Catalogue of requirements for Breast Cancer Centres

of the German Cancer Society

Developed by the DKG/DGS (German Cancer Society/German Society for Senology)
Certification Commission for Breast Cancer Centres

Chairmen Prof. Dr. J. Blohmer, Prof. A. Scharl

Members (in alphabetical order):
ADT – Working Group on German Tumour Centres
AET – Working Group on Genetic Tumour Diseases
AGO – Gynaecological Oncology Working Group
AIO – Working Group on Mediacl Oncology
PSO – Working Group on Psychological Oncology
ARO – Working Group on Radiological Oncology
ASO – Working Group on Social Work in Oncology
ASORS - Working Group for Supportive Care in Oncology, Rehabilitation and Social Medicine
AG BZ – Working Group on Breast Cancer Centres
BVP - Professional Association of German Pathologists
BVF - Professional Association of Gynaecologists
BNHO - Professional Association of Haematologists and Oncologists
FSH - National Association for Women's Self-Help after Cancer
BNGO - Association of Gynaecological Oncologists
DGPRÄC - German Society of Plastic, Reconstrucive and Aesthtic Surgery
DGCh – German Society of Surgery
DGGG – German Society for Gynaecology and Obstetrics
DGN – German Society for Nuclear Medicine
DGP – German Society for Palliative Medicine
DGP – German Society of Pathology
DEGRO – German Society of Radiation Oncology
DGS – German Society of Senology
DRG – German Radiology Society
DVSG – German Association of Social Work in Health Care
KOK – Conference of Oncological Nurses and Children's Nurses
Mammography Screening
Chairman of Certification Commission for Gynaecological Cancer Centres
Rep. of group of auditors (Oncological Experts conducting the audits)
Rep. of Guideline for the Early Detection of Breast Cancer

Effective as of 14th July 2017

This Catalogue of Requirements is binding for all audits from 01.01.2017. All changes to the previously applicable versions of this Catalogue (of the audit years 2015 and 2016) are marked in green colour.

Important notice: These translations are for your convenience only; in case of any discrepancy or divergence of interpretation, the German text shall prevail.

Information on the Breast Cancer Centre

		This questionnaire applies to
Breast Cancer Centre (BCC)		
Director of the Breast Cancer Centre		
Coordinator of the Centre		
Clinical site 1 (hospital/city or town)		☐
Clinical site 2 (hospital/city or town) only in the case of cooperating BCC		☐

QM system certification

QM standard ☐ ISO 9001 ☐ KTQ

QM certification agency _____

Network/main cooperation partners

The (main) cooperation partners of Breast Cancer Centres are registered with the certification agency OnkoZert in what is referred to as a master data sheet. All information regarding this registration are published on www.oncomap.de. The centre is obliged to report all new and also all invalid cooperations. All other updates (change in management, contact data etc.) must be corrected in the “master data sheet and must be regularly updated before the annual audit/monitoring. This master data sheet can be requested from OnkoZert.

Compilation/Updating

The Breast Cancer Centre is certified on the basis of this electronically compiled questionnaire. The information provided here was verified to ensure that it is correct and complete.

The data on outcome quality are based on calendar year	
The questionnaire was compiled/updated on	

Contents

1 General information on the Breast Cancer Centre

1.1 Structure of the network

Chapt.	Requirements	Comments by the Breast Centre	
1.1.1	Written agreements (cooperation contracts) are to be signed with each of the main treatment partners. The agreements are to be reviewed annually by the Breast Cancer Centre to ensure that they are up-to-date. The BCC must be located adjacent to a department that provides hospital beds for inpatient treatment.		
	This is not necessary if the centre is run by/located at only one hospital. This does not, however, affect the obligation to define relevant procedural processes as well as to adopt other necessary rules. This can, for example, be covered by a general handbook.		
	Main cooperation partners include: surgeons, gynaecological oncologists, radiologists (with the exception of cooperating radiological facilities that only provide services for the Breast Cancer Centre in conjunction with breast MRIs), pathologists, internal oncologists, radiation therapists and specialists in nuclear medicine		
	The following points must be regulated in the agreements with the main treatment partners: • Mandatory participation in tumour boards (with the exception of nuclear medicine) • Assurance of availability • Description of the treatment processes relevant to the Breast Cancer Centre with a special focus on the interfaces • Obligation to implement established guidelines (S3 Guideline as a basic requirement) • Description of the cooperation on the tumour documentation • Declaration of consent to cooperate with internal/external audits • Commitment to adhere to the relevant criteria of the Requirements for Breast Cancer Centres and to provide the relevant data annually • Agreement on the part of the treatment partners to be publicly named as a part of the Breast Cancer Centre (e.g., on the website) • 24h access to the main clinical cooperation partners: surgeons, radiologists (with the exception of MRI), oncologic pharmaceutical therapist (gynaecological and/or internal), radiation therapists		
1.1.2	Agreements with other treatment partners: Written agreements in which the willingness to engage in cooperation is confirmed are to be signed with treatment partners for the following: • Psycho-oncology • Social services • Self-help		

1.1 Structure of the network

Chapt.	Requirements	Comments by the Breast Centre	
	• Genetic counselling Gene analysis, family anamnesis (BRCA-1, BRCA-2) and genetic counselling • Physiotherapy • Laboratory (with a round robin test certification) • Hospice/palliative medicine Medical aids supplier/~~orthopaedic workshop~~		
	The following points can, for example, be regulated in the agreements with the treatment partners: • Cooperation on further training measures and public relations work • Description of the cooperation and interfaces • Type of communication between the two parties • Confidentiality		
1.1.3	Presentation of the Centre and contact persons The overall structure of the Breast Cancer Centres must be presented to the public (e.g., via the Internet). This includes providing the following data for all of the internal and external cooperation partners: • Name and address of the cooperation partner • Who to contact by telephone/ e-mail The responsibilities of the individual medical disciplines must be defined on the level of a medical specialist.		
1.1.4	Malpractice • Malpractice determined by a court or through an out-of-court settlement must be reported to the certifier during an on-site audit. Only cases that have been settled must be taken into consideration. • The centre should not focus on the proceedings as such but instead only on the indicated actions and reactions to ensure quality. • The period presented is the calendar year relevant to the audit.		

1.2 Interdisciplinary cooperation

Chapt.	Requirements	Comments by the Breast Centre	
1.2.1 a)	Schedule The tumour board must meet at least once a week. ~~Videoconference~~ ~~Videoconferences can, under certain circumstances, serve as a substitute for personal~~		

1.2 Interdisciplinary cooperation

Chapt.	Requirements	Comments by the Breast Centre	
	~~participation (requirements see "Basisinformation Zertifizierung" OnkoZert). Telephone conferences without video are not an alternative.~~ Web-/online-conference • If web-conferences are held, sound and presented material must be transmitted. It must be ensured, that every main cooperation partner is able to present documents and images. Telephone conferences without image material are not permitted.		
b)	Tumour board participants Participation in the tumour board on the specialist level is mandatory for the following specialties and must be documented by an attendance list: • Breast surgeon • Radiologist • Pathologist • Radiation therapist Internal oncology • Gynaecological oncologist (when chemotherapy was administered by gynaecology)		
	Associated specialties are to be included in the tumour boards as needed (e.g., psycho-oncology, care, plastic surgery).		
	If a number of cooperation partners are designated for the specialty, then the attendance of one representative is sufficient, provided that a regular exchange of information takes place between them (e.g., via quality circles).		
	Regardless of this, every cooperation partner must participate in a tumour board at least once a month.		
c)	Tumour board preparation A written summary of the most important patient data should be compiled and sent to the participants beforehand. Preliminary consideration should be given to patients suited for participation in studies.		
d)	Images used for demonstration purposes Patient-related images (radiological/pathological) must be available during the tumour board and equipment suitable for presenting it must be available.		
e)	Tumour Board Protocol • One of the results of the tumour board will be a written, interdisciplinary treatment plan ("Tumour Board Protocol"). • The Tumour Board Protocol must be part of the patient's file and can, at the same time, serve as a physician's report. • The distribution of the treatment plan to the individual treatment partners (incl. the referring physician) must be ensured.		

1.2 Interdisciplinary cooperation

Chapt.	Requirements	Comments by the Breast Centre	
	• The "Tumour Board Protocol" should be automatically generated by the tumour documentation system.		
1.2.2	Post-operative case discussions Volume of primary cases discussed: ≥ 95%	Enter the value in the Data Sheet (Appendix)	
1.2.3	Pre-therapeutic case discussions Participants: Surgeon (gyn and/or surgeon and/or plast. surgeon), radiologist, pathologist, additional participants are to be invited depending on the indication (medical oncologist, gynaecological oncologist, ~~plast.surgeon,~~ radiotherapist, …). Cooperation partners for plastic surgery are to be invited. The screening conference can be recognised if the participants match the aforementioned list of required participants.		
	If possible, every vacuum assisted and punch biopsy should be discussed within the preoperative TB. At least, all vacuum and punch biopsies with BIRADS 4 and 5 and a B1- B4 pathology should be discussed.		
	Proportion of pre-therapeutic presentations	Enter the value in the Data Sheet (Appendix)	
1.2.4 a)	Patients with (local) recurrence/distant metastases All patients of the Breast Cancer Centre with local recurrence/distant metastases are to be presented to the pre- and/or post-therapeutic tumour board. The presentation must include all of the cooperation partners of the BCC.		
	In addition to the specialties cited in 1.2.1 b), the following medical specialties should be included in decisions regarding therapy – depending on the location of the metastases (based on the S3 guideline): neurosurgery, orthopaedics, general and visceral surgery, thorax- or trauma surgery, palliative medicine		
	All tumour board meetings including their minutes must be documented.		
b)	Number of cases with local recurrence/newly diagnosed metastases presented in the tumour board.	Enter the value in the Data Sheet (Appendix)	
1.2.5	Therapy deviations • In principle, the treatment plans and/or recommendations of the tumour board are binding. • In case any deviation from the original therapy plan or divergence from the guidelines is ascertained, they must be noted and assessed. Measures to avoid such divergence are to be introduced, depending on the cause. • It must be noted if the patient refuses to begin or prematurely interrupts treatment (despite an existing indication).		

1.2 Interdisciplinary cooperation

Chapt.	Requirements	Comments by the Breast Centre	
1.2.6	Treatment plan An interdisciplinary treatment plan is to be drawn up for every patient. This is also true of patients whose cases were never presented to a tumour board.		
1.2.7	Morbidity/mortality conferences (MM conferences) • Participants in the Tumour Board and the referring primary care physician are invited to participate • The date of the conference can be combined with the tumour board or with scheduled events for the referring physicians • After their completion of local primary therapy, patients in follow-up treatment will be discussed • At least 5 % of the cases should be discussed. Cases that develop positively and negatively are to be presented. Morbidity conferences are to be held at least twice a year. • The minutes of the MM conferences must be taken		
1.2.8	Therapy recommendations radiotherapy/quality indicators S3 guideline • Proportion of primary patients with invasive breast cancer receiving radiotherapy after BCCT: ≥ 80% (reasons must be given for deviations) (quality indicator guideline no. 6) • Proportion of primary patients with invasive breast cancer receiving radiotherapy after a mastectomy: ≥ 95% (target) in cases of indication of adjuvant radiotherapy according to the S3 guideline) (quality indicator guideline no. 10) • Proportion of primary patients with DCIS with radiotherapy after BCCT: ≥ 95% If the target standards are not achieved, a stage- and indication-dependent analysis is to be undertaken.	Enter the value in the Data Sheet (Appendix)	
1.2.9	Therapy recommendations systemic therapy/quality indicators S3 guideline • Proportion of primary patients with chemo therapy = PST (primary systemic therapy), adjuvant chemotherapy (CHT) in cases of negative steroid receptor status: ≥ 80% (quality indicator guideline no. 9) • Proportion of primary patients with chemo therapy in cases of pos. receptor status and positive nodal status Requirement: ≥ 60% • Proportion of primary patients receiving endocrine therapy in cases of positive steroid	Enter the value in the Data Sheet (Appendix)	

1.2 Interdisciplinary cooperation

Chapt.	Requirements	Comments by the Breast Centre	
	receptor status: ≥ 80% (quality indicator guideline no. 7) • Proportion of HER2/neu-positive patients with trastuzumab therapy (quality indicator guideline no. 8) • Endocrine therapy as the first therapy option in cases of steroid rec. pos. metastases: ≥ 95% (quality indicator guideline no. 11) Determining the indication/type of chemotherapy in light of the DKG's S3 guideline on adjuvant therapy.		

1.3 Cooperation with referring physician and follow-up care

Chapt.	Requirements	Comments by the Breast Cancer Centre	
1.3.1	Cooperating referring physician A list of the cooperating physicians who most frequently refer must be kept up to date. The referring physicians are to be provided with information regarding cooperation within the Breast Cancer Centre on the following topics.		
	Obligations of the Breast Cancer Centre Referring physicians have the right to participate in the tumour board when their patients are presented. Referring physicians must have the opportunity to present patients in cases of palliative care or recurrence.		
1.3.2	Providing records The following records must be provided to the referring physicians as soon as possible: Optional: • OP report • Histology Mandatory: • Tumour Board Report/treatment plan • Doctor's report/discharge report • Changes in the therapy		
1.3.3	Feedback system A written procedure must be in place for compiling, processing and responding to feedback from the referring physician on general and case-specific sues/questions/complications.		
1.3.4	Further training At least once a year, scheduled events for the purpose of exchanging ideas and further training are to be offered by the Breast Cancer Centre. A record must be kept of the participants as well as of the topics covered/results.		
1.3.5	Survey of referring physicians' satisfaction		

1.3 Cooperation with referring physician and follow-up care

Chapt.	Requirements	Comments by the Breast Cancer Centre	
	• Every three years, a survey of the referring physician's satisfaction must be conducted. The result of this survey is to be assessed and analysed. • The first survey of referring physicians' satisfaction must be completed by the time of recertification (3 years after the initial certification).		
	• The response rate should be at least 50%		
1.3.6	Contact person Referring physicians must be provided with relevant information regarding the contact person at the Breast Cancer Centre (e.g., telephone, e-mail). This can be included in the information on cooperation partners that must be published.		
1.3.7	Tumour documentation/follow-up • A description of the cooperation with the referring physician during follow-up care must be provided. • The requirements for this can be found under "10. Tumour documentation".		

1.4 Psycho-oncology

Chapt.	Requirements	Comments by the Breast Cancer Centre	
1.4.1	Psycho-oncology – qualification • Qualified psychologists or • Physicians In each case with additional training in psychotherapy and further training in psycho-oncology.		
	Recognised further training includes: "Further Training in Psycho-social Oncology" offered by the PSO or dapo (see: http://www.psoag.org/de/index.php and http://www.dapoev.de) or other adequate further training with > 100 teaching units. This can be verified by a special training curriculum.		
	Representatives of other psychosocial professions (such as qualified social pedagogues, social workers etc.) can be accredited when they can provide proof of the additional qualifications cited above. In such cases an individual examination is required. The provision of psycho-oncological care by social services, self-help groups or spiritual counsellors is insufficient.		
1.4.2	Psycho-oncology – Availability and access Every patient must have access to psycho-oncological counselling nearby and without delay. The threshold for accessing such options must be low.		

1.4 Psycho-oncology

Chapt.	Requirements	Comments by the Breast Cancer Centre	
	Documentation and evaluation In order to identify the need for treatment, a screening regarding the level of psychosocial stress is recommended (e.g., the screening procedure in psycho-oncology recommended by the DKG). As a rule, a record should be kept of the number of patients who have taken advantage of psycho-oncological care as well as the frequency, length and topics discussed.	Enter the value in the Data Sheet (Appendix)	
1.4.3	Psycho-oncology – resources At least ~~0.5 full time staff members per 150 patients~~ 1 psycho-oncologist should stand at the disposal of the centre (designation by name).		
1.4.4	Space A suitable room is to be made available for the psycho-oncological counselling of patients.		
1.4.5	Organisational plan To the extent that psycho-oncological care is provided by external cooperation partners or for a number of locations or hospital facilities, the provision of services is to be regulated by an organisational plan displaying information that includes the availability of resources and local presence.		
1.4.6	Psycho-oncology – responsibilities Psycho-oncological care should be offered to patients in all phases of care (diagnosis, inpatient, post-inpatient). Goals and responsibilities of care: • Prevention/treatment of subsequent psycho-social problems • Activation of personal resources for coming to terms with the situation • Maintaining quality of life • Consideration of the social context • Organisation of subsequent outpatient care through cooperation with providers of outpatient psycho-oncological services • Public relations work (scheduled events for patients etc.)		
	Also recommended are: • Supervision, further training and training measures for the staff • A conceptual discussion twice a year between psycho-oncologists, nursing and medical staff • Regular written and, if needed, verbal feedback to the physician in charge of treatment regarding psycho-oncological activities (e.g., in a consultant's report or documentation in the medical file). • Participation in tumour boards as needed • Close cooperation with social services		

1.4 Psycho-oncology

Chapt.	Requirements	Comments by the Breast Cancer Centre	
	• Psycho-oncologists should present their work within the centre at least twice a year.		
1.4.7	Further training/additional training/supervision • Specific further/additional training at least once a year per staff member (at least 1 day per year) • Participation in regular external supervision must be possible		

1.5 Social work and rehabilitation

Chapt.	Requirements	Comments by the Breast Cancer Centre	
1.5.1	Qualification of social services Social worker/social pedagogue Space: A suitable room must be made available for social counselling. Resources: At least 1 social worker must be available for the centre. Organisational plan: If social services are provided for a number of departments or locations or in the form of outpatient counselling, the performance of these services must be regulated by an organisational plan delineating the availability of resources and local presence.		
1.5.2	Social services Every patient must have access to social service counselling during all phases of the disease nearby and without delay (proof required). The threshold to these services must be low.		
1.5.3	Extent of care A record must be kept of the number of patients who receive social service counselling.	Enter the value in the Data Sheet (Appendix)	
1.5.4	Topics of counselling: • Identification of social, economic and psychological crises • Initiation of medical rehabilitation measures • Counselling in relation to economic questions and social law (particularly with regard to medical/occupational rehabilitation, disability law, benefits in lieu of pay, retirement benefits etc.) • Provision of support for application procedures • Counselling on in- and outpatient services and transfer to specialised service providers • Support for reintegration into working life		

1.5 Social work and rehabilitation

Chapt.	Requirements	Comments by the Breast Cancer Centre	
	• Cooperation with providers of support and services • Intervention in crisis situations		
1.5.5	Further tasks: • Public relations and networking • Participation in department conferences and tumour boards, supervision, further training • Interdisciplinary cooperation, especially with physicians, nurses, physiotherapists, psycho-oncologists, spiritual counsellors etc. • Documentation of activities		
1.5.6	Further training/additional training Specific further/additional training at least once a year per staff member (at least 1 day per year)		

1.6 Patient participation

Chapt.	Requirements	Comments by the Breast Cancer Centre	
1.6.1	Patient surveys • All inpatients must have the opportunity to participate in the patient survey. • The survey should be conducted at east every three years and should have a duration of a minimum of three months.		
	• The response rate should be over 30% ~~50%~~ (if rates are lower, measures should be taken)		
1.6.2	Assessment of the patient survey • Responsibility for the assessment must be assigned • The assessment must be in relation to the patients of the Breast Cancer Centre • A documented assessment must take place • Further action is to be determined on the basis of the assessment		
1.6.3	Patient information (general) • The Breast Cancer Centre must present itself and the treatment options comprehensively (e.g., in a brochure, patient folder or on a website). • The cooperation/treatment partners must be named along with their contact information. The treatment options must be described. • The options presented must include rehabilitation/follow-up treatment, self-help, treatment measures and alternatives.		
1.6.4	Discharge counselling Every patient receives counselling and information on the following topics before they are discharged: disease status, therapy planning, follow-up care, support measures (e.g., rehabilitation, medical aids suppliers, psycho-social programmes). Information provided		

1.6 Patient participation

Chapt.	Requirements	Comments by the Breast Cancer Centre	
	includes the “Patientenleitlinien Brustkrebs” (Patient Guidelines Breast Cancer): http://leitlinienprogramm-onkologie.de/Brustkrebs.70.0.html		
1.6.5	Results from the tumour board The patient must be informed of the recommendations of the tumour board. The patient’s decision must be documented; the information provided should be based on Statement Info-3 of the S3 guideline.		
	Patient information (case related): The patient should receive the following documents: • The tumour board report/treatment plan • Doctor’s report/discharge report • Follow-up plan/follow-up calender • Study documentation (if applicable)		
1.6.6	Programmes for patients The BCC must hold scheduled events at least once a year providing information to patients.		
1.6.7	Complaint management A regular system of complaint management must be in place. Patients must receive a response. Complaints are taken into consideration in improving processes.		
1.6.8	Self-help groups The self-help groups with which the Breast Cancer Centre actively cooperates must be named. Written agreements must be signed with the self-help groups; they should cover the following: • Access to self-help groups in all phases of therapy (first diagnosis, inpatient treatment, chemotherapy, …) • Publication of contact data for the self-help groups (e.g., in patient brochures, BCC website) • Space for self-help groups to lay out their brochures • Space regularly made available at the Breast Cancer Centre for discussions with patients • Quality circle in which psycho-oncology, self-help groups, social services, spiritual counselling, nursing and medical staff are represented. • Personal discussions between self-help groups and the Breast Cancer Centre with the goal of staging and mutually coordinating joint activities and events. A record is to be kept of the results of such discussions. • Participation of staff physicians in events staged by self-help groups		

1.7 Study management

Chapt.	Requirements	Comments by the Breast Cancer Centre	
1.7.1	Studies Access to studies The patients must have access to studies. The studies conducted at the Breast Cancer Centre must be compiled in a list and this list should be available to the patients with a short description of the study.		
1.7.2	Study commissioner The physician who serves as the study commissioner must be named.		
	Study assistant/study nurse • A study assistant is to be named for each "unit conducting studies" in the organigram for studies. • The same assistant can act on behalf of a number of "units conducting studies" in parallel.		
1.7.3	Study assistant – responsibilities The spectrum of responsibilities must be determined in writing (e.g., by means of a job description) and can include the following: • Cooperation with the physician commissioned to conduct the study in its execution • Look after patients during the study and follow-up care • Organising and coordinating diagnostic and laboratory measures, the investigational medicinal product and the sending of samples • Collection and documentation of all data relevant to the study • Preparing and overseeing the audit and inspections by authorities • The study assistant's activities can be combined with other activities such as tumour documentation.		
1.7.4	Process description: The processes and responsibilities must be determined before beginning/initiating new studies and conducting studies. This includes: • Selecting new studies incl. decisions to give clearance • Internal disclosure of new studies (updating list of studies, …) • Study organisation (particular characteristics, looking after study patients, documentation, …) • Way in which study results are made known (e.g., staff members, patients)		
1.7.5	Proportion of study patients Initial certification: some patients must already have been recruited for studies After 1 year: at least 5% of the primary cases	Enter the value in the Data Sheet (Appendix)	

1.7 Study management

Chapt.	Requirements	Comments by the Breast Cancer Centre	
	Only patients recruited for studies with a vote by the ethics commission count as participants (non-interventional/diagnostic studies are also recognised). All study patients can be counted in calculating the study rate (proportion of study patients in relation to all primary cases at the centre).		
	General precondition for the definition of the study rate: • Patients can be counted once per study, the relevant date is the date of patient consent • Patients in palliative and adjuvant situations can be counted, no limitation on stages • Patients who are recruited for a number of studies in parallel can be counted more than once		
1.7.6	Cooperation with external institutions Cooperation with external institutions on studies must be regulated by cooperation agreements.		

1.8 Care

Chapt.	Requirements	Comments by the Breast Cancer Centre	
1.8.1	Specialised oncological nurses • At least one active oncological nurse must be involved at the centre. • Oncological nurses are to be designated by name.		
	At the time of initial certification, the previous submission of at least one application for training as an “oncological nurse” is required. In this case, it must be explained how the “responsibilities/tasks” described in the following are to be performed during the training period. Cooperation with previously trained oncological nurses, who provide support in performing tasks, is recommended during the training phase. After 3 years, an oncological nurse must be documented.		
	Training of oncological nurses According to the outline of an ordinance formulated for the Länder by the Deutsche Krankenhausgesellschaft e.V. (German Hospital Society) or the laws of the Land in question or as an academically trained nurse (Master of Oncology).		
1.8.2	Responsibilities/tasks • Counselling the patients and their relatives on care options in the sense of case management and/or transitional care (to the network of outpatient care)		

	• Assessment and management of stress, symptoms and adverse effects • Counselling colleagues with regard to further training (theoretical/practical) • Planning for further training required by oncological nurses • Implementation of the most recent findings in (nursing) research in actual nursing practice • Joint oncological care visits • Responsibility for implementing the requirements for nurses administering chemotherapy (see chapter 6.2)		
1.8.3	Nursing concept A nursing concept that takes specific aspects of oncological care into consideration is to be developed and implemented.		
1.8.4	Further and additional training A plan for the further qualification of the nursing staff is to be submitted in which the qualification measures for the coming year are described. At least one specific further/additional training measure per staff member per year (at least 1 day per year), to the extent that the staff member performs tasks relevant to the quality of the centre.		
1.8.5	Qualification of personnel - nursing personnel • At least 1 quality circle in which an oncological nurse participates		

1.9 Areas of general care

	The questionnaires for organ cancer centres and oncological centres have a uniform table of contents. In relation to this chapter, however, there are no requirements for Breast Cancer Centres.		

2 Organ-specific diagnostics

2.1 Clinics

Chapt.	Requirements	Comments by the Breast Cancer Centre	
2.1.1	Information for/dialogue with patients within the context of the participatory decision making model Patients with primary breast cancer Patients with recurrence/distant metastases Inform patients of the diagnosis, discuss the diagnosis, describe of the various therapy options • The advantages of the recommended therapy		

2.1 Clinics

Chapt.	Requirements	Comments by the Breast Cancer Centre	
	• The risks of adverse effects from the therapy along with treatments and/or possible long-term effects • Possibility, if any, of participating in a clinical study • Information regarding support measures • Offer (and arrange for) a second opinion • Give the patient sufficient time to make a decision • Information must be provided according to the patient's needs during the entire treatment process • This requirement must be fulfilled in connection with chapter 1.6 • A general description must be provided of the way in which information is given and dialogue is initiated. In relation to individual patients, this is to be documented in doctors' reports as well as in minutes/notes.		
2.1.2	Breast clinics On which basis are the special clinics conducted (contract physician, personal authorisation, institute authorisation, hospital authorisation)		
2.1.3	The breast clinics must be held at least once a week and address the following topics: • Breast cancer detection • Therapy planning • Counselling on operations (in cases of planned reconstruction) • Follow-up care (e.g., counselling in cases of lymphedema) • Survey of family anamnesis in relation to breast cancer risk in the family • Counselling regarding benign breast conditions • Counselling in cases of growth or development disorders of the breast • Counselling, diagnosis and therapy in cases of inflammatory breast disease • If it should prove useful, the topics can be addressed in special, independent clinics.		
2.1.4	Breast cancer in the family The algorithm for referral to genetic counselling must be defined and must take checklists as well as the recognised centres of S3 guideline-early detection into consideration. Proof of cooperation with centres for counselling and genetic examinations must be provided through documented cases from the period currently under consideration. A checklist to identify high-risk persons with hereditary risk can be downloaded on www.krebsgesellschaft.de/checkliste_erbliche_belastung		

2.1 Clinics

Chapt.	Requirements	Comments by the Breast Cancer Centre	
	An algorithm and a model cooperation agreement for the cooperation with the declared Centres (of the S3 guidelines) can be downloaded on www.krebsgesellschaft.de/		
2.1.5	Waiting time during the clinics Requirement: < 60 min (target) How long is the wait for an appointment Requirement: < 2 weeks The waiting periods are to be surveyed by random sampling and statistically assessed (Recommendation: assessment period 4 weeks per year).		
2.1.6	In the case of (special) breast clinics, the following services must be guaranteed: • Mammography appointment within 48 h; an assessment of the mammography by a specialist must be available during the breast clinic (can also be realised in cooperation with an external radiologist) • Ultrasound examinations of the breast on the same day as the breast clinic Requirement for performance: breast ultrasound: at least DEGUM stage 1 or proof of basic, advanced and final courses in breast ultrasound or Association of Statutory Health Insurance Physicians' license according to the Ultrasound Agreement Standardised diagnosis documentation according to the S3 guideline (e.g., application of the US BI RADS classification) • Biopsy for histology directly during the breast clinic and/or appointment within a week; exception: stereotactic vacuum biopsy within 2 weeks		
2.1.7	Waiting time for a histological result (punch) Requirement: within 2 working days		
2.1.8	Clarification as to whether tumour is malignant or not dignity Proportion of Pretherapeutic/ interventional measures (punch/ vacuum biopsy) for histologic verification: ≥ 90% (quality indicator guideline no. 1)	Enter the value in the Data Sheet (Appendix)	
2.1.9	Disclosure of the diagnosis and dignity • The diagnosis – especially in cases of malignancy – is to be disclosed personally by a physician and in direct contact with the patient. • Time until final diagnosis (disclosure of the histological results to the patient): < 1 week		

2.1 Clinics

Chapt.	Requirements	Comments by the Breast Cancer Centre	
2.1.10	The waiting period between the results of the histological punch biopsy (disclosure of the diagnosis) and the operation date should leave sufficient time for consideration and counselling (at least 3 days) but no more than 14 days.		
2.1.11	The renewed presentation in cases of adverse effects of the diagnostic procedures or therapy must be organised.		
2.1.12	The following processes, which determine quality, are to be described specifying responsibilities: • Diagnosis of breast diseases incl. disclosure of diagnostic findings • Therapy planning (prior to operation) • Pre-inpatient admission • Diagnosis in cases of patients with local recurrence/distant metastases Sufficient resources must be available to execute the processes.		
2.1.13	Mammography screening At least 1 surgeon from the centre must participate in the mammography screening programme as a cooperating hospital physician (proof of the Association of Statutory Health Insurance Physicians' authorisation must be provided, this requires at least 50 primary procedures, participation in multidisciplinary conferences). Designation by name:		

2.2 Diagnostic procedures

	The questionnaires for organ cancer centres and oncological centres have a uniform table of contents. In relation to this chapter, however, there are no requirements for Breast Cancer Centre.		

3 Radiology

Chapt.	Requirements	Comments by the Breast Cancer Centre	
3.1	Specialists • At least 2 specialists with experience in the diagnosis of breast diseases • Specialists are to be designated by name All of the specialists named for the Breast Cancer Centre must participate in the TB (preoperative, at least 12 x per year).		
3.2	Radiology technicians		

	At least 2 qualified radiology technicians must be available and designated by name.		
3.3	Mammography equipment • The X-Ray Ordinance and the guidelines for quality assurance laid down by the German Medical Association for x-ray diagnostics and/or the corresponding European guidelines (European guidelines for quality assurance in mammography screening, ISBN 92-894-1145-7) must be fulfilled. The fulfilment of the requirements can, for example, be confirmed by a certificate recognised by the Arbeitsgruppe der Deutschen Röntgengesellschaft (Working Group of the German X-ray Society) (Qualitätsring Radiologie – Quality Ring Radiology). • Equipment for enlargement must be available		
3.4	Mammography results Obligatory disclosure of the BI-RADS classification and the mammographic parenchymal density (ACR)		
3.5	Professional qualification for evaluating mammographies All of the “curative” (diagnostic) mammographies performed in the centre must be assessed by at least one qualified specialist. As proof of qualification, at least one of the following conditions must be fulfilled: • Active participation as a diagnostician in a mammography screening programme evaluating at least 5000 screening mammographies per year and • License to invoice “curative mammographies” (see the Quality Assurance Agreement according to Art. 135, para. 2, Book Five of the Social Code on curative mammographies) with successful participation in the collected case examination every two years or • Regular assessment of the mammographies of at least 1000 patients per year or • successful participation in the Association of Statutory Health Insurance Physicians’ collected case examination every 2 years		
	If the curative mammography is performed by a physician who does not fulfil the requirements cited above, supervision and a second assessment by a physician with the corresponding qualifications are required.		
3.6	Double assessment at the BCC A double assessment of the mammographies of asymptomatic patients and patients in follow-up care should be conducted at the BCC For these mammographies: • The process of second/double assessment must be described. • Discrepancies between findings should be recorded and considered within a quality circle		

3.7	Preoperative marking At least 25 preoperative markings per physician responsible for marking per year		
3.8	Breast ultrasound • For breast diagnostics only ultrasound equipment with a frequency of ≥7.5 MHz is to be used • Ultrasound equipment must correspond with DIN EN 61157		
3.9	Requirement for performing breast ultrasound • Proof of a qualification in breast ultrasound (Fachkunde Mammasonografie [safeguarded], Ultrasound Agreement National Association of Statutory Health Insurance Physicians, DEGUM 1) • Standardised documentation of the diagnostic findings according to the S3 guideline (e.g., use of US BI-RADS classification)		
3.10	Stereotaxis • The procedure should be digital and analogue only in exceptional cases • Marking and biopsies must be possible and this option should be employed		
3.11	MRI Access to MRI examinations must be ensured. An MRI intervention option must be ensured. In the event that an MRI cannot be performed directly on the site of the Breast cancer Centre, access must be regulated by a cooperation agreement.		
3.12	Percutaneous biopsies - number • Sonographic biopsy • Stereotactic biopsy • MRI biopsy (optional) (number per treatment unit)		
3.13	Image-based localisation - number • Mammographic • Sonographic • MRI (number per treatment unit)		
3.14	Number of galactographies per year (number per treatment unit)		
3.15	Descriptions of radiological processes (SOP's) The imaging and marking procedures must be described and assessed once a year to ensure that they are up to date.		
3.16	Further/additional training • A qualification plan for physicians and other staff members (radiological technicians) must be submitted in which the qualification measures for the coming year are described. • At least one breast disease-specific further/additional training measure per staff member per year (duration > 0.5 days), to the extent that the staff member performs tasks relevant to the quality of the Breast cancer centre. • The further/additional training should be conducted by a specialised professional		

	organisation (German Radiological Society) and/or DKG, DGS, German Society of Obstetrics and Gynaecology) etc..		
3.17	Quality circle • Quality circles focussing on specific breast disease topics are to meet at least 4 x per year • Scheduling through such means as the qualification plan • The minutes are to be taken during quality circles		

4 Nuclear medicine

Chapt.	Requirements	Comments by the Breast Cancer Centre	
4.1	Specialists • At least 1 specialist • A qualified back-up plan in case of failure must be documented • Qualified specialists must be designated by name • Physicians who have demonstrated specialised knowledge of nuclear medicine within the context of an individual examination will be recognised as specialists for nuclear medicine		
4.2	MTA in nuclear medicine: At least 2 qualified MTAs must be available and designated by name.		
4.3	Number of skeletal scintigraphies (for all tumour types) Initial certification: ≥ 200 ~~After 3 years ≥ 400~~		
4.4	Sentinel node procedure Performance, quality control and documentation of sentinel node biopsies and sentinel lymph node scintigraphies must adhere to the DGS consensus paper (Kuehn T. et al., Cancer 2005; 103:451–61). Sentinel node biopsy (scintigraphie) At initial certification: ≥ 20 per year. After 3 years: ≥ 30 per year. (Expertise per treatment unit) Experience with injections, measurements using a probe, resection and pathological assessment must be documented.		
4.5	Proof of detection rate The proportion of sentinel lymph nodes detected in relation to the examinations conducted: Using a sentinel node biopsy probe At initial certification: ≥ 80% After 3 years: ≥ 90%		

4 Nuclear medicine

Chapt.	Requirements	Comments by the Breast Cancer Centre	
	Using sentinel node scintigraphy (optional) At initial certification: ≥ 80% After 3 years: ≥ 90% The clinical detection rate is to be subject to a regular quality control assessment (at least once a year) by an interdisciplinary group (isosulfan blue/patent blue dye and radioactivity).		
4.6	Further/additional training • A qualification plan for physicians and other staff members (radiology assistants) is to be submitted in which the qualification measures planned for the coming year are described. • At least 1 unit of breast-cancer specific further/additional training per staff member (duration > 0.5 days), to the extent that the staff member performs tasks relevant to the quality of the Breast Cancer Centre. • The further/additional training should be conducted by a specific professional organisation and/or DKG, DGS, DGGG etc..		
4.7	Quality circle • Quality circles in which breast-cancer specific topics are considered are to meet at least 4 x per year • Scheduling by such means as the qualification plan • The minutes of the quality circles are to be recorded		

5 Surgical oncology

5.1 Multi-organ surgical therapy

Chapt.	Requirements	Comments by the Breast Cancer Centre	
	The questionnaires for organ cancer centres and oncological centres have a uniform table of contents. In relation to this chapter, however, there are no requirements for Breast Cancer Centres.		

5.2 Organ-specific surgical oncology

Chapt.	Requirements	Comments by the Breast Cancer Centre	
5.2.1	Number of primary cases of mammary carcinoma per year At initial certification: ≥ 100 primary cases Definition of a primary case:	Enter the value in the Data Sheet (Appendix)	

5.2 Organ-specific surgical oncology

Chapt.	Requirements	Comments by the Breast Cancer Centre	
	• Patients and not hospital stays or operations • One primary case per breast is counted • There must be a histological diagnosis • DCIS are counted as primary cases • A case can only be counted for 1 centre. Therapy planning (interdisciplinary tumour board) and therapy administered through the Breast Cancer Centre (main therapy) • The date counted is the date of the first diagnosis • Mammary carcinomas found in male patients and primary M1 patients are counted as primary cases		
5.2.2	Cooperating Breast cancer centres (consisting of multiple operational locations) • Cooperative centres with more than two locations are no longer authorised • Initial certification/expansion as a cooperating centre is only possible when each location has ≥ 100 primary cases Cases of existing cooperation Cases of existing cooperation are safeguarded under the following conditions: • At least 50 primary cases per location • Cooperative centres with 2 locations with more than 150 primary cases • Proof of a positive certification result in audit report • Strict adherence to the Q-standards, joint treatment regimens, … • Proven back-up plan for the breast surgeon Cooperation between multiple locations requires a previous structural assessment (is also required for expansion and/or mergers).		
5.2.3	Inpatient care Beds for breast patients must be available. Inpatient admission should not be for fewer than 4 days.		
5.2.4	OP for breast operations: Number of operating rooms regularly available for breast operations: min. 1 operating room		
5.2.5	Specialists for the Breast cancer centre At least 2 specialists working on behalf of the Breast Cancer Centre according to the personnel plan (can also work in parallel as breast surgeons). The specialists are to be designated by name. The director of the BCC must be one of the main cooperation partners and a physician.		
5.2.6	Breast surgeons (per location): • At least 1 breast surgeon with specialist status (name and operating experience during the previous year must be disclosed)		

5.2 Organ-specific surgical oncology

Chapt.	Requirements	Comments by the Breast Cancer Centre	
	• In the event that only 1 surgeon is named, a substitution scheme that has proved effective must be in place • At least 50 breast operations (excision of invasive tumour/DCIS, not only primary cases) per year per designated surgeon		
	Cases in which the surgeon served as a second surgeon can only be counted if the surgeon assisted for training purposes. Each procedure can only be counted for one surgeon. (Situation: operation is performed by 2 designated breast surgeons. Exception, see 5.2.7 Prolongation "senior breast surgeon"). ~~Recognition of the OP: see definition of a primary case.~~		
5.2.7	Expertise of breast surgeon with long years of experience In cases where 150 ~~primary~~ procedures (excision of invasive tumour/DCIS, not only primary cases) have been performed in 5 years, annual proof according to 5.2.6 of this questionnaire is no longer required. (Documentation form from OnkoZert).		
	Prolongation "senior breast surgeon": Certificate of "senior breast surgeon" issued before 07.04.2014: Single prolongation for 5 years, if a minimum of 75 procedures (excision of invasive tumour/DCIS, not only primary cases) have been performed within the last 5 years). - after 07.04.2014: a minimum of 150 procedures (excision of invasive tumour/DCIS, not only primary cases) within the last 5 years. Procedures performed as second surgeon (for the purpose of training or assisting a designated breast surgeon) can be counted.		
5.2.8	Training of new breast surgeons The training of one breast surgeon must be organised for each location and for every 100 primary cases. Breast surgeons in training must provide evidence of at least 20 operations per year (not as a second surgeon).		
5.2.9	Accreditation of new breast surgeons At least 60 ~~primary~~ (excision of invasive tumour/DCIS, not only primary cases)mammary carcinoma procedures during the previous 3 years; proof by means of a list that includes OP reports.		
5.2.10	Qualification of the Breast cancer centre surgeons Description of special qualification (training) of the breast surgeons through curricula. • Ablative procedures and, if necessary, radical tumour surgery with removal of the breast muscles		

5.2 Organ-specific surgical oncology

Chapt.	Requirements	Comments by the Breast Cancer Centre	
	• Lymph node removal (incl. sentinel node technique) • Ability to deal with post-operative complications • Reconstruction, reduction, correction procedures • Breast-conserving procedures: sectoral resections, skin sparing mastectomy, subcutaneous mastectomy (if necessary intramammary flaps, oncoplast. procedures including autologous tissue transfer) • Removal of local recurrences including plastic surgery to provide coverage if needed		
5.2.11	How often are breast-conserving approaches taken in this context? Breast conserving operations for pT1 tumours: Requirement: 70 – 90% (Values in excess of 90% are to be viewed critically)	Enter the value in the Data Sheet (Appendix)	
5.2.12	How often is a mastectomy performed as an initial procedure? Requirement: currently no target value	Enter the value in the Data Sheet (Appendix)	
5.2.13	Pre-invasive lesions • Number of pTis in primary procedures in relation to the entire number (orientation value) Requirement: currently no target standard • Axillary LN dissection in cases of DCIS: requirement ≤ 5% (quality indicator guideline no. 3)	~~Enter the value in the Data Sheet (Appendix)~~	
5.2.14	Determination of the nodal status • The nodal status should be determined by means of sentinel lymph node dissection (SLND) • When the decision to perform an axillary dissection is made (see S3 guideline), ≥ 10LN should be removed		
	Determination of nodal status in cases of invasive mammary carcinoma: Requirement: ≥ 95%	Enter the value in the Data Sheet (Appendix)	
5.2.15	Sentinel Indication for performing a sentinel lymph node biopsy only Requirement: ≥ 80% (quality indicator guideline no. 4)	Enter the value in the Data Sheet (Appendix)	
5.2.16	Wire localisation Intraoperative specimen radiography/sonography after preoperative localisation Requirement: ≥ 95% (quality indicator guideline no. 2)	Enter the value in the Data Sheet (Appendix)	
5.2.17	Postoperative complications Revision operations due to intra- or postoperative complications in the same facility	Enter the value in the Data Sheet (Appendix)	

5.2 Organ-specific surgical oncology

Chapt.	Requirements	Comments by the Breast Cancer Centre	
	Requirement: ≤ 5%		
	~~Postoperative wound infections~~ ~~Requirement: ≤ 5%~~	~~Enter the value in the Data Sheet (Appendix)~~	
5.2.18	Operative therapy (R0) with BCT involving: 1 procedure 2 procedures ≥ 3 procedures Number of R1 resections after completion of the operative therapy.		
5.2.19	Further/additional training: • A qualification plan for the physicians and nursing staff is to be submitted in which the qualification measures for the coming year are described. • At least one specific further/additional training measure per staff member (at least 1 day per year), to the extent that the staff member performs tasks relevant to the quality of the Breast Cancer Centre. • Further/additional training should be conducted by specific professional organisations including the DKG, DGS, German Society of Obstetrics and Gynaecology) etc..		
5.2.20	Quality circle • Quality circles focussing on breast-specific topics are to be held at least 4 x per year • Scheduled by such means as the qualification plan • The minutes of the quality circle are to be recorded		
5.2.21	Breast reconstruction • Description of responsibilities • Internal: specification of the surgeon(s) • External: Name/address of cooperation partner		
5.2.22	Topics covered by the cooperation agreement (if breast reconstructions are covered by external cooperation) • The contents of the Procedural Instruction“ are to be followed in full; Download at www.onkozert.de • Mandatory adherence to S3 Guideline, Annex 2 (breast reconstruction) • Resources available to the Breast Cancer Centre (to ensure rapid care in cases of larger ulcerated mammary carcinomas) • Determination of the OT location(s) • Regulated procedure for therapy decisions/coordination (related to the preoperative tumour board), patient is informed (as described in chapt.1.6, 2.1), post-operative follow-up care		

5.2 Organ-specific surgical oncology

Chapt.	Requirements	Comments by the Breast Cancer Centre	
	• Exchange of information regarding the cosmetic results from the patients' viewpoint		
5.2.23	Procedures for breast reconstruction The Breast Cancer Centre must offer the following breast reconstruction procedures: • Oncoplastic and glandular rotation flaps • Implant reconstruction • Expander reconstruction Procedures using autologous tissue as in the S3 guideline must be offered (internal or in an external cooperation agreement). The alternative breast reconstruction procedures must be explained to the patients by an appropriately qualified/experienced surgeon.	Enter the value in the Data Sheet (Appendix)	
5.2.24	Qualification The surgeon's qualification is to be documented by means of a curriculum or the certificate. More information see Procedural Instruction 5.2.22).		
5.2.25	General requirements • The indication, number and results are to be recorded for each individual case (photo-documentation). • Treatment according to the S3 Guideline, annex 2 (breast reconstruction) • Compilation of a preoperative and postoperative photo documentation (100%) • Positioning standards for all breast reconstruction procedures offered • The patient must be informed regarding the advantages and disadvantages of each of the breast reconstruction options and her decision documented • The handling of implants must be regulated (choice of implant, supply of fitting prostheses, traceability, stock keeping), Implant should be registered in the Implant Registry (AWOgyn)		

6 Internal oncology

6.1 Haematology and oncology

Chapt.	Requirements	Comments by the Breast Cancer Centre	
	The questionnaires for organ cancer centres and oncological centres have a uniform table of contents. In relation to this chapter, however, there are no requirements for Breast Cancer CentreCentre.		

6.2 Organ-specific oncological pharmaco-therapy

Chapt.	Requirements	Comments by the Breast Cancer Centre	
6.2.0	Alternatively, the requirements for oncological therapy using medicinal products can be described in the "Questionnaire on Outpatient Oncology". This is recommended particularly when the therapy using medicinal products is provided by a cooperation partner also named by other certified organ cancer centres (one description for multiple organs). In this case, the "Questionnaire on Outpatient Internal Oncology" serves as an annex to this questionnaire and is, therefore, to be submitted along with it. The questionnaire "Outpatient Internal Oncology" can be downloaded under http://www.onkozert.de/praxen_kooperationspartner.htm.		
6.2.1	Specialist's qualifications • A specialist in internal medicine/haematology and oncology • A specialist for gynaecology and obstetrics with further specialisation in "gynaecological oncology" or • A specialist for gynaecology and obstetrics with further specialisation in "oncological pharmacotherapy" Familiarity with and execution of • Procedures for endocrine treatment • Procedures for immunological treatment • Neo-/adjuvant therapy concepts • Palliative therapy concepts • Supportive therapy concepts • Treatment of adverse effects (e.g., concept for extravasation)		
	A representative with the qualifications cited above is to be designated. The specialists designated here must monitor oncological pharmaco-therapy. It is not possible to delegate the responsibilities to physicians without the qualifications cited above.		
6.2.2	Specialised Nurses Requirements for the specialised nurse responsible for administering chemotherapy: • At least 1 year of professional experience in oncology • At least 50 chemo therapy applications (estimations possible for initial certification, proof must be provided in the following years) • Proof of training according to the recommendations of the KOK (Handlungsempfehlungen der KOK,		

6.2 Organ-specific oncological pharmaco-therapy

Chapt.	Requirements	Comments by the Breast Cancer Centre	
	Applikation von Zytostatika durch Pflegefachkräfte (Recommendations of the Conference of Oncological Nurses and Children's Nurses on the Application of Cytostatic Agents by Nursing Personnel)) • Active integration in the implementation of requirements for the emergency treatment and therapy of comorbid conditions and sequelae. • The provision of advice and/or information to the patient by nurses must be documented.		
6.2.3	qualification of the treatment unit • At least 50 chemotherapy treatments per year for breast cancer patients or • At least 200 chemotherapy treatments per year (for various types of tumours) • Counting method: chemotherapy per patient (consisting of a number of cycles or applications) • If fewer, expertise cannot be proved through cooperation		
6.2.4	Chemotherapy outpatient/inpatient Chemotherapy must be available both on an outpatient as well as an inpatient basis.		
6.2.5	Options to be offered • Cytostatic monotherapy • Cytostatic combination therapy • Immune and antibody therapy (incl. small-molecules) • Hormone therapy, bisphosphonate therapy General chemotherapy • Cytostatic workspace (in accordance with the legal guidelines), if necessary • Appropriate waste disposal • 24-hour on call service		
6.2.6	Chemotherapy rooms • Description of the rooms for outpatient intravenous tumour therapy • Number of spaces (at least 2)		
6.2.7	Process descriptions • All phases of the chemotherapy procedure must be described (therapy begin, therapy application and therapy end). • Support measures in keeping with the guidelines must be described for the individual therapy concepts and documented in detail for each patient.		
6.2.8	Regimens for systemic therapy • The establishment/alteration of existing therapy regimens must be regulated by an approval process. • The therapy regimens must be protected against unintentional alteration.		

6.2 Organ-specific oncological pharmaco-therapy

Chapt.	Requirements	Comments by the Breast Cancer Centre	
	• The therapy regimens in the outpatient and inpatient units must be comparable.		
	Therapy plans • The planning of all systemic therapy must follow a therapy regimen • The therapy plan must be verified and approved		
6.2.9	Standards for accompanying and secondary conditions • Standards must be established for the therapy of comorbid conditions and sequelae. especially for the treatment of extravasation, infections, and thromboembolic complications.		
6.2.10	Emergency treatment Emergency equipment and a written procedural plan for emergencies must be available.		
6.2.11	Chemotherapy in case of metastases • The procedure for care (diagnosis/therapy) of patients with local recurrences/metastases must be described (illustration of the clinical pathway) • A regular assessment of the toxicity of the therapy must be undertaken using selected and documented parameters (symptoms, indicator metastasis or the like). • An evaluation of the effect of the therapy must be documented in relation to the patient every 3 months		
6.2.12 a)	Pain therapy • A pain therapist must be available • The process for the pain therapy (algorithm) must be described • When performed by a cooperation partner, a cooperation agreement must be signed		
b)	Supportive therapy • Description of the options for supportive therapy (process description/algorithm)		
6.2.13	Information for/dialogue with the patient In view of the diagnosis and the therapy planning, sufficient information must be conveyed and an appropriate dialogue must be conducted. This includes: • The description of possible treatment concepts • Offering and arranging for a second opinion • Discharge consultation as a standard procedure The general way in which information is provided and the dialogue conducted must be described. They are to be documented in relation to the patient in the doctor's report and in minutes taken/notes.		
6.2.14	Further/additional training • A plan for the further qualification of physicians, nursing and other staff members		

6.2 Organ-specific oncological pharmaco-therapy

Chapt.	Requirements	Comments by the Breast Cancer Centre	
	is to be submitted in which the qualification measures for the coming year are described. • At least 1 specific further/additional training measure per staff member per year (duration > 0.5 days per year), to the extent that the staff member performs tasks relevant to the quality of the breast cancer centre. • The further/additional training should be conducted by a professional organisation such as the DKG, DGS, DGGG, DEGRO		
6.2.15	Meetings as part of Continued Professional Development (CPD) • Meetings focussing on breast-specific topics are to be held at least 4 x per year • Scheduled by such means as the qualification plan • The minutes of this CPD-meetings must be taken.		

7 Radiation oncology

Chapt.	Requirements	Comments by the Breast Cancer CentreCentre	
7.0	Alternatively, the requirements for radiation oncology can be set forth in the “Questionnaire on Radio-oncology”. This is recommended especially when the provider of radiation oncology is designated as a cooperation partner for additional certified organ cancer centres (one description for multiple organs). In this case, the “Questionnaire on Radiatio-oncology” serves as an annex to this questionnaire and is, therefore, to be submitted along with it. The questionnaire “Radio-oncology” can be downloaded under http://www.onkozert.de/praxen_kooperationspartner.htm.		
7.1	Specialists • At least two specialists • ~~Specialists are to be designated by name~~		
7.2	Medical physicist • At least one medical physicist must be available in the department on workdays • Medical physicists and their backups are to be designated by name • A back-up plan must be formulated in writing		
7.3	Medical-technical radiology assistant • ~~At least two qualified MTRAs must be available per accelerator and be designated by name~~ • 2 MTRAs must be present per linear accelerator during radiotherapy		

7 Radiation oncology

Chapt.	Requirements	Comments by the Breast Cancer CentreCentre	
	• A back-up plan must be formulated in writing		
7.4	Accessibility/obligation to be on call ~~No requirement for Breast cancer centres.~~A specialist for radiotherapy must be present during working-hours, 24 hours on call-duty also possible in cooperation (incl. weekends and holidays)		
	Counting method expertise If a patient receives multiple radiation series with separate radiation plans (i.e. bilateral synchronous breast cancer, 2 separate cancerous diseases), these series can be counted separately. Attribution of radiation series to a calendar year is based on the date of first radiation administered.		
7.5	~~Number of radiation treatments~~ Total expertise of clinical site Number of complete radiation series for cancer patients (not limited to Centre patients): ~~No requirement for Breast Cancer Centres.~~		
	• Network of radio-oncology institutes/practicesTarget per tumour entity: a minimum of 10 patients per tumour entity with completed radiation series per institute/practice • In a network of radio-oncology institutes/practices, at least 2 specialists must be working at each clinical site • Specialists of the institutes/practices of the network work with a specific clinical focus, i.e. all patients with one disease are treated by one predefined team • Based on the division of labour, a specialisation of all specialists on separate tumour entities must be proven • Professional interaction between the specialists is organised and documented. • Linear accelerators are compatible with one another and are adjusted to a joint planning system. Radiation parameters are available in a joint planning system. • There are coherent radio-oncology SOP's for all partners of the network • A contingency plan must be realisable within the next working day. Utilisation of linear accelerators must account for capacities needed for contingency plans. • Distance between clinical site and Centre: max. 45 km • All clinical sites of the radio-oncology network are under joint ownership (simple cooperation structures are not sufficient)		
7.6	Technical requirements		

7 Radiation oncology

Chapt.	Requirements	Comments by the Breast Cancer CentreCentre	
	~~and radiotherapy plan/techniques~~ • An accelerator ~~with a back-up concept ≥ 6 MV photons and at least 6-15 MeV electrons~~ • ~~Description of the technical features~~ • ~~Back-up concept (tandem solution) in writing~~ Radiation treatment planning: • Therapy simulator ~~(optional:~~ or virtual simulation) • Planning CT • 3D and IMRT radiation treatment planning system		
	Radiotherapy techniques Intensity Modulated Radiation Therapy (IMRT) Image guided radiotherapy (IGRT) 3D-confrom radiotherapy		
7.7	On-site inspection by medical authorities (according to Art. 83 of the Radiation Protection Ordinance) • The assessment by the medical authorities must correspond with Category I (no defects), II (low-degree defect, new on-site inspection in 2 years) or degree III once. • Any deficiencies determined must be eliminated. • ~~The medical authorities must be informed of the participation in an oncological centre or an organ cancer centre and of the corresponding quality requirements before the on-site inspection.~~		
7.8	Waiting time • Period between patient's first contact and the initial presentation: < 10 Days • Period between the initial presentation and beginning of treatment, provided there are no medical reasons to the contrary: < 4 weeks • The actual overall treatment time should not exceed the prescribed overall treatment time by more than 10%. Interruptions in radiotherapy for medical reasons or by the patient constitute exceptions • The waiting periods are to be surveyed by random sampling and statistically assessed (recommendation: assessment period 4 weeks per year).		
7.9	Clinics • It must be ensured that every patient is presented to a physician before the beginning of a radiation treatment series • At least one additional contact with a physician must be documented at the radiotherapy facility during a radiation treatment series		
7.10	Case-related information/dialogue with the patient		

7 Radiation oncology

Chapt.	Requirements	Comments by the Breast Cancer CentreCentre	
	In view of the diagnosis and therapy planning, sufficient information must be conveyed and a consultation with the physician must be held. This includes: • Structured information regarding the indication, effects, adverse effects and course of therapy • Presentation of alternative treatment concepts • Offer and arrangement of second opinions • Discharge consultations as a standard procedure • The patient must be provided with written information on what precautions to take during and after radiotherapy. All discussions with patients are to be documented for each individual patient.		
7.11	Documentation/tumour monitoring • The doses that are prescribed are to be recorded according to the guidelines. A documented reason must be given for deviations from the prescribed dose. • Support measures in keeping with the guidelines are to be described for individual therapy concepts and documented in detail in relation to the individual patient.		
7.12	Radiation processes The specifications of the radiation protection laws and the “Guideline for Radiation Protection in Medicine” must be implemented.		
7.13	Radiochemotherapy No requirements for Breast Cancer Centre.		
7.14	Palliative radiotherapy • In cases of palliative radiotherapy, the intention of the therapy (local control or solely to alleviate symptoms) must be documented. • Palliative medical measures, as well as the development of symptoms and adverse effects, must be described especially in relation to therapy concepts intended to alleviate symptoms and documented in relation to the individual patient. • Simultaneously administered pharmacotherapy (e.g. pain or tumour-specific therapy) must be documented.		
7.15	Follow-up care The process of tumour-specific follow-up care must be described (taking the “Guideline for Radiation Protection in Medicine” into consideration). This means: • Appointment schedule/reminder (follow-up care calendar) • Type of documentation		

7 Radiation oncology

Chapt.	Requirements	Comments by the Breast Cancer CentreCentre	
	• Information regularly relayed to the centre's internal tumour documentation system in cases of recurrences, metastases or death of the patient		
7.16	Treatment plan/minutes of the tumour board • In principle, treatment plans and/or recommendations by the tumour board ~~are binding and~~ represent the basis for treatment. • Treatment plan/minutes of the tumour board must be included in the patient-related documentation. • Any deviations from the recommended therapy plan must be presented to the tumour board before therapy and must be documented in the patient´s file		
7.17	Induction courses etc. of newly appointed staff members No requirement for Breast Cancer Centre.		
7.18	Further/additional training: • A plan for the further qualification of the physicians, nursing and other staff is to be submitted in which the qualification measures planned for the coming year are described. • At least one further/additional training measure per staff member per year (duration > 0.5 days per year), to the extent that the staff member performs tasks relevant to the quality of the Breast Cancer Centre		
7.19	Meetings as part of Continued Professional Development (CPD) • CPD meetings focussing on breast-specific topics are to be held at least ~~4~~ 3 x per year • Scheduled by such means as the qualification plan • The minutes of the meetings must be recorded		

8 Pathology

Chapt.	Requirements	Comments by the Breast Cancer CentreCentre	
8.0	Alternatively, the requirements for pathology can be described in the "Questionnaire Pathology". This is recommended especially when the provider of pathology services is also designated as a cooperation partner by other organ cancer centres (one description for multiple organs). In this case the "Questionnaire Pathology" must be included as an annex to this questionnaire and is, therefore, to be submitted along with it. The questionnaire "Pathology" can be downloaded under		

8 Pathology

Chapt.	Requirements	Comments by the Breast Cancer CentreCentre	
	http://www.onkozert.de/praxen_kooperations-partner.htm.		
8.1	Specialists • At least 2 qualified specialists for pathology • The specialists are to be designated by name		
8.2	Qualification of the specialist • Histological assessment of breast tissue samples • Assessment of tissue from other parts of the body • Serous effusion cytology, aspiration cytology • Qualified back-up plans must be in place • Experience with the work-up of sentinel lymph nodes according to currently valid guidelines • Experience with the processing of tissue samples from the breast and the axillary lymph nodes according to the S3 Guideline for the early detection of breast cancer as well as for the diagnosis, therapy and follow-up care of a breast cancer • Familiarity with the quality indicators stipulated in the guidelines		
8.3	The specialist's experience • At least 200 routine histological samples from breast tissue per year • Over 3000 histological examinations per year (documented by journal number)		
8.4	MTA A sufficient number of qualified MTAs must be available.		
8.5	Case number of the pathological institute At least 15,000 histological examinations, incl. cytological examinations (case number documented by journal number).		
8.6	Procedures that must be available • Immuno-histochemical examinations • In-situ hybridisation • Molecular pathology These special services can only be assigned to pathological institutes which have to be named in the cooperation contract. The institutes should have a recognised QM system or a valid accreditation or be able to document successful participation in round robin tests.		
8.7	Frozen section analysis (cryosection) • The technical and organisational prerequisites for frozen section analysis must be fulfilled. • An operational cryostat must be available • Virtual slide telepathology is not acceptable		
8.8	Parameters for frozen section analyses Time required measured from time of submission to pathology until the disclosure of the result (target value max. 30 min.)		

8 Pathology

Chapt.	Requirements	Comments by the Breast Cancer CentreCentre	
	Assessment time requirement: min./max./range value		
8.9	Time needed for a routine histology result incl. immuno-histochemistry Requirement: max. 5 workdays		
8.10	Autopsy Execution of autopsies must be made possible (if necessary in collaboration with others).		
8.11	Retention time • Archiving of paraffin blocks ≥ 10 years, • Retention of wet tissue ≥ 4 weeks after incoming. • Cryopreservation should also be possible		
8.12	Lymph node (LN) • All of the lymph nodes in surgical specimens must be examined macro- and microscopically • The lymph nodes must be examined according to the S3 Guideline. • The localisation (at least regional vs. distant of tumour site) is to be specified		
8.13	Pathology reports Pathology reports for the macroscopic and the microscopic assessment must contain 100% of the information required by the guideline.		
8.14	Content of the pathology report • pT, pN • Histological type • Grading • Lymphatic vessel invasion and blood vessel invasion (Lx, Vx) • Oestrogen and progesterone receptor status • HER2 status (procedure in cases of questionably positive HER2 status (2+) must be regulated (e.g., through FISH/CISH assays))		
	• Resection margin and safety margin Requirement: ≥ 95%	~~Enter the value in the Data Sheet (Appendix)~~	
8.15	Breast cancer in the family The pathologist should point out the possibility of a cause within the family if the following occur simultaneously: • Invasive Ca (NOS) with a growth pattern similar to medullary Ca • G3 morphology • Oestrogen, progesterone and HER2 status neg. (triple negative)		
8.16	Assessment of the HER2 status • Annual assessment of the IHC score subdivided according to 0, 1+, 2+ and 3+		
8.17	External quality assurance • Regular successful participation in external quality assurance measures, especially annual round robin tests		

8 Pathology

Chapt.	Requirements	Comments by the Breast Cancer CentreCentre	
	• Facilitation of a second consultant opinion at the request of the hospital or the patient or when a final assessment is not possible.		
8.18	Discussion of special cases Special cases are discussed in the CPD meetings and/or at the interdisciplinary tumour board.		
8.19	Further training • A plan for the further qualification of physicians is to be submitted in which the measures planned for the coming year are described. • At least 1 specific further/additional training measure per staff member per year, to the extent that the staff member performs tasks relevant to the quality of the Breast Cancer Centre. • The further/additional training should be conducted by a professional organisation • The further/additional training should be conducted by a professional organisation and/or the DKG, DGS, DGGG.		
8.20	Quality circle • Quality circles focussing on breast-specific topics are to be held at least 4 x per year. • Scheduled by such means as the qualification plan • The minutes of the CPD meetings		

9 Palliative care

Chapt.	Requirements	Comments by the Breast Cancer CentreCentre	
9.1	Palliative care • Cooperation agreements with various providers of specialised in- and outpatient palliative care, palliative medical consulting services, inpatient hospices and palliative wards must be documented. ~~Regional concepts for the integration of palliative care must be described in accordance to the pathways of the S3 guideline (p174) and the participants designated.~~ • A physician with additional training in palliative medicine must be available for consultation and, if necessary, for participation in tumour boards. • The group of terminally ill patients must be defined, e.g. in TB. These patients must be informed about the palliative care possibilities at an early stage. (SOP, S3 guideline) • The access to palliative medical care can be offered at the same time as the tumour-specific treatment.		

9 Palliative care

Chapt.	Requirements	Comments by the Breast Cancer CentreCentre	
	• The number of terminally ill patients (primary cases) must be documented. • ~~Standards (e.g. interdepartmental) for the care of terminally ill patients and ethical guidelines must be described and adhered to.~~		
9.2	Supportive therapy and alleviation of symptoms in palliative care • The options for supportive/palliative inpatient therapy must be described (process description/algorithm). • A pain therapist must be available. Pain therapy procedures (algorithm) must be described and verified for the documented cases during the period under examination • Access to nutritional counselling must be described • Access to psycho-oncological and psychosocial care as well as to spiritual counselling must be described. • A cooperation agreement must be signed when required services are provided by cooperation partners		

10 Tumour documentation/outcome quality

Chapt.	Requirements	Comments by the Breast Cancer CentreCentre	
10.1	Tumour documentation system A system of tumour documentation that contains patient data for a period of at least 3 months must be in place at the time of initial certification Name of the centre's tumour documentation system or of the responsible cancer registry		
10.2	Period represented by the data The data must represent the whole of the previous calendar year		
10.3	Requirements for tumour documentation: The dataset used must correspond with the basic dataset used by the Arbeitsgemeinschaft Deutscher Tumorzentren (Working Group of German Tumour Centres or ADT). The centre must ensure that the data is entered as soon after the completion of the primary therapy as possible.		
10.4	Cooperation with the cancer/tumour registry (in Germany: see §65c SGB V) The data must be transmitted to the cancer registry continuously and completely.		

10 Tumour documentation/outcome quality

Chapt.	Requirements	Comments by the Breast Cancer CentreCentre	
	• The requirements for the quality of the results and the tumour documentation should be fulfilled by the cancer/tumour registry. • Parallel systems should be avoided • For as long as the responsible clinical cancer registry is unable to fulfil the requirements, supplementary or alternative solutions should be employed by the Breast cancer centre.		
	~~Report to the cancer registry~~ ~~Report to the clinical and/or epidemiological cancer registry: Requirement ≥ 95% (quality indicator guideline no. 11)~~	~~Enter the value in the Data Sheet (Appendix)~~	
10.5	Documentation commissioner A documentation commissioner must be designated as the person responsible for tumour documentation. Name/Function: The documentation commissioner is responsible for the following: • Verifying the quality of the interdisciplinary documentation • Promoting motivation for intersectoral cooperation between the participating specialties in the cancer registry (pathol. diagnostic findings, radiotherapy and chemotherapy treatments) • Ensuring and monitoring the rapid, complete and correct compilation of patient data • Qualification and support of the personnel responsible for data collection • Regular compilation of assessments		
10.6	Provision of resources Sufficient personnel should be made available for the execution of the documentation tasks as well as for the collection of data, (e.g., 0.5 full-time empl. per 200 primary cases and 0.1 full-time empl. per 200 follow-up cases)		
10.7	The tumour documentation system should offer at least the following selection options: • Year of birth • TNM classification and prognosis factors • Form of therapy (operative therapy, radiotherapy, hormone therapy, immune therapy, chemotherapy) • Date of the recurrence/metastases • Deaths • Follow-up status (last update)		
10.8	Indicators of outcome quality Kaplan-Meier curves:		

10 Tumour documentation/outcome quality

Chapt.	Requirements	Comments by the Breast Cancer CentreCentre	
	• Overall survival (OAS) for all patients in subgroups according to pT categories, stages • Metastases-free survival for all patients and for subgroups • Disease-free survival for all patients and for subgroups • Local reoccurrence rate for all patients and for subgroups • Survival after progression • Initially, all cases can be included in one cohort (for 3 years). When the number of patients and events increases, separate cohorts can be defined and assessed. • A table with the number of patients and the survival data must accompany every Kaplan-Meier curve. The detailed organ-specific requirements are compiled as a matrix of the outcome quality in the annex. Concerning special treatment of the data voluntarily submitted, see 10.11. of this questionnaire		
10.9	Assessment of the data • The assessment of the indicators of outcome quality (above) must be available by the time of re-certification. • Data in the tumour documentation system must be assessed and analysed at least once a year • The data published in the quality report according to Art.137 of the Fifth Book of the Social Code must be evaluated in relation to their comparability; a corresponding evaluation must be documented. • In cases of participation in benchmarking, the results of the benchmarking are to be taken into consideration during the analysis. • The analysis of every closed cohort (defined by year of birth) must be recorded in a short report along with any concrete activities that needed to be undertaken (verification of selected case histories, e.g., local recurrence in relation to such topics as guideline-appropriate treatment). • The results must be discussed in an interdisciplinary context and in conjunction with the Breast Cancer Centre.		
10.10	Collection of follow-up data A description must be provided of how data on follow-up care are collected and what the current follow-up status is (s. outcome matrix).		
10.11	The submission of the matrix on the quality of results is only mandatory for centres that have a working cancer registry. Locations that apply for		

10 Tumour documentation/outcome quality

Chapt.	Requirements	Comments by the Breast Cancer CentreCentre	
	a reduction in the audit cycle or where – due to the positive assessment of the application are still obliged to submit the matrix on outcome quality (follow-up rate ≥ 70%).		