



SIS/ISS INTERNATIONAL ACCREDITATION PROGRAM FOR BREAST CENTERS / UNITS

The concept of Multidisciplinary Breast Centers is a true reflection and result of the changes that have taken place in breast cancer care.

In past years, EUSOMA developed widely accepted standards of care for breast patients and has initiated a sophisticated survey and accreditation program for European Breast Centers.

More recently, a NAPBC - National Accreditation Program for Breast Centers, was elaborated in the USA.

The SIS – Accreditation Program for Breast Centers/Units is designed to accredit established Breast Centers and aid Centers developing programs, in order to improve the quality, evaluation, and management of patients. It is a voluntary program, offered to Breast Centers with medical teams integrated by colleagues who are members of affiliated societies of the SIS.

The purpose of this program is to provide a model of organization and maintenance of quality of Breast Centers, to ensure the multidisciplinary care of breast diseases, based on recognized international standards.

Goals of Accreditation

1. **Universality:** quality processes in the diagnosis and treatment of breast cancer should be accessible to all women regardless of the geographical location of their homes.
2. **Uniformity:** The quality indicators required must be equal for all Breast Centers.

STANDARDS FOR QUALITY REQUIREMENTS

1. Breast Centers should be independent units possessing autonomous capacities.
2. The Multidisciplinary Centers should include specialists of all diagnosis and treatment disciplines and hold weekly meetings for the discussion of all individualized clinical cases.
3. All specialists of the Breast Center should undergo continuous updating training. It is highly recommended that all members of the Breast Center have accredited training in Communication and Interview Skills. The quality of communication between medical staffs and between the patients and physicians is considered to be a key point of the team approach and the patient should be at the center of this approach.

4. The Center should have updated protocols for diagnosis, treatment and monitoring of Breast Cancer.
5. The Center should provide services in the fields of prevention, early diagnosis and treatment of breast cancer, breast pathology, genetic studies, psycho-oncology assistance and social support. It should also provide promotion of breast health.
6. A Database Unit should record all quality indicators. These data will be available to conduct an audit. Records of activities should be dated back for the last year for the first accreditation process and for the last three years for further re-accreditations .
7. Patients should be provided with information on clinical trials and all treatment options.
8. Accreditation will be offered to Breast Centers with medical teams that are members of societies affiliated to SIS.

Breast Center Components

1. Imaging

- a. Screening mammography – (digital or analog)
- b. Diagnostic mammography (additional views beyond screening mammography and workup of a clinical abnormality)
- c. Ultrasound
- d. Breast MRI

2. Needle Biopsy (core preferred)

- a. Palpation-guided
- b. Image guided – stereotactic
- c. Image guided – ultrasound
- d. Image guided – MRI

3. Pathology

- a. Report /CAP protocols
- b. Radiology-pathology correlation
- c. Prognostic and predictive indicators
- d. Genetic studies (if available)

4. Interdisciplinary Conference

- a. History and findings

- b. Imaging studies
- c. Pathology
- d. Pre- and post-treatment interdisciplinary discussion

5. Genetic Evaluation and Management

- a. Genetic risk assessment
- b. Genetic counseling
- c. Genetic testing

6. Surgical Care

- a. Surgical correlation with imaging/concordance
- b. Pre-operative planning after biopsy for surgical care
- c. Breast surgery: lumpectomy or mastectomy
- d. Lymph node surgery: sentinel node/axillary dissection
- e. Post initial surgical correlation/treatment planning

7. Plastic Surgery Consultation/Treatment

- a. Tissue expander/Implants
- b. TRAM/Latissimus flaps
- c. DIEP flap/free flaps (if available)

8. Nursing

BREAST CENTERS – SPECIALIST MEMBERS

1. **Head of the Breast Unit, Clinical Director or Coordinator of the Breast Center:** It is advisable be a Specialist in any of the disciplines related to Breast Diseases.
2. **Breast surgeons:** trained in Breast Surgery and updated on all aspects of Diagnosis and Treatment of Breast Pathology and particularly in Breast Cancer
3. **Plastic Surgeon:** specialist in reconstructive surgery and oncoplastic breast surgery as member of the Center. In the case that it is not feasible, should be established a link with a Service of Plastic Surgery in a Referral Center.
4. **Breast Radiologists:** specialists reading at least 1000 mammograms /year or 5000 mammograms/year if they are engaged in screening programs.

5. **Radiology Technicians:** with special training and experience in mammography, sonography, MRI.
6. **Pathologists:** experts in benign and malignant breast diseases are responsible for pathology and cytology diagnosis.
7. **Medical Oncologists:** responsible for the systemic adjuvant and neoadjuvant systemic treatments.
8. **Radiotherapy Oncologists:** experts in all breast radiation treatment options. If not available at the Center, the treatment could be at a Referral Center.
9. **Oncology Nurse:** well trained in providing information, health education and psychological help to patients. Must have experience in postoperative care and rehabilitation.
10. **Navigator:** collaborates with the patients conducting them through the whole process of consultations, diagnostic procedures, treatment, rehabilitation, etc. The Navigator function may be performed by a nurse, a well trained patient or well trained advocate.
11. **Psycho – oncologist:** expert specialized in providing assistance to breast cancer patients.
12. **Case Manager** responsible for the database in all aspects of diagnosis, treatment, monitoring and control of delays in all the processes.

SERVICES PROVIDED BY THE BREAST CENTERS

1. Health Education and Psycho-Social Support for patients with Breast Cancer
 - Education and written information on the aspects of treatment and its side effects
 - Psycho-Social Support: Individual and Family
 - Interaction with Support Groups
 - Recommendations for the treatment of post-treatment symptoms
 - Physical Treatment and Rehabilitation of shoulder mobility and prevention and treatment of lymphedema
2. Service of psychological care
 - Specially dedicated for patients with Breast Cancer
 - Programs of Psychological care, from the moment of diagnosis, and throughout the entire treatment process
3. Programs for patients following breast cancer treatment
 - Monitoring
 - Rehabilitation Services

- Health promotion training and awareness training to reduce risks
4. Fertility preservation program for young women with breast cancer
 5. Palliative Care in patients with metastatic disease
 6. Work in Multidisciplinary Teams

The key professional personnel involved in diagnosing and treating breast cancer are the surgeon, radiologist, pathologist, medical oncologist, and radiotherapist.

Every woman's case and results should be discussed in a multidisciplinary meeting before and after surgery.

All members of the multidisciplinary team must have special training in Breast Cancer obtained by spending one year in an accredited training unit.

All members of the multidisciplinary team must attend a multidisciplinary meeting at least once a week, to discuss diagnosis, and pathological findings following surgery, and to evaluate treatment options.

7. Pathology

- Full reports including Predictive and Prognostic Factors
- Radiological / Histological correlation

8. Imaging Diagnosis:

- Mammography
- Ultrasound
- MRI
- Marking of non palpable lesions or in neoadjuvant treatment.

9. Interventional Radiology

Needle biopsies:

- Ultrasound guided
- Mammography guided
- MRI guided
- Placement of markers and wires

10. Surgical Care (also, see below)

- Preoperative strategy in multidisciplinary teams

- Conservative Surgery and Mastectomy
- Sentinel Node Biopsy and axillary lymph dissection
- Oncoplastic Surgery

11. Immediate or Delayed Reconstructive Surgery

- Breast Implants and Tissue Expanders
- Latissimus and TRAM (flaps)
- DIEP
- Symmetrization of the contra lateral breast
- Reconstruction by Lipofilling

12. Radiation therapy:

- Irradiation of all or part of the Breast
- Boost
- Irradiation of regional lymphatics
- Palliative irradiation for bone metastases (including emergency radiation procedures).

13. Medical Oncology:

- Adjuvant and Neoadjuvant Chemotherapy
- Adjuvant and Neoadjuvant Hormonal Therapy
- Hormonal therapy and Chemotherapy treatment for advanced and metastatic disease
- Molecular Therapy
- Chemoprevention
- Hematologic support for treatment complications
- Immunotherapy with Monoclonal Antibodies, when necessary
- Molecular therapy

14. Nursing:

- Nurse with expertise in benign and malignant breast pathology
- Psychological Care

- Postoperative care
- Rehabilitation of shoulder mobility
- Prevention/Treatment of lymphedema

15. Data Management:

- Database of the Clinical Management
- Administrative integrated programming of visits and diagnostic tests
- Control of delayed assistance

16. Genetic Council

- Evaluation of Genetic Risk. BRCA 1, BRCA 2, others if adequate.
- Genetic Testing
- Genetic Council

17. Research:

- Multicenter studies
- Clinical Trials
- Basic Research in Breast Cancer

18. Teaching:

- Education Programs to the public in all aspects of health promotion; prevention, diagnosis and treatment of Breast Cancer.
- Training Programs in early diagnosis and treatment of Breast Cancer
- Training Courses for Breast Health specialists
- Training Programs on breast diseases for family doctors

19. Continuous Improvement of the quality of care

- Annual internal audits to identify fields of improved care and implementation of programs for advanced monitoring

Pathology

Quality Assurance/Quality Control

Pathology is involved in the process of diagnosing diseases whether tumorous or non tumorous.

- In the non tumorous diseases, the diagnoses must aid in:
therapeutic decisions.
- In tumorous diseases the diagnoses aid also in:
 - prediction of therapeutic response.
 - monitoring cure.
 - identifying risk factors.
 - Targeted therapy.

Quality assurance (QA) in pathology is the practice of assessing performance in all steps of the lab testing cycle, including preanalytic, analytic and postanalytic phases to promote excellent outcomes in an analytical process.

Quality control (QC) is an integral component of QA and is the aggregate of processes and techniques to detect, reduce and correct deficiencies in an analytical process.

Quality improvement is the practice of continuously assessing and adjusting performance using statistically and scientifically accepted procedures.

Pathology QA

- a) Accuracy
- b) Timeliness
- c) Completeness
- d) Availability
- e) The ability to change

- a) Accuracy
All accuracy issues listed below should be defined and monitored according to guidelines defined by good laboratory practice standards.

* Pre-analytic issues

- Specimen fixation:
fixation method and time to and time of fixation
- Specimen delivery.
- Specimen identification.
- Adequacy of clinical history.
- Accessioning errors.

* Analytical issues

- Intraoperative assessment of Sentinel Lymph Nodes (SLNs).
- Intraoperative assessment of surgical margins.
- Assay validation.
- Equipment calibration.
- Standard laboratory procedures.
- Paraffin block and slide quality.
- labeling errors (blocks, slides).
- Immunohistochemistry (IHC) -
 - * Automation
 - * Antigen retrieval methods.
 - * Frequency of repeat slides.
 - * Quality of controls.
 - * External validation of antibodies
relevant for targeted therapy (ER, PR, Her2).
- Molecular studies Fluorescent/Chromogen/Silver In situ Hybridization (FISH, CISH, SISH)-
 - * Quality of controls.
 - * Concordance with IHC and statistics.
 - * External validation.
- Staff training assessment.

* Post analytical issues

- * Interpretation.
- * Image analysis.
- * Reporting - completeness
 - Transcription errors
 - Verification errors
 - Report delivery errors

b) Timeliness /Turn Around Time (TAT)

The TAT should be defined in each clinical setting in order to support the patient's management to the best of medical requirements and to the best of the unit's ability.

The TAT relates to all of the following:

- * Frozen section (FS) results.
- * Cytology specimens results.
- * Core needle biopsies results.
- * Mammotomy specimens results.
- * Lumpectomy/mastectomy specimens results.

* Special studies (IHC, FISH) results.

c) Completeness of pathology report.

A full report should contain all of the following:

- Demographic details.
- A comprehensive macroscopic description.
- Assignment of all paraffin blocks to specific locations.
- Diagnosis.
- Tumor grade.
- Tumor size.
- Margin status.
- Receptor status (IHC, FISH).
- SLN/Axillary lymph Node Dissection (ALND) with protocol description (of SLN examination method).
- Correlation of diagnosis with previous cytology, core needle biopsy (CNB), FS results.
- Concordance of diagnosis with ancillary results.
- Additional pathology in breast tissue.
- All above should be enclosed in templates/summary checklists in order to turn these very elaborate reports into more accurate and more readable reports (Ref.1).

d) The pathologist has to be an integral part of the multidisciplinary breast cancer team:

The timely crosstalk with the radiologists, surgeons and oncologists enables:

- To find out discrepancies as soon as possible.
- To learn and understand the different clinical and pathological setups.

e) The ability to change

- The pathologist has to develop the ability to change and develop along with the rapidly developing molecular testing and QA/QC requirements.

Special Issues

1) Her 2 testing

Factors underling Her2 testing variation are found in many steps:

a) Pre-analytical preparation of the tumor sample.

- Time of slicing and fixation of the specimen.

- Thoroughness of tissue processing.
- Type of fixative and fixation duration.
- Storage of tissue blocks and sections.
- Pretreatment procedures, e.g. antigen retrieval: heat induced/protease pretreatment.

b) Analytical phase

- The Her 2 testing protocol (standardization/validation).
- For immunohistochemistry - the antibody used.
- For in situ hybridization methods - the probe/kit used.
- Test reagents and storage.
- Controls.
- Assay conditions.
- Automation platforms.
- Image analysis.

c) Post-analytical phase

- Interpretation of controls.
- Scoring systems.
- Reporting element.
- External proficiency testing.
- Trouble shooting.
- Minimal recommended case load in local laboratory.

Because of the variations observed in many steps in the 3 phases, the use of guidelines is recommended in order to

- improve outcomes and minimize inappropriate practice variation.
- Improve medical practice.
- Produce a reliable decision support for clinical practitioners.

The ASCO/Cap guidelines issued in 2007 are comprehensive and easy to follow but are not exclusive of other guidelines that may obtain similar results (Ref.2).

- 2) ER/PR testing: Should also be performed with strict adherence to guidelines, as all the issues mentioned for the Her 2 testing are applicable for the ER/PR testing as well. The CAP/ASCO issued guidelines for the ER/PR testing in 2010 and adherence to these or other guidelines is recommended in order to minimize testing errors/variation (Ref.3).

3) Sentinel Lymph Node assessment:

- 1) There are no widely accepted guidelines as to the pathological protocol of sentinel lymph node assessment, therefore numerous protocols were issued by different pathology departments.
- 2) The sensitivity of metastases evaluation should be considered and should be appropriate with the breast disease center requirements.
- 3) There should be protocols relating to the intra-operative assessment and to the permanent assessment of the sentinel lymph nodes.

Quality assessment programs should be performed regularly for all steps involved in breast cancer pathology diagnosis, such as:

- Double signing of pathology reports by 2 certified pathologists.
- Monitoring regularly the discrepancies between Final diagnoses and cytology, CNB and F/S results.
- Monitoring regularly the turnaround time of all diagnostic procedures.
- External proficiency testing of Her 2, IHC, FISH, CISH or SISH testing.
- External proficiency testing of ER/PR immunohistochemistry.

Pathology laboratory accreditation is a formal recognition that a lab is competent to carry out a specific test.

Minimal standards are required for the following issues:

- External QA
- Internal QC
- SOPs
- Personnel education and training.

In conclusion for Pathology to remain relevant in a breast disease center set up, it has to adopt high quality standards, according to appropriate Good Laboratory Practice guidelines.

It has to adhere to rigid QA/QC protocols and thus provide the highest quality diagnoses, including therapeutic predictive factors.

References:

- 1) Protocol for examination of specimens from patients with invasive carcinoma of the breast.
Based on the AJCC/UICC TNM latest edition.
- 2) American Society of Clinical Oncology/College of American Pathologists Guideline. Recommendations for Human Epidermal growth Factor Receptor 2 Testing in Breast Cancer.
Antonio C. Wolff et al.
J Clin Oncol 2007;25:118-145
- 3) Pathologists Guideline Recommendation for Immunohistochemical Testing of Estrogen and Progesteron Receptors in Breast Cancer.
Hammond ME et al.
Arch Pathol Lab Med 2010;134:e48-e72.

RADIOLOGY – GUIDELINES FOR QUALITY ASSURANCE IN BREAST CANCER SCREENING AND DIAGNOSIS

1. Radiologists take prime responsibility for mammogram image quality and diagnostic interpretation
2. Requirements of the radiologist;
 - a. Medical qualification
 - b. Specific training in screening and diagnostic mammography
 - c. Participation in continuing medical education program and external quality assessment
 - d. Breasts Radiologist read at least 1000 mammograms /year or 5000 mammograms/year if engaged in screening programs
 - e. Radiologists should refuse to accept unsatisfactory mammograms and demand that they be repeated. All repeated mammograms should be recorded.
 - f. The radiologist should lead the assessment process when women are recalled for examination based on abnormal findings at screening. This process should entail a triple assessment involving clinical examination, further imaging and tissue sampling.
 - g. Radiologists must review cases of interval cancers.
 - h. Radiologists must work closely with other colleagues as part of a multidisciplinary team. The multidisciplinary teams should be comprised of specialists of all diagnosis and treatment disciplines and hold frequent meetings to discuss individualized clinical cases.

Equipment

1. Mammography

Technical aspects

Analog mammography – should be tested according the standard quality control testing, including the developer equipment used as an adjunct to mammography.

Some measurements can be performed by the local team, others by the medical physicists as indicated by the company. These measurements should be recorded according to a known protocol.

Parts of the system that should be monitored:

The mammography machine

Bucky (film cassette holder) and image receptor

The developer unit

Printers

Reading room

Digital mammography :

Quality control adjusted for digital system, since the systems are new, they should be continuously updated on the instructions.

2. Ultrasound

3. MRI

4. Image guided biopsies – via ultrasound guidance, stereotactic guidance, and MRI guidance

5. Preoperative needle localization procedures, under all imaging modalities

The equipment should be recorded as follows:

- Analog Mammography Device Model..... Year:.....
- Digital Mammography DeviceModel:..... Year:.....
- Processing system:.....
- Ultrasound Device :.....Model..... Year:.....
- MRI: Model..... Year.....

- Biopsy equipment:..... Model..... Year:.....

Radiographers

1. The radiographers must have the experience and the special training to perform mammography.
2. Radiographers are responsible for producing high quality mammograms necessary to detect breast irregularities, and for processing and assessing the mammograms.
3. Their duties include implementing and conducting quality control procedures to monitor equipment
4. Radiographers in screening programs must work a minimum of two days per week in order to maintain their mammography skills.
5. Radiographers not working in a screening program should perform at least 20 mammography examinations per week.
6. More than 97% of the women screened should have an acceptable examination and be satisfied with their screening visit.
7. Less than 3% of the women should have a repeat examination; this should be audited.
8. Radiographers should undergo three days to one week of academic mammography training and two to six weeks of clinical training.
9. Radiographers should participate in multidisciplinary team meetings.

Diagnostic breast imaging center

1. Perform at least 2000 mammograms in a year
2. Possess the ability to perform mammography, clinical breast examination, image guided biopsies – Fine needle aspiration and core needle biopsies-using different imaging modalities
3. Radiologist who has experience reading scans, about 1000 mammograms a year or 5000 mammograms a year, in a screening program.
4. Be a part of a regular multidisciplinary team
5. Participate in a continuing medical education
6. Monitoring the data and the results of the mammograms and biopsies
7. 90% of symptomatic women should be examined within two weeks
8. Mammogram results should be received within < 5 working days

Surgery

Surgeons

As a member of the multidisciplinary team, the surgeon plays a role in both the diagnosis and treatment of breast cancer.

Surgeons must be specially trained in breast surgery and have undergone courses in communication and counseling. They must personally carry out the primary surgery on at least 50 newly diagnosed cancers per year.

The diagnosis of Breast Cancer should be communicated in a personal clinical interview (never by phone or letter) and within 5 working days after the completion of the biopsy.

The team should always see and examine a woman before operating on her.

The majority of women should not have to undergo an operation to determine the diagnosis; the use of non-surgical diagnostic techniques should help limit the operations performed on women who in fact do not have cancer. • Histological diagnosis of cancer should be known prior to surgery in > 90 % of cases. i.e. the number of surgical biopsy should be < 10%.

In case of non-palpable lesion, radiography of the specimen should be performed during surgery, and breast conserving surgery should be the treatment of choice for most small detected cancers and should be provided in 70-80% of cases.

The Surgeon should offer a mastectomy to women who prefer this procedure and to those who are not good candidates for breast conserving surgery due to tumor size, or high risk for recurrence. He should offer the woman the choice of reconstruction at time of surgery or afterward.

Women with larger tumors should be offered chemotherapy before surgery (neoadjuvant treatment).

Surgeons should leave clear margins around the removed tumor tissue and the pathologist should document the margins in all patients.

All surgeons performing the sentinel node procedure should be specifically trained in the procedure and be evaluated.

The percentage of non-detection of sentinel node must be < 5%

The surgical specimens of axillary dissection must contain at least 10 nodes in 90 % of the cases.

All women who are treated for breast cancer should undergo follow-up at least once a year by the surgeon.

Surgical management of mammographically detected lesions

- a. Surgeons should be fully involved in the assessment of screen-detected cancers and no more than one week should elapse between a woman's first recall appointment and her assessment for surgery.

- b. In 90% of cases with a clear malignant diagnosis, the woman should only have to undergo one operation to remove the tumor. The surgeon must make sure that the woman is aware of all her treatment options.
- c. In 90% of cases, women should not have to wait more than two weeks for surgery.
- d. Each screening centre must nominate a surgeon responsible for recording audit information on screening, treatment and outcome in order to generate reports on these issues and provide annual results.

Loco regional treatment for invasive breast cancer

- a. Every woman with invasive cancer considered a suitable candidate for breast conserving surgery must be informed of this option.
- b. Women undergoing breast conserving surgery or mastectomy should consult with a radiation oncologist.
- c. The surgeon or plastic reconstructive surgeon should inform women having a mastectomy about the possibility of breast reconstruction.
- d. Over 80% of patients with locally advanced breast cancer should have combined therapy of upfront chemotherapy, surgery and radiation therapy
- e. The use of adjuvant radiotherapy should be discussed with all women after complete removal of ductal carcinoma in situ.

Minimal requirements in a Breast Centre

Surgeons in the Breast Center must perform surgery in a minimum of 50 new breast cancer cases per year and attend at least one diagnostic clinic per week.

ACCREDITATION

1. ACCREDITATION COMMITTEE Accreditation Committee will consist of two/three members of the SIS appointed by the Director of the SIS/ISS (Senologic International Society/International Senology School), one of which will serve as Coordinator and another as Secretary

2. THE ACCREDITATION PROCESS

The Breast Center applicant shall carry out the following steps:

- a. Carefully read the standards of quality required by the Program of Accreditation of Breast Centers.
- b. Complete the Application Form
- c. The Accreditation Committee has a period of 40 days to study all documentation provided by the applicant.

The following should be recorded in the Visit Agenda:

- Date

- Schedule
- Documents to be presented by the Center applicant

Travel costs of the members of Accreditation Committee shall be borne by the Applicant Center

This Visit Agenda of the applicant Center will be prepared by the 2/3 members of the Committee for accreditation with the following protocol:

- Contact with the Head/Coordinator of the Center
- Verify the information provided by the Center in the application form.
- Meeting of the members of the Accreditation Committee with the Head/Coordinator of the Center and specialists responsible for the diagnosis and treatment process standards and quality indicators. There must be at least one representative for each one of the specialties (radiology, pathology, surgery, medical oncology, radiotherapy, plastic surgery, psycho-oncology, oncology nurse and cases/manager/). Would also be beneficial to have a representative of the patient support groups present.

Time: 1-2 hours

- Assisting a Multidisciplinary Breast Committee Meeting in discussing clinical cases.

Time: 1 hour

- Review of Clinical Histories: 5 stories of the file and 5 stories of patients awaiting visit that same day.

Time: 1 hour

DOCUMENTATION TO EXAMINE:

- Radiology Report
- Pathology Report
- Care Report
- Informed Consent Forms
- Information on Clinical Trials
- Samples of written documents provided to patients: Information/Health Education and in relation to the diagnosis and treatment of Breast Cancer
- Visiting all the facilities of the Center:

Time: 1 hour

- Meeting of the members of the Accreditation Committee

Time: 30 minutes

Final Meeting with all the members of the Breast Center in which Accreditation Committee members explain the strengths and weaknesses of the Center and offer suggestions for addressing any shortcomings.

- Greeting and informing the Hospital Director.

The Accreditation Committee has a period of 30 days to prepare a report on the status of accreditation of the Center which it will send to the applicant via the web/e-mail, with suggestions for improvement, if appropriate. In the case that the Center complies with all the requirements, it will also be notified via the web/ e-mail. The favorable report of the Accreditation Committee has to be sent to the President of the SIS so that the Certification of accreditation will be issued.

3. CERTIFICATION OF ACCREDITATION

LEVELS OF ACCREDITATION:

3.1 ONE STAGE ACCREDITATION:

When the Breast Center applicant meets all the requirements, the Accreditation Committee issues a favorable report. Then the SIS grants an ACCREDITED CENTER CERTIFICATION. The Accreditation will be valid for a period of five years, renewable every five years, provided that the Center fulfills all the conditions as described in 3.1.1

In case that the Center does not have all the technological equipment and human resources, it can obtain technical and human collaboration from another well qualified medical institution.

3.2 TWO STAGES ACCREDITATION

This level of accreditation occurs when the evaluated Center meets 90 per cent of the standards of quality required. In this case the Center has to achieve all required quality standards within 12 months.

3.3 THREE STAGES ACCREDITATION

This level occurs when the evaluated Center meets less than 90 percent of the standards of quality required.

In this case, the Center has to achieve all required quality standards within 24 months.

3.1.1 COMITMENTS OF THE ACCREDITED BREAST CENTER

The Accredited Breast Center must forward each year to the Coordinator of the Accreditation Committee:

- a. An annual report on Breast Care activity conducted.
- b. The results of the Quality Indicators during that period.
- c. Participation of the Breast Center members in training courses on breast diseases.
- d. Research and teaching activities performed by the staff of the Center.

- e. Changes in Diagnosis and Treatment Protocols, if any.

Appendix 1

ACCREDITATION APPLICATION FORM

Dr

Serving as... Head of the Breast Center

Coordinator of the Breast Center

Applying for the accreditation for the Breast Center of

The HOSPITAL.....

The CLINIC.....

Address.....

Breast Center phone No.....

Breast Center e-mail.....

Head/Coordinator's mobile phone.....

Head /Coordinator's e-mail.....

REQUESTED DOCUMENTATION

1. Certification of application by the Hospital Director
2. Composition of the Breast Center by Specialties, identifying each one of the specialists
3. Reference Services (if any), identifying each one of the specialists
4. Diagnosis and Treatment Protocols for Breast Diseases
5. Non-medical personnel assigned to the Breast Center. Specification of names and positions
6. Specification of diagnostic imaging equipment
7. Records of the care activity over the last year for the first accreditation.
8. Records of scientific research and teaching activities

Appendix 2

Form to be completed by the Breast Center applicant

1. Head/Coordinator of the Breast Center:

Name:.....

Specialty:.....

Mobile phone:.....

Member of the SIS.....

2. The Hospital to which the Breast Center belongs is under management:

Public YES NO

Private YES NO

3. The Breast Center incorporates services provided by different Hospitals

YES NO

Specify:.....

4. Number of Hospital beds assigned to Breast Care.....

5. The Breast Center has management autonomy

YES NO

Is under the authority of

Is under the authority of the Director of the Hospital/Clinic-----

6. The Breast Center has its own designated area and is conveniently signposted in the Hospital's labeling

system

YES Surface....m2

NO

7. If the answer is no, specify the location.....

8. The Breast Center has assigned full-time staff

YES, Specify:

Specialties

Title of specialists

Members of the SIS

Specific Training in Senology (Master's degree or specific courses)

NO Part-Time shared with the service of:

Number of staff members assigned exclusively to the Breast Center
.....

9. Number of Nurses assigned to the Breast Center

Number of Auxiliary Staff.....

10. The Breast Center has Administrative Staff

YES

Full-time

Part-time

NO

11. There is a population screening program for Breast Cancer:

YES NO

The Breast Center is the referral center of the Program

YES NO

The Breast Center participates in the management of the Program

YES NO

12. Office hours of Outpatient Clinic devoted exclusively to Breast Diseases

MondayHours

TuesdayHours....

Wednesday... Hours.....

Thursday... Hours.....

Friday..... Hours.....

13. The Breast Center serves ONLY patients with cancer YES NO

Serves patients with Benign Pathology YES NO

14. Number of total number of patients with benign pathology attended over the last year

15. Outpatient consultation activity conducted over the last year:

Number of 1st visits pathological benign

Number of 1st visits pathological malignant

Number of 2nd visits pathological benign

Number of 2nd visits pathological malignant

16. Schedule of operating theater devoted exclusively to Breast Surgery

Monday.....Tuesday..... WednesdayThursdayFriday

Activity over the last year

1. Surgical Statistics

a. Number of interventions for

Benign Diseases

Breast Cancer

Conserving Surgery

Mastectomies

Reconstructive Surgery:

Immediate

Deferred

Oncoplastic Surgery

Surgical Biopsies

2. Sentinel lymph node biopsies:

Number per year:.....

Average nodes studied per patient

Average node biopsies in the internal mammary.....is not performed.....

Technique :

Isotopic

ROLL/SNOLL

Coloring	Linfazurin
	Patent Blue
	Methylene Blue
In Neoadjuvancy:	Pre-treatment Biopsy
	Post-treatment Biopsy
Preoperative Study of SLN	YES..... NO....
Technique:	Imprint
	Freezing
	Mixed
	Immunohistochemistry
	AutoAnalyzer

3. Diagnostic radiology statistics:

Number of	Mammographies
	Sonographies
	Galactographies
	Guided Biopsies
	Diagnostic MRI
	Pretreatment MRI

4. Casuistry of new cases of Breast Cancer cared for in the last three years (specify Staging)

Stage 0

Stage I

Stage II A

Stage II B

Stage III A

Stage III B

Stage III C

Stage IV

5. The Center has a specific database for Breast Diseases

YES....

NO.....

6. Types of Quality Controls used by the Center

Specify.....

7. Delays control system in the care network

- For the first visit
- For additional tests:

Mammograms

Ultrasound

Biopsies

- For the Histological/Cytological Report of the biopsies of the surgical specimens
- For the beginning of treatment of Breast Cancer patients
- For the beginning of Chemotherapy after Surgery
- For the beginning of RT after Surgery
- For the beginning of RT after Chemotherapy

8. The Breast Center has Computerized Clinical Records

YES NO

9. The Breast Center provides Breast Cancer patients with written information or Audio-Visual

material on:

- Health Education about treatments and side effects
- Prevention of Breast Cancer
- Early Diagnosis
- Breast Health Promotion

- Participation in clinical trials
- Follow up monitoring
- Contacts with Support Groups
- Psycho-Social Support
- Palliative Care

10. Equipment of Imaging Diagnosis:

- Analogue mammography device Model..... Year:.....
- Digital Mammography deviceModel:..... Year:.....
- Processing system.....
- Ultrasound device:.....Model..... Year:.....
- MRI: Model..... Year.....
- Biopsy equipment..... Model..... Year.....

11. Laboratory of Pathological Anatomy:

- Uses Immunohistochemistry YES NOT
- FISH Technology YES NOT

12. Radiotherapy Equipment:

Model..... Year

13. For the follow-up of Breast Cancer patients:

- There is a Protocol
- Involved staff: Surgeons
Gynecologists
Medical oncologists
RT Oncologists

14. Psycho-oncology Consultation services

YES NO

15. Genetic counseling

YES NO

16. Treatment of fertility preservation for young Breast Cancer patients

YES NO

17. Services provided:

Nuclear Medicine	Own	Referral. If necessary: Bone scan; Hormonal determinations; PET-CT Scan
Bone Mass evaluation	Own	Referral. If necessary: P/Ca determinations, bone loss measurements
MRI	Own	Referral
Radiation therapy	Own	Referral
Plastic Surgery	Own	Referral
Psycho-oncology	Own	Referral
Rehabilitation	Own	Referral

18. The psycho-morbidity of cancer patients is evaluated:

- By the QLQ C-30 (EORTC) questionnaire
- By the B-23(EORTC) questionnaire
- Other

19. Patients satisfaction is evaluated through some kind of survey

YES NO

20. Publications and Communications of the Center staff on topics related to Breast Diseases.

- Research activity and involvement in Clinical Trials. (National and International)
- Educational activity
- Participation in training courses

Multidisciplinary Meetings

1. Breast Cancer treatments committees with all the specialists:

Weekly Frequencyhours invested.....

Average number of cases studied.....

Monthly frequencyhours dedicated.....

Average number of cases studied.....

2. Breast Cancer diagnosis committees with the specialists involved (Surgeons, radiologists, pathologists, etc)

Weekly frequency..... hours invested.....

Average number of cases studied.....

Bi-weekly Frequencyhours invested.....

Average number of cases studied.....

Appendix 3

QUALITY INDICATORS IN THE CLINICAL CARE FOR PATIENTS

The following data are objectives that the Center must achieve in the medium term and that the SIS Accreditation Committee does not consider essential at this time for the granting accreditation. However, is recommended that the Center introduce them into its database to be used in the follow-up checks that the accreditation Committee conduct for all units 3-5 years after the granting of accreditation.

- The Diagnosis of Breast Cancer should be communicated in an interview (never by phone or by letter) and within < 5 working days after the completion of the biopsy
- Histologic diagnosis of cancer must be prior to surgery in > 90 per cent of cases i.e. the number of surgical biopsies for Breast Cancer diagnosis is considered an exceptional practice (< 10%). Breast Cancer patients should be taken to the operating room knowing the diagnosis
- Conserving Surgery for Breast Cancer should be > 65 % for States I and II • Conserving surgery should be achieved with a maximum of 2 interventions
- Histological assessment of margins should be carried out in 100 % of cases
- The percentage of Non-Detection of Sentinel node must be < 5%
- The surgical specimens for axillary dissection may contain less than 10 nodes in < 10 % of the cases
- Breast Cancers should statistically be classified using stages according to the UICC classification for the Database
- Global survival and Disease-free survival should be recorded at 5 and 10 years of follow up in all cases of breast cancer
- Local recurrences in Conserving Surgery for IDC at 5 years < 5% , for CIS at 5 years <10%

- Local recurrences post Mastectomy within 5 years < 5%
- Axillary recurrence after axillar dissection at 5 years < 5% on N +, <3% in NO
- Axillary recurrence after LNB < 3%

Delay Control:

First visit for suspected cancer < 5 working days

First visit for benign disease < 10 days

Histological Report after biopsy < 5 days

Histological Report after Surgery < 10 days

Beginning of Surgical Treatment < 15 days

- Percentage of Breast Reconstructions out of Total Mastectomies performed:

Immediate.....

Deferred.....

- Establishment of a Program for Preserving Fertility in young women
- Genetic counseling for young patients if appropriate
- Patients survey on level of satisfaction with the care received
- Continuous Training of the Breast Center staff in Breast Diseases. A minimum of 10 hours per year