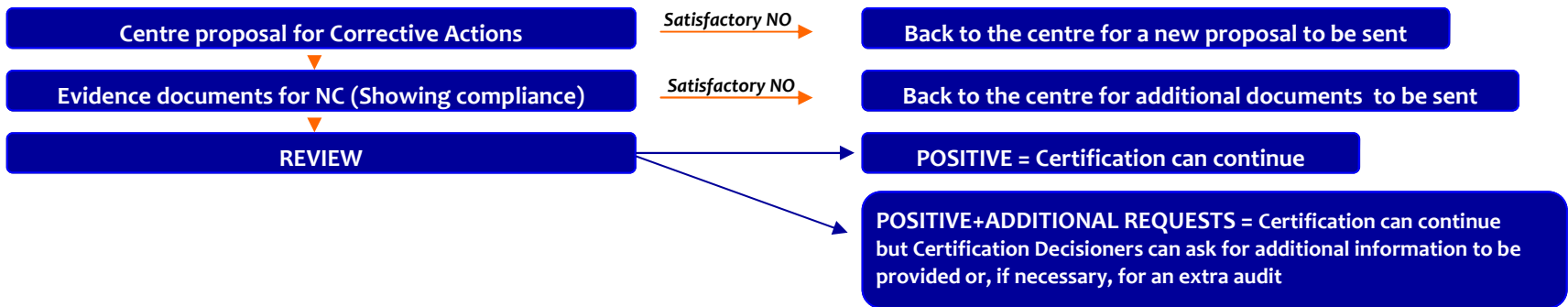
POSITIVE+ADDITIONAL REQUESTS = Certification can continue but Certification Decisioners can ask for additional information to be provided or, if necessary, for an extra audit

YEAR 3- 3rd SURVEILLANCE AUDIT OFFSITE



AUDIT REPORT

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



YEAR 4 - RENEWAL AUDIT

