**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

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| **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 Medical Oncology  PSO – Working Group on Psychological Oncology  ARO – Working Group on Radiological Oncology  ASO – Working Group on Social Work  ASORS - Working Group for Supportive Care in Oncology, Rehabilitation and Social Medicine  AG ZBZ – Working Group of Certified 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 Aesthetic 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 28 November 2017**

This Catalogue of Requirements (CR) is binding for all audits conducted from 1 January 2017. The changes made to this version valid in audit year 2017 are highlighted in “turquoise” in this Catalogue of Requirements.

The following were incorporated:

* Interdisciplinary S3 Guidelines for the diagnosis, therapy and aftercare of breast carcinomas
* Level 3 Guidelines on Early Breast Cancer Detection

This Catalogue of Requirements is based on the TNM classification of malignant tumours, 8th edition 2017, and the ICD classification ICD-10-GM 2017 (DIMDI and the OPS classification OPS 2017 (DIMDI).

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

**Information on the Breast Cancer Centre**

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| Breast Cancer Centre (BCC) |  |
| Director of the Breast Cancer Centre |  |
| Coordinator of the Centre |  |

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|  |  |  | This questionnaire applies to | | |
|  |  |  |  |  |  |
| Clinical site 1 (hospital/city or town) |  |  |  |  |  |
|  |  |  |  |  |  |
| Clinical site 2 (hospital/city or town) |  |  |  |  |  |
| only in the case of cooperating BCC |  |  |  |  |  |

**QM system certification**

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| QM system certification |  | yes |  | no |

A certified QM system is not a binding requirement within the framework of DKG certification but should, however, be available.

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| QM standard |  | ISO 9001 |  | KTQ |
|  |  |  |  |  |
|  |  | Joint Commission |  | proCum Cert |

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| --- | --- |
| Certification body QM |  |

Colour legend: Change to the version of 14 July 2016

**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.

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| The data on outcome quality are based on calendar year |  |

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| The questionnaire was compiled/updated on |  |

**Contents**

1. General information on the Breast Cancer Centre
   1. Structure of the network
   2. Interdisciplinary cooperation
   3. Cooperation with referring physicians and follow-up treatment
   4. Psycho-oncology
   5. Social work and rehabilitation
   6. Patient participation
   7. Study management
   8. Nursing Care
   9. General health care services (pharmacy, nutrition counselling, speech therapy, …)
2. Organ-specific diagnostics
   1. Clinics
   2. Diagnostic procedures
3. Radiology
4. Nuclear medicine
5. Surgical oncology
   1. General surgical oncology
   2. Organ-specific surgical oncology
6. Medical/internal oncology
   1. Haematology and oncology
   2. Organ-specific oncologic pharmacotherapy
7. Radio-oncology
8. Pathology
9. Palliative and hospice care
10. Tumour documentation/outcome quality

Appendix: Data Sheet

**1 General information on the Breast Cancer Centre**

| * 1. **Structure of the network** | | | |
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| Chapt. | Requirements | Comments by the Breast Cancer 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 * 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 |  |  |
|  | 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. **Interdisciplinary cooperation** | | | |
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| Chapt. | Requirements | Comments by the Breast Cancer Centre |  |
| 1.2.0  ~~5.2.1~~ | Number of primary cases of breast carcinoma per year  On initial certification ≥ 100 primary cases  Definition primary case:   * Patients and not stays and not procedures * One primary case is calculated for each breast. * Histological results must be available. * DCIS are counted as primary cases. * Case can only be counted for 1 centre. Therapy planning (interdisciplinary tumour conference) and conduct of therapy by the Breast Cancer Centre (main therapy) * Count time is the time of initial diagnosis. * Mammary carcinomas in men and primary M1 patients are counted as primary cases   Colour legend: Moved from Chapter 5.2.1 to Chapter 1.2.0 compared to the version of 14 July 2016 |  |  |
| 1.2.0  ~~5.2.2~~ | Cooperating Breast Cancer Centres (consisting of several surgical locations)   * Cooperating centres with more than 2 locations are no longer authorised * Initial certification/expansions as a cooperating centre are only possible if each location documents ≥ 100 primary cases   Existing cooperations  Existing cooperations benefit from protection of the status quo subject to the following preconditions:   * For each location at least 50 primary cases * Cooperating centre with 2 locations with more than 150 primary cases * Proof of a positive certification outcome in the audit report (= no deviation) * Strict compliance with Q standards, joint treatment regimens * Tried-and-tested cross-cover rules for the breast surgeon   Cooperation between several locations requires prior structural assessment (is also required for expansions and/or mergers).  Colour legend: Moved from Chapter 5.2.2 to Chapter 1.2.0 compared with the version of 14 July 2016 |  |  |
| 1.2.1  a) | Schedule  The tumour board must meet at least once a week.  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. * 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, radiotherapist, …) The cooperation partners Plastic Surgery are to be invited. The screening conference can be recognised when the circle of participants corresponds to the required participants. |  |  |
|  | If possible, every vacuum-assisted and punch biopsy should be discussed within the preoperative tumour conference. At least, all vacuum-assisted and punch biopsies with BIRADS 4 and 5 and a B1- B4 pathology should be discussed. |  |  |
| new | In addition, patients with a planned mastectomy should be presented at the preoperative tumour conference (see “Procedural instruction for handling oncoplastic and reconstructive surgery in certified Breast Cancer Centres” on this [link](https://www.krebsgesellschaft.de/zertdokumente.html?file=files/dkg/deutsche-krebsgesellschaft/content/pdf/Zertifizierung/Checklisten%20und%20Algorithmen/BZ_Verfahrensanweisung_rekonstrOP_170809.pdf)). .  Colour legend: Addition to the version of 14 July 2016 |  |  |
|  | 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). |  |  |
| 1.2.6 | 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 | Radiotherapy indicatory / QI-LL  If the target values are not met, a stage- and indication-dependent analysis is to be undertaken.  Definition of the indicator(s) directly in the data sheet (Excel template) | Enter the value in the Data Sheet (Appendix) |  |
| 1.2.9 | Therapy recommendations Systemic therapy / Quality indicators S3-LL  Indication / specification of chemotherapy bearing in mind the DKG S3 Guidelines on specifying adjuvant therapy  Definition of the indicator(s) directly in the data sheet (Excel template) | Enter the value in the Data Sheet (Appendix) |  |

| * 1. **Cooperation with referring physician and follow-up care** | | | |
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| 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   * 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. **Psycho-oncology** | | | |
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| Chapt. | Requirements | Comments by the Breast Cancer Centre |  |
| 1.4.1 | Psycho-oncology – qualification   * Qualified psychologists / M.Sc. psychology or * Physicians   In each case with additional training in psychotherapy and further training in psycho-oncology.  Colour legend: Addition to the version of 14 July 2016 |  |  |
|  | 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. | Enter the value in the Data Sheet (Appendix) |  |
|  | 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. |  |  |
| 1.4.3 | Psycho-oncology – resources  At least1 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 * 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. **Social work and rehabilitation** | | | |
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| 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 fort he centre.~~  At least 1 full-time position should be available for 400 counselling sessions of patients of the Centre (= primary cases, secondary metastasis, recurrence). The staff resources can be made available centrally. An organisation plan must be available.  ~~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.~~  Colour legend: Addition to/deletion from the version of 14 July 2016 |  |  |
| 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.) * Support for applications * Advice on outpatient and inpatient care options and referral to support schemes and specialised services * Support for reintegration into working life * 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. **Patient participation** | | | |
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| 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% (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 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 group and should be updated at least every 5 years and they should cover the following:   * Access to self-help groups in all phases of therapy (first diagnosis, inpatient treatment, chemotherapy, follow-up care …) * 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. * A contact person (preferably from the nursing staff) has to be known to the self-help group. * Participation of staff physicians in events staged by self-help groups   Colour legend: Additions to the version of 14 July 2016 |  |  |

| **1.7 Study management** | | | |
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| 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  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). | Enter the value in the Data Sheet (Appendix) |  |
|  | 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. |  |  |

**List of Studies**1)

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| Responsible cooperation partner 2) | | Study name | Number of  centre patients  recruited in 20173) |
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|  | Numerator: Indicator no. 12 „study quota “ | |  |

1) The list of studies is obligatory to be filled out. Referencing to the catalogue of requirements for oncology centres is not possible.

2) Responsible cooperation partner: Study unit/ speciality unit who is supervising the study (e.g. department for radio oncology; joint haematology/oncology practise Dr. Smisth…). Name of cooperation partner has to be identical with name on [www.oncomap.de](http://www.oncomap.de) if it is listed there,

3) Only study patients can be count that are a centre patient in the centre and that were included in 2017 in the study (no double counting of patients in more than 1 centre).

Colour legend: Changes to the version of 14 July 2016

| **1.8 Care** | | | |
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| 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. **Areas of general care** | | | |
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|  | 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. |  |  |

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| 2 Organ-specific diagnostics |

| 2.1 Consulting hours | | | |
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| 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 * 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 a hereditary risk can be downloaded on this [link](https://www.krebsgesellschaft.de/zertdokumente.html?file=files/dkg/deutsche-krebsgesellschaft/content/pdf/Zertifizierung/Checklisten%20und%20Algorithmen/checkliste_erbliche_belastung_brust-a5-160330.xlsx).  An algorithm and a standard cooperation agreement for cooperation with the centres designated in the S3 Guidelines are available on this [link](https://www.krebsgesellschaft.de/deutsche-krebsgesellschaft-wtrl/deutsche-krebsgesellschaft/zertifizierung/erhebungsboegen/organkrebszentren.html). |  |  |
| 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 |  |  |
| 2.1.10 | 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 should ~~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:  Colour legend: Additions to/deletions from the version of 14 July 2016 |  |  |

| **2.2 Diagnostic procedures** | | | |
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|  | 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 | | | |
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| 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  Mandatory indication of the results category 0-6 ~~BI-RADS classification~~ and assessability (4-stage, A-D) ~~mammographic parenchymal density (ACR)~~  Colour legend: Additions to/deletions from the version of 14 July 2016 |  |  |
| 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) * For the sonography the requirements like those for the ultrasound agreement are to be implemented (link).   Colour legend: Additions to/deletions from the version of 14 July 2016 |  |  |
| 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.  For the conduct of the MRI the recommendations of the Breast Imaging Working Group of the German Radiological Society are to be implemented (Updated Recommendations for MRI of the Breast. Fortschr Röntgenstr 2014; 186: 482–483).  Colour legend: Additions to/deletions from the version of 14 July 2016 |  |  |
| 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 | | | |
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| 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 |  |  |
| 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%  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 (blue solution 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 |  |  |

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| 5 Surgical oncology |

| 5.1 Multi-organ surgical therapy | | | | |
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| 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 | | | |
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| Chapt. | Requirements | Comments by the Breast Cancer Centre |  |
| 5.2.1 | Number of primary cases of breast carcinoma per year  Colour legend: moved from Chapter 5.2.1 to Chapter 1.2.0 vis-à-vis version of 14 July 2016 | Enter the value in the Data Sheet (Appendix) |  |
| 5.2.2 | Cooperating Breast cancer centres (consisting of multiple operational locations)  Colour legend: moved from Chapter 5.2.2 to Chapter 1.2.0 vis-à-vis version of 14 July 2016 |  |  |
| 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) * 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”). |  |  |
| 5.2.7 | Expertise of breast surgeon with long years of experience  In cases where 150 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 senior breast surgeon issued before 7 April 2014:  one-off prolongation by 5 years if, in the previous 5 years, at least 75 procedures (removal of an inv. tumour/DCIS, not limited to primary cases).  after 7 April 2014:  in the previous 5 years at least 150 interventions (removal of an inv. tumour/DCIS, not restricted to primary cases).  Procedures as a second surgeon (for the purpose of training or assisting a named 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 (excision of invasive tumour/DCIS, not only primary cases) breast 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 * 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) |  |  |
| 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 breast 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  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 the breast reconstruction is covered by an externa cooperation)   * The contents of the “Procedural instruction for handling oncoplastic and reconstructive procedures in certified Breast Cancer Centres” are to be fully taken into account. Download from 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 breast 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 * 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.  For this, the patient should be given the “Information leaflet - Breast Reconstruction” ([Link](https://www.krebsgesellschaft.de/zertdokumente.html?file=files/dkg/deutsche-krebsgesellschaft/content/pdf/Zertifizierung/Erhebungs-%20und%20Kennzahlenboegen/BZ_Infoblatt_Brustaufbau_Pat_170809.docx)).  Colour legend: Addition to the version of 14 July 2016 | 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 VA, 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)   * Direct perioperative care after reconstruction is to be ensured under the supervision of a specialist trained in the operating method used. * 24h availability of a surgeon with the corresponding expertise must be ensured.   Colour legend: Addition to the version of 14 July 2016 |  |  |

Table “Breast surgeons”

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| --- | --- | --- | --- | --- |
| Title, Name, First name | Senior breast surgeon 1) yes/no | Period 2) from … to | Number of procedures 3) in line with CR 5.2.6 | Location/Clinic 4) |
|  |  |  |  |  |
|  |  |  |  |  |
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|  |  |  |  |  |

1) Precondition senior breast surgeon (described in line with CR 5.2.7): positive qualification assessment by OnkoZert

2) Period normally the previous calendar year (= indicator year); deviations for instance in the case of staff fluctuation; appointment of breast surgeons during the year; in the case of unclear fulfilment 1 breast surgeon can also be included twice for 2 periods (e.g. previous calendar year and current year up to date of submission of CR)

3) For senior breast surgeons there is no requirement about annual expertise whereby the preconditions for the prolongation of the certificate after 5 years in line with CR 5.2.7 are to be taken into account.

4) Relevant for multi-location centres or in the event that a surgeon is active on a regular basis as an operator in several locations/clinics (surgical expertise is to be indicated separately for each location/clinic)

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| 6 Internal oncology |

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| 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 Centre. |  |  |

| 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, 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. * 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 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 | | | |
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| Chapt. | Requirements | Comments by the Breast Cancer Centre |  |
| 7.0 | The Technical and Medical Requirements to be met by radio-oncology are summed up in the "Catalogue of Requirements Radio-Oncology" in a cross-organ manner. Independently of the number of Organ Cancer Centres / Modules, which work with a radio-oncology unit, this "Catalogue of Requirements Radio-Oncology" is only to be processed once and also only updated once per audit year (goal: no multiple presentations or on-site inspections within one audit year). The "Catalogue of Requirements Radio-Oncology" therefore constitutes an annex to this Catalogue of Requirements.  Download cross-organ "Catalogue of Requirements Radio-Oncology" on [www.onkozert.de](http://www.onkozert.de/). |  |  |

| 8 Pathology | | | |
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| Chapt. | Requirements | Comments by the Breast Cancer Centre |  |
| 8.0 | The Technical and Medical Requirements to be met by pathology are summed up in the "Catalogue of Requirements Pathology" in a cross-organ manner. Independently of the number of Organ Cancer Centres / Modules, which work with a pathology unit, this "Catalogue of Requirements Pathology" is only to be processed once and also only updated once per audit year (goal: no multiple presentations or on-site inspections within one audit year). The "Catalogue of Requirements Pathology" therefore constitutes an annex to this Catalogue of Requirements.  Download cross-organ "Catalogue of Requirements Pathology" on [www.onkozert.de](http://www.onkozert.de/). |  |  |

| 9 Palliative care | | | |
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| Chapt. | Requirements | Comments by the Breast Cancer Centre |  |
| 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 the palliative medical care can be offered at the same time as the tumour-specific treatment. * The number of terminally ill patients (primary cases) must be documented. |  |  |
| 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 | | | |
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| Chapt. | Requirements | Comments by the Breast Cancer Centre |  |
| 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 in cancer registry and/or centre  Colour legend: Addition to/deletion from the version of 14 July 2016 |  |  |
| 10.2 | Period represented by the data  The data must represent the whole of the previous calendar year |  |  |
| 10.3 | Requirements to be met by tumour documentation  A data set ~~should~~ must be used in line with the uniform basic oncological data set and its modules of the Working Group of German Tumour Centres (ADT) and the Association of Population-based Cancer Registries in Germany (GEKID).  The Centre must ensure that the data ~~capture~~ transfer to the competent cancer registry is done promptly at the end of primary therapy. Any existing regional laws for notification deadlines are to be taken into account.  Colour legend: Addition to/deletion from the version of 14 July 2016 |  |  |
| 10.4 | Cooperation with the cancer~~-/ tumour~~ registry   * Cooperation with the competent 65c cancer registry is to be documented on the basis of the cooperation agreement   [Link Tumorzentren.de](http://www.tumorzentren.de/tl_files/dokumente/Kooperationsvereinbarung%20ADT_DKG_07.07.2015%20.docx)   * The OncoBox is to be filled by the competent cancer registry. * The full data are to be made available to the cancer registry in an ongoing manner. * The ~~requirements for~~ presentation of the data sheet and outcome quality ~~and tumour documentation~~ should be ~~covered~~ ensured via the cancer~~-/ tumour~~ registry to the extent that these details have to do with cancer registration. * Parallel systems are to be avoided. * As long as the competent ~~clinical~~ cancer registry is unable to meet the requirements imposed, the Breast Cancer Centre is to use additional or alternative solutions. The Centre is responsible in the event of a non-functioning external solution.   Colour legend: Additions to/deletions from the version of 14 July 2016. |  |  |
| 10.5 | A documentation officer is to be appointed who bears responsibility for tumour documentation.  Name/Function:  The documentation officer has the following tasks:   * ~~Examination~~ Ensuring and monitoring the timely, complete, full and correct transfer and quality of the patient data of relevance for certification by all cooperation partners to the cancer registry ~~interdisciplinary documentation.~~ * Motivation of trans-sectoral cooperation by participating speciality units in the cancer registry (pathology reports, radiotherapy and medicinal treatments) * Ensuring and monitoring the timely, complete and correct recording of patient data * Qualification and support for the staff involved in data collection * Regular ~~preparation of~~ analysis of the evaluations particularly over the course of time   Colour legend: Additions to/deletions from the version of 14 July 2016 |  |  |
| 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. through cancer registries) (e.g. 0.5 full-time position per 200 primary cases and 0.1 full-time position per 200 follow-up cases)  Colour legend: Additions to/deletions from the version of 14 July 2016 |  |  |
| 10.7 | The tumour documentation system should offer at least the following selection options:   * Year of birth * TNM classification or comparable classifications 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)   Colour legend: Additions to/deletions from the version of 14 July 2016 |  |  |
| 10.8 | Indicators of outcome quality  Kaplan-Meier curves:   * Overall survival (OAS) for all patients in subgroups according to pT categories, stages * Metastases-free survival for all patients and for subgroups * Progression-free survival (PFS) or disease-free survival for all patients or disease-free survival ~~surviva~~l 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  Colour legend: Additions to/deletions from the version of 14 July 2016 |  |  |
| 10.9 | Data evaluation   * The ~~evaluations for the indicators~~ presentation of outcome quality (see point above) must ~~be available~~ be possible for recertifications. * The data in the tumour documentation system are to be evaluated and analysed at least once a year. * ~~The published data from the quality report in line with Section 137 Social Code Book V are to be examined for comparability and a corresponding evaluation is to be documented..~~ * If a benchmarking/annual report is ~~is participated in~~ offered, the results of the benchmarking are to be included in the analysis. * ~~The analysis of each completed age cohort is to be specified with any initiated concrete actions (examination of selected casuistics e.g. with local recurrence inter alia with regard to treatment in line with the guidelines).~~ * The results must be discussed in an interdisciplinary manner and in the network of Breast Cancer Centres.   Colour legend: Additions to/deletions from the version of 14 July 2016 |  |  |
| 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 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%). | |  |

**Data sheet**

An EXCEL template is available to Centres to record the indicators and data on outcome quality. This EXCEL template also contains an automatic evaluation of data quality. Only those presentations of indicators are eligible for certification which are undertaken on the basis of the EXCEL template made available by OnkoZert. The EXCEL template may not be changed.

The EXCEL template can be downloaded from [www.krebsgesellschaft.de](http://www.krebsgesellschaft.de/) and [www.onkozert.de](http://www.onkozert.de/)