**Catalogue of Requirements for**

**Colorectal Cancer Centres**

All of the requirements for Colorectal Cancer Centres (CrCC) are laid down in this catalogue. The certification of

Colorectal Cancer Centres is based on the fulfilment of these requirements.

**Developed by the DKG (German Cancer Society) Certification Committee for Colorectal Cancer** **Centres**

**Chairmen** Prof. Dr. Thomas Seufferlein, Prof. Dr. Stefan Post

**Members (in alphabetical order):**

|  |
| --- |
| ABO - Working Group on Imaging in OncologyADT - Working Group of German Tumour CentresADDZ - [Working Group of DKG-Certified CRCC Centres](http://www.ag-darmzentren.com/)AIO - Working Group on Internal OncologyAOP - Working Group on Oncological PathologyAPM - Working Group on Palliative MedicinePRIO - Working Group on Prophylaxis and Integrative Medicine in OncologyPSO – Working Group on Psychological OncologyARO - Working Group on Radiological OncologyASO – Working Group on Social Work in OncologyASORS - Working Group for Supportive Care in Oncology, Rehabilitation and Social MedicineAUO - Working Group on Urological OncologyBNHO – Professional Association of Haematologists and OncologistsBDI - Professional Association of German InternistsBDVST – Professional Association of German Radiation TherapistsBNG - German Association of Practising GastroenterologistsBVGD - Gastroenterology AssociationBDP - Professional Association of German PathologistsCAO - Working Group on Surgical OncologyCAO-V - Working Group on Surgical Oncology – Visceral SurgeryDGHO–German Society for Haematology and OncologyDGN – German Society for Nuclear MedicineDGP – German Society for Palliative MedicineDGP – German Society of PathologyDGVS - German Society for Digestive and Metabolic DiseasesDGAV- German Society for General and Visceral SurgeryGerman ILCODeGIR – German Society of Interventional RadiologyDRG - German Radiological SocietyDEGRO - German Society for Radiation OncologyDVSG - German Association for Social Work in Health CareKOK - Conference of Oncological Nursing and Paediatric Nursing careJoint Project on Familial Colorectal Cancer |

**Valid from 22 July 2018**

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| This Catalogue of Requirements is binding for all audits from 1 January 2017. All changes to the previouslyapplicable versions of this Catalogue (of the audit years 2015 and 2016) are highlighted in turquoise.The modifications served to integrate: The Interdisciplinary S3 Guideline for the Diagnosis, Treatment and Follow-up of Colorectal Carcinoma

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| The following was incorporated:S3 Guideline “Diagnosis and Treatment of the Colorectal Carcinoma” |

The Catalogue of Requirements is based on the TNM classification of malignant tumours, 8th edition 2017, the ICD classification ICD-10-GM 2017 (DIMDI) and the OPS classification OPS 2017 (DIMDI).CColour legend: changes to version dated 18 November 2016 |

**Information on the Colorectal Cancer Centre**

|  |  |
| --- | --- |
| Colorectal Cancer Centre (CrCC) |  |
| Director of the Centre |  |
| Coordinator of the Centre |  |

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| --- | --- | --- | --- |
|  |  |  | This questionnaire is valid for |
|  |  |  |  |  |  |
| Clinical site 1 (hospital/clinical site) |  |  |  |  |  |
|  |  |  |  |  |  |
| Clinical site 2 (hospital/clinical site) |  |  |  |  |  |
| only in the case of cooperating CrCCs |  |  |  |  |  |

**QM system certification**

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

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

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

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

**Network/ main cooperation partners**

The (main) cooperation partners of Colorectal Cancer Centres are registered with the certification agency OnkoZert in a "master data sheet" (*"Stammblatt"*). All the information contained therein is published on [www.oncomap.de](http://www.oncomap.de). The Centre must report all new and also all invalid cooperations. All other updates (changes in management, contact data etc.) must be corrected in the “master data sheet and must be regularly updated prior to the annual surveillance audit. This master data sheet can be requested from OnkoZert.

**Compilation/Update**

The electronically generated questionnaire serves as the basis for certification of the CrCC. The correctness and completeness of the information contained therein have been verified.

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| --- | --- |
| The data on outcome quality relate to the calendar year: |  |
|  |  |
| Date on which the questionnaire was compiled /updated: |  |

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	1. Medical oncology
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Annexes to the questionnaire (separate Excel document)

Data Sheet

Outcome quality matrix

| 1. General information on the Colorectal Cancer Centre* 1. **Structure of the network**
 |
| --- |
| Section | Requirements | Comments by the Colorectal Cancer Centre |  |
| 1.1.1 | The following persons in authority must be named:* Director(s) of the Centre (maximum two directors per Centre, one of whom is the designated contact person)
* Centre Coordinator

Centre Coordinator – tasks* Coordination of internal/ external audits
* Monitoring technical and medical requirements and ensuring compliance
* Communications interface
* Control/ supervision of interdepartmental activity
 |  |  |
| 1.1.2 | Main cooperation partners and cooperation partners can be part of one hospital or separate practices.Main cooperation partnersVisceral surgery, gastroenterology, radiotherapy, haematology/oncology, pathology, radiologyCooperation partnersPsycho-oncology, social services department, stomatherapy, nutritional counselling, physiotherapy, genetics, pain therapy and self-help group, palliative care |  |  |
| 1.1.3 | Cooperation agreementsCooperation agreements must be entered into with cooperating treatment partners. These partners must verifiably meet the appropriate technical and medical requirements of the questionnaire (not every care provider must also be a cooperation partner). The cooperation partners must be listed in the "master data sheet" ("*Stammblatt*") (administered via OnkoZert).If the cooperation partners of a Centre work under one funding body or at one clinical site, no written agreements are needed (however, the implementation of the following points must be ensured).The following points must be regulated:* Roles and responsibilities
* Description of the treatment procedures that are relevant for the Centre, taking interfaces into account
* Obligation to implement published guidelines
* Description of cooperation with respect to tumour documentation
* Declaration of willingness to cooperate with internal/ external audits
* Commitment to comply with the relevant DKG criteria and to provide the relevant data on an annual basis
 |  |  |
|  | * Compliance with the confidentiality obligation
* Participation in continuing education courses and public relations work
* Declaration of willingness to be publicly named as part of the Colorectal Cancer Centre (e.g. homepage)
* 24h/7d availability of main clinical cooperation partners: surgeons, gastroenterologists, radiotherapists, radiologists.

Tumour conference(only if participation is required under "1.2 Interdisciplinary cooperation")* Mandatory participation
* Ensuring the availability of a specialist in the discipline required to attend
* Rules on participation and coordination if there is more than one cooperation partner per discipline (see also "Interdisciplinary cooperation")
 |  |  |
| 1.1.4 | Description of the Colorectal Cancer Centre (CrCC)The structure of the CrCC must be described in its entirety and publicly (e.g. on the Internet). This also includes providing the following details for all internal/external cooperation partners:- Name and address of the cooperation partner- Phone number/email address of contact person |  |  |
| 1.1.5 | Strategy planning/reportingAn annual review at management level is recommended. It should take into account for instance the following aspects:* Definition/assessment (and, if appropriate, realignment) of objectives
* Consideration of audit findings (internal/external)
* Human resources for management of the Centre (Centre coordinator)
* Public relations/patient information
* Tumour documentation/outcome quality
 |  |  |
| 1.1.6 | Malpractice* The certifier must be informed in detail, prior to certification, of any treatment errors established by a court of law or determined out-of-court (by a medical expert/conciliation commission).
* Later certification must examine in particular the actions/reactions of the Centre resulting from the proceedings.
* The period presented is the calendar year relevant to the audit.
* Non-compliance will be rated as a deviation.
 |  |  |

| **1.2 Interdisciplinary cooperation**  |
| --- |
| Section | Requirements | Comments by the Colorectal Cancer Centre |  |
| 1.2.1 | Frequency/participantsThe tumour board must meet at least once a week. Tumour board participantsParticipation in the tumour board on the specialist level is mandatory for the following specialties and must be recorded in a list of attendance:* visceral surgery
* gastroenterology
* radiotherapy
* haematology/oncology
* pathology
* radiology

Metastases:A surgeon with the corresponding specialty and with specific expertise must be consulted on organ metastases.Additional participants may be invited (e.g. palliative care, psycho-oncology, etc.) depending on the indication.If the haematologist/oncologist is unable to attend the conference, he/she can be represented by the specialist responsible for chemotherapy who completes/meets the requirements of Section 6.2.Color legend: Change to version dated 5 October 2017 |  |  |
| 1.2.2 | Tumour conferences: general requirementsSeveral cooperation partnersIf several 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 (for instance in quality circles).Aside from this, each main cooperation partner must attend a tumour board at least once a month. Web/online conferenceIf web conferences are held, the sound and the material presented must be transmitted. It must be ensured that every main cooperation partner is able to present documents and images. Telephone conferences with no image material are not permitted.  |  |  |
| 1.2.3 | Presentation at tumour conferenceAll cases should be presented in a pre-therapeutic/post-surgical tumour conference (in accordance with the indicator definition).If no presentation was made, this must be justified and explained in the patient's records. |  |  |
|  | Presentation at tumour conferencePatients with a rectal carcinoma should be presented again at the tumour-conference after neoadjuvant therapy with full clinical remission to discuss a “watch and wait strategy”. |  |  |
| 1.2.4 | Recurrence/metastasis* Surgical responsibilities for resection of recurrences must be laid down (particularly liver, lung), if applicable in cooperation.
* Therapeutic approaches (curative and palliative) to metastatic surgery and radiotherapy (e.g. stereotactic radiotherapy in the case of brain tumours) must be laid down in standard operating procedures (SOPs).
* Patients with primarily unresectable liver metastasis should be presented regularly for evaluation at the tumour conference during systemic treatment.
 |  |  |
| 1.2.5 | Demonstration using image materialPatient-related image material (e.g. pathology, radiology) on advanced tumours must be available at the conference, and suitable technical equipment must be available to present the image material.  |  |  |
| 1.2.6 | Preparation of the tumour conference* The essential patient and treatment data must be summarised in writing beforehand and made available to the conference participants.Suitable study patients must be observed beforehand.
* All patients with recurrences and/or metastases who have asked the Centre for treatment must be presented.
 |   |  |
| 1.2.7 | Minutes of the tumour conference* The outcome of the tumour conference consists of, *inter alia*, a written, interdisciplinary treatment plan ("minutes of the tumour conference").
* The minutes of the tumour conference must be available at all times for all main cooperation partners and can simultaneously constitute the medical report.
* The "minutes of the tumour conference" should be automatically generated from the tumour documentation system.
* The outcome of the tumour conference must be recorded in the tumour documentation system.
 |  |  |
| 1.2.8 | Participation in the tumour conference as continuing educationParticipation in the tumour conference must be made possible for the following functions/professions:* Assistant staff (medical-technical assistants, radiology technicians, etc.) from the fields of radiology and radiotherapy
* Social services and psycho-oncology staff
* One specialised oncology nurse and at least two nurses from each treatment unit
* Participation in the tumour conference is recognised as continuing education for the above functions/professions.
 |  |  |
| 1.2.9 | Therapy deviations * In principle, the treatment plans and/or recommendations of the tumour board are binding.
* If deviations from the original therapy plan or divergences from the Guidelines are ascertained, they must be noted and assessed. Measures to avoid such divergences are to be introduced, depending on the cause.
* It must be recorded if the patient refuses to begin or prematurely interrupts treatment (despite an existing indication).
 |  |  |
| 1.2.10 | Morbidity/mortality conference* This conference can be scheduled to coincide with the tumour conference.
* The date of the conference can be combined with the tumour board or with scheduled events for the referring physicians.
* A list of participants must be kept.
* Morbidity conferences are to be held at least twice a year.
* Cases with a special history or a history that could be improved should be discussed. Patients who died after surgery/intervention must be discussed at the conference.
* Minutes must be taken of the MM conferences.
 |  |  |
| 1.2.11 | Quality circle* The tasks, participants and content of the quality circle must be laid down.
* At least 4 quality circles must be held every year.
* A list of participants must be kept.
* The quality circles must lead to unequivocal results (actions, decisions) which seem likely to significantly develop/improve the Colorectal Cancer Centre.
* Minutes must be taken of the quality circle.

Possible topics are:* Analysis of outcome quality (benchmarking)
* Interdisciplinary continuing education
* Interdisciplinary case discussions
* Structural improvements to the Centre
* Public relations work

A quality circle must have taken place by the time of initial certification. |  |  |
| 1.2.12 | Continuing education* At least 2 continuing education events a year must be offered to the CrCC network (possibly in combination with a morbidity/mortality conference or a quality circle).
* Contents, results and participation must be recorded. A continuing education plan must be submitted.
 |  |  |
| 1.2.13 | Events at the CentreEvery main cooperation partner must attend at least 2 of the CrCC's events. The following are recognised:* Quality circle
* Morbidity/mortality conference
* Continuing education courses
 |  |  |

| **1.3** **Cooperation with referring physician and aftercare** |
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| Section | Requirements | Comments by the Colorectal Cancer Centre |  |
| 1.3.1 | Cooperating referring physician A list of the cooperating physicians who most frequently refer patients must be kept up to date. The referring physicians are to be provided with information regarding cooperation within the CrCC on the following topics.Obligations of the CrCC:* Referring physicians are entitled to attend the tumour conference when their patients are presented.
* Referring physicians must be given an opportunity to present patients at the tumour conference.
 |  |  |
| 1.3.2 | Contact personReferring physicians must be provided with relevant information regarding the contact person at the Colorectal Cancer Centre (e.g. telephone number, e-mail). This can be included in the information on cooperation partners that must be published.  |  |  |
| 1.3.3 | Providing documentsThe following documents must be provided to the referring physicians as promptly as possible (as individual documents or summarised in the medical report):* Histology
* Tumour conference minutes/treatment plan
* Surgical report (optional)
* Changes to therapy

Timeframe for attending doctors to be provided with the necessary information < 2 weeks. |  |  |
| 1.3.4 | Feedback systemA written standard operating procedure (SOP) for the referring physicians must be in place for compiling, processing and responding to feedback on general and case-specific issues/questions/complications. |  |  |
| 1.3.5 | Satisfaction survey of referring physicians* Every three years, a satisfaction survey of the referring physician must be conducted. The results of this survey are to be assessed and analysed. It is possible to conduct the survey across departments.
* The first satisfaction survey of referring physicians must be completed by the time of the first surveillance audit (1 year after initial certification).
 |  |  |
| 1.3.6 | Continuing educationThe Colorectal Cancer Centre must offer physicians continuing education courses at least 2 x a year. Contents, results and participation must be recorded. |  |  |

| **1.4 Psycho-oncology**  |
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| Section | Requirements | Comments by the Colorectal Cancer Centre |  |
| 1.4.1 | Psycho-oncology – qualifications* qualified psychologists or
* physicians,

in each case with additional training in psychotherapy and specialty training in psycho-oncology.Recognised specialty training includes: “Specialty Training in Psycho-social Oncology” offered by the PSO or dapo or other adequate specialty training schemes 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 in the vicinity and without delay. The threshold for accessing such options must be low.Documentation and evaluationIn order to identify the need for treatment, screening of the level of mental stress is mandatory (see: S3 Guideline Psycho-Oncology)Psycho-oncological counselling must be continuously documented and evaluated using appropriate instruments, e.g. “Basic Documentation for Psycho-Oncology” (PO-BaDo). |  |  |
|  | Psycho-oncological counsellingThe number of patients who take up psycho-oncological counselling must be recorded. |  |  |
| 1.4.3 | Psycho-oncology-resourcesAt least 1 psycho-oncologist should be available to the Centre (name to be provided). |  |  |
| 1.4.4 | PremisesA suitable room must be made available for psycho-oncological patient meetings. |  |  |
| 1.4.5 | Organisation planTo the extent that psycho-oncological care is provided by external cooperation partners or for a number of clinical sites or hospital facilities, the provision of services is to be regulated in 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 at all stages of care (diagnosis, inpatient, post-inpatient).Goals and responsibilities of care:* Diagnostic clarification after positive screening
* 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.)
 |  |  |
| 1.4.7 | Also recommended are:* Supervision, continuing education and training measures for staff
* A conceptual discussion twice a year between psycho-oncologists, nursing and medical staff
* Regular written and, if necessary, 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. |  |  |
| 1.4.8 | Continuing educationAt least 1 specific continuing education course per employee and year (at least 1 day per year).  |  |  |

| **1.5** **Social work and rehabilitation**  |
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| Section | Requirements | Comments by the Colorectal Cancer Centre |  |
| 1.5.1 | Qualification of social services Social worker/social pedagoguePremises:A suitable room must be made available for social counselling.Resources: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 grouped centrally. An organisation plan must be available. |  |  |
| 1.5.2 | Social servicesEvery patient must have access to social service counselling during all phases of the disease in the vicinity and without delay (documentation required). The threshold to these services must be low.A record must be kept of the number of patients who receive social service counselling.  |  |  |
| 1.5.3 | 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 with applications
* Advice on outpatient and inpatient care options and referring of patients to support and specialist services
* Support with occupational and social reintegration
* Cooperation with social insurance institutions and care providers
* Intervention in crisis situations
 |  |  |
|  | Further tasks:* Public relations and networking
* Participation in department conferences and tumour boards, supervision, continuing education
* Interdisciplinary cooperation, especially with physicians, nurses, physiotherapists, psycho-oncologists, spiritual counsellors etc.
* Documentation of activities
 |  |  |
| 1.5.4 | Available servicesThe social services department must have information material or maintain a database of the cooperating institutions (e.g. oncological rehab) and other regular points of contact including the details of the contact persons. This information must be available to all social services staff. |  |  |
| 1.5.5 | Continuing educationAt least 1 specific continuing education course per employee and year (at least 1 day per year). |  |  |

| **1.6 Patient participation** |
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| Section | Requirements | Comments by the Colorectal Cancer Centre |  |
| 1.6.1 | Patient surveys:* At least every three years, over a period of 3 months, all patients (of the Centre) must have the opportunity to participate in the patient survey.
 |  |  |
| The response rate should be over 50%. |  |  |
| 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 Colorectal Cancer Centre.
* Documented assessment must take place
* Further action is to be determined on the basis of the assessment.
* The assessment can be considered in the context of a quality circle.
 |  |  |
| 1.6.3 | Patient information (general)* The Colorectal Cancer Centre must present itself and the treatment options in a comprehensive manner (e.g., in a brochure, patient folder or on a website).
* The cooperation/treatment partners must be named along with their contact details. The treatment options must be described.
* The options presented must include rehabilitation/follow-up treatment, self-help, treatment measures and alternatives.
* Information presented: for instance patient guidelines and/or S3 Guidelines of the German Guideline Program in Oncology
 |  |  |
| 1.6.4 | Discharge counsellingA session is held with each patient on discharge (short documentation/check list), in which at least the following topics are covered:* Therapy planning
* Individual follow-up plan (handover of aftercare pass)
 |  |  |
| 1.6.5 | Patient information (case related):The patient should be given the following documents:* The tumour board report/treatment plan
* Medical report/discharge report
* Follow-up plan/follow-up calendar
* Study documentation (if applicable)

Results from the tumour boardThe patient must be informed of the recommendations of the tumour board. The procedure for providing information for patients should be standardised. |   |  |
| 1.6.6 | Programmes for patientsAt least 1 x year the Colorectal Cancer Centre must hold scheduled events for patients and/or interested parties.(can be considered together with 1.6.9) |  |  |
| 1.6.7 | Complaint managementA regular system of complaint management must be in place. Patients must receive a response. Complaints are taken into consideration for the improvement of processes. |  |  |
| 1.6.8 | Self-help groupsThe self-help groups with which the Colorectal Cancer Centre actively cooperates must be named. Wherever possible, the self-help group should take into account the specific needs of colorectal cancer patients (focus on people who are similarly affected). |  |  |
| 1.6.9 | Self-help groupsThe areas of activity for self-help groups can be, for instance, patient involvement, psychosocial support or representing patients’ interests. In this role, it is possible for self-help-groups to participate actively in the audit. The self-help groups with which the Colorectal Cancer Centre actively cooperates must be named. Written agreements must be signed with the self-help groups; they should cover the following:* Access to self-help groups at all stages of therapy (first diagnosis, inpatient treatment, chemotherapy, …)
* Publication of contact data for the self-help groups (e.g. in patient brochures, CrCC website)
* Space for self-help groups to display their brochures
* Space regularly made available at the Colorectal 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 Colorectal Cancer Centre with the goal of staging and mutually coordinating joint activities and events. A record is to be kept of the results of these discussions.
* Participation of staff physicians in events staged by self-help groups
 |   |  |

| **1.7 Study management** |
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| Section | Requirements | Comments by the Colorectal Cancer Centre |  |
| 1.7.1 | StudiesAccess to studiesThe patients must have access to studies. The studies conducted at the Colorectal Cancer Centre must be compiled in a list and this list should be available to the patients (e.g. on the website) (with a short description of the study). |  |  |
| 1.7.2 | Study leader The physician who serves as the study leader must be named.Study assistant/study nurse* A study assistant is to be named for each “unit conducting studies” in the organisation chart for studies.
* The same assistant can act on behalf of a number of “units conducting studies” in parallel.
 |  |  |
| 1.7.3 | Study assistants – qualificationVocational trainingMedical training (e.g. medical-technical assistant, nurse, doctor's receptionist)TrainingThe study assistants must prove that they have specific training (benchmark: several-day course).There must be at least one registration for a course at the time of initial certification. The course must then be completed within a year. During the period of training, the investigator/study leader must compensate for the shortage of skills. |   |  |
| 1.7.4 | Study assistant – responsibilitiesThe spectrum of responsibilities must be laid down in writing (e.g. in a job description) and can include the following:* Cooperation with the physician commissioned to execute the study
* Looking after patients during the study and aftercare
* 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.
 |  |  |
| 1.7.5 | Cooperation between study assistant and investigatorThe study assistant must have direct access to the investigator or study leader (documentation e.g. via regular meetings). |  |  |
| 1.7.6 | Proportion of study patientsInitial certification: at the time of initial certification ≥ 1 patient must already have been recruited for studies (benchmark: ≤ 6 months before certification)After 1 year: at least 5% of primary casesOnly patients recruited for studies with a vote by the ethics committee count as participants (non-interventional/diagnostic studies are also recognised).All study patients can be counted when calculating the study rate (proportion of study patients in relation to all primary cases in the Centre).General conditions for defining 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 can be counted for preventive studies on colorectal cancer.
* Patients who are recruited for a number of studies in parallel can be counted more than once.
* Patients in the follow-up of a study no longer count towards the study rate.
 |  |  |
| 1.7.7 | Process description:If not centrally regulated, the standard operating procedures (SOPs) for beginning/initiating new studies and for conducting studies (including responsibilities) must be laid down for each "unit conducting a study". This comprises for example:* Selecting new studies including release decision
* Internal announcement of new studies (updating study list, etc.)
* Study organisation (special features, supervision, study patients, documentation, etc.)
* How study results are announced (e.g. staff, patients)
 |  |  |
| 1.7.8 | Introduction to a studyBefore a patient is recommended for participation in a study, this must be preceded by a patient-related discussion at the interdisciplinary tumour conference. |  |  |

**List of studies**1)

|  |  |  |  |
| --- | --- | --- | --- |
| Responsiblecooperation partner 2) | Study name | Centre’s patients | Total patients |
| recruited in 20183) | Total number recruited incl. previous years | recruited in 2018 | Total number recruited incl. previous years |
| !! indication voluntary !! |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  | Numerator: Indicator no. 6 “study rate” |  |  |  |  |

For a list of accredited studies and for the studies counted in the study rate, please go to www.studybox.de

The list of studies must be completed. Reference to the Catalogue of Requirements for Oncology Centres is not possible.

2) Responsible cooperation partner: Study unit = department that coordinates the study (e.g. for radio-oncology; haematological/oncological practice-based physician Dr. Joe Doe …). Name of cooperation partner has to be identical with name in [www.oncomap.de](http://www.oncomap.de) if it is listed there.

3) Only those study patients listed as Centre patients in the centre and who were recruited in 2018 to the study can be counted

 (no double counting of patients in more than 1 Centre).

| **1.8 Nursing care**  |
| --- |
| Section | Requirements | Comments by the Colorectal Cancer Centre |  |
| 1.8.1 | Specialised oncological nurses* At least 1 ~~active~~ specialist oncology nurse must be actively employed ~~involved~~ on day duty at the Colorectal Cancer Centre.
* Oncological nurses are to be designated by name.

The precondition for recognition as a specialist oncology nurse is● specialty training specialist oncology nurse in line with the respective federal state regulations● or with the Model Federal State Ordinance of the German Hospital Federation (*Deutsche Krankenhausgesellschaft e.V.*) ● or advanced practice nurse (master title) plus 2 years’ practical professional experience (equivalent to a full-time position) in the Colorectal Cancer Centre.Colour legend: Change to version dated 5 October 2017 |  |  |
| 1.8.2 | Responsibilities/Tasks* ~~Nursing counselling of affected individuals and their family members along the lines of nursing case management or follow-up care (outpatient care network)~~
* Specialised assessment and management of strains, symptoms and side-effects
* Individual derivation of interventions from nursing standards
* Conduct and evaluation of nursing and therapeutic measures
* Establishment of individual patient-based need for counselling
* The need for specialised counselling is to be defined already in the nursing concept of the Colorectal Cancer Centre.
* Ongoing provision of information to and counselling of patients (and their family members) throughout the entire course of the disease
* Conduct, coordination and documentation of structured counselling sessions and instructions to patients and their family members. Depending on the concept these activities may also be carried out by other long-serving specialist nurses with oncological expertise.
* Participation in the tumour board (optional)
* Initiation of and participation in multi-professional case discussions/nursing visits. The objective is to find solutions in complex nursing situations. Criteria for the selection of patients are to be laid down. At least 12 case discussions/nursing visits are to be documented for each year and Centre.

Superordinate activities:* A nursing concept is to be developed and implemented in which the organ-specific aspects of oncological nursing care are taken into account in the Colorectal Cancer Centre.
* Drawing up of specialised, in-house standards on the basis of (if possible) evidence-based guidelines (e.g. S3-LL Supportive).
* Offer of consultation with/supervision by colleagues
* Networking between oncology nurses in a joint quality circle and participation in the quality circle in the Colorectal Cancer Centre
* Interdisciplinary exchange with all professional groups involved in treatment
* ~~Counselling along the lines of continuing education (theoretical / practical) provided by colleagues~~
* ~~Planning of continuing education needs of specialised oncology nurses~~
* ~~Implementation of the latest (nursing-) scientific research findings in nursing practice~~
* Responsibility for implementing the requirements for specialist nurse responsible for carrying out chemotherapy (see Section 6)
* ~~Joint oncology nursing visits~~

Colour legend: Change to version dated 5 October 2017 |  |  |
| 1.8.3 | ~~Nursing concept~~~~A nursing concept that takes specific aspects of oncological care into consideration is to be developed and implemented.~~ Colour legend: Change to version dated 5 October 2017 |  |  |
| 1.8.4 | On-the-job trainingThe process of familiarising new members of staff must follow a specified oncological on-the-job training concept.Colour legend: Change to version dated 5 October 2017 |  |  |
| 1.8.5 | Continuing educationA plan for the continuing education of the nursing staff is to be submitted in which the training measures for the forthcoming year are set out.At least one specific continuing education course per staff member and year (at least 1 day per year) if the staff member performs tasks relevant to the quality of the centre. |  |  |
| 1.8.6 | Stomatherapy (1.8.6 – 1.8.12)StaffQualifications of management in stomatherapy Availability of qualified cover must be ensured.Members of staff have to be named.If stomatherapy services are provided externally, a cooperation agreement must be entered into.Recognised training in stomatherapy:* The following specialty training courses run by the FgSKW (Expert association for stoma, continence and wound) are recognised: nursing expert for stoma, continence and wound with 720 specialty training hours or other ~~adequate~~ comparable specialty training courses. ~~Length of specialty training at least 400 hours plus practical units (contents like “Curriculum nursing expert stoma, continence and wound) of the FgSKW excluding sections incontinence and wound.~~
* ~~Transition deadlines same as for “Specialist oncology nurses”~~

Colour legend: Change to version dated 5 October 2017 |  |  |
| 1.8.7 | Definition of the tasks of stomatherapy* Guidance, counselling and training of patients and relatives prior to hospital admission, before surgery and after discharge
* Participation in pre-operative marking (or regulated exchange of information)
* Holding stomatherapy consultation hours, if necessary
 |  |  |
| 1.8.8 | Equipment/infrastructure* Own premises
* Possibilities for presenting demo material
* Storage space for stoma care materials
 |  |  |
| 1.8.9 | Communication with other specialties* Formalised interprofessional information exchange with surgeons, radio-oncology and oncology ~~particularly in the case of infections, need for surgical corrections, …)~~

Colour legend: Change to version dated 5 October 2017 |  |  |
| 01.8.10 | Documentation of therapy* Documentation in inpatient file (separate documentation by the stoma therapists alone is not sufficient).
* Stoma pass for patients
 |  |  |
| 1.8.11 | DischargeOngoing care after discharge including provision of information to patients has to be described. |  |  |
| 1.8.12 | Continuing education* Regular training of nurses on wards and in relevant departments
* Regular continuing education courses for all other professionals involved, as well as for patients and relatives
* Active support for the work of the self-help organisations by providing technical training courses
* Regular own participation in technical and non-technical training measures
 |  |  |

| * 1. **General service areas**
 |
| --- |
| Section | Requirements | Comments by the Colorectal Cancer Centre |  |
| 1.9.1 | Pastoral services* Provision of pastoral services must be ensured at the Centre.
* Patients must have access to support (needs must be actively determined).
 |  |  |
| 1.9.2 | Nutritional counselling* Nutritional counselling must be a component of the Centre's services.
* Cooperation must be regulated in a cooperation agreement.
* Demand for nutritional counselling must be actively identified and provided for each patient.
 |  |  |
|  | The nutritional risk should be assessed for as many patients as possible at the time of their hospitalisation using the Nutritional Risk Screening (NRS) (measure by analogy to S3 Guideline) |  |  |

| 2. Organ-specific diagnostics**2.1 Consultation hours** |
| --- |
| Section | Requirements | Comments by the Colorectal Cancer Centre |  |
| 2.1.1 | Special consultation hours* What is the basis for implementation? (statutory health insurance (SHI)-authorised physician, personal authorisation, authorisation by institute or policlinic)
* At least 1 x week
 |  |  |
| 2.1.2 | Waiting times for special consultation hours* < 2 week wait for an appointment
* < 60 minute waiting time during consultation hours
 |  |  |
| 2.1.3 | Assessment of malignancy100% assessment of malignancy before radical surgical measures (any deviations must be explained) |  |  |
| 2.1.4 | Determination of cancer spreadThe following examinations are obligatory within 1 week:* Abdominal sonography
* Thorax x-ray (lung)
* CEA determination

Where necessary (also within 1 week):* Further x-rays
* CT/MRI, PET-CT (optional).
* Scintigraphy
* Urological assessment
* Gynaecological examination
 |  |  |
| 2.1.5 | Qualifications for rectal diagnosisExpertise per treatment unit in:* Rectal endosonography
* Rigid rectoscopy
* Chromoendoscopy
* Proctology

must be specified. |  |  |
| 2.1.6 | StenosisIn the event of a stenosis that is not passable by colonoscopy, another full colonoscopy must be carried out in 100% of patients within 3-6 months of surgery. The unit responsible for carrying out the colonoscopy (deadline monitoring) must be clearly defined. |  |  |
| 2.1.7 | Prevention/screening for the asymptomatic population* External or internal programmes for counselling on risk groups, lifestyles and dietary recommendations (information events, information material, etc., ...)
* Activities to increase participation in colonoscopy screening and FOBT
 |  |  |
| 2.1.8 | List of attending physicians/preventive network An up-to-date internal list must be kept of the attending doctors and members of the preventive network (distinction between attending doctors and prophylaxis).  |  |  |
| 2.1.9 | Genetic counsellingCooperation with a genetic counselling service must be regulated in a cooperation agreement.The cooperation must be documented on the basis of cases recorded during the current period.The "Centres for Familial Colorectal Cancer" designated by *Deutsche Krebshilfe* (German Cancer Aid) are particularly well suited for this task.(http://www.hnpcc.de) |  |  |
| 2.1.10 | Identification of high-risk groups, action towards such groups (familial and hereditary risk)People at risk must be identified and documented in accordance with the S3 Guideline's classification of risk as part of the admission interview to record a patient's medical history. In particular, these people are patients:* aged 50 and over
* with a previous history of colorectal carcinoma or endometrial carcinoma
* with one or more colorectal carcinomas among direct family members
* with endometrial, urothelial, small-intestine or gastric carcinoma among direct family members.
 |  |  |
|  | The algorithm for the genetic counselling procedure and the molecular pathological investigation for patients with suspected Lynch syndrome (also known as hereditary non-polyposis colorectal cancer - HNPCC) as well as case history forms for identifying high-risk persons and assessing familial and hereditary risk, information letters on the increased cancer risk and recommended screening tests for direct family members can be downloaded from: https://www.krebsgesellschaft.de/deutsche-krebsgesellschaft/zertifizierung/erhebungsboegen.html |  |  |
| 2.1.11 | Individual prevention planning * Individual prevention planning according to the S3 Guideline is mandatory in the case of identified high-risk individuals.

Procedure if Lynch syndrome is suspected:A standard operating procedure (SOP) for Lynch syndrome assessment must take account of the following:* Responsibility for identifying persons at risk
* Responsibility for initiating the primary immunohistochemical MSI examination and further follow-on analytics
* Who is in charge of MSI testing
* Responsibility for passing on information to the patient
* Responsibility for referring the patient for genetic counselling/testing
 |  |  |

| **2.2 Diagnostic procedures**  |
| --- |
| Section | Requirements | Comments by the Colorectal Cancer Centre |  |
| 2.2.1 | Qualification of diagnosticians performing colonoscopySpecialists.* At least 2 specialists(in the field of practice-based physicians 1 specialist with appropriate cover arrangements)
* Specialists must be named
* Specialist in internal medicine and gastroenterology
* Specialist in visceral surgery ~~with specialty training in special visceral surgery (~~*~~Muster-WbO 2003~~* ~~[model training ordinance], version dated 25 June 2010). Or specialist in visceral surgery or with subspecialisation in visceral surgery according to an older model training ordinance; or specialist in general surgery with the European EBSQ Coloproctology qualification.~~
* Surgeons and internists with a qualification in colonoscopy (grandfathering)or colonoscopy authorisation by the responsible health insurance fund

Experience of examining physicians* Colonoscopies: 200 patients per year.
* Polypectomies (only loop): 25 ~~50~~ patients per year.

Approval of new examining physiciansat least 200 colonoscopies and 50 polypectomies (only loop) in the last 3 years.Each colonoscopy and polypectomy must be performed or supervised by an examiner with the above-mentioned experience.Colour legend: Change to version dated 5 October 2017 |  |  |
| 2.2.2 | Performing colonoscopy* Signed documentation of briefing
* Patient monitoringPulse oximetryDocumentation using monitoring form after an examination with sedation
* Photo documentationCompleteness of the examination (ileocaecal valve, caecal pole, terminal ileum)Sites where polyps have been removed (before/after)
* Follow-up recommendationTiming of check-up colonoscopy
 |  |  |
| 2.2.3 | Complications* Information on possible complications after colonoscopy (information material)
* Data collection/evaluation of complication rates
 |  |  |
|  | Definition and presentation of indicators (see annex)* Complication rate in therapeutic colonoscopies
* Complete elective colonoscopies
 |  |  |
| 2.2.4 | Colonoscopy requirements* Complete colonoscopy with biopsy of each suspicious area, including a rectal examination
* Comparison with referrer's diagnosis
 |  |  |
| 2.2.5 | Outpatient polyp removal* Possibilities of haemostasis
* Recording of complications
* Arrangements for transfer to the CrCC's in-patient unit if polyps cannot be removed in the practice.- Contact person must be named- Definition passing on of information
 |  |  |
| 2.2.6 | Pathology report in the case of adenoma* Distinction between low-grade and high-grade intraepithelial neoplasia
* Information on the completeness of the ablation
* Pathology report in the case of carcinoma in the adenoma
* Depth of infiltration (sm/pT category)
* Histological degree of differentiation (grading)
* Presence or absence of lymph-vessel invasion (L classification)
* Assessment of resection edges (R classification)
* Low-risk/high-risk classification
 |  |  |
| 2.2.7 | Presentation at the tumour conferenceEvery carcinoma in the adenoma must be presented at the tumour conference. |  |  |
| 2.2.8 | Communication of polypectomy diagnosisFace-to-face conversation/information (not by phone) if diagnosis is malignant by the unit that performed the colonoscopy or by the family physician. |  |  |
| 2.2.9 | Infrastructure/working environment* Emergency equipmentAvailability of emergency equipment and written standard operating procedure for emergency situations.
* Equipment preparation/tracingCompliance with the Robert Koch Institute (RKI) recommendation on the preparation of flexible endoscopes (including traceable batch documentation of preparation)
 |  |  |

# Experience of examining physicians

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Unit performing the colonoscopy(practice/hospital department) | Title, name, first name | Periodfrom... until | Number of colonoscopies≥ 200 patients per year | Number of polypectomies (only loop)≥ 25 ~~50~~ patients per year |
|  |  |  |  |  |
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Colour legend: Change to version dated 5 October 2017

| 3. Radiology |
| --- |
| Section | Requirements | Comments by the Colorectal Cancer Centre |  |
| 3.1 | Specialists* At least 1 radiology specialist
* Cover arrangements with the same qualifications must be documented in writing.
* Specialists and their cover are to be designated by name.
 |  |  |
| 3.2 | Radiology technicians (MTRAs)At least 2 qualified radiology technicians must be available and designated by name. |  |  |
| 3.3 | Radiology methods/ devices to be offered * Conventional X-ray
* Spiral CT
* MRI (field strength at least 1.5 tesla)
 |  |  |
|  |
| 3.4 | Radiology standard operating procedures (SOPs)The imaging SOPs have to be described and verified that they are up to date 1 x year. |  |  |
| 3.5 | Writing findingsThe radiologist's written findings report must be available to the attending doctors no later than 24 hours after the examination. |  |  |
| 3.6 | Continuing education* A training plan for physicians and other staff members (radiological technicians) must be submitted in which the training measures for the forthcoming year are described.
* Each year at least 1 specific continuing education course (at least 1 day per year) for each employee who is responsible for quality-relevant work at the Centre.
 |  |  |

|  |
| --- |
| 4. Nuclear medicine |
| Section | Requirements | Comments by the Colorectal Cancer Centre |  |
|  | The questionnaires of the Organ Cancer Centres and Oncology Centres have a standardised table of contents. This section does not specify any technical and medical requirements for Colorectal Cancer Centres. |  |  |

| 5. Surgical oncology**5.1 Multi-organ surgical therapy** |
| --- |
| Section | Requirements | Comments by the Colorectal Cancer Centre |  |
|  | The questionnaires of the Organ Cancer Centres and Oncology Centres have a standardised table of contents. This section does not specify any technical and medical requirements for Colorectal Cancer Centres. |  |  |

| **5.2 Organ-specific surgical oncology** |
| --- |
| Section | Requirements | Comments by the Colorectal Cancer Centre |  |
| 5.2.1 | Inpatient careNames of the wards (If there are several wards, they must be centralised) |  |  |
| 5.2.2 | Post-operative careCare in the following areas must be organised according to a standard operating procedure (SOP):* Intensive care (including artificial respiration, tracheotomy, etc.)
* Physiotherapy
* Post-operative pain management
* Return to regular diet
 |  |  |
| 5.2.3 | Surgical capacityAt least 1 operating theatre must be regularly available for colorectal operations. |  |  |
| 5.2.4 | Surgical expertise at the Centre* 30 colon carcinomas
* 20 rectal carcinomas
 |  |  |
|  | Definition and presentation of indicators (see annex)* Surgical primary cases: colon
* Surgical primary cases: rectum.
 |  |  |
| 5.2.5 | Colorectal surgeons2 colorectal surgeons must be named.* Basic qualification is that of a specialist in visceral surgery with specialty training in special visceral surgery (*Muster-WbO* 2003 [Model Training Ordinance], version dated 25 June 2010). The following are also recognised: qualification as a specialist in visceral surgery or with subspecialisation in visceral surgery according to an older model training ordinance or specialist in general surgery with the European EBSQ Coloproctology qualification. The qualifications of a specialist in general surgery or specialist in visceral surgery according to *MWbO* 2010 or later are not recognised.
 | The surgeons’ names have to be given in the table “Colorectal Surgeons” at the end of this section. |  |
|  | Expertise per colorectal surgeon (primary cases)15 colon carcinomas per year10 rectal carcinomas per year* Approval of new colorectal surgeonsAt least 20 rectal and at least 30 colorectal carcinomas cumulatively over the last 3 years (documented in surgical reports).
* AssistantsRecognition as an assistant is only possible in the context of training (no parallel recognition of cases if there are 2 colorectal surgeons).
* All patients in the CrCC must be operated on by one of these surgeons either directly or under his/her supervision (second surgeon).
 |  |  |
|  | Senior colorectal surgeon (optional/alternative)* Maximum 1 senior colorectal surgeon per Centre (not per clinical site)
* An application for assessment of qualification must be submitted to OnkoZert
* Centre is responsible for appointment (dependent on a positive qualification assessment by OnkoZert)
* Annual rotation is possible
 |  |  |
|  | Expertise of senior colorectal surgeon (primary cases)* In the case of appointment45 colon carcinomas and 30 rectal carcinomas in the last 5 years
* In the case of extensionQualification certificate valid for 5 years; requirement for extension is 45 colon carcinomas and 30 rectal carcinomas in the last 5 years
 |  |  |
| 5.2.6 | Emergency service* Emergency services (e.g. intestinal obstruction) must be organised according to a standard operating procedure(SOP)
* Deployment planning of qualified personnel (duty roster/on-call service)
 |  |  |
| 5.2.7 | Surgically removed lymph nodesOperation must be performed in an oncologically correct manner (e.g. at least 12 lymph nodes). Any deviations must be discussed with the pathologist. |  |  |
| 5.2.8 | Induction of new staff membersInduction of new staff members must follow a systematic, documented system that imparts knowledge on the Centre in relation to the respective area of activity.This induction must be carried out within 3 months of the commencement of employment. |  |  |
| 5.2.9 | Information/dialogue with patients:Sufficient information must be provided on diagnosis and therapy planning, and a dialogue must take place. This encompasses *inter alia*:* Presenting alternative treatment concepts
* Offering and arranging second opinions
* Discharge consultations as standard

The type and manner of information provision and dialogue has to be described in general terms. It has to be documented in medical reports and minutes/records in a patient-based manner. |  |  |
| 5.2.10 | Continuing education:* A training plan for medical and nursing staff must be submitted setting out the training measures planned for a one-year period:
* Each year at least 1 specific continuing education course (at least 1 day per year) for each employee who is responsible for quality-relevant work at the Centre.
 |  |  |

# Colorectal surgeons

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Title, name, first name | Has basic qualification 1)yes/no | Senior colorectalsurgeon 2)yes/no | Period 3)from … to | Number of ops 4)colon ≥ 15 | Number of ops 5)rectum ≥ 10 | Clinical site/hospital 4) |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

1. Precondition for basic qualification (in line with CR Section 5.2.5): specialist for visceral surgery with additional specialty training visceral surgery (Model Specialty Training Ordinance 2003, status 25.06.2010). The following are deemed to be equivalent: specialist for visceral surgery or focus visceral surgery in line with older Model Specialty Training Ordinances or specialist for general surgery with the European qualification EBSQ Coloproctology. The following qualifications are not recognised: specialist for general surgery or specialist for visceral surgery in line with the Model Specialty Training Ordinance 2010 or later.
2. Prerequisite for senior colorectal surgeon (as defined in CR EB 5.2.5): positive qualification assessment by OnkoZert and appointment by the Colorectal Cancer Centre (max. 1 senior colorectal surgeon per centre)
3. The period is usually the previous calendar year (= indicator year); deviations e.g. as a result of staff turnover or appointment of colorectal surgeons during the year; if compliance is unclear, 1 colorectal surgeon can also be listed twice for 2 periods (e.g. last calendar year and current year up to the date of submission of CR)
4. There are no requirements for the annual expertise of senior colorectal surgeons.
5. Relevant in the case of Centres with several clinical sites or if a surgeon is regularly active as a surgeon at several clinical sites/hospitals (surgical expertise must be documented separately for each clinical site/hospital)

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| 6. Medical oncology / systemic therapy**6.1 Medical oncology** |
| --- |
| Section | Requirements | Comments by the Colorectal Cancer Centre |  |
|  | The questionnaires of the Organ Cancer Centres and Oncology Centres have a standardised table of contents. This section does not specify any technical and medical requirements for Colorectal cancer centres. |  |  |

| **6.2** **Organ-specific systemic therapy** |
| --- |
| Section | Requirements | Comments by the Colorectal Cancer Centre |  |
| 6.2.1 | Specialist’s qualifications Specialist in internal medicine and haematology/oncology, or specialist in internal medicine and gastroenterology, or specialist in radiotherapyThe radiation oncologist can conduct chemotherapy in the context of radio-chemotherapeutic approaches.Cover with the above-mentioned qualification must be named.The specialists mentioned here must actively carry out the drug-based tumour therapy. Responsibility must not be delegated to doctors who do not have the above-mentioned qualification. |  |  |
| 6.2.2 | Specialised nursesRequirements for the specialised nurse responsible for administering chemotherapy:* At least 1 year of professional experience in oncology
* 50 chemotherapy applications/annually (estimations possible for initial certification, documentation must be provided in the following years in the audits)
* Proof of training according to the recommendations of the Conference of Oncological Nursing and Paediatric Nursing Care (*Konferenz Onkologischer Kranken- und Kinderkrankenpflege* – KOK), administration of cytostatics by specialised nurses (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 | On-call service/availability medical staff* Must be reachable 24h/7d outside working hours, including weekends and public holidays
* Access to the therapy data must be possible during 24h/7d availability
 |  |  |
| 6.2.4 | Qualification of the treatment unit* At least 200 patients with chemotherapy per year or at least 50 patients with specific indication (colon/rectum)
* Counting method: chemotherapy per patient (consisting of a number of cycles or applications)
* If the required number is not met by the treatment unit, it is not possible to document the expertise in a cooperation (each treatment unit needs to documents its qualifications separately)
 |  |  |
| 6.2.5 | Structural information per treatment unit* Number of outpatient therapy places
* Number of in-patient therapy places
 |  |  |
| 6.2.6 | Basic diagnostics: laboratoryBasic diagnostics including laboratory for emergencies must be possible 24h/7d. If not possible in-house, documentation of external cooperation agreement for 24h/7d laboratory must be provided.  |  |  |
| 6.2.7 | Basic diagnostics: imagingCooperation for emergency and routine diagnostics in sonography and radiology. If imaging is not possible 24h/7d, proof of a cooperation agreement for 24h/7d emergency diagnostics. |  |  |
| 6.2.8 | Treatment plan/minutes of tumour conference* The therapeutic approach should be based on the treatment plans and/or the recommendations of the tumour conference.
* Treatment plan/minutes of tumour conference must be part of the patient-related documentation.
* If there is any deviation from the recommended therapy plan, this must be presented at the tumour conference.
 |  |  |
| 6.2.9 | Procedures for systemic therapy* The creation of therapy procedures and the modification of existing ones must be regulated by an approval system.
* The pharmacist can be consulted before the therapy procedures are approved or modified.
* The therapy procedures must be protected from unintended change.
* The therapy procedures are comparable between the outpatient and inpatient units.

Therapy plans* Every systemic therapy plan must be drawn up according to a therapy procedure.
* The therapy planning must be reviewed and released.
 |  |  |
| 6.2.10 | Preparation of cytostatics* Cytostatics are produced in a pharmacy in line with the legal requirements (e.g. German Drugs Act (*Arzneimittelgesetez* - AMG), GMP, GCP, Eudralex (vol. 10)). If this pharmacy does not belong to the Centre, a supply contract must be entered into.
* Consultations with the pharmacy must be possible during the period when the therapy is being applied. 24-hour on-call duty is necessary in the case of hospitalised patients.
* Standard operating procedures (SOPS) must be drawn up.
 |  |  |
| 6.2.11 | Standard operating procedures (SOPs)* All phases of the procedure to be followed for drug-based oncological therapy (start, implementation and conclusion of therapy) must be described.
* Supportive measures in line with guidelines for the individual therapeutic concepts must be described and documented in detail in a patient-based manner.
 |  |  |
| 6.2.12 | Standards on concomitant and secondary diseasesStandards must be drawn up for treating concomitant and secondary diseases, in particular extravasation, infections and thromboembolic complications. |  |  |
| 6.2.13 | Emergency treatmentEmergency equipment and a written standard operating procedure (SOP) plan must be available for emergency situations. |  |  |
| 6.2.14 | Information for/dialogue with the patient For the purposes of diagnosis and therapy planning, sufficient information must be conveyed and an appropriate dialogue must be conducted. This includes:* A 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 medical report and in minutes taken/notes. |  |  |
| 6.2.15 | Information on the implementation and planning of therapyEvery time a systemic therapy is applied, the patient and/or the follow-up doctors are subsequently informed about the current therapy status and planning (blood tests, etc.), for instance in an aftercare pass.Writing medical reportsAfter completion of systemic therapy (final application), the follow-up or attending physician receives the final report within 7 days. |  |  |
| 6.2.16 | Induction of new staff membersInduction of new staff members must follow a systematic, documented system that imparts knowledge on the Centre in relation to the respective area of activity.This induction must be carried out within 3 months of commencement of employment.  |  |  |
| 6.2.17 | Continuing education:* A plan for the continuing education of physicians, nursing and other staff members is to be submitted in which the training measures for the forthcoming year are described.
* At least 1 specific continuing education course per staff member and year (duration > 0.5 days per year) if the staff member performs tasks relevant to the quality of the Colorectal Cancer Centre.
 |  |  |

| **7.** **Radiation oncology** |
| --- |
| Section | Requirements | Comments by the Colorectal Cancer Centre |  |
| 7.0 | The technical and medical requirements are summed up in the “Catalogue of Requirements Radio-oncology” in a cross-organ manner. Independently of the number of Organ Cancer Centres/Modules that work with a radio-oncology unit, this “Catalogue of Requirements Radio-oncology” is only to be processed and 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..  |  |  |

| 8. Pathology |
| --- |
| Section | Requirements | Comments by the Colorectal Cancer Centre |  |
| 8.0 | The technical and medical requirements are summed up in the “Catalogue of Requirements Pathology” in a cross-organ manner. Independently of the number of Organ Cancer Centres/Modules that work with a pathology unit this “Catalogue of Requirements Pathology” is only to be processed and 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..  |  |  |

| **9. Palliative care and hospice work** |
| --- |
| Section | Requirements | Comments by the Colorectal Cancer Centre |  |
| 9.1 | Palliative care* Cooperation agreements with various providers of specialised inpatient and outpatient palliative care and inpatient hospices must be documented. Regional concepts (based on the treatment path of the S3 Guideline for palliative care, p. 174) for integrating palliative care must be described 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 number of palliative medical cases must be documented.
* The group of terminally ill patients must be defined. These patients have to be informed about palliative care options at an early stage.
* In order to identify the symptoms and stress experienced by patients on a palliative ward, validated screening tools (e.g. MIDOS, iPOS) should be used repeatedly.
* Access to palliative care can be offered at the same time as tumour therapy. The procedure in the Centre is to be described in a standard operating procedure (SOP).
* The number of primary cases with terminal cancer must be documented.
 |  |  |
| 9.2 | Supportive therapy and alleviation of symptoms in the palliative situation* The options for supportive/palliative inpatient therapy must be described (process description/algorithm).
* A pain therapist must be available. The pain therapy standard operating procedure (algorithm) must be described and verified for the documented cases during the period under examination.
* Access to nutritional counselling must be described and documented in recorded cases for the period under review.
* 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** |
| --- |
| Section | Requirements | Comments by the Colorectal Cancer Centre |  |
| 10.1 | Tumour documentation systemA 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 tumour documentation system in the cancer registry and/or CentreA data set 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 of the Association of Population-based Epidemiological Cancer Registries in Germany (GEKID). The Centre must ensure that data are passed on promptly to the competent cancer registry. Any existing laws for notification deadlines of the federal states *(Länder)* are to be complied with. |  |  |
| 10.2 | Period covered by the dataFull data are to be presented for the previous calendar year. |  |  |
| 10.3 | Cooperation with the cancer 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 should be fed with data from the competent cancer registry. The data must be transmitted to the cancer registry continuously and fully.
* The presentation of the Data Sheet and outcome quality should be ensured by the cancer registry to the extent that the data concern cancer registration.

Until the competent cancer registry can fulfil these requirements, additional or alternative solutions are to be employed by the Centre. The Centre bears responsibility for any external solution that is not working.   |  |  |
| 10.4 | Documentation officerAt least 1 documentation officer must be designated as the person responsible for tumour documentation including name/function. Tasks documentation officer:* Safeguarding and monitoring the rapid, full, complete and correct transfer and quality of the patient data of relevance for certification by all cooperation partners to the cancer registry
* Motivation of specialty units that participate in the cancer registry (pathology reports, radiotherapeutic and medicinal treatments) to engage in trans-sectoral cooperation
* Training and support for the staff responsible for data collection
* Regular analysis of the evaluations particularly over the course of time
 |  |  |
| 10.5 | Provision of resources:The necessary staff capacities (e.g. 0.5 full-time equivalent (FTE) per 200 primary cases and 0.1 FTE per 200 aftercare cases) are to be made available to carry out the tasks of documentation and data collection (e.g. by a cancer registry).  |  |
| 10.6 | Selection optionsThe following selection options must be available in the tumour documentation system:* Year of birth
* TNM classification or comparable classification and prognosis factors
* Therapy forms (surgery, radiotherapy, hormone therapy, immunotherapy, chemotherapy)
* Date of recurrence/metastasis
* Mortalities
* Follow-up status (last update)
 |  |  |
| 10.7 | Indicators of outcome quality/scale of aftercare data:Kaplan-Meier curves:* Overall survival (OAS) for all patients in the subgroups in line with pT categories, stages
* Metastasis-free survival for all patients and subgroups
* Progression-free survival (PFS) or disease-free survival for all patients and subgroups
* Local recurrence rate for all patients and subgroups
* Survival after progression (PDS)
* Initially, all years of birth are to be grouped together (3 years). In the case of larger patient and outcome numbers, several years of birth can be evaluated separately.
* A table with patient numbers and survival data is a component of each Kaplan-Meier curve.
 |  |  |
| 10.8 | Evaluation of the data* The depiction of outcome quality (see point above) must be possible for recertifications.
* Data in the tumour documentation system must be evaluated at least 1x year in line with the corresponding indicators.
* If benchmarking/an annual report is offered, the benchmarking results are to be taken into account in the analysis.
* Discussion of the results must be interdisciplinary and within the network of Colorectal Cancer Centres.
 |  |  |
| 10.9 | Requirements for the follow-up of patients included in the outcome quality matrix |  | From 1 January. 2012 |  |  |
| Minimum requirement for successful recertification |  | ≥ 80% |  |
| Recertification or maintenance of certification only subject to certain conditions (e.g. shorter period of validity, concept for raising the response rate, etc.) |  | 60 – 79% |  |
| Recertification or maintenance of certification not given. |  | < 60% |  |

**Data Sheet/Outcome quality matrix**

A structured EXCEL template is available for Centres to record indicators and outcome quality data. This EXCEL template also includes an automatic calculation of data quality. Only indicators presented on the basis of the EXCEL template provided by OnkoZert can be used for certification. No changes may be made to the EXCEL template.

The EXCEL template is available for download at [www.ecc-cert.org](http://www.ecc-cert.org) and [www.onkozert.de/en](http://www.onkozert.de/en).

|  |  |  |
| --- | --- | --- |
| **Period** | General information for processing the Annex* The actual figures (no estimates) must be entered.
* Data must always relate to a calendar year.
* Data must not be more than 1 year old (data from 2008 are not acceptable for an audit in 2011).
* If the "targets" are not reached for one item, an explanation must be given at the appropriate point in the questionnaire.
 | Definition of periods for initial certification* At the time of initial certification, data must be available for at least a 3-month period (ideally for a full year); data on primary cases (CR 5.2.4), surgical interventions per surgeon (CR 5.2.5) and experience of examining physicians (CR 2.2.1) are always required for a full year.
* If a shorter period than a full calendar year is shown, this period may not date back more than 4 full months (related to the certification date).
* The period selected must consist of whole months (select complete quarters if possible).
 |

|  |  |  |
| --- | --- | --- |
| **Primary case definition** |  |  |
| The total number of primary cases for the Colorectal Cancer Centre consists of the total sum of the primary case types mentioned below.* A malignant diagnosis (adenocarcinoma) must have been given.
* Requirements for the tumour conference, tumour documentation and follow-up apply in full.

Primary case types* Only endoscopic
* Surgical
* Palliative (not surgical)
* Watch and wait (not surgical-curative, not endoscopic)
 | Primary case definition (only endoscopic)* No additional removal of tumour by surgery
* Time of counting = endoscopic ablation

Primary case definition (surgical)* Malignant first diagnosis of rectum (up to 16 cm from the anocutaneous line)/colon
* Resectioning surgery (artificial anus alone is not sufficient).
* Transanal wall resection
* Time of counting = date of surgical tumour removal

Primary case definition: palliative (not surgical)* No surgical tumour removal planned
* Time of counting = date of histological finding

Primary case definition watch and wait* In the case of watch and wait patients these are newly diagnosed rectal carcinomas which, after radiotherapy and/or chemotherapy pre-treatment and full clinical remission, are not surgically treated initially\*. If these patients undergo secondary surgery in the event of tumour recurrence or for other reasons, they are counted as primary surgical cases.
* Time of counting: histological result
 | The following (*inter alia*) are not recognised as surgical primary cases:* Anal carcinomas (C21)
* Palliative bypass operation
* High-grade intraepithelial neoplasias
* Palliative stoma application
* Neoadjuvant chemotherapy(tumour yet to be surgically removed)
* Port placements(tumour yet to be surgically removed))
* Recurrence
* Metastatic surgery
 |