**Catalogue of Requirements for**

**Gynaecological Cancer Centres**

**of the German Cancer Society (*Deutsche Krebsgesellschaft* - DKG)**

**Catalogue of Requirements Audit Year 2019 with no changes to the previous year’s content**

**Chairs of the Certification Committee:** Prof. Dr. M.W. Beckmann

**prepared by the Certification Committee of the Gynaecological Cancer Centres**

**Expert groups involved (in alphabetical order)**

AGO - Working Group for Gynaecological Oncology

ADT - Association of German Tumour Centres

AIO - Working Group for Internal Oncology

AOP - Working Group for Oncological Pathology

AET – Working Group for Hereditary Tumour Diseases

APM – Working Group for Palliative Medicine

AG CPC – Working Group Cervix Pathology and Colposcopy

PSO - Working Group for Psycho-Oncology

PRIO – Working Group for Prevention and Integrative Oncology

ARO - Working Group for Radio-Oncology

ASO - Working Group for Social Work in Oncology

ASORS - Working Group for Supportive Measures in Oncology

AUO - Working Group for Radio-Oncology

BNHO - Association of Practice-based Haematologists and Oncologists in Germany

BLFG - Federal Association of Senior Physicians in Gynaecology and Obstetrics

FSH - Federal Association of Women's Self-Help after Cancer

CAO-V - Surgical Working Group for Oncology - Visceral Surgery

DGGG - German Society for Gynaecology and Obstetrics

DGP - German Society for Palliative Medicine

DGP - German Society for Pathology

DEGRO - German Society for Radio-Oncology

DGS - German Society of Senology

DGU - German Society of Urology

DRG - German X-Ray Society

DVSG - German Association of Social Work in Health Care

ESGO - European Society of Gynaecological Oncology

KOK - Conference on Oncological and Paediatric Oncological Care

BDP- National Association of German Pathologists

BVDST – National Association of German Radiotherapists

BVF – German Association of Obstetricians and Gynaecologists

CAO – Surgical Working Group for Oncology

DGHO – German Association of Haematology and Medical Oncology

DeGIR – German Association for Interventional Radiology and Minimal-invasive Therapy

DGN- German Society of Nuclear Medicine

OPH – German Society of Ophthalmology

**Entry into force on 12.10.2017**

This Catalogue of Requirements (CR) is binding for all audits conducted from 1 January 2018. The changes made to the version valid in the audit years 2015 and 2016 are highlighted in "blue" in this Catalogue of Requirements.

The evidence-based S3 Guidelines were incorporated:

diagnosis, therapy and aftercare of malignant ovarian tumours (2013) and cervical carcinoma – diagnosis, therapy and aftercare (2014)

In cooperation with the Certification Committee for Breast Cancer Centres of the German Cancer Society (DKG) and the German Society of Senology (DGS)

The basis for the catalogue of requirements is the TNM-Classification of malignant tumours, 8th edition 2017 as well as the ICD-classification ICD-10-GM 2017 (DIMDI) and the OPS-classification OPS 2017 (DIMDI)

**Details of the Gynaecological Cancer Centre**

|  |  |
| --- | --- |
| Centre |  |
| Head Centre |  |
| Centre Coordinator |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  | This Catalogue of Requirements is valid for | | |
|  |  |  |  |  |  |
| Clinical site (clinic/place) |  |  |  |  |  |
|  |  |  |  |  |  |

**QM system certification**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| QM system certification |  | yes |  | no |

A certified QM system is not obligatory for the DKG certification, but is advisable.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| QM Standard |  | ISO 9001 |  | KTQ |
|  |  |  |  |  |
|  |  | Joint Commission |  | proCum Cert |

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

Colour legend: Changes to the version of 14.07.2016

**Network/Main cooperation partners**

The Centre's cooperation partners are registered in a master data sheet with OnkoZert. The details in the master data sheet are published on [www.oncomap.de](http://www.oncomap.de/). Any new or no longer valid cooperation is to be notified immediately to OnkoZert, outside the certification period, too. Other updates (e.g. changes to the head, contact data) are to be indicated in the corrected master data sheet in the run-up to the annual follow-up audit. The master data sheet with the registered cooperation partners can be requested from OnkoZert as a file.

**Preparation / Update**

The electronically generated Catalogue of Requirements serves as the basis for the certification of the Centre. The details provided there have been checked for correctness and completeness.

|  |  |
| --- | --- |
| The data on outcome quality refer to the calendar year. |  |

|  |  |
| --- | --- |
| Preparation/update date of the Catalogue of Requirements |  |

**Table of Contents**

1. General details of the Gynaecological Cancer Centre
   1. Structure of the network
   2. Interdisciplinary cooperation
   3. Cooperation referrers and aftercare
   4. Psycho-oncology
   5. Social work and rehabilitation
   6. Patient involvement
   7. Study management
   8. Nursing care
   9. General service areas (pharmacy, nutritional counselling, speech therapy,...)
2. Organ-specific diagnostics
   1. Consulting hours
   2. Diagnostics
3. Radiology
4. Nuclear medicine
5. Surgical oncology

5.1 Cross-organ surgical therapy

5.2 Organ-specific surgical therapy

1. Medicinal / Internal Oncology
   1. Haematology and oncology
   2. Organ-specific medicinal oncological therapy
2. Radio-oncology
3. Pathology
4. Palliative care and hospice work
5. Tumour documentation / Outcome quality

Annex:

Indicator sheet / Matrix outcome quality  
(Excel template)

**1.** **General details of the Gynaecological Cancer Centre**

| * 1. **Structure of the network** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks of the Centre |  |
| 1.1.1 | Written agreements (cooperation agreements) are to be entered into with the main cooperation partners when they work under different funding bodies. The agreements are to be examined annually by the Gynaecological Cancer Centre to ensure that they are up to date.  If the Centre has only one funding body or comes under one clinical site, then no such agreement is needed. The obligation to define relevant standard operating procedures and to establish any other necessary rules is not affected by this. This can be covered, for instance, in a general manual.  The main cooperation partners come from the following areas: Surgical oncology, pathology, medicinal oncology (gynaecological oncology, haematology and internal oncology), radiotherapy and radiology  The following points are to be covered in the agreements with the main cooperation partners:   * Participation in the tumour conference by gynaecological oncology, pathology, radiotherapy, radiology, and haematology and internal oncology in an advisory capacity * Ensuring availability * Description of the treatment processes of relevance for the Gynaecological Cancer Centre bearing in mind the interfaces * Obligation to implement indicated guidelines * Description of cooperation on tumour documentation * Declaration of willingness to cooperate on internal/external audits * Undertaking to comply with the relevant criteria and the annual submission of the relevant data * Declaration of consent of the treatment partner to be publicly identified as part of the Gynaecological Cancer Centre (e.g. homepage) |  |  |
| 1.1.2 | Agreements with other treatment partners:  Written agreements are to be entered into for the following treatment partners in which a willingness to engage in cooperation is declared  Anaesthesiology, intensive medicine   * Nuclear medicine * Genetic counselling, genetic analyses, family medical history (BRCA-1, BRCA-2, HNPCC) and genetic counselling * Palliative medical care * Laboratory (with interlaboratory experiment certificate) * Physiotherapy * Psycho-oncology * Self-help * Social services * Stoma care * Transfusion medicine   The following points, for instance, can be covered in the agreements with the cooperation partners:   * Participation in specialty training programmes and public relations work * Description of cooperation and interfaces * Type of reciprocal communication * Upholding of medical confidentiality |  |  |
| 1.1.3 | Gynaecological dysplasia units and consulting hours   * The separate certification of gynaecological dysplasia units and consulting hours can be done by the Gynaecological Cancer Centre or by one of its cooperation partners in line with the Catalogue of Requirements "Gynaecological Dysplasia". <http://www.onkozert.de/praxen_kooperationspartner.htm> * Cooperation with certified gynaecological dysplasia units/consulting hours must be in place and the names must be given. Reasons for non-compliance are to be given separately. |  |  |
| 1.1.4 | Contact at the Gynaecological Cancer Centre  The names of the contacts at the Gynaecological Cancer Centre at the clinic site and for the individual cooperation partners are to be given and published (e.g. on the Internet). In medical areas the responsibilities on the specialist level are to be defined. |  |  |
| 1.1.5 | Treatment errors   * The corresponding documentation about any treatment errors determined inside and outside of court is to be presented to the certifier in the run-up to certification. * The re/actions of the Centre resulting from the proceedings are to taken into account by the certifier for the follow-up audit. * The relevant calendar year is the period covered by the audit. * Non-compliance will be deemed to be a deviation. |  |  |

| **1.2** **Interdisciplinary cooperation** | | | |
| --- | --- | --- | --- |
| Chapter | Requirements | Explanatory remarks of the Centre |  |
| 1.2.1 | Performance indicators Gynaecological Cancer Centre  Number of cases with a genital malignoma (i.e. invasive neoplasias of the female genitals (no precancerous) and borderline tumours of the ovaries) per year:  ≥ 75 cases (= total case number), of which ≥ 50 primary cases  Definition primary case:   * A primary case includes all stays and treatments (surgery, radio(-chemo)therapy) of a patient to treat a disease * Recurrence/metastasis of a patient is a new case, not a primary case * Histology report, medical report and, where appropriate, treatment/surgical report should be available * Planning/conduct of therapy via the Gynaecological Cancer Centre Count time is the time of the initial diagnosis or the time of the recurrence/metastasis |  |  |
| 1.2.2  a) | Cycle  The tumour conference must be regularly held at least once a week.  Web/online conference   * If web conferences are used, it must be possible to transmit the sound and documents presented. It must be possible for each main cooperation partner to present its own documents/imaging material.   Telephone conferences with no imaging material are not an option. |  |  |
| b) | Participants tumour conference  For the following specialties participation by specialists in the conference is mandatory and to be confirmed by a list of participants:   * Operator * Radiologist * Pathologist * Radiotherapist * Internal oncologist * Gynaecological oncologist (if systemic treatment is given by gynaecology)   In line with needs, associated specialty groups (e.g. psycho-oncology, nursing care) are to be involved in the tumour conference.  If several cooperation partners are indicated for a specialty, then the presence of one representative is sufficient as long as the formalised exchange of information between the partners has been put in place (e.g. via quality circles).   * Independently thereof, each cooperation partner must take part in the tumour conference at least once a month. * One of the attending physicians should know the patient personally. |  |  |
| c) | Preparation tumour conference The main patient data are to be summed up in writing prior to the conferences and distributed to the participants. A pre-appraisal of suitable study patients is to be undertaken. |  |  |
| d) | Demonstration imaging material Patient-related images (radiological / pathological) must be available at the tumour conference. Suitable technical equipment must be available to present the imaging material. |  |  |
| e) | Minutes of the tumour conference   * The results of the tumour conference consist, *inter alia*, of a written, interdisciplinary treatment plan ("Minutes tumour conference"). * The minutes of the tumour conference must be part of the patient’s medical record and can, at the same time, constitute the medical report. * The distribution of the treatment plan to the individual treatment partners (incl. referrers) is to be ensured. * The "minutes of the tumour conference" should be automatically generated from the tumour documentation system. |  |  |
| 1.2.3 | Case discussion  All patients, who come to the Centre with a first manifestation, a new recurrence or remote metastasis, must be presented at the tumour conference.  Requirement: ≥ 80%  If the specified treatment plan is changed by partners of the Centre, then there must be a renewed discussion of the patient's case. | Details in indicator sheet (Excel template) |  |
| 1.2.4 | Treatment plan  An interdisciplinary treatment plan is to be prepared for all patients. This also applies to patients who are not been at any tumour conference. |  |  |
| 1.2.5 | Therapy deviation   * In principle, all treatment plans or recommendations of the tumour conference are binding for the Centre's partners. * If any deviations from the original therapy plan or deviations from the Guidelines are observed, they must be minuted and evaluated. Depending on the cause, avoidance measures are to be taken. * If therapy is not started or terminated prematurely at the patient's request (despite existing indication), this must also be minuted. |  |  |
| 1.2.6  New | If a radiotherapy unit cooperates with several clinics, then all primary case patients with a cervical carcinoma, who are to undergo radiochemotherapy, should be presented in a centre. To this end, the radiotherapy unit is to draw up a list of all patients presented to it that includes a centre assignment (certified centre, certification ongoing, not a centre). The presentation rate of 90% is to be achieved in each of the cooperating centres. This assignment of the patients is also of relevance for the tumour documentation.  Colour legend: Additions to the version of 14.07.2016. |  |  |
| 1.2.7  ~~1.2.8~~ | Quality circles   * Quality circles of the Centre are to be conducted at least twice a year with the main cooperation partners and referrers. * Scheduling, e.g. in qualification plan * Minutes of quality circles are to be taken. |  |  |
| 1.2.8  ~~1.2.7~~ | Morbidity /mortality conferences (MM conferences)   * The invited participants are the participants in the tumour conference and referrers. * The dates of these conferences can be timed to coordinate with the tumour conference or with events for referrers. * Patient cases are discussed after conclusion of primary therapy who are in aftercare. All patients deceased peri-therapeutically are discussed. * Cases with both a negative and positive course are to be presented. Morbidity conferences are to be held at least twice a year. * MM conferences are to be minuted. |  |  |

| **1.3** **Cooperation referrers and aftercare** | | | |
| --- | --- | --- | --- |
| Chapter | Requirements | Explanatory remarks of the Centre |  |
| 1.3.1 | Cooperating referrers  An up-to-date list is to be kept of the main cooperating referrers. Referrers are to be informed about cooperation within the Gynaecological Cancer Centre.  Referrers are entitled to attend the tumour conference when their referred patients or their own patients are presented. |  |  |
| 1.3.2 | Provision of documents  The following documents are to be given to the referrer in a timely manner:   * Surgical report * Histology * Tumour conference minutes / treatment plan * Medical report / discharge letter * Changes to therapy |  |  |
| 1.3.3 | Feedback system  A written procedure for the recording, processing and feeding back of the general and case-related concerns/questions of the main referrers is to be put in place. |  |  |
| 1.3.4 | Further training  Events for the exchange of experience and further training events are to be staged at least once a year by the Gynaecological Cancer Centre. Contents/results and participation are to be recorded. |  |  |
| 1.3.5 | Referrer satisfaction survey   * Every three years a referrer satisfaction survey must be conducted. The results of this survey are to be evaluated and analysed. * The referrer satisfaction survey must be available for the first time at recertification (3 years after initial certification). * The response rate should be documented. |  |  |
| 1.3.6 | Tumour documentation / follow-up   * A description is to be given of cooperation with the referrers. * The relevant requirements are presented in "10. Tumour documentation". |  |  |

| **1.4** **Psycho-oncology** | | | |
| --- | --- | --- | --- |
| Chapter | Requirements | Explanatory remarks of the Centre |  |
| 1.4.1 | Psycho-oncology – qualifications   * Qualified psychologist or * Physicians   with psychotherapeutic specialty training and psycho-oncological further training  The following further training courses are recognised:  "Specialty training in psychosocial oncology" recognised by the Working Group for Psycho-Oncology (PSO) or *dapo* (German Working Group for Psychosocial Oncology) or other adequate further training with a volume of > 100 teaching units Proof is to be supplied via a special training curriculum.  The representatives of other psychosocial professional groups (like qualified pedagogues, social workers, etc.) can be approved on presentation of the above-mentioned psycho-oncological qualifications. For this, a case-by-case examination is required.  The assumption of psycho-oncological tasks by the social services, self-help groups or pastoral care is not sufficient. |  |  |
| 1.4.2 | Offer and access  Each patient must be offered the option of psycho-oncological counselling in a timely manner in the vicinity. The offer must be made in a low-threshold manner. |  |  |
|  | Documentation and evaluation  In principle, the number of patients, who received psycho-oncological counselling, the frequency, duration and contents of the sessions are to be recorded.  To identify treatment needs it is necessary to conduct standardised screening for mental strain (see S3 Guidelines Psycho-Oncology: e.g. distress thermometer (DT) or the Hospital Anxiety and Depression Scale - HADS), and to document the result. |  |  |
| 1.4.3 | Psycho-oncology resources  At least 0.5 full-time positions should be available for 150 oncological cases (names to be given). |  |  |
| 1.4.4 | Premises A suitable room is to be provided for psycho-oncological patient consultations. |  |  |
| 1.4.5 | Organisation plan  If psycho-oncological care is provided by external cooperation partners or for several clinical sites and clinic facilities, the performance of tasks is to be laid down in an organisation plan that contains details, *inter alia*, of the availability of resources and local presence. |  |  |
| 1.4.6 | Psycho-oncology – tasks  The psycho-oncological care of patients is to be offered at all stages of care (diagnosis, inpatient, post-inpatient).  Goals and tasks of care:   * Diagnostic clarification after positive screening * Prevention/treatment of resulting psychosocial problems * Activation of personal coping mechanisms * Maintenance of quality of life * Consideration of social environment * Organisation of further outpatient care through cooperation with outpatient psycho-oncological service providers * Public relations (patient event or the like) |  |  |
| The following are also recommended:   * Provision of supervision, further training and initial training schemes for staff * Twice yearly discussions between psych-oncologists and the nursing and medical area; * The regular written and, where appropriate, oral feedback on psycho-oncological activities to the medical staff (e.g. through a referral report or documentation in the medical record); * Regular participation in ward conferences and tumour conferences; * Close cooperation with social services and self-help   The psycho-oncologists should present their work at least once a year at the tumour conferences or in the quality circles. |  |
| 1.4.7 | Further/specialty training/supervision   * At least 1 dedicated further/specialty training session a year for each staff member (at least 1 day a year) * External supervision is to be made possible on a regular basis. |  |  |

| **1.5**  **Social work and rehabilitation** | | | |
| --- | --- | --- | --- |
| Chapter | Requirements | Explanatory remarks of the Centre |  |
| 1.5.1 | A suitable room is to be provided for social counselling work.  Resources:  ~~At least 1 social worker is available to the Centre.~~  For the counselling of the patients in the Centre at least 1 full-time staff member is available for 400 counselling sessions (= primary cases, secondary metastasis, recurrence). The staff resources can be made available centrally. An organisation plan must be available.  ~~Organisation plan:~~  ~~If the social service provides its services to several specialty units or locations, the performance of tasks is to be laid down in an organisation plan that contains,~~ *~~inter alia~~*~~, details of the availability of resources and local presence.~~  Colour legend: deletions from/additions to the version of 14.07.2016 |  |  |
| 1.5.2 | Each patient must be offered the option of counselling by the social services at all stages of the disease in a timely manner in the vicinity (proof required). The offer must be made in a low-threshold manner. |  |  |
|  | The number of patients who received counselling from the social services is to be recorded. | Details in indicator sheet (Excel template) |  |
| 1.5.3 | Contents of counselling   * Identification of social, economic and mental health emergencies * Start of medical rehabilitation measures * Advice on social law and economic issues (e.g. severely disabled persons' legislation, wage replacement benefits, pensions, benefit requirements, co-payments, etc.) * Support for submitting applications * Advice on outpatient and inpatient care treatment options and referral to support schemes and specialised services * Support for professional and social reintegration * Cooperation with service funding agencies and service providers * Intervention in emergencies |  |  |
| 1.5.4 | Further tasks:   * Public relations and networking * Participation in ward conferences and tumour conferences, supervision, further training * Interdisciplinary cooperation particularly with physicians, nursing staff, physiotherapists, psycho-oncologists, pastoral services *inter alia* * Documentation of activities |  |  |
| 1.5.5 | Further/specialty training  At least 1 dedicated further/specialty training session a year for each staff member (at least 1 day a year) |  |  |

| **1.6** **Patient involvement** | | | |
| --- | --- | --- | --- |
| Chapter | Requirements | Explanatory remarks of the Centre |  |
| 1.6.1 | Self-help groups  The self-help groups/groups of affected persons, with whom the Gynaecological Cancer Centre actively cooperates, are to be named. Written agreements with the self-help groups, which should be updated at least every 5 years, are to be entered into which cover the following points:   * Access to self-help groups at all stages of treatment (initial diagnosis, hospitalisation, chemotherapy, follow-up care...); * The name of a contact for self-help must be provided. * Provision of contact data of self-help groups (e.g. in patient brochure, homepage of the Gynaecology Cancer Centre) * Options to display information brochures of self-help groups * Regular provision of rooms at the Gynaecological Cancer Centre for consultations * Quality circles with the participation of representatives of psycho-oncology, self-help groups, social services, pastoral care, nursing care and medicine (optional) * Personal discussions between the self-help groups and the Gynaecological Cancer Centre with a view to jointly staging or mutually agreeing on actions and events The results of the discussions are to be recorded. * A contact person (preferably from the nursing staff) is known to the self-help group. * Involvement of medical staff in the events of the self-help group * The formulated tasks can only be carried out by the persons affected.   Colour legend: Amendments to the version of 14.07.2017 |  |  |
| 1.6.2 | Patient surveys   * All patients must have an opportunity to take part in a patient survey. * The survey must be conducted at least every three years over a period of at least three months. |  |  |
| * The return rate should be more than 30% (steps to be taken if this rate is not reached) * Tumour-specific questions are to be taken into account. |  |
| 1.6.3 | Evaluation patient survey   * Responsibility for the evaluation is to be specified. * The evaluation must encompass the patients of the Gynaecological Cancer Centre. * A recorded evaluation must take place. * Based on the evaluation, actions are to be specified in which all (main) cooperation partners should be involved. |  |  |
| 1.6.4 | Patient information (general)   * The Gynaecological Cancer Centre should give a full presentation of itself and its treatment options (e.g. in a brochure, patient folder, on the homepage). * The cooperation/treatment partners are to be named with details of the contact. A description is to be given of the treatment offering. * The presented treatment offering must encompass: Rehabilitation / post-hospital rehabilitation, self-help, treatment measures * Information provided: amongst other things patient guidelines of the Guideline Programme Oncology  (http://leitlinienprogramm-onkologie.de/Patientenleitlinien.8.0.html) |  |  |
| 1.6.5 | Discharge consultation  Each patient is given a discharge consultation in which the following topics are addressed: e.g. disease status, therapy planning, aftercare, supportive measures (e.g. rehabilitation, health care supply store, psychosocial offering). |  |  |
| 1.6.6 | Results tumour conference  The recommendations of the tumour conference must be explained to the patient. The patient's decision must be recorded.  Patient information (case-related):  The patient is given the following documents:   * Tumour conference minutes / treatment plan * Medical report / discharge letter * Aftercare plan / aftercare pass * where applicable, study documents |  |  |
| 1.6.7 | Event for patients  An information event for patients is to be staged by the Gynaecological Cancer Centre at least once a year. |  |  |
| 1.6.8 | Complaint management  An official procedure for complaint management is in place. Patients are given feedback. Complaints are taken into account in the improvement process. |  |  |

| **1.7** **Study management** | | | |
| --- | --- | --- | --- |
| Chapter | Requirements | Explanatory remarks of the Centre |  |
| 1.7.1 | Access to studies The patient must have access to studies with an ethical vote. The studies conducted at the Gynaecological Cancer Centre are to be listed. Patients are to be given access to this list and a short description of the studies. |  |  |
| 1.7.2 | Study manager  The name of the physician in charge of the study is to be given.  Study assistant /study nurse   * The name of a study assistant is to be included in the "study organisation chart" for "each active study unit". * He/she can work in a parallel manner for several "units conducting studies". |  |  |
| 1.7.3 | Study assistant - Tasks  The range of tasks is to be laid down in writing (via position/function descriptions) and can encompass, *inter alia*, the following contents:   * Conduct of studies together with the physician in charge of the studies * Patient care during the study and in aftercare * Organisation, coordination of diagnosis, laboratory, sample dispatch and test medication * Collection and documentation of all data of relevance for the studies * Preparation of and support for audits and authority inspections * The activity of the study assistant can be combined with other activities like tumour documentation. |  |  |
| 1.7.4 | Process description: The processes including responsibilities are to be laid down for the inclusion /initiation of new studies and the conduct of studies. This encompasses for instance:   * Selection of new studies including release decision * Internal announcement of new studies (update study list, ...) * Study organisation (special features care study patients, documentation...) * Type of announcement of study results (e.g. MA, patients) |  |  |
| 1.7.5 | Proportion study patients  1. Initial certification:  At the time of initial certification ≥ 1 patients must have been included in the studies.  2. After one year: at least 5% of the primary case number | Details in indicator sheet (Excel template) |  |
|  | * All study patients can be taken into account when calculating the study rate (share study patients based on the Centre's primary case number). * Only the inclusion of patients in studies with an ethical vote counts as study participation (non-interventional/diagnostic studies are also recognised). |  |  |
|  | General preconditions for the definition of the study quota:   * Patients can be counted once per study, time: Date of patient consent * Patients in the palliative and adjuvant situation can be counted, no limitations regarding stage of disease. |  |  |

| **1.8** **Nursing care** | | | |
| --- | --- | --- | --- |
| Chapter | Requirements | Explanatory remarks of the Centre |  |
| 1.8.1 | Specialist oncology nurses   * At least 1 active specialist oncological nurse must be involved in the Gynaecological Cancer Centre. * The names of specialist oncology nurses are to be provided.   For initial certification at least one registration for training as a "Specialist oncology nurse" must be available. In this case details must be given of how the "responsibilities/tasks" outlined below are to be covered during training. During the training phase, cooperation with a fully trained specialist oncology nurse is recommended, who supervises the performance of the tasks during the training phase. After 3 years the activity of a specialist oncology nurse is to be proven.  Training specialist oncology nurse  in line with the model of the federal state ordinance of the German Hospital Federation (*Deutsche Krankenhausgesellschaft e.V.* – DKG) or the respective federal state regulations or academically trained specialist nurse. |  |  |
| 1.8.2 | Responsibilities / tasks   * Care counselling for affected individuals and family members for the purposes of care case management or follow-up care (network of outpatient care) * Assessment and management of strain, symptoms and side effects * Advice for colleagues from colleagues along the lines of further training (theoretical/practical) * Planning of the further training needs of the specialist oncology nurses * Implementation of the latest (care-related) scientific research findings in day-to-day care practice * joint oncological nursing visits |  |  |
| 1.8.3 | Nursing concept  A nursing concept is to be developed and implemented which includes the specifics of oncological nursing care. |  |  |
| 1.8.4 | Further and specialty training   * A qualification plan for nursing staff is to be presented listing the planned qualification sessions for the period of one year. * At least 1 dedicated further/specialty training session is to be staged for each staff member (at least 1 day a year), who carries out quality-relevant activities for the Gynaecological Cancer Centre. |  |  |
| 1.8.5 | Induction concept  The induction of new staff members must be done in line with a specified induction concept. |  |  |

| **1.9**  **General service areas** | | | |
| --- | --- | --- | --- |
|  | The Catalogues of Requirements of the Organ Cancer Centres and Oncology Centres have a uniform table of contents.  For the Gynaecological Cancer Centres this section does not specify any Technical and Medical Requirements. |  |  |

# 2 Organ-specific diagnostics

| **2.1**  **Consulting hours** | | | |
| --- | --- | --- | --- |
| Chapter | Requirements | Explanatory remarks of the Centre |  |
| 2.1.1 | Information / dialogue with the patient  Adequate information must be provided about diagnosis and therapy planning and a dialogue is to be entered into. This includes *inter alia*:   * Presentation of alternative treatment concepts * Offer of and aid in obtaining second opinions * Discharge consultation as a standard procedure |  |  |
|  | * A general description is to be given of the way in which information is provided and the dialogue organised. This is to be documented for each patient in medical reports and minutes/records. |  |  |
|  | * The patient should be given the option of including his/her partner or family members in the consultation. |  |  |
|  | * Information is to be provided and the level of knowledge increased in as timely a manner as possible in line with the basic principles of patient-centric communication which facilitates participatory decision-making. |  |  |
|  | * The patient should be informed about all the therapy options of relevance for her described in the Guidelines, the chances of success and their possible effects. In particular, attention should be drawn to the effects on her physical appearance, sex life, urine and stool control (incontinence) and aspects of self-perception (self-image, fertility). |  |  |
| 2.1.2 | Outpatient care in the Gynaecological Cancer Centre  The options of pre-inpatient/post-inpatient care or outpatient presentation should be provided and cover the following topics:   * Diagnosis and therapy planning * Special aftercare problems * Counselling for familial malignoma disease with the genetic specialty unit   If appropriate, the topics can be covered in special, separate consulting hours (e.g. gynaecological dysplasia). |  |  |
| 2.1.3 | Waiting times during the consulting hours  Requirement: < 60 min (target value)  How long are the waiting times for an appointment  Requirement: < 2 weeks  The waiting times are to be recorded on a random basis and statistically evaluated (recommendation: evaluation period 4 weeks a year). |  |  |
| 2.1.4 | The following services are to be provided:   * Colposcopy * Tissue sampling for histology * Ultrasound examination |  |  |
| 2.1.5 | Diagnosis   * Information about diagnosis by a doctor in a personal consultation * Time for the ensuing diagnosis   (Informing patient of histological result) < 2 weeks |  |  |
| 2.1.6 | Repeated presentation of patient is to be organised in the event of therapeutic side effects. |  |  |
| 2.1.7 | Hereditary stress  Check lists to record hereditary stress are to be applied in the case of:   * Patients with breast/ovarian cancer (mainly familial breast/ovarian cancer) * Patients with endometrial cancer (EC) ( mainly HNPCC/Lynch syndrome   The check lists and the algorithm can be downloaded from <http://www.krebsgesellschaft.de/deutsche-krebsgesellschaft-wtrl/deutsche-krebsgesellschaft/zertifizierung/erhebungsboegen/organkrebszentren.html> in the section Gynaecological types of cancer. |  |  |
| 2.1.8 | Recording risk of HNPCC/Lynch syndrome   * The algorithm described under 2.1.7 for dealing in particular with Lynch is to be used and responsibilities described. * Immunohistochemical determination of MMR proteins in patients with EC with positive check list (2.1.7) |  |  |

| **2.2**  **Diagnosis** | | | |
| --- | --- | --- | --- |
|  | The Catalogues of Requirements of the Organ Cancer Centres and Oncology Centres have a uniform table of contents.  For the Gynaecological Cancer Centres this section does not specify any Technical and Medical Requirements. |  |  |

| **3** **Radiology** | | | |
| --- | --- | --- | --- |
| Chapter | Requirements | Explanatory remarks of the Centre |  |
| 3.1 | Specialists   * At least 1 specialist for radiology * Cross-cover provision of staff with the same qualification is to be documented in writing. * The names of the specialist and cross-cover staff are to be given. |  |  |
| 3.2 | Radiology RTAs  At least 2 qualified RTAs must be available and their names given. |  |  |
| 3.3 | Conventional x-ray diagnosis  Access to x-ray examinations (e.g. x-ray thorax, intravenous pyelogram, mammography) is to be ensured. |  |  |
| 3.4 | CT, MRI  Access to these examinations is to be ensured. If this is not possible at the clinical site, access is to be regulated in a cooperation agreement. |  |  |
| 3.5 | Sonography   * Transvaginal sonography:   Transvaginal probes with a frequency of ≥ 5 MHz are to be inserted.   * Transabdominal sonography:   Probes of ≥ 3.5 MHz are to be inserted.   * Mammary sonography:   Only ultrasound devices with a frequency of ≥ 7.5 MHz are to be inserted. |  |  |
| 3.6 | Further and specialty training   * A qualification plan for medical and other staff (RTAs) is to be presented listing the planned qualification sessions for the period of one year. * Every year at least 1 gynaecological-oncological specialty training session must be organised for each staff member (duration > 0.5 days) who carries out quality-relevant activities for the Gynaecological Cancer Centre. |  |  |

| **4** **Nuclear medicine** | | | |
| --- | --- | --- | --- |
| Chapter | Requirements | Explanatory remarks of the Centre |  |
| 4.1 | Specialists   * at least 1 specialist * proof must be provided of a qualified contingency plan * The names of the specialists are to be given. * Doctors with the specialist subject nuclear medicine are also recognised as specialists in a individual case examination. |  |  |
| 4.2 | MTAs of nuclear medicine:  At least 2 qualified MTAs must be available and their names given. |  |  |
| 4.3 | PET  The access to PET is to be described.  Colour legend: Moved from the Radiology section to the Nuclear Medicine section compared with the version dated 18 September 2014 |  |  |
| 4.4 | Proof detection rate  The share of detected sentinel lymph nodes compared with the tests conducted:  Sentinel node biopsy probe measurement  For initial certification: ≥ 80%  After 3 years: ≥ 90%  Sentinel node scintigraphy (optional)  For initial certification: ≥ 80%  After 3 years: ≥ 90%  The clinical detection rate is to be considered in a regular quality control (at least once a year) in an interdisciplinary round (blue solution and radioactivity). |  |  |
| 4.5 | Quality control of apparatus  The probe systems and the gamma cameras are to undergo regular quality control.   * Constancy tests (zero effect, yield) recorded every working day * Further quality controls in line with the manufacturer's instructions (normally every six months) |  |  |
| 4.6 | Further and specialty training   * A qualification plan for medical and other staff (RTAs) is to be presented listing the planned qualification sessions for the period of one year. * Every year at least 1 gynaecological-oncological specialty training session must be organised for each staff member (duration > 0.5 days) who carries out quality-relevant activities for the Gynaecological Cancer Centre. |  |  |

# 5. Surgical oncology

| **5.1** **Cross-organ surgical therapy** | | | |
| --- | --- | --- | --- |
|  | The Catalogues of Requirements of the Organ Cancer Centres and Oncology Centres have a uniform table of contents.  For the Gynaecological Cancer Centres this section does not specify any Technical and Medical Requirements. |  |  |

| **5.2** **Organ-specific surgical therapy** | | | |
| --- | --- | --- | --- |
| Chapter | Requirements | Explanatory remarks of the Centre |  |
| 5.2.1 | Specialists for the Gynaecological Cancer Centre   * At least 2 specialists for gynaecology with the focus designation Gynaecological Oncology in line with the staffing schedule working for the Gynaecological Cancer Centre * The names of the specialists are to be given.   Initial certification:  At least 1 specialist for gynaecology with the focus designation Gynaecological Oncology. A second specialist for gynaecology should be undergoing specialty training for the focus designation Gynaecological Oncology. This must have been successfully concluded before recertification (after 3 years) and notified. |  |  |
| 5.2.2 | Cross-organ surgery   * For cross-organ surgery cooperation with urologists and visceral surgeons must be in place. * Cooperation is to be proven by means of documented cases for the assessment period. |  |  |
| 5.2.3 | Inpatient care  Beds must be available for gynaeco-oncological patients. |  |  |
| 5.2.4 | The waiting time between diagnosis and surgery should allow sufficient time for reflection and advice and not be longer than four weeks. |  |  |
| 5.2.5 | Surgical capacity  Sufficient surgical capacity is to be made available. |  |  |
| 5.2.6 | Definition of surgical oncology  Stage-appropriate surgical treatment including cross-organ and reconstructive measures  Number of operated cases with a genital malignoma (i.e. invasive neoplasias of the female genitals and borderline tumours of the ovaries (BOT)) a year: 40 | Details in indicator sheet (Excel template) |  |
| Number of surgeries per named operator:  20 surgeries a year, also possible when senior surgeon supervises surgery as an assisting surgeon |  |
| 5.2.7 | How many surgeries involving genital malignomas are conducted in total every year?   * Precancerous lesions (VIN, VAIN, CIN) atypical hyperplasia)   The number of surgeries is to be listed separately for each of the tumour entities ovaries, cervix, endometrium and vulva. |  |  |
| 5.2.8 | Further and specialty training  A qualification plan for medical, nursing and other staff is to be presented listing the planned qualification sessions for the period of one year. |  |  |

# 6. Medicinal / Internal Oncology

| **6.1** **Haematology and oncology** | | | |
| --- | --- | --- | --- |
|  | The Catalogues of Requirements of the Organ Cancer Centres and Oncology Centres have a uniform table of contents.  For the Gynaecological Cancer Centres this section does not specify any Technical and Medical Requirements. |  |  |

| **6.2**  **Organ-specific medicinal oncological therapy** | | | |
| --- | --- | --- | --- |
| Chapter | Requirements | Explanatory remarks of the Centre |  |
| 6.0 | Alternatively, the requirements to be met by "Organ-specific medicinal oncological therapy" can be set out in the "Catalogue of Requirements Outpatient Internal Oncology". This is especially recommended when the treatment unit is named for further certified Organ Cancer Centres as a cooperation partner (one-off, cross-organ presentation). In this case the Catalogue of Requirements "Outpatient Internal Oncology" is an annex to the Catalogue of Requirements and, consequently, is to be submitted, too.  The Catalogue of Requirements "Outpatient Internal Oncology" can be downloaded from <http://www.onkozert.de/praxen_kooperationspartner.htm>. |  |  |
| 6.2.1 | Qualification specialist   * Specialist for gynaecology with the focus designation Gynaecological Oncology or * Specialist for gynaecology with the additional designation Medicinal Tumour Therapy or * Specialist for internal medicine and haematology and oncology or   mastery and conduct of   * endocrine treatment methods * immunological treatment methods * neoadjuvant/adjuvant therapy concepts * palliative therapy concepts * supportive therapy concepts * treatment of side effects (e.g. concept for paravasates)   The name of one representative with the above-mentioned qualification is to be given.  The specialists named here must actively carry out the medicinal oncological therapy. The delegation of responsibilities to doctors without the above-mentioned qualification is not possible. |  |  |
| 6.2.2 | Specialist nurse / specialist medical assistant  The preconditions for the specialist nurse / specialist medical assistant who is responsible for administering chemotherapy in line with the treatment protocol are:   * at least 1 year's professional experience in oncology * at least 50 chemotherapy administrations (for initial certification an estimate is possible, in the ensuing years proof must be provided.) * proof of training in line with the recommendations of the Conference of Oncological Nursing and Paediatric Nursing Care (*Konferenz Onkologischer Kranken- und Kinderkrankenpflege* - KOK) (KOK recommended actions, administration of cytostatics by specialised nurses) * Active involvement in the implementation of the requirements to be met by emergency treatment and therapy of comorbidities and secondary diseases * Proof of nursing counselling and/or education of the patient is to be provided by way of documents. |  |  |
| 6.2.3 | Qualification treatment unit/partner   * at least 50 chemotherapy/anticoagulant therapies every year in the case of patients with gynaecological / senologic forms of cancer * Calculation method: completed chemotherapy/antibody therapy per patient (consisting of several cycles or administrations). * When this number is not reached, expertise cannot be proven by means of cooperation. |  |  |
| 6.2.4 | Medicinal oncological therapy outpatient/inpatient  Provision must be made for medicinal oncological therapy to be offered in both an outpatient and inpatient setting. |  |  |
| 6.2.5 | Options to be offered   * Cytostatics therapy * Antihormone therapy * Antibody therapy, biphosphonate therapy   General systemic therapy   * Cytostatics workplace (in line with the statutory guidelines) if necessary * professional waste disposal * 24-hour on-call service |  |  |
| 6.2.6 | Rooms medicinal oncological therapy   * Description of rooms for outpatient medicinal therapy * Number of places (at least 2) |  |  |
| 6.2.7 | Process descriptions   * The procedure for chemotherapy is to be described for all phases (start, conduct and conclusion of therapy). * Supportive measures in accordance with the guidelines are to be described for the individual therapy concepts and documented in detail for each patient. |  |  |
| 6.2.8 | Systemic therapy regimens   * The drawing up of / changes to existing therapy regimens must be undertaken by means of regulated release. * The therapy regimens are to be protected from any unauthorised changes. * The therapy regimens are comparable between the outpatient and inpatient units.   Therapy plans   * All systemic therapy must be planned on the basis of a therapy regimen. * The therapy plans are to be checked and released. |  |  |
| 6.2.9 | Standards comorbidities and secondary diseases  Standards are to be drawn up for the treatment of comorbidities and secondary diseases, in particular for the treatment of paravasates, infections and thromboembolic complications. |  |  |
| 6.2.10 | Emergency treatment  Available emergency equipment and written action plan for emergencies |  |  |
| 6.2.11 | Medicinal therapy in the metastasised situation   * The procedures for the care (diagnosis/therapy) of patients with local recurrence/metastasis are to be described (presentation of the patient pathways). * A regular toxicity assessment of therapy must be undertaken using selected and documented measurement parameters (symptoms or the like). * An evaluation of the therapeutic effect must be documented for each patient every 3 months. |  |  |
| 6.2.2012 | Pain therapy   * A pain therapist must be available. * The pain therapy process (algorithm) must be described. * A cooperation agreement is to be entered into when provided through an external cooperation partner. |  |  |
| 6.2.13 | Supportive /palliative therapy  A description of the options of supportive/palliative inpatient therapy is to be given (process description / algorithm). |  |  |
| 6.2.14 | Information / dialogue with the patient  Adequate information must be provided about diagnosis and therapy planning and a dialogue is to be entered into. This includes *inter alia*:   * Presentation of alternative treatment concepts * Offer of and aid in obtaining second opinions * Discharge consultation as a standard procedure   A general description is to be given of the way in which information is provided and the dialogue organised. This is to be documented for each patient in medical reports and minutes/records. |  |  |
| 6.2.15 | Further and specialty training  A qualification plan for medical, nursing and other staff is to be presented listing the planned qualification sessions for the period of one year.  At least 1 dedicated gynaecological-oncological further/specialty training session must be organised every year for each staff member (duration > 0.5 days) who carries out quality-relevant activities for the Gynaecological Cancer Centre. |  |  |

| **7** **Radio-oncology** | | | |
| --- | --- | --- | --- |
| Chapter | Requirements | Explanatory remarks of the 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** | | | |
| --- | --- | --- | --- |
| Chapter | Requirements | Explanatory remarks of the 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, 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 and hospice work** | | | |
| --- | --- | --- | --- |
| Chapter | Requirements | Explanatory remarks of the Centre |  |
| 9.1 | * Proof is to be provided for each cooperation agreement with service providers of specialist inpatient and outpatient palliative care and inpatient hospices. * Regional care concepts for the integration of palliative care are to be described on the basis of the treatment pathway for patients and family members from the S3 Guideline Palliative Medicine (Figure 3, p. 174) with the names of all involved persons. * A physician with additional specialty training must be available for consultations and tumour conferences. * The group of patients with incurable cancer is to be defined, for instance in the tumour conference. They are to be informed in a timely manner about palliative medical support services (SOPs). (S3 Palliative Medicine Guidelines) * The access to palliative care can be offered in parallel to tumour-specific therapy. The procedure in the Centre is to be described in an SOP. * The number of primary cases with incurable cancer, specified for instance in the tumour conference, is to be documented. |  |  |

| **10.** **Tumour documentation / Outcome quality** | | | | | |
| --- | --- | --- | --- | --- | --- |
| Chapter | Requirements | Explanatory remarks of the Centre | | |  |
| 10.1 | Tumour documentation system  A tumour documentation system, which contains the patient data for a minimum period of 3 months, must be in place at the time of initial certification.  Name of the tumour documentation system in the cancer register and/or Centre |  | | |  |
| 10.2 | Period covered by the data  The full data are to be presented for the respective last calendar year. |  | | |  |
| 10.3 | Requirements to be met by tumour documentation  A data set must~~s~~ be used in line with the uniform basic oncological data set and its modules of the Working Group of German Tumour Centres (*Arbeitsgemeinschaft Deutscher Tumorzentren* - ADT) and the Association of Population-based Cancer Registries in Germany (*Gesellschaft der epidemiologischen Krebsregister in Deutschland e.V.* - GEKID).  The Centre must ensure that data transfer and capture are undertaken in a timely manner. Any existing regional laws for notification deadlines are to be complied with. |  | | |  |
| 10.4 | Cooperation with cancer ~~/tumour~~ register   * Cooperation with the competent cancer register is to be documented in a cooperation agreement. [Link Tumorzentren.de](http://www.tumorzentren.de/tl_files/dokumente/Kooperationsvereinbarung%20ADT_DKG_07.07.2015%20.docx) * The full data are to be made available to the cancer register in an ongoing manner. * The presentation of the indicator sheet and outcome quality should be ensured via the cancerregister. * As long as the competent ~~l~~ cancer register is unable to meet the requirements imposed, the Centre is to use additional or alternative solutions. The Centre is responsible in the case of a non-functioning external solution. |  | | |  |
| 10.5 | Documentation officer  At least 1 documentation officer is to be appointed who bears responsibility for the tumour documentation system.  Name/Function:  The documentation officer has the following tasks:   * Ensuring the transfer and quality of patient data by all cooperation partners * Motivation of trans-sectoral cooperation with participating specialty units in the cancer register (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 analysis of the evaluations particularly over the course of time   Colour legend: Additions to / deletions from the version  dated 18 September 2014 |  | | |  |
| 10.6 | Provision of resources  For documentation and data recording tasks (e.g. through a cancer register) the required staff capacity should be made available (guidance value: 0.5 full-time positions for 200 primary cases. |  | | |  |
| 10.7 | The following selection options must be provided at least in the tumour documentation system:   * Years of birth * TNM classification or comparable classifications (e.g. FIGO) * Forms of therapy (surgical therapy, radiotherapy, hormone therapy, immunotherapy, chemotherapy) * Date of recurrence/metastasis * Deaths * Follow-up status (latest update) |  | | |  |
| 10.8 | Indicators of outcome quality should be recorded.  1. Disease-free survival (DFS)  2. Overall survival of the age cohorts (OAS)  3. Kaplan-Meier curves for progression-free survival (PSS) and survival (OAS)  The PSS and OAS must be available for each recertification (every 3 years, ongoing) |  | | |  |
| 10.9 | Data evaluation   * The depiction of outcome quality (see point above) must be possible for recertifications. * The data in the tumour documentation system are to be evaluated~~.~~at least once a year. * If benchmarking/annual report ~~p~~ is offered is offered, the results of benchmarking are to be taken into account in the analysis. * The results must be discussed in an interdisciplinary manner. If there are any regional or national networks, they are to be participated in. |  | | |  |
| 10.10 | Recording follow-up  Details are to be given of how aftercare data are collected and what the current follow-up status is (see outcome matrix)  Functioning cancer registers present the follow-up status.  The follow-up status includes:   * any progressions (local recurrences, where appropriate regional lymph node recurrences, distant metastases, at least for the first progression) * secondary malignancy * Deaths * lives currently at the address * termination of follow-up (e.g. moves away from catchment area, federal region) |  | | |  |
| 10.11 | Requirements to be met by follow-up  Return rate after 3 years (recertification) |  | From 01/01/2012 |  |  |
| Minimum requirement for successful recertification |  | ≥ 80 % |  |  |
| Recertification or maintenance of certification only possible subject to conditions (e.g. reduced validity term, concept for increasing the return rate ,...). |  | 60 – 79 % |  |  |
| Certification was not reconfirmed or maintained. |  | < 60 % |  |  |

**Indicator sheet / Matrix outcome quality**

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/)