CERTIFICATION RULES AND REGULATIONS

September 2019

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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 Centres Certification® – ITALCERT Scheme, in partnership with BCCERT
in compliance with the standard
Eusoma guidelines ***The requirements of a specialist Breast Centre***

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 Centre during the whole procedure.
ITALCERT maintains the certification's responsibility of Breast Centre 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 Eusoma guidelines "The requirements of a specialist Breast Centre".
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 and Eusoma 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 Breast Centre 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 Centre: 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. A 'Centre' is defined by all aspects of Breast Cancer Care being offered by a multidisciplinary team (MDT) of specialists in breast disease.
Lead Auditor: 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 Centres Certification.

3 CERTIFICATION PRINCIPLES

3.1 General considerations

The procedure is based on the Eusoma guidelines "The requirements of a specialist Breast Centre".

Seven basic criteria underlay the judgement of a Breast Centre:
- A single integrated Unit
- Sufficient cases to allow effective working and continuing expertise
- Care by breast specialists in all the required disciplines
- Working in multidisciplinary fashion in all areas
- Providing all the services necessary – from genetics and prevention, through the treatment of the primary tumour, to care of advanced disease and palliation.
- Patient support
- Data collection and Audit

Certification is based on the capacity of the Breast Centre to meet the recommendations of the EUSOMA Guidelines "The Requirements of a Specialist Breast Centre".
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 (on the basis of a detailed check list that the Breast Centre will receive prior the visit) and a report to evaluate the Breast Centre outcomes on the quality indicators indicated by Eusoma.

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 Breast Centre of the system requirements, subject of the conformity evaluation.

3.3 Privacy Policy / Data Protection

All the data directly supplied by the Breast Centre 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. Breast Centre 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 Breast Centre will be published on the "Register of Certified Breast Centres" 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 Breast Centres as submitted in the ***Breast Centres Certification***® scheme.
In this certification scheme, data is co-processed by both ITALCERT and BCCERT.
In the certification process, EUSOMA is the external manager responsible for the processing of data needed for the certification process, precisely: the validation activity of the databases, the yearly data transfer of the performance of the Quality Indicators, and the control / approval of any corrective actions against the Quality Indicators set by EUSOMA for the certification.
Processing of sensitive data: consultation and Analysis of clinical records and/or other similar documents of the patients of the Breast Centre are made by the Team Leader, 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 and the responsible for the outsourced data, EUSOMA, are resident.

4 HOW TO START THE PROCEDURE

4.1 Request for application

Any Breast Centre, can ask for a certification procedure offer.
Application Form, Certification Rules and Regulation and Regulation for the use of Certification Logo are available on Breast Centres Certification website, www.breastcentrescertification.com.
In order to be able to issue the offer on the basis of Breast Centre structure and sites, Breast Centres who wants to start certification procedure are requested to fill the Application Form and send it back to BCCert Operating Office (see more details in the form).

To start certification procedure, Breast Centre has to fulfill the following three mandatory entry requirements:

1. 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
2. the Breast Centre has a Clinical Director
3. the Breast Centre has a database validated by Eusoma (validation not older than 2 years)

For what concerns points 1 and 2, at the time of certification application, they are honour based and will be checked during the Initial Audit.
Regarding point 3, the database in use at the Breast Centre has to be validated by Eusoma on the basis of successful data transfer showing correct calculation of the indicators and data completeness. Once database validation will be completed, the Breast Centre has two years to apply for Breast Centre Certification otherwise the database validation has to be repeated.

Once the fulfilment of mandatory entry requirement 3 is verified, BCCERT will send to the applicant Breast Centre:

- Agreement
- Privacy Policy
- Data Protection Document

4.2 Location of the audit

In the Application Form the Breast Centre must indicate in details where the audit will take place (Name of the Breast Centre and complete address).
In order to organize the visit, the Breast Centre must give a detailed description (including geographical location and addresses) of its structure: main building and departments and any other external site.
The Breast Centre must notify in writing, by fax or by record delivery letter R.R., any relocation of the Breast Centre or the Hospital or activation of any additional sites.

The Breast Centre 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 Breast Centre (i.e. lack of information in the Application Form), the audit will be consider as an "extra audit" (see paragraph 6.6) and could cause an additional cost for the Breast Centre.

4.3 Acceptance of the application and contract execution.

To make official certification offer, Breast Centre has to send back to ITALCERT the following documents filled in and signed:
-Application Form
-Agreement
-Regulation for the use of the Certification Logo
-Certification Rules and Regulations
-Privacy Policy
- Data Protection Document
In case of lacking of just one of the above-mentioned documents, ITALCERT may not issue the Certificate.
In case the Breast Centre 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 Centre 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 Breast Centre
-audit visit
-report of Breast Centre outcomes on Quality Indicators.

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

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 Breast Centre 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 Breast Centre. 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 Breast Centre receives the detailed check list of the documents to be available onsite for audit and the audit plan with the indication of the detailed schedule of the visit.
The Breast Centre is also requested to send to Eusoma the outcome on Quality Indicators regarding the whole calendar year prior the date of the audit (both in case of Initial or Surveillance Audit). On the basis of the results of the Eusoma data report on mandatory Quality Indicators, Breast Centre may be also requested to make available for the audit visit some clinical charts in relation to the analysis of the mandatory Quality Indicators.
During the visit, each member of the Audit Team collects all the necessary information to express his/her evaluation on the conformity of Eusoma Requirements through:

- Inspection of the documents prepared by the Breast Centre for each single discipline/issue

- Interview with the Breast Centre team members
- Evaluation of daily activity /work

The Breast Centre 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.
Breast Centre 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 Lead Auditor 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 Breast Centre must report to Breast Centres Certification at least whithin 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).
Breast Centres Certification cannot accept a deadline superior to 4 months; if this situation will occur, the Breast Centre 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 Breast Centre.
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 Centre).
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 Centre. In sending the proposed corrective actions regarding the Quality Indicators, the Breast Centre has to declare if the corrective action is referred to registration problems or problems of performance or both.
If the non compliance for a quality indicator is due to registration or data transfer problems, the Breast Centre has to make the appropriate corrections and perform a new data transfer to Eusoma database, within 4 months following the audit visit.
If the non compliance regards a problem of performance, within 4 months following the audit visit, the Breast Centre has to send a new set of data of a 3-month period (after the implementation of the corrective actions), showing evidence. If necessary, in order to evaluate the Breast Centre performance, the Breast Centre may be requested to send all available data referring to the year of the audit visit.
In both cases the Breast Centre has to send a report describing in some detail actions that have been taken.
Breast Centres Certification 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 fulfilment (see paragraph 6.6 "unplanned/extra audit").
In case the evidence documents consist of an extended description/document in original language (i.e Italian, Dutch, Spanish, Portuguese etc…), ITALCERT can request the Breast Centre to attach also a short abstract in English describing contents in particular with regard to the Non-Conformity.
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 Breast Centre will give evidence of the Major Non-Conformity resolution.
The fulfillment of corrective actions regarding Minor Non Confomities and Recommendation will be verified during the subsequent audit. However, on the basis of possible different situations, Breast Centres Certification can decide, after formally informing the Breast Centre, to proceed with a different examination of the corrective actions implemented by the Breast Centre.
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 Decisioners Committee

The members of the Certification Decisioners Committee are experts in breast disease in the different disciplines approved by Eusoma.
It is the responsibility of the Certification Decisioners Committee to decide on the Certification status of each Breast Centre.
In considering Certification status, the Board must take note of the object of Certification: it is to certify the Breast Centres capable of complying with the Eusoma standards indicated in the referring guidelines and complying with Eusoma mandatory performance indicators.
The evaluation will be based on the questionnaire, the results of the visit, the evidence of the corrective actions and of the Breast Centre outcomes on Quality Indicators.
Once the Certification Decisioners Committee has unanimously reached the agreement on the Certification status of the Breast Centre, the Certificate and Logo will be issued and then sent to the Breast Centre.

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 Centre)
- Initial Audit
- Surveillance Audit
- Re-audit
- Unplanned Audit/Extra Audit

All audits are upon payment for the Breast Centre and the fees are indicated in the Agreement

6.2 Pre-audit

If Breast Centre find it useful, they can ask for a Pre-audit visit, before applying to Certification.
The Pre-audit visit aims at checking if a Breast Centre is suitable to apply for Certification with regard to the Eusoma requirements but not analyzing in details features of each discipline. The Pre-audit visit is usually carried out by Lead Auditor or if unavailable by a single professional auditor/visitor, not necessarily medical doctor. The Pre-audit is carried out at Breast Centre 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 Breast Centre is in compliance with the certification requirements, including what requested by Eusoma recommendations and what stated by the Breast Centre in the questionnaire: meeting members of the Breast Centre team from the different specialities which will describe the activity of the Breast Centre, inspecting the facilities, ensuring that multidisciplinary working is carried out.

Visitors will verify the evidence of the single aspects by checking, where possible, the objective evidence on the different items indicated in the questionnaire.
The Initial Audit has a duration of one day and a half.
The first half day (usually afternoon) is dedicated to documental audit, during which the Breast Centre Clinical Director (and/or the contact person indicated in the Application Form) and the Lead Auditor will examine the documents the Breast Centre has been asked to prepare at the time of Initial Audit confirm (rif. Check list) in order to facilitate the second day of the visit.
BCCERT will evaluate the need to ask to the Breast Centre the official translation of the documents to be available at the audit visit and, if necessary, the presence of a translator.
It should be also verified if there are particular activities or requirements, not declared by the Breast Centre, 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 Lead Auditor, a surgeon, a radiologist, a pathologist and a breast care nurse. Visitors, except for the Lead Auditor, should be as far as possible from countries outside of the applicant Breast Centre.
During the second whole day the Initial Audit is carried out according to the following schedule:
- Meeting with the Breast Centre
- Visitors divide to separate tasks
- MDT meeting observed by visiting team
- Meeting of the visiting team and feed back to the Breast Centre

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

Meeting with the unit
It is essential that the Clinical Director of the Breast Centre, and at least one specialist of each disciplines, are present.
The presentation by the Breast Centre is discussed as it goes along. Presentations on individual topics must be short and must leave plenty of time for interruptions from the Visitors and be based on the questionnaire. The subjects to be addressed are: who are the specialist team in each discipline, their timetables, what are the working arrangements and protocols, case flow, attendance at Multidisciplinary Meetings (MDM's). Outcomes and results of most performance indicators may only be presented briefly. Questions and discussion are continuous throughout. There should be no presentation on techniques (e.g. sentinel node biopsy; use of MRI) or details of research projects.

Visitors split to separate tasks
The Visitors must check what indicated by the Breast Centre in the questionnaire and make sure to verify all mandatory and recommended requirements as indicated in the Eusoma document "The requirements of a specialist breast centre".
To do this:
The Visiting ***Radiologist*** visits the imaging unit for breast disease and meets the breast radiologists and radiographers (technicians); inspects the location of the diagnostic unit (within the Breast Centre, in campus, outside campus), the dedicated rooms and equipment availability etc.
The Visiting ***Pathologist*** visits the Pathology laboratory (within the Breast Centre, in campus, outside campus) and meets with the pathologists reporting breast disease and checks equipment availability.
The Visiting ***Breast Care Nurse*** meets with those on the team primarily responsible for patient support (psycho-oncologists/clinical psychologists, breast care nurses, social workers); a representative of any patient volunteer group which is active in helping with support;
The Visitor must be shown the information literature provided to patients;
The Visitor should inspect some of the facilities – the out-patient (ambulatory) clinic, the chemotherapy suite and accommodation for patients admitted for surgery.
The Visiting ***Breast Surgeon*** meets the clinical genetics and visits the service of the surgeon, the reconstructive surgeon, the radiation oncologist, the medical oncologist.

Multidisciplinary meeting
Breast Centre 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 Breast Centre who do not regularly attend these meetings, should not be invited. The visiting team is not present to discuss neither individual case management nor Breast Centre policies.

MDT meeting has to be held in English. It is the style of the MDT 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 Breast Centre 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 Breast Centre. In this regard the Lead Auditor will write the visit report.

6.4 Surveillance Audit

To maintain the Certification each year a surveillance visit will take place, the Breast Centre will be asked to fill in a questionnaire and to send the outcomes on the Quality Indicators regarding the whole calendar year, of the year prior each Surveillance Audit.
If the Breast Centre had to comply with the missing requirements on Quality Indicators, they will be requested to send data from the previous last data transfer.
The validity of Certification will depend on the positive results of the yearly surveillance procedures, aiming at evaluating each requirement as foreseen by the Eusoma document "The Requirements of a Specialist Breast Centre".

During the first 3-year Certification period, two Surveillance Audits are foreseen, scheduled as follows:

- 1st Surveillance Audit 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 is normally scheduled at 12 months following the 1st Surveillance Audit.
- Re-audit 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 3-year Certification period:

- 1st Surveillance Audit is normally scheduled at 10 months following the issue date of the certificate.
- 2nd Surveillance Audit is normally scheduled at 12 months following the 1st Surveillance Audit.
- Re-audit is scheduled at least 4 months before the expiration date of the Certificate, to ensure the completion of the recertification process in time.

If the Breast Centre could not comply with the rules and conditions foreseen for the carrying out of the first Surveillance Audit, ITALCERT will evaluate whether or not to determine the suspension of the certificate.

For any other kind of audit, the Breast Centre is requested to respect the scheduled time audit proposed by ITALCERT; any request of variation shall be submit 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 Breast Centre 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 Eusoma Requirement has to be verified at least one time in the three-year period.

During 1st surveillance the requirements which are always verified are:

- General requirements
- Other services
- Breast Care Nursing
- Breast Centre Multidisciplinary Meeting

The additional requirement is decided according to the visitor's discipline (among Breast surgery and reconstructive surgery, Breast radiology or Breast pathology).

During 2nd surveillance the requirements which are always verified are:

- Breast medical oncology
- Breast radiation oncology

The additional two requirements among Breast surgery and reconstructive surgery, Breast radiology or Breast pathology are those not verified during the 1st surveillance.

Making available the six months trend of Breast Centres data

In the case of planning demand, remarks and/or compliance with the timing of Surveillance and Re-audit implementation, as two visits are scheduled in the same calendar year, the Breast Centre can be requested to make available a six-month trend data referred to the current year. Breast Centres Certification will communicate such request to the Breast Centre at least 3 months prior the date of the audit.

6.5 Re-audit

Certification renewal follows a Re-audit visit with the aim of verifying the maintenance of the compliance to Eusoma standards requirements.
The Breast Centre has to make available all data/information showing improvements achieved thanks to the management system implemented during the 3-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 Breast Centre and/or Certification extension request made by the Breast Centre
- critical situation that may require a monitoring increase onsite
- 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 Breast Centre 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 Breast Centres Certification.

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 Eusoma standard requirements has a maximum validity of 3 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.

Certificate of Conformity is issued following an unanimously positive evaluation of Certification Decisioners 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 Breast Centre 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 Decisioners Committee).
Certificate and Certification Logo can be used by the Breast Centre exclusively in conformity with what indicated in the Regulation for the Use of Certification Logo (Rif. RUCL).
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 Breast Centre from the list on the website, or undertaking legal actions.

8 DEFERMENT REQUESTS

BCCERT informs in due time the Breast Centre about scheduling and timing of surveillance and Re-audit visits.
Breast Centres can ask for a deferment as long as:

- at least one mandatory audit visit a year is guaranteed;
- Breast Centre formally asks for a postponement. In case of a postponement superior to 2 months, the Breast Centre 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, Breast Centre 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 Centre. 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, Breast Centre 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, Breast Centre 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 Centre 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 Breast Centre makes changes to its organisation without informing ITALCERT or without their acceptance;
- the Breast Centre refuses or obstructs Surveillance or Renewal Certification Audits within the agreed time limit;
- the Breast Centre makes incorrect use of references to the Certification;
- the Breast Centre is not up to date with procedure's payments;
- the Breast Centre 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 Breast Centre 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 Breast Centre may request that the Certification is suspended on the basis of proven technical and organisational grounds. In this case the Breast Centre 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 Breast Centre (via fax or e-mail) together with the conditions needed to avoid such action.
Suspension is formally communicated to the Breast Centre 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 Breast Centre 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 Breast Centre 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 Breast Centre has implemented what was requested and restored the conditions of validity of Certificate. Cancellation of the suspension will be communicated to the Breast Centre 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 Breast Centre by written notice (fax or e-mail).
Following to revocation, ITALCERT cancels references of the Breast Centre in the Register of Certified Units; communicates the revocation to the Accreditation Bodies and/or other parties following to their explicit request.
The Breast Centre 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 Breast Centre to any refund.
A Breast Centre 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 Breast Centre to receive a refund of the amounts already paid.
Certificate renunciation entails the termination of the contract.

10 MULTISITE CERTIFICATE

In case of the Breast Centre applying for Certification has services geographically located in different sites and we have evidence that the Breast Centre 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, ASL (only for Italy) 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 Breast Centre for which the Certification following Eusoma requirements is requested (i.e. it has to be identified the Main Organization/Institution of reference and coordination and the Breast Centre 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 Centre, Breast Centre 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 Breast Centre together with the Certification offer. Breast Centres 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 CENTRE'S RIGHTS AND OBLIGATIONS

In addition to that specified in the previous paragraphs, the Breast Centre 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 Centre 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 Eusoma requirements and provide the documentation requested (i.e. appointment of a new Clinical Director);
d) guarantee the presence of the Breast Centre'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 Breast Centre is responsible for any errors or shortages in information provided to ITALCERT.
ITALCERT does not accept liability for any damage caused by the Breast Centre's workforce or of their subsidiaries placed at the disposal of ITALCERT during the audit. In such case, the Breast Centre undertakes to hold ITALCERT harmless from any requests for compensation from the same Breast Centre 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 Centre cannot 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 Breast Centre 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 Breast Centre 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 Breast Centre 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 Centre by written notice.

13 CLAIMS

The Breast Centre 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 o 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 o e-mail) when all foreseen actions will be finalized.

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

The Breast Centre 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, Breast Centres Certification will take care to promptly publish the updated version on Breast Centres Certification website, www.breastcentrescertification.com. The Breast Centre 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 Breast Centre, the new updated version of the Certification Rules and Regulations will be considered as accepted for tacit approval.
If the updating regards Eusoma standard referring requirements, the Breast Centre is asked to comply with the new rules within the foreseen schedule indicated by Eusoma, otherwise it has to renounce to the Certification.
Any modification / update to the EUSOMA standard will be communicated by ITALCERT through the institutional site www.breastcentrescertification.com and circulated by mail to the Breast Centre, and any modification / update will be effective according to a procedure in which times and ways will be defined to guarantee impartiality.

For Breast Centre approval
(stamp, signature and date)

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