

CERTIFICATION RULES AND REGULATIONS

for

BREAST DIAGNOSTIC UNIT

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1 PURPOSE AND PREMISE

ITALCERT S.r.l. undertakes to perform, in a professional manner, through a collaboration with the Breast Centres Certification (BCCERT), a system conformity evaluation in relation to the reference standards identified and agreed between the parties and, if successful, to issue the Certificate of conformity reporting on it the Certification Logo (property of ITALCERT) and the following disclosure:

***Breast Screening and Diagnostic Services Certification - ITALCERT Certification Scheme
in partnership with BCCERT
In compliance with the standard EUREF Guidelines
“EUREF Requirements for Breast Screening and Diagnostic Services”***

BCCERT will take care of the procedure from an operative, organizational and scientific point of view and will represent the single reference for the Breast Diagnostic Unit (hereafter referred to as **Breast Diagnostic Unit** or simply **Unit**), during the whole procedure.

ITALCERT maintains the certification's responsibility of **Breast Screening and Diagnostic Services Certification**, leaving some operative aspects of the activity to BCCERT (e.g: audit planning, set up and dispatch of audit plan, confirm of the remarks etc.)

This Regulation sets the conditions and the operating modalities followed by ITALCERT and BCCERT to carry out certification procedure in compliance with EUREF Guidelines “EUREF Requirements for Breast Screening and Diagnostic Services”.

More details (i.e. economic fares) not included or specified in the regulation are defined in the Agreement. Being the certification scheme based on international documents like European Community Resolutions, Eusoma Guidelines and EUREF Guidelines, issued and published in English, all the contractual documents, included this regulation, will be in English.

Any changes from previous version of this document are marked by a lateral bar on the right side of the text.

2 DEFINITIONS

Entry Requirement: necessary to apply for Certification.

Mandatory requirement: necessary to reach Certification.

Non mandatory requirement: desirable but not necessary to reach Certification.

Major Non Conformity (MNC): inability to comply with a mandatory requirement.

Minor Non Conformity (MinNC): inability to comply with a mandatory requirement that cannot be considered as Major Non Conformity.

Recommendation (REC): non satisfaction of a non mandatory requirement that indicates improvement opportunities. In case of recommendation the Unit is requested to foresee a pathway to achieve those missing non mandatory requirements. In this setting also situations that could potentially generate any Non Conformities are included.

Breast Diagnostic Unit: working entity and does not have to be contained (although preferable) within a single geographical entity, although the constituent buildings must be sufficiently closely sited to allow true multidisciplinary working. An ‘Breast Diagnostic Unit’ is defined by all aspects of Breast Diagnostic Services being offered by a multidisciplinary team (MDT) with others responsible for diagnostic and treatment services, including the radiologist(s), pathologist and preferably the surgeon, breast care nurse and radiographer.

Visit Manager: manages the audit team activity and coordinates visitors/auditors activity.

Visitor/auditor: members of the audit team with special scientific competencies in the different fields subject of Breast Screening and Diagnostic Services Certification.

3 CERTIFICATION PRINCIPLES

3.1 General considerations

The procedure is based on the EUREF Guidelines "**EUREF Requirements for Breast Screening and Diagnostic Services**".

The basic criteria underlay the assessment of a Breast Diagnostic Unit are:

- a single integrated Unit
- a centralized system of diagnostic assessment for mammographically or clinically detected lesions
- a full range of assessment facilities provided in order to allow complete and adequate work up by the Unit without necessarily having to refer the woman on for further investigation elsewhere
- a sufficient number of Mammograms performed to allow effective working and continuing expertise (the Unit must perform at least 2,000 mammograms a year)

In addition, the Unit must:

- perform physical examinations and ultrasound examinations as well as the full range of radiographic procedures
- to monitor data and feedback of results
- keep a formal record of mammogram results, assessment processes and outcomes (including internal audit)
- Have an organised and specialist cyto/histopathological support service with the ability to obtain the routine used immune-histopathological tests for breast lesions
- working in multidisciplinary fashion

Certification is based on the capacity of the Breast Diagnostic Unit to meet the recommendations of the EUREF Guidelines.

Certification activity foresees, as main core, information collection through a web questionnaire (to be filled in prior the audit), the preparation of a set of documents available for the inspection onsite and offsite (on the basis of a detailed check list that the Unit will receive prior the visit).

3.2 Independence and impartiality

ITALCERT must follow what indicated in the referring rules for accreditation. ITALCERT must guarantee independence and impartiality principles and therefore ITALCERT cannot provide any activity of consulting about the realization and/or maintenance by the Unit of the system requirements, subject of the conformity evaluation.

3.3 Privacy Policy and Data Protection

All the data directly supplied by the Breast Diagnostic Unit to ITALCERT and BCCERT (including personal data and all the necessary information/data supplied by the Centre to ITALCERT and BCCERT for certification purposes) will be processed by ITALCERT and BCCERT in order to ensure a regular performance of the contractual relationship both legally (e.g. compliance with accounting requirements, tax, etc..) and commercially (e.g. sending of our catalogs, brochures, etc..), and to allow the timely execution of the agreements that will eventually be entered into between the parties in the future.

In relation to the aforementioned purposes, the processing of personal data takes place by computer, manual and telematics tools strictly related to the same purposes and, however, to ensure the safety and privacy of data. The provision of personal data is therefore essential in relation to the proper performance of the contractual relationships, so that any refusal to provide them causes the inability of ITALCERT to continue the same relationships.

Unit data may be communicated by ITALCERT or BCCERT to public bodies and in general to every public and private entities, as within their competence, and to nominated insiders both responsible or in charge of data processing, as well as to ITALCERT or BCCERT external staff, such as managers and / or agents to whom the communication is necessary for the execution of the services arranged and for which ITALCERT/BCCERT have obligation or need of communication.

Following Certification release, details of Unit will be published on the "Register of Certified Breast Diagnostic Unit" which will be regularly sent to the referring Bodies. Such register has to be available in case of any written request, on the same way ITALCERT will make available the possible certification renounce, suspension or revocation, in case of any written request.

ITALCERT also guarantees privacy on all the information collected during the audit, including what stated in the audit report. ITALCERT auditors/visitors must also guarantee privacy, concerning all the information they will have access during the whole certification process.

ITALCERT and BCCERT are partners for the certification of the Unit as submitted in the **Breast Screening and Diagnostic Services Certification** scheme.

In this certification scheme, data is co-processed by both ITALCERT and BCCERT.

Processing of sensitive data: consultation and Analysis of clinical records and/or other similar documents of the patients of the Unit are made by the Visit Manager, the Visitor and specific personnel, is conducted exclusively on the audit stage: the subject of processing is made by ITALCERT that outsources directly each professional.

The reference Legislation is the EU Regulation 2016/679 of the European Parliament and of the Council of the 27th April 2016 in relation to the protection of natural person and free movement of personal data that may be supplemented with implementing measures adopted by the EUROPEAN PARLIAMENT and the EUROPEAN COUNCIL that issued the Regulation and by the Italian Authorities where the data controllers ITALCERT and BCCERT are resident.

4 HOW TO START THE PROCEDURE

4.1 Request for application

Any Breast Diagnostic Unit, can ask for a certification procedure offer.

Application Form, Certification Rules and Regulations for Breast Diagnostic Unit (R.010) and Regulation for the use of Certification Logo (R011) are available on **Breast Screening and Diagnostic Services Certification** website, or they must be sent by ITALCERT together in the Agreement.

In order to be able to issue the offer on the basis of Unit structure and sites, the Unit who wants to start certification procedure are requested to fill the Application Form and send it back to BCCert Operating Office or ITALCERT (see more details in the form).

To start certification procedure, Breast Diagnostic Unit has to fulfill the following three 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 outcome).

Once the application form is received, ITALCERT will send to the applicant Breast Diagnostic Unit:

- Agreement
- Privacy Policy.

4.2 Location of the audit

In the Application Form the Unit must indicate in details where the audit will take place (Name of the Breast Diagnostic Unit and complete address).

In order to organize the visit, the Unit must give a detailed description (including geographical location and addresses) of its structure: main building and departments and any other external site.

The Unit must notify in writing, by fax or by record delivery letter R.R., any relocation of the Unit or the Hospital or activation of any additional sites.

The Unit must guarantee visitors access to all the structure/departments. The possibility to carry out inspections also in external sites, is at ITALCERT complete discretion.

Subsequently to the start of Certification process, ITALCERT may request, at its discretion, an extension of the foreseen time for the audit to visit, for example, additional site or an outsourcer. If this unexpected need is due to a miscommunication from the Unit (i.e. lack of information in the Application Form), the audit will be considered as an "extra audit" (see paragraph 6.6) and could cause an additional cost for the Unit.

4.3 Acceptance of the application and contract execution.

To make official certification offer, Unit has to send back to ITALCERT the following documents filled in and signed:

- Application Form
- Agreement
- Regulation for the use of the Certification Logo (Document R011)
- Certification Rules and Regulations for Breast Diagnostic Unit (Document R.010)
- Privacy Policy

In case of lacking of just one of the above-mentioned documents, ITALCERT may not issue the Certificate.

In case the Unit should subscribe and sign the agreement but could not be available for the audit visit, ITALCERT will have the right to close the procedure within one year, following a written formal communication by record delivery letter R.R or e-mail.

ITALCERT will not refund the Breast Diagnostic Unit of the payment already done.

5 AUDIT IMPLEMENTATION – GENERAL PRINCIPLES

5.1 Audit operating modalities

The Certification procedure consists of:

- questionnaire to be filled in by the Unit
- audit visit off site
- audit visit on site.

Once the Certification Agreement and all the other mandatory requested documents are finalized, BCCERT sends to the applicant Unit the login details to access the online questionnaire. Unit is expected to fill it in one month. Longer time could be accepted, under request by the Unit.

The answers given to the questionnaire will be considered for the Initial Audit feasibility.

Once the audit feasibility has been confirmed, the visit scheduling is agreed on the basis of auditors/visitors and Unit availability. Normally the visit shall be scheduled within 4 months.

Audit scheduling and composition of the Audit Team are formally communicated by e-mail to the Unit (with a similar mode is that the audit is **onsite** whether it's conducted **offsite**).

The composition of the Audit Team will be considered accepted if BCCERT will not receive any motivated remarks (i.e. in case of motivated conflict of interest) within 3 working days from receipt of the communication.

Together with this official communication, the Unit receives the detailed check list of the documents to be available onsite or offsite for audit and the audit plan with the indication of the detailed schedule of the visit.

During the visit, each member of the Audit Team collects all the necessary information to express his/her evaluation on the conformity of EUREF Requirements through:

- Inspection of the documents prepared by the Unit for each single discipline/issue
- Interview with the Unit team members
- Evaluation of daily activity /work (only during visit onsite)

The Unit must ensure to the Audit Team and ACCREDIA personnel (if occurs – see § 11.1) the access to all the activities/departments and related team, indicated in the audit plan, including those run outside the main building/headquarter.

Unit must also ensure the presence of the contact person indicated in the Application Form who will act as "guide" to assist the Audit Team during the whole visit.

The Breast Centre must ensure that each visitor can interview at least one professional of Unit team members.

If necessary (see § 4.2), ITALCERT can ask to verify an outsourcer in its headquarter in addition to what has been scheduled. Such audit can be considered as "extraordinary audit" or be included in the scheduled audit at incontestable discretion of ITALCERT.

The inability to carry out an outsourcer's inspection can be considered by ITALCERT as a sufficient motivation for a negative evaluation on Certification release, or cause a certification suspension.

At the end of each audit, the Visit Manager issues an Audit Report ("AR") containing all the Non-Conformities, Recommendations and Observations.

5.2 Management of missing requirements

For each Non Conformity and Recommendation, the Unit must report to BCCERT at least within 15 days from the date of the visit, a proposal of subsequent activities indicating the immediate correction planned, an analysis of the causes of the Non Conformity/Recommendation, a description of the proposed corrective action and personnel involved, the timing for the closure of the Non Conformity/Recommendation and for sending evidence documents on the compliance to BCCERT (max. 4 months from the date of the visit).

BCCERT cannot accept a deadline superior to 4 months; if this situation will occur, the Unit will be requested to modified the deadline.

The proposal of corrective actions has to be sent by fax or e-mail to BCCERT using the Corrective Action Form, through which BCCERT can monitor the progress in the management of each corrective action by verifying the action plan indicated in it, by the Unit.

The corrective action proposal has to be correlated to the cause of the Non-Conformity and should take into account the possibility that the Non-Conformity could be present also in similar situations or in additional/external sites (in case of multisite Breast Diagnostic Unit).

The corrective action proposal has to be evaluated by the Audit Team that carried out the visit. The evaluation outcome and any possible additional request have to be formally communicated to the Breast Diagnostic Unit.

BCCERT has to receive evidence documents showing compliance with the missing Major Non-Conformities by a defined deadline (usually not more than 4 months from the date of the visit). Some requirements may need a visit by an expert to check fulfillment (see paragraph 6.6 "unplanned/extra audit").

After this deadline, ITALCERT will proceed to suspend the Certificate.

In case the Major Non-Conformity is reported during an Initial or Renewal Audit, the Certificate cannot be issued until the Unit will give evidence of the Major Non-Conformity resolution.

The fulfillment of corrective actions regarding Minor Non Conformities and Recommendation will be verified during the subsequent audit. However, on the basis of possible different situations, *Breast* BCCERT can decide, after formally informing the Unit, to proceed with a different examination of the corrective actions implemented by the Unit.

In order to be able to close a Non-conformity, the corrective action proposal has to be implemented and effective. In case the Audit Team not have evidence that the corrective action proposed has been implemented, the Non-Conformity can be upgraded from Minor to Major.

5.3 Certification Decision Committee

The members of the Certification Decision Committee are experts (Decision Maker) in breast disease in the different disciplines approved by EUREF.

It is the responsibility of the Certification Decision Committee (also called Board) to decide on the Certification status of each Breast Diagnostic Unit.

In considering Certification status, the Board must take note of the object of Certification: it is to certify the Breast Diagnostic Unit capable of complying with the EUREF standards indicated in the referring guidelines.

The evaluation will be based on the questionnaire, the results of the visit, the evidence of the corrective actions of the Unit.

Once the Certification Decision Committee has unanimously reached the agreement on the Certification status of the Unit, the Certificate and Logo will be issued and then sent to the Breast Diagnostic Unit.

6 TYPE OF AUDITS

6.1 Type of applicable audits

Within the Certification procedure, ITALCERT can ask the carrying out of the following audit:

- Pre-audit (not mandatory and it can be requested directly by the Breast Diagnostic Unit)
- Initial Audit (stage 1 **offsite**¹ and stage 2 **onsite**²)
- Surveillance Audit onsite
- Surveillance Audit offsite
- Re-audit
- Unplanned Audit/Extra Audit

All audits are upon payment for the Breast Diagnostic Unit and the fees are indicated in the Agreement.

6.2 Pre-audit

If Unit find it useful, it can ask for a Pre-audit visit, before applying to Certification.

The Pre-audit visit aims at checking if a Unit is suitable to apply for Certification with regard to the EUREF requirements but not analyzing in details features of each discipline. The Pre-audit visit is usually carried out by Visit Manager or if unavailable by a single professional auditor/visitor, not necessarily medical doctor. The Pre-audit is carried out at Breast Diagnostic Unit headquarter using the same registration documents foreseen for the audit activity (exclusive of the audit plan).

At the end of the Pre-audit, a report is issued. Possible critical points are indicated as aspects to be implemented as recommendations with regard to mandatory requirements. The Pre-audit is not part of the Certification procedure.

6.3 Initial Audit

The Initial Audit has the aim of verifying if the Unit is in compliance with the certification requirements, including what requested by EUREF recommendations and what stated by the Unit in the questionnaire: meeting members of the Breast Diagnostic Unit team from the different specialities which will describe the activity of the Unit, inspecting the facilities, ensuring that multidisciplinary working is carried out.

It should be also verified if there are particular activities or requirements, not declared by the Breast Diagnostic Unit, which could cause changes in the audit. In this case the persons who are carrying out the evaluation must inform ITALCERT so that the contract could be changed (if the changes regard contractual requirements or required competences, etc..).

The visiting team is made up by a Visit Manager, a Physicist, a Clinician (i.e Surgeon or Pathologist), a Radiologist, a Radiographer.

Visitors, except for the Visit Manager, should be as far as possible from countries outside of the applicant Breast Diagnostic Unit.

Visitors will verify the evidence of the single aspects by checking, where possible, the objective evidence on the different items indicated in the questionnaire.

BCCERT will evaluate the need to ask to the Unit the official translation of the documents to be available at the audit visit.

The Initial Audit has a duration of one day minimum.

During the day (onsite) the Initial Audit is carried out according to the following schedule:

- ✓ Meeting with the Breast Diagnostic Unit
- ✓ Visitors divide to separate tasks
- ✓ Multidisciplinary communication and review meeting observed by visiting team
- ✓ Meeting of the visiting team and feed back to the Unit

Visitors will verify evidence of what stated by the Breast Diagnostic Unit in the questionnaire, checking all mandatory and non-mandatory requirements.

Meeting with the Breast Diagnostic unit: general consideration

It is essential that the Clinical Director of the Diagnostic Unit, and at least one Specialist of each disciplines (Physician, Radiographer, Radiologist, Pathologist, Surgeon) are present.

The Unit, i.e. the clinical director will make a general presentation of the Unit describing how the activity is organised and is carried out. Questions may arise on the basis of what stated by the Unit in the questionnaire.

¹ *offsite = not at the headquarters Unit*

² *onsite = at the headquarters Unit*

Visitors split to separate tasks

The Visitors must check what indicated by the Unit in the questionnaire and make sure to verify all mandatory and recommended requirements as indicated in the EUREF document "EUREF Requirements for Breast Screening and Diagnostic Services".

To do this:

The Visiting **Radiologist** visits the imaging unit for breast disease and meets the breast radiologists inspects the location of the diagnostic unit, the dedicated rooms and equipment availability, the assessment facilities, the quality of the images, radiologic procedures.
etc.

The Visiting **Radiographer** visits the imaging unit for breast disease and meets the breast radiographers (technicians); inspects the location of the diagnostic unit, the dedicated rooms and equipment availability, evaluates the quality of mammograms, etc.

The Visiting **Clinician (Pathologist or Surgeon)** meets with the pathologists reporting breast disease and evaluates the service provided by an organised and specialist cyto/histopathological support, evaluates formal records of the discussion and management decisions of the meeting.

Usually the **Physicist** works offsite by evaluating the data / information inherent in the physical and technological aspects of the treatment and equipment used in the imagines service. The Visiting Physicist is present onsite when its offsite evaluation (see Initial Audit or Renewal Audit report) is non-positive (significant and numerous Non-conformities).

Multidisciplinary communication and review meeting

Breast Diagnostic Unit is asked to arrange for one of its regular multidisciplinary case management meetings to be held, which the visiting team observes. The meeting must be a real case discussion meeting and not a demonstration.

Those members of the Unit who do not regularly attend these meetings, should not be invited.

The visiting team is not present to discuss neither individual case management nor Unit policies.

MDT meeting can be held in the Unit own language. It is the style of the multidisciplinary meeting the participation of all staff, the method of presentation etc., rather than the actual decisions made which the visitors need to see.

Meeting of Audit Team

The visiting team meets in confidence to briefly go through the issues, exchange information and views on the Unit and making sure all-important issues have been taken into consideration during the visit. The visitors will point out if there are any requirements which are not satisfied by the Unit. In this regard the Visit Manager will write the visit report.

6.4 Surveillance Audit

To maintain the Certification the Breast Diagnostic Unit will be asked to fill in a questionnaire of the year prior each offsite Surveillance Audit and provide documents and data both for Onsite Surveillance Audit.

The validity of Certification will depend on the positive results of the yearly surveillance procedures, aiming at evaluating each requirement as foreseen by the EUREF document "EUREF Requirements for Breast Screening and Diagnostic Services".

During the first 4-year Certification period, three Surveillance Audits are foreseen, scheduled as follows:

- ✓ 1st Documental Surveillance Audit (offsite or onsite or on site considering the results of previous audits or evaluations of complexity or changes in the organization. The choice of an audit onsite or off-site audit is made by ITALCERT in his judgment) must always be carried at latest 12 months following the date of the Initial Audit. For this reason, it is normally scheduled at 10 months following the date of the initial audit.
- ✓ 2nd Surveillance Audit (**onsite**) is normally scheduled at 12 months following the 1st Surveillance Audit.
- ✓ 3rd Documental Surveillance Audit (offsite or onsite or onsite considering the results of previous audits or evaluations of complexity or changes in the organization. The choice of an audit onsite

or off-site audit is made by ITALCERT in his judgment) is normally scheduled at 12 months following the 2nd Surveillance Audit.

- ✓ Re-audit (**onsite**) is scheduled at least 4 months before the expiration date of the Certificate, to ensure the completion of the recertification process in time.

In the subsequent 4-year Certification period:

- ✓ 1st Documental Surveillance Audit (offsite or onsite or on site considering the results of previous audits or evaluations of complexity or changes in the organization. The choice of an audit onsite or off-site audit is made by ITALCERT in his judgment) must always be carried at latest 12 months following the date of the Initial Audit. For this reason, it is normally scheduled at 10 months following the date of the initial audit.
- ✓ 2nd Surveillance Audit (**onsite**) is normally scheduled at 12 months following the 1st Surveillance Audit.
- ✓ 3rd Documental Surveillance Audit (offsite or onsite or on site considering the results of previous audits or evaluations of complexity or changes in the organization. The choice of an audit onsite or off-site audit is made by ITALCERT in his judgment) is normally scheduled at 12 months following the 2nd Surveillance Audit.
- ✓ Re-audit (**onsite**) is scheduled at least 4 months before the expiration date of the Certificate, to ensure the completion of the recertification process in time.

If present numerous and significant Non-Conformities (especially after Initial Audit or Renewal Audit), offsite surveillance can be switched to onsite surveillance with related charges and costs (see contract signed by the Unit with ITALCERT): the decision will be set by the **Certification Decision Committee** or by the Scheme Manager.

If the Breast Diagnostic Unit could not comply with the rules and conditions foreseen for the carrying out of the first Surveillance Audit, this will cause the Certification suspension.

For any other kind of audit, the Unit is requested to respect the scheduled time audit proposed by ITALCERT; any request of variation shall be submitted to ITALCERT judgment and could cause the Certification suspension.

Surveillance planning is edited by BCCERT Operating Officer and approved by Certification Scheme Manager.

The surveillance planning is edited taking into consideration:

- The Non-Conformities and Observations raised up during the Initial, Surveillance or Renewal Audits and indicated on the Audit report;
- Changes in the Unit organisation/personnel;
- Yearly check of the use of reference to Certification, Certificate and Logos (included that of the Accreditation Body if or when applicable);
- Auditor/visitor availability (when applicable);

Each EUREF Requirement has to be verified at least one time in the four-year period.

During 1st Documental Surveillance Audit (offsite or onsite or on site considering the results of previous audits or evaluations of complexity or changes in the organization. The choice of an audit onsite or off-site audit is made by ITALCERT in his judgment) the requirements which are always verified are:

General requirements (*) that is to say:

(*) It must be verified that the Unit constantly

- ✓ performs at least 2,000 mammograms a year
- ✓ is able to perform physical examinations and ultrasound examinations as well as the full range of radiographic procedures.
- ✓ provides cytological examination and/or core biopsy sampling under radiological (including stereotactic) or sonographic guidance.
- ✓ monitors data and feedback of results.
- ✓ keeps a formal record of mammogram results, assessment processes and outcomes.
- ✓ advances improvement actions decided in line with EUREF requirements for breast cancer patients and Breast Diagnostic Unit professionals.

During 2nd Surveillance Audit (onsite) the requirements which are always verified are:

- ✓ Breast Radiology
- ✓ Breast Radiographers
- ✓ Diagnostic Unit Multidisciplinary Meeting

During 3rd Documental Surveillance Audit (offsite or onsite or on site considering the results of previous audits or evaluations of complexity or changes in the organization. The choice of an audit onsite or off-site audit is made by ITALCERT in his judgment) the requirements which are always verified are:

- ✓ General requirements (*)
- ✓ Breast pathology support

6.5 Re-audit

Certification renewal follows a Re-audit visit with the aim of verifying the maintenance of the compliance to EUREF standards requirements.

The Unit has to make available all data/information showing improvements achieved thanks to the management system implemented during the 4-year period starting from Certification procedure and the commitment demonstrated to keep efficacy, aiming at giving a better service to breast cancer patients.

Usually the Re-audit is scheduled at least 4 months before Certificate expiration date.

In case of failure to carry out Re-audit in the deadline indicated, the Certificate will not be longer effective until further possible renewal.

6.6 Unplanned Audit/ Extra Audit

Additional audits can be requested by ITALCERT, following the release of Certification and this can be asked in case of:

- substantial re-organization within the Unit and/or Certification extension request made by the Unit
- critical situation that may require a monitoring increase onsite or offsite
- lack in sending the corrective action proposal following a Non-Conformity
- lack in sending evidence on the compliance of a Non-Conformity
- need to inspect an outsourcer; this situation could occurs, for example, when the outsourcer was not indicated by the Unit during the Application Form or if it was changed or added during certification validity.
- need to inspect processes/services out of the regular audit schedule/plan
- claims, contentiousness formally received and /or verified by ITACERT or BCCERT.

Unplanned Audit and /or Extra Audit can be carried out in a simplified way, considering their target and aims and may not foresee a detailed audit plan.

7 CERTIFICATE ISSUE

Certificate of conformity to EUREF Standard Requirements has a maximum validity of 4 years.

The issue of a Certificate with a duration less than 3 year is foreseen in some specific cases as following:

- Certificate has been issued following an extension/change of a previous Certificate not coinciding with its renewal.
- The referring rule on which the Certificate has been issued is in a transient phase with a new edition of the rule itself.
- The Unit after Initial Audit has resolved non-compliance beyond 4 months, ie maximum time required by the present document.

Certificate of Conformity is issued following an unanimously positive evaluation of Certification Decision Committee, on the basis of the information and documents collected during the audit, the visitors feedback on the audit, the corrective action proposal and the evidence documents provided by the Unit showing compliance with the missing mandatory requirements classified as Major Non Conformity.

In case of a negative evaluation related to Certification release, an additional audit will be necessary (extension and duration will be set by the Certification Decision Committee).

Certificate and Certification Logo can be used by the Unit exclusively in conformity with what indicated in the Regulation for the Use of Certification Logo (Rif. Document R011).

Any reference to the Certification is considered incorrect if used before receiving the communication of certification release; if used in any circumstances different from its applicability; causing discredit to ITALCERT and/or BCCERT or when applicable to the Accreditation Body.

The use of the Certificate and the Certification Logo is forbidden in case of expired, not-released, suspended and revoked Certificate.

In case of incorrect use of any reference to Certification, ITALCERT will take appropriate action to save guard its own interests by issuing a Non-Conformity, suspending Certification and cancelling the Unit from the list on the website, or undertaking legal actions.

8 DEFERMENT REQUESTS

BCCERT informs in due time the Unit about scheduling and timing of Surveillance and Re-audit visits.

Breast Centre can ask for a deferment as long as:

- at least one mandatory audit visit a year is guaranteed;
- Unit formally asks for a postponement. In case of a postponement superior to 2 months, the Unit has to send evidence on the compliance of missing mandatory requirements (if applicable);
- the deferment does not require a gap superior to 18 months between two audits.

In any case ITALCERT reserves the right to not accept the requested deferment.

In case of audit postponement, Unit is aware that Certificate validity cannot be extended. Therefore, postponement request of a Re-audit visit can be accepted only in extraordinary cases, duly justified in written form by the Breast Diagnostic Unit. ITALCERT reserves the right to not accept the postponement at its incontestable discretion.

In case ITALCERT accepts a postponement request of a Re-audit visit further Certificate expiring date, Unit is demanded:

- to not use Certificate and Certification Logo until a re-issue of the Certificate;
 - to be available to carry out the audit not further six months after the Certificate expiring date.
- In case this is not possible, Unit is aware that Certification procedure cannot be kept open and in case they wish to continue the procedure, they will have to start from the beginning (Initial Audit).

9 SUSPENSION, REVOCATION OR RENUNCIATION OF CERTIFICATION

ITALCERT may suspend the Certification in the event that:

- non-conformities are found related to the obligatory requirements of a Surveillance or Renewal Audit for which suspension is recommended due to the gravity of the same;
- a follow-up audit detects the persistence of non-conformities previously recorded related to mandatory requirements;
- the Breast Diagnostic Unit does not inform ITALCERT, does not implement or does not send to ITALCERT evidence of the implementation of the corrective actions related to Non-Conformities within the agreed time;
- impossibility to carry out audit to outsourcers (when specifically requested by ITALCERT);
- the Unit makes changes to its organisation without informing ITALCERT or without their acceptance;
- the Unit refuses or obstructs Surveillance or Renewal certification Audits within the agreed time limit;
- the Unit makes incorrect use of references to the Certification;
- the Unit is not up to date with procedure's payments;
- the Unit does not comply with legal prescriptions related to the field of application of Certification and the provisions of these regulations;
- the Breast Centre does not respect the limit of time fixed for relevant activities (i.e. maximum time to transmit corrective action plan)
- serious shortcomings inherent to the Unit are found based on complaints, legal actions, judicial proceedings and other objective evidence, even if not deriving from audits;
- other circumstances that could harm the image, reputation or credibility of ITALCERT and/or

BCCERT or that are in contrast with the ethical principles of the same.

A Unit may request that the Certification is suspended on the basis of proven technical and organisational grounds. In this case the Unit must send any request for suspension to ITALCERT by written notice with a return receipt at least one month before the expiry date of an audit.

Before the order of suspension, ITALCERT formally communicates this possibility to the Unit (via fax or e-mail) together with the conditions needed to avoid such action.

Suspension is formally communicated to the Unit by written notice (fax or e-mail), together with the indications for restoring the Certification.

During suspension, Certification is no longer valid for all legal intents and purposes, therefore the Unit must suspend the use of references to the Certification in any form (logo, wording, certificate) from the date of communication of suspension of the Certification until its cancellation.

Suspension entails cancellation of the Unit from the certification list and communication of the suspension to the Accreditation Body (if applicable) and other interested parties on receipt of their explicit request.

To cancel the suspension, ITALCERT must ascertain that the Unit has implemented what was requested and restored the conditions of validity of Certificate. Cancellation of the suspension will be communicated to the Unit in writing.

Suspension is allowed for a maximum period of six months, after which, if the causes that led to suspension are not removed, the Certification will be revoked.

Revocation is formally communicated to the Unit by written notice (fax or e-mail).

Following to revocation, ITALCERT cancels references of the Unit in the Register of Certified Units; communicates the revocation to the Accreditation Bodies (if applicable) and/or other parties following to their explicit request.

The Unit is not more entitled to use any reference to Certification (Certificate and/or Logo) and must interrupt any advertisement containing references to Certification.

Certification revocation does not entitle the Unit to any refund.

A Unit may renounce the Certification at any time and when they consider it most appropriate.

Renunciation must be communicated to ITALCERT by written notice with a return receipt. Renunciation does not entitle the Unit to receive a refund of the amounts already paid.

Certificate renunciation entails the termination of the contract.

10 MULTISITE CERTIFICATE

In case of the Unit applying for Certification has services geographically located in different sites and ITALCERT has evidence that the Unit has an adequate level of control on all the external sites, ITALCERT can decide to manage the Certificate following the multisite rules.

In case the multisite is applicable for Bodies/Institutions/Organizations or Regional Districts, etc...and in any case, for Organizations that have different business names, the Main Organization/Institution of reference and coordination has to establish an agreement among all sites to acknowledge the establishment of the Unit for which the Certification following EUREF Requirements is requested (i.e. it has to be identified the Main Organization/Institution of reference and coordination and the Breast Diagnostic Unit Clinical Director. It has also to be clear that in case of a Major Non-Conformity, the Certificate can be suspended and/or revoked for the whole group).

In case of multisite Breast Diagnostic Unit, *Breast Screening and Diagnostic Services Certification* can decide to examine the different sites/services using the sampling rules. The Main Centre is examined every time.

The preliminary sampling plan is communicated to the Unit together with the Certification offer. *Breast Screening and Diagnostic Services Certification* can modify the plan at a later stage.

Usually ITALCERT issues a single Certificate, reporting the list of the external sites/services included in the Certification procedure. In some cases, ITALCERT can issue an appendix to the Certificate bearing such list. In some particular cases, ITALCERT can decide to issue a Certificate for each site, guaranteeing the link among all Certificates.

11 BREAST DIAGNOSTIC UNIT'S RIGHTS AND OBLIGATIONS

In addition to that specified in the previous paragraphs, the Unit has the right to formally object to the appointment of Audit Team members (including those of the Accreditation Body if applicable) and request their replacement in the presence of valid and justified cause.

In addition to that defined in the reference normative and the technical procedure, the Breast Diagnostic Unit must:

- a) guarantee the assistance needed from personnel in charge and free access for ITALCERT personnel and personnel of the Accreditation Body (in the capacity of observer of ITALCERT work) to all internal and external areas in which the Breast Centre's activities are conducted;
- b) inform ITALCERT about legal or organizational aspects related to the property;
- c) give timely notice of any significant changes to their organisation or other changes that could affect their compliance with EUREF Requirements and provide the documentation requested (i.e. appointment of a new Clinical Director);
- d) guarantee the presence of the Unit's Clinical Director or a person delegated by the same during the audit;
- e) inform ITALCERT about any changes related to contact details and addresses;
- f) inform ITALCERT with regards to potential hazards that could affect the Audit Team's safety;
- g) update ITALCERT following to clarification requests or requests for additional information.

In case of proved lack of communication regarding any of the above, ITALCERT can approve:

- to carry out an Unplanned Audit/ Extra Audit
- to suspend the Certificate

The Unit is responsible for any errors or shortages in information provided to ITALCERT.

ITALCERT does not accept liability for any damage caused by the Breast Diagnostic Unit's workforce or of their subsidiaries placed at the disposal of ITALCERT during the audit. In such case, the Unit undertakes to hold ITALCERT harmless from any requests for compensation from the same Unit or from third parties.

11.1 ACCREDIA PERSONNEL DURING THE AUDIT

ITALCERT as Certifying Body can be subject to periodical examination by Accredia (Italian Accreditation Body).

The Breast Diagnostic Unit can not refuse the presence of Accredia personnel during the audit.

If such a situation occurs for initial or recertification audit, ITALCERT will not issue the Certificate; if it occurs for a surveillance audit, ITALCERT will suspend the certification. Suspension will last until the Unit will accept the presence of Accredia personnel.

In the event of persistent default over 6 months from the suspension, the Certificate will be revoked.

12 APPEALS

The Unit may appeal against decisions made by ITALCERT in relation to its Certification within 30 days of notification by written letter.

To be considered valid the appeal must:

- contain a clear description of the decision notified;
- contain a clear and detailed motivation to support the appeal itself.

Once the appeal has been received, ITALCERT informs the Unit within 7 days if it has been accepted and in this case the date by which a decision will be taken (max 30 days from the date of appeal receipt).

Any accepted appeal will be evaluated by the Approval Committee, independent from the personnel involved in the circumstances/actions that caused the appeal.

The decisions taken by the Approval Committee are not open to appeal and are communicated to the Breast Diagnostic Unit by written notice.

13 CLAIMS

The Unit may claim to ITALCERT for the activities carried out in relation to its Certification.

ITALCERT formally manages each claim received in a written form (letter, fax or e-mail). Claims received in an oral form will be managed in a documented way only if considered appropriate.

Claims management foresees:

- a) written answer (letter, fax or e-mail) containing claim analysis and any necessary further action foreseen with related timing, by 7 days from the claim;
- b) written answer (letter, fax or e-mail) when all foreseen actions will be finalized.

14 ACCEPTANCE OF REGULATION AND/OR EUREF STANDARDS UPDATING AND CHANGES

The Unit asking for Certification must formally accept what indicated in this Regulation by stamp, signature and date on the last page of this document.

In case of updating and changes of the Certification Rules and Regulations for Breast Diagnostic Unit, *Breast Screening and Diagnostic Services Certification* will take care to promptly publish the updated version on *Breast Screening and Diagnostic Services Certification* website. The Unit has 60 days time after the date of publication, to formally communicate the non-acceptance of such changes, which will cause the Certification renunciation. After the 60 days period, without any communication from the Unit, the new updated version of the Certification Rules and Regulations for Breast Diagnostic Unit will be considered as accepted for tacit approval.

If the updating regards EUREF standard referring requirements, the Breast Diagnostic Unit is asked to comply with the new rules within the foreseen schedule indicated by EUREF, otherwise it has to renounce to the Certification.

**For Breast Diagnostic Unit approval
The Legal Representative**

Date _____

(Stamp and signature)