Catalogue of Requirements for Colorectal Cancer Centres

All of the requirements for Colorectal Cancer Centres 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 Commission for Colorectal Cancer Centres

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

Members (in alphabetical order):

ABO - Working Group on Imaging in Oncology
ADT - Working Group of German Tumor Centres
ADDZ - Working Group of DKG-Certified CRCC Centres
AIO - Working Group on Internal Oncology
AOP - Working Group on Oncological Pathology
APM - Working Group on Palliative Medicine
PRIO - Working Group on Prophylaxis and Integrative Medicine in Oncology
PSO – Working Group on Psychological Oncology
ARO - Working Group on Radiological Oncology
ASO – Working Group on Social Work in Oncology
ASORS - Working Group for Supportive Care in Oncology, Rehabilitation and Social Medicine
AUO - Working Group on Urological Oncology
BNHO – Professional Association of Hematologists and Oncologists
BDI - Professional Association of German Internists
BDVST – Prof. Ass. of German Radiation Therapists
BNG - German Association of Practicing Gastroenterologists
BVGD - Gastroenterology Association
BDP - Professional Association of German Pathologists
CAO - Working Group on Surgical Oncology
CAO-V - Working Group on Surgical Oncology – Visceral Surgery
DGHO–German Society for Haematology and Oncology
DGN – German Society for Nuclear Medicine
DGP – German Society for Palliative Medicine
DGP – German Society of Pathology
DGVS - German Society for Digestive and Metabolic Diseases
DGAV-Germ. Society f. General a. Visceral Surgery
German ILCO
DeGIR – German Society of Interventional Radiology
DRG - German Radiological Society
DEGRO - German Society for Radiation Oncology
DVSG - German Association for Social Work in Health Care
KOK - Conference on Oncological Nursing
Joint Project on Familial Colorectal Cancer

Valid from July, 14 2016

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

The modifications served to integrate:
The Interdisciplinary S3 Guideline for the Diagnosis, Treatment and Follow-up of Colorectal Carcinoma

Information on the Colorectal Cancer Centre

Colorectal Cancer Centre (CrCC) _____

Director of the Centre _____

Coordinator of the Centre _____

This questionnaire is valid for

Location 1 (hospital/ location) _____ ☐

Location 2 (hospital/ location) _____ ☐

only in the case of cooperating CrCCs

QM system certification

QM standard ☐ ISO 9001 ☐ KTQ ☐ Joint Commission

QM certification agency _____

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 contained information is published on **www.oncomap.de**. The centre is obliged to report all new and also all invalid cooperations. All other updates (change in management, contact data etc.) must be corrected in the “master data sheet and must be regularly updated before the annual audit/monitoring. This master data sheet can be requested from OnkoZert.

Compilation/Update

The electronically generated questionnaire serves as a basis for the CrCC's certification. The correctness and completeness of the information provided here has been reviewed.

The data on outcome quality relate to the following calendar year: ☐

Date on which the questionnaire was compiled /updated: ☐

Table of contents

1. General information on the Colorectal Cancer Centre

1.1 Structure of the network

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
1.1.1	The following persons in authority must be named: • Director(s) of the centre (max. two directors per centre, one of whom is the designated contact person) • Coordinator of the centre Centre Coordinator – tasks • Coordination of internal/ external audits • Monitoring technical 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 partners Visceral surgery, gastroenterology, radiotherapy, haematology/oncology, pathology, radiology Cooperation partners Psycho-oncology, social services department, stomatherapy, nutritional counselling, physiotherapy, genetics, pain therapy and self-help group, palliative care		
1.1.3	Cooperation agreements Cooperation agreements must be signed with cooperating treatment partners. These partners must verifiably meet the appropriate technical 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). 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 the 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 annually provide the relevant data		

1. General information on the Colorectal Cancer Centre

1.1 Structure of the network

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	• Compliance with the confidentiality obligation • Participation in further-training 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") • Compulsory participation • Ensuring the availability of a specialist in the discipline obliged to take part • Rules on participation and coordination if there is more than one cooperation partner per discipline (see also "Interdisciplinary cooperation") Colour legend: Addition to version dated 15 October 2015		
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. via the Internet). This also includes naming all internal/ external cooperation partners with the following information: - Name and address of the cooperation partner - Contact person with phone number/ email address		
1.1.5	Strategy planning/reporting An annual review at the management level is recommended. It should taking into consideration e.g. 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). • A later certification must examine in particular the actions/reactions of the Centre as a result of the proceedings. • The period presented is the calendar year relevant to the audit.		

1. General information on the Colorectal Cancer Centre

1.1 Structure of the network

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	• Non-compliance will be rated as a deviation.		

1.2 Interdisciplinary cooperation

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
1.2.0	Number of primary cases		
	Surgical expertise of the centre • 30 colon carcinoma • 20 rectum carcinoma See last page of this catalogue for a detailed definition of a primary case.	Indicator Sheet	
1.2.1	Frequency/participants The tumour board must meet at least once a week. Tumour board participants Participation in the tumour board on the specialist level is mandatory for the following specialties and must be documented by an attendance list: • visceral surgery • gastroenterology • radiotherapy • haematology/oncology • pathology • radiology Metastases: a correspondingly specialised surgeon 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.		
1.2.2	Tumour conferences: general requirements Several cooperation partners If a number of cooperation partners are designated for the specialty, then the attendance of one representative is sufficient, provided that a regular exchange of information takes place between them (e.g., via quality circles). Regardless of this, each main cooperation partner must participate in a tumour board at least once a month. ~~Videoconference~~ ~~Videoconferences can, under certain circumstances, serve as a substitute for personal participation (requirements see "Basisinformation Zertifizierung" OnkoZert). Telephone conferences without video are not an alternative.~~ Web-/online-conference If web-conferences are held, sound and presented material must be transmitted. It must be ensured, that every main cooperation partner is able to present documents and images. Telephone conferences without image material are not permitted. Colour legend: Addition to version dated 15 October 2015		

1.2 Interdisciplinary cooperation

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
1.2.3	Indicator on presentations at tumour conference • Pre-therapeutic case presentation • Post-operative case presentation All cases should be presented in a pre-therapeutic/post-surgical tumour conference (in accordance to the indicator definition). If no presentation took place, this must be justified and explained in the patient's records.	Indicator Sheet	
NEW	Presentation at tumour conference Patients with rectal carcinoma should be presented again at the tumour-conference after the neoadj. therapy with full clinical remission to discuss a “Watch and Wait-Strategy”. Colour legend: Addition to version dated 15 October 2015		
1.2.4	Patients with (local) recurrence/distant metastases • 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 procedure descriptions. • Patients with primarily unresectable liver metastasis should be presented regularly for evaluation at the tumour conference during systemic treatment.		
1.2.5	Demonstration using picture material Patient-related picture material (e.g. pathology, radiology) on advanced tumours must be available at the conference, and suitable technical equipment must be available for presenting the picture 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 relapses 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, among other things, of a written, interdisciplinary treatment plan ("minutes of the tumour conference"). • The minutes of the tumour conference must be reliably available at all times for all main cooperation partners and can simultaneously represents the doctor's letter. • The "minutes of the tumour conference" should be automatically generated from the tumour documentation system.		

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1.2 Interdisciplinary cooperation

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	• The outcome of the tumour conference must be recorded in the tumour documentation system.		
1.2.8	Participation in the tumour conference as advanced training Participation 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 2 nurses per treatment unit • Participation in the tumour conference is recognised as further training for the above functions/professions.		
1.2.9	Therapy deviations • In principle, the treatment plans and/or recommendations of the tumour board are binding. • In case any deviation from the original therapy plan or divergence from the guidelines is ascertained, they must be noted and assessed. Measures to avoid such divergence are to be introduced, depending on the cause. • It must be noted if the patient refuses to begin or prematurely interrupts treatment (despite an existing indication).		
1.2.10	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 is 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 deceased after surgery/ after intervention must be subject to the conference. • The minutes of the MM conferences must be taken Colour legend: Addition to version dated 15 October 2015		
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 per year. • A list of participants is kept. • The quality circles must lead to unequivocal results (actions, decisions) which seem likely to significantly develop/improve the Colorec-		

1.2 Interdisciplinary cooperation

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	tal Cancer Centre. • Minutes of the quality circle must be taken. Possible topics are: • Analysis of outcome quality (benchmarking) • Interdisciplinary further training • Interdisciplinary case discussions • Structural improvements to the Centre • Public relations work A quality circle must have taken place by the time of the first certification.		
1.2.12	Further training • At least 2 further-training events a year must be offered for the CrCC network (possibly in combination with Morbidity/mortality conference or quality circle). • Contents, results and participation must be recorded. A further-training plan must be submitted. Colour legend: Addition to version dated 15 October 2015		
1.2.13	Events at the Centre Every main cooperation partner must take part in least 2 of the CrCC's events. The following are recognised: • Quality circle • Morbidity/mortality conference • Further-training courses		

1.3 Cooperation with referring physician and follow-up care

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
1.3.1	Cooperating referring physician A list of the cooperating physicians who most frequently refer must be kept up to date. The referring physicians are to be provided with information regarding cooperation within the CrCC on the following topics. Obligations of the CrCC: • Referring physicians are entitled to take part in 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 person Referring physicians must be provided with relevant information regarding the contact person at the Colorectal Cancer Centre (e.g., telephone, e-mail). This can be included in the information on cooperation partners that must be published.		

1.3 Cooperation with referring physician and follow-up care

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
1.3.3	Providing documents The following documents must be provided to the referring physicians as soon as possible (as individual documents or summarised in the doctor's letter): • Histology • Tumour conference minutes/treatment plan • Operation report (optional) • Changes to the therapy Time frame until the attending doctors are provided with the necessary information < 2 weeks.		
1.3.4	Feedback system A written procedure for the referring physicians must be in place for compiling, processing and responding to feedback on general and case-specific sues/questions/complications		
1.3.5	Survey of referring physicians' satisfaction • Every three years, a survey of the referring physician's satisfaction must be conducted. The result of this survey is to be assessed and analysed. It is possible to realize the survey across departments. • The first survey of referring physicians' satisfaction must be completed by the time of the first surveillance audit (1 year after the initial certification). Colour legend: Addition to version dated 15 October 2015		
1.3.6	Further training The Colorectal Cancer Centre must offer physicians advanced-training courses at least 2 x per year. Contents, results and participation must be recorded.		

1.4 Psycho-oncology

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
1.4.1	Psycho-oncology – qualification • Qualified psychologists or • Physicians, In each case with additional training in psychotherapy and further training in psycho-oncology. Recognised further training includes: "Further Training in Psycho-social Oncology" offered by the PSO or dapo or other adequate further training with > 100 teaching units. This can be verified by a special training curriculum. Representatives of other psychosocial professions (such as qualified social pedagogues, social workers etc.) can be accredited when they		

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1.4 Psycho-oncology

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	can provide proof of the additional qualifications cited above. In such cases an individual examination is required. The provision of psycho-oncological care by social services, self-help groups or spiritual counsellors is insufficient.		
1.4.2	Psycho-oncology – Availability and access Every patient must have access to psycho-oncological counselling nearby and without delay. The threshold for accessing such options must be low. Documentation and evaluation In order to identify the need for treatment, a screening regarding the level of mental stress is obligatory (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 counselling The number of patients who make use of psycho-oncological counselling must be recorded.	Indicator Sheet	
1.4.3	Psycho-oncology-resources At least 1 psycho-oncologist should stand at the disposal of the centre (designation by name).		
1.4.4	Premises A suitable room must be made available for psycho-oncological patient meetings.		
1.4.5	Organisation plan To the extent that psycho-oncological care is provided by external cooperation partners or for a number of locations or hospital facilities, the provision of services is to be regulated by an organisational plan displaying information that includes the availability of resources and local presence.		
1.4.6	Psycho-oncology – responsibilities Psycho-oncological care should be offered to patients in all phases of care (diagnosis, inpatient, post-inpatient). Goals and responsibilities of care: • Diagnostic clarification after positive screening • Prevention/treatment of subsequent psychosocial 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:		

1.4 Psycho-oncology

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	• Supervision, further training and training measures for the staff • A conceptual discussion twice a year between psycho-oncologists, nursing and medical staff • Regular written and, if needed, verbal feedback to the physician in charge of treatment regarding psycho-oncological activities (e.g., in a consultant's report or documentation in the medical file). • Participation in tumour boards as needed • Close cooperation with social services Psycho-oncologists should present their work within the centre at least twice a year.		
1.4.8	Further/advanced training At least 1 specific further/advanced training course per employee per year (at least 1 day per year).		

1.5 Social work and rehabilitation

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
1.5.1	Qualification of social services Social worker/social pedagogue Premises: A suitable room must be made available for social counselling. Resources: At least 1 social worker must be available for the centre. Organisation plan: If social services are provided for a number of departments or locations or in the form of outpatient counselling, the performance of these services must be regulated by an organisational plan delineating the availability of resources and local presence.		
1.5.2	Social services Every patient must have access to social service counselling during all phases of the disease nearby and without delay (proof required). The threshold to these services must be low. 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		

1.5 Social work and rehabilitation

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	law, benefits in lieu of pay, retirement benefits etc.) • Provide support with applications • Give advice on outpatient and inpatient care options and refer patients to support and specialist services • Provide support with vocational and social reintegration • Cooperate with social insurance institutions and care providers • Intervention in crises situations		
	Further tasks: • Public relations and networking • Participation in department conferences and tumour boards, supervision, further training • Interdisciplinary cooperation, especially with physicians, nurses, physiotherapists, psycho-oncologists, spiritual counsellors etc. • Documentation of activities		
1.5.4	Available services The social services department must keep information material or a database of the cooperating institutions (e.g. oncological rehab) and other regular points of contact including the contact data of the relevant people. These informations must be available to all social-service staff.		
1.5.5	Further/advanced training At least 1 specific further/advanced training course per employee per year (at least 1 day per year).		

1.6 Patient participation

Chapt.	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 • A documented assessment must take place • Further action is to be determined on the basis of the assessment • The evaluation 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 comprehensively (e.g., in a brochure, patient folder or on		

1.6 Patient participation

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	a website). • The cooperation/treatment partners must be named along with their contact information. The treatment options must be described. • The options presented must include rehabilitation/follow-up treatment, self-help, treatment measures and alternatives. • Information presented: e.g. Patient-Guidelines and/or S3-Guidelines of the German Guideline Program in Oncology		
1.6.4	Discharge counselling A meeting is held with each patient on discharge (short documentation/check list), in which at least the following topics are mentioned: • Therapy planning • Individual follow-up plan (handover of aftercare pass)		
1.6.5	Patient information (case related): The patient should receive the following documents: • The tumour board report/treatment plan • Doctor's report/discharge report • Follow-up plan/follow-up calendar • Study documentation (if applicable) Results from the tumour board The patient must be informed of the recommendations of the tumour board. The procedure of providing information for patients should be standardised.		
1.6.6	Programmes for patients At least 1 x per 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 management A regular system of complaint management must be in place. Patients must receive a response. Complaints are taken into consideration in improving processes.		
1.6.8	Self-help groups The self-help groups with which the Colorectal Cancer Centre actively cooperates must be named. Wherever possible, the self-help group should observe the specific needs of colon-cancer patients (focus on people who are similarly affected).		
1.6.9	Self-help groups The area of activity for self-help groups can be e.g. 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		

1.6 Patient participation

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	the self-help groups; they should cover the following: • Access to self-help groups in all phases of therapy (first diagnosis, inpatient treatment, chemotherapy, …) • Publication of contact data for the self-help groups (e.g., in patient brochures, CrCC website) • Space for self-help groups to lay out 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 such discussions. • Participation of staff physicians in events staged by self-help groups		

1.7 Study management

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
1.7.1	Studies Access to studies The 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 commissioner The physician who serves as the study commissioner must be named. Study assistant/study nurse • A study assistant is to be named for each “unit conducting studies” in the organigram for studies. • The same assistant can act on behalf of a number of “units conducting studies” in parallel.		
1.7.3	Study assistants – qualification Vocational training Medical training (e.g. medical-technical assistant, nurse, doctor's receptionist) Training The study assistants must prove that they have		

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1.7 Study management

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	specific training (benchmark: course over several days). There must be at least one registration for a course at the time of the first 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 – responsibilities The spectrum of responsibilities must be determined in writing (e.g., by means of a job description) and can include the following: • Cooperation with the physician commissioned to conduct the study in its execution • Look after patients during the study and follow-up care • Organising and coordinating diagnostic and laboratory measures, the investigational medicinal product and the sending of samples • Collection and documentation of all data relevant to the study • Preparing and overseeing the audit and inspections by authorities • The study assistant's activities can be combined with other activities such as tumour documentation.		
1.7.5	Cooperation between study assistants and investigator The investigator or study leader must be directly available for the study assistants (proof e.g. via regular meetings).		
1.7.6	Proportion of study patients Initial certification: at the time of the first certification ≥ 1 patient must already have been recruited for studies (benchmark: ≤ 6 months before certification) After 1 year: at least 5% of primary cases Only patients recruited for studies with a vote by the ethics commission count as participants (non-interventional/diagnostic studies are also recognised). All study patients can be counted in calculating the study rate (proportion of study patients in relation to all primary cases at the centre). General conditions for defining the study ratio: • 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.		

1.7 Study management

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	• 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 ratio.		
1.7.7	Process description: If not centrally regulated, the processes 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 incl. decision to release • 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 study Before a patient is recommended to participate in a study, this must be preceded by a patient-related discussion at the interdisciplinary tumour conference.		

Study list

Unit conducting the study	Study	Centre´s patients		Patients overall	
		Recruited in 2016	Recruited overall, incl. previous years	Recruited in 2016	Recruited overall, incl. previous year
			!! information optional !!		
Numerator indicator No. 6 „Participation in studies“					

For a list of accredited studies go to www.studybox.de

1.8 Nursing Care

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
1.8.1	Specialised oncological nurses • At least one active oncological nurse must be involved at the centre. • Oncological nurses are to be designated by name. At the time of initial certification, the previous submission of at least one application for training as an “oncological nurse” is required. In this case, it must be explained how the “responsibilities/tasks” described in the following are to be performed during the training period. Cooperation		

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1.8 Nursing Care

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	with previously trained oncological nurses, who provide support in performing tasks, is recommended during the training phase. After 3 years, an oncological nurse must be documented. Training of oncological nurses According to the outline of an ordinance formulated for the Länder by the Deutsche Krankenhausgesellschaft e.V. (German Hospital Society) or the laws of the Land in question or as an academically trained nurse (Master of Oncology).		
1.8.2	Responsibilities/tasks • Counselling the patients and their relatives on care options in the sense of case management and/or transitional care (to the network of outpatient care) • Assessment and management of stress, symptoms and adverse effects • Counselling colleagues with regard to further training (theoretical/practical) • Planning for further training required by oncological nurses • Implementation of the most recent findings in (nursing) research in actual nursing practice • Joint oncological care visits • Responsibility for implementing the requirements for nurses administering chemotherapy (see chapter 6)		
1.8.3	Nursing concept A nursing concept that takes specific aspects of oncological care into consideration is to be developed and implemented.		
1.8.4	On-the-job training concept The process of familiarising new members of staff must follow a specified on-the-job training concept.		
1.8.5	Further and additional training A plan for the further qualification of the nursing staff is to be submitted in which the qualification measures for the coming year are described. At least one specific further/additional training measure per staff member per year (at least 1 day per year), to the extent that the staff member performs tasks relevant to the quality of the centre.		
1.8.6	Stomatherapy (1.8.6 – 1.8.12) Staff Qualifications of management in stomatherapy Availability of qualified stand-ins must be ensured Members of staff have to be named If stomatherapy services are provided externally, a cooperation agreement must be concluded. Recognised training in stomatherapy: • Advanced training courses provided by FgSKW and others are recognised. Advanced		

1.8 Nursing Care

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	training takes at least 400 hours plus practical units (courses like the FgSKW's "Curriculum for nursing experts in stomatherapy, continence, wounds", excluding the sections on incontinence and wounds). • Transitional periods are identical to those for "oncology nurses"		
1.8.7	Definition of the tasks of stomatherapy • Guidance, counselling and training of patients and relatives before 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 in surgery • Regulated information to surgeon, especially in the event of infections, need for surgical corrections, etc.		
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	Discharge Ongoing care after discharge incl. provision of information to patients has to be decribed		
1.8.12	Further/advanced training • Regular training of nurses on wards and in relevant departments • Regular further-training 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		

1.9 Areas of general care

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
1.9.1	Chaplain services • Provision of chaplain 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		

1.9 Areas of general care

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	• Cooperation must be regulated by a cooperation agreement • Demand for nutritional counselling must be actively determined and provided for each patient		
new	The Nutritional Risk should be assessed by as many patients as possible at the time of their hospitalization using the Nutritional Risk Screening (NRS) (measure by analogy to S3-Guideline) Colour legend: Addition to version dated 15 October 2015		

2. Organ-specific diagnostics

2.1 Consultation hours

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
2.1.1	Special consultation hours • What is the basis for implementation? (SHI-authorised physician, personal authorisation, authorisation by institute or policlinic) • At least 1 per week		
2.1.2	Waiting times for special consultation hours • < 2 weeks wait for an appointment • < 60 minutes waiting time during consultation hours		
2.1.3	Assessment of malignancy 100% assessment of malignancy before radical surgical measures (any deviations must be explained)		
2.1.4	Determination of cancer spread The 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 rectum diagnosis Expertise per treatment unit in: • Rectal endosonography • Rigid rectoscopy • Chromoendoscopy • Proctology has to be specified		
2.1.6	Stenosis In the event of a stenosis that is not passable by colonoscopy, another full colonoscopy must be		

2. Organ-specific diagnostics

2.1 Consultation hours

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	carried out in 100% of patients within 3-6 months after 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 own 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	Indicators on early detection/prevention • CRCC patients with a positive family history • Genetic counselling • Immunhistochemical determination DNA-mismatch repair protein MLH1, MSH2, MSH6 and PMS2		
2.1.9	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 (distinguishing between attending doctors and prophylaxis).		
2.1.10	Genetic counselling Cooperation with a genetic counselling service must be regulated by a cooperation agreement. The cooperation must be proofed on basis of documented cases in the current period. The "Centres for Familial Colorectal Cancer" designated by *Deutsche Krebshilfe* (German Cancer Aid) are particularly well suited for this purpose. (http://www.hnpcc.de)		
2.1.11	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 determine 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, urothel, small-intestine or gastric carcinoma among direct family members		
	The algorithm for the procedure of genetic counselling and the molecular pathological investigation for patients with suspected HNPCC, as well		

2. Organ-specific diagnostics

2.1 Consultation hours

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	as case-history forms for identifying high-risk persons and assessing familial and hereditary risk, and information letters on the increased cancer risk and recommended screening tests for direct family members are to download from: https://www.krebsgesellschaft.de/deutsche-krebsgesell-schaft/zertifizierung/erhebungsboegen.html		
2.1.12	Individual prevention planning • Individual prevention planning according to the S3 guideline is compulsory in the case of identified high-risk people. Procedure if Lynch-Syndrom is suspected: A procedure description for Lynch-Syndrom assessment must take account of the following points: • Responsibility for identifying persons at risk • Responsibility for initiating the primary immunohistochemically MSI examination and further following analytics • Who is in charge of MSI testing • Responsibility for passing on information to the patient • Responsibility for referring the patient to genetic counselling/testing		

2.2 Diagnostic procedures

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
2.2.1	Qualification of diagnosticians performing colonoscopy Specialists. • At least 2 specialists (in the GP field 1 specialist with appropriate stand-in arrangements) • Specialists must be named - Specialist in internal medicine and gastroenterology - Specialist in visceral surgery with additional 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 re-		

2.2 Diagnostic procedures

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	sponsible health insurance Experience of examiner(s): • Colonoscopies: 200 patients per year. • Polypectomies: 50 patients per year. Approval of new examiners at least 200 colonoscopies and 50 polypectomies in the last 3 years. Each colonoscopy and polypectomy must be performed or supervised by an examiner with the above-mentioned experience.		
2.2.2	Performing colonoscopy • Signed documentation of briefing • Patient monitoring Pulse oximetry Documentation using monitoring form after an examination with sedation • Photo documentation Completeness of the examination (ileocecal valve, caecal pole, terminal ileum) Places where polyps have been removed (before/after) • Follow-up recommendation Timing of check-up colonoscopy		
2.2.3	Complications • Information on possible complications after colonoscopy (info material) • Data collection/evaluation of complication rates		
	Definition and presentation of indicators (see annex) • Complication rate in therapeutic colono-scopies • Complete elective colonoscopies		
2.2.4	Demands on colonoscopy • Complete colonoscopy with biopsy on each suspicious area, including a rectal examina-tion • Comparison with referrer's diagnosis		
2.2.5	Outpatient polyp removal • Possibilities of haemostasis • Recording of complications • Arrangements on transfer to the CrCC's in-patient sections if polyps cannot be removed in practice. - Contact person must be named - It has to be defined how information is passed on		
2.2.6	Pathological findings in the case of adenoma • Distinction between low-grade and high-grade intraepithelial neoplasia • Information on the completeness of the abla-tion •		

2.2 Diagnostic procedures

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	Pathological findings 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 conference Every carcinoma in the adenoma must be presented at the tumour conference.		
2.2.8	Communication of polypectomy diagnosis Face-to-face conversation/information (not by phone) if diagnosis is malignant by the facility that conducted the colonoscopy or by the family doctor.		
2.2.9	Infrastructure/working environment • Emergency equipment Availability of emergency equipment and written procedure for emergency situations. • Equipment preparation/tracing Compliance with the RKI recommendation on the preparation of flexible endoscopes (including traceable batch documentation of preparation)		

Experience of examiners

Unit performing the colonoscopy (practice/hospital department)	Title, name, first name	Period from... until	Number of colonoscopies ≥ 200 patients per year	Number of polypectomies ≥ 50 patients per year

Colour legend: Addition to version dated 15 October 2015

3. Radiology

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
3.1	Specialists • At least 1 specialist in radiology • Stand-in arrangements assuring the same qualifications must be documented in writing • Specialists and their stand-ins 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		

3. Radiology

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	• Conventional X-ray • Spiral CT • MRI (field strength at least 1.5 tesla)		
	In the MRI/thin-slice CT findings report Information on distance to mesorectal fascia (quality indicator derived from the guideline) Colour legend: Addition to version dated 15 October 2015	Enter the value for the indicator under "Quality Indicators"	
3.4	Radiology process descriptions (SOPs) The imaging processes and check topicality 1 x annually have to be described.		
3.5	Writing findings The radiologist's written findings report must be available to the attending doctors no later than 24 hours after the examination.		
3.6	Further/additional training • A qualification plan for physicians and other staff members (radiological technicians) must be submitted in which the qualification measures for the coming year are described • Each year at least 1 specific further/advanced training course (at least 1 day per year) for each employee who is responsible for quality-relevant work at the Centre.		

4. Nuclear medicine

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	The questionnaires of the organ cancer centres and oncological centres have a standardised table of contents. The present chapter does not issue technical requirements for Colorectal cancer centres.		

5. Surgical oncology

5.1 Multi-organ surgical therapy

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	The questionnaires of the organ cancer centres and oncological centres have a standardised table of contents. The present chapter does not issue technical requirements for Colorectal cancer centres.		

5.2 Organ-specific surgical oncology

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
5.2.1	Inpatient care Names of the wards (If there are several wards, they must be centralised)		

5.2 Organ-specific surgical oncology

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
5.2.2	Post-operative care Care in the following areas must be organised according to a procedure description: • Intensive care • Physiotherapy • Post-operative pain management • Return to regular diet		
5.2.3	Surgical capacity At least 1 operating theatre must be regularly available for colorectal operations.		
5.2.4	Operative expertise at the Centre • 30 colon carcinomas • 20 rectal carcinomas		
	Definition and presentation of indicators (see annex) • Operative primary cases: colon • Operative primary cases: rectum.		
5.2.5	Colorectal surgeons 2 colorectal surgeons must be named. • Basic qualification is that of a specialist in visceral surgery with additional training in special visceral surgery (*Muster-WbO* 2003 [model training ordinance], version dated 25 June 2010). Also recognised is the 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 written in the table "Colorectal-Surgeons" at the end of this chapter.	
	<u>Expertise per colorectal surgeon (primary cases)</u> 15 colon carcinomas per year 10 rectal carcinomas per year • Approval of new colorectal surgeons At least 20 rectal and at least 30 colorectal carcinomas cumulatively over the last 3 years (evidenced by operating reports). • Assistants Recognition as an assistant is only possible in the context of training (no parallel recognition of cases if there are 2 colorectal surgeons). • All patients at 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 of 1 senior colorectal surgeon per centre (not per location) • Assessment of qualification must be applied for from OnkoZert • Appointment is the Centre's own responsibility (depends on a positive qualification as-		

5.2 Organ-specific surgical oncology

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	sessment by OnkoZert) • Annual rotation is possible		
	Expertise of senior colorectal surgeon (primary cases) • In the case of appointment 45 colon carcinomas and 30 rectal carcinomas in the last 5 years • In the case of extension Qualification 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 procedure description • Deployment planning of qualified personnel (duty roster/on-call service)		
5.2.7	Definition and presentation of indicators (see annex) • Postoperative morbidity - revision surgery: colon - revision surgery: rectum - post-operative wound infection - anastomotic leaks: colon (quality indicator derived from the guideline) - anastomotic leaks: rectum (quality indicator derived from the guideline) • Post-operative mortality • Local R0 resection: colon • Local R0 resection: rectum • Quality of the TME rectal preparation • Pre-operative marking of the stoma position (quality indicator derived from the guideline)		
5.2.8	Indicators on resection of liver metastases • Primary resection of liver metastases (UICC stage IV CRCC) • Secondary resection of liver metastases (UICC stage IV CRCC)		
5.2.9	Surgically removed lymph nodes Operation must be performed oncologically correct (e.g. at least 12 lymph nodes). If there is a deviation from this, it must be discussed with the pathologist.		
5.2.10	On-the-job training for new members of staff Familiarising new members of staff must follow a systematic, documented system that teaches knowledge on the Cente in relation to the staff's respective scope of activity. This familiarising process must be carried out within 3 months after employment begins.		
5.2.11	Information/dialogue with patients: Sufficient information must be provided on diagnosis and therapy planning, and a dialogue must take place. This incorporates, among other things:		

5.2 Organ-specific surgical oncology

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	• Presenting alternative treatment concepts • Offering and arranging second opinions • Discharge interviews as standard The type and manner of information provision and dialogue has to be described in general terms. It has to be documented in doctor's letters and minutes/records in a patient-centred manner.		
5.2.12	Further/advanced training: • A qualification plan for medical and nursing staff must be submitted showing the training measures planned for a one-year period: • each year at least 1 specific further/advanced training 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	Senior colorectal surgeon [1)] yes/no	Period [2)] from … to	Number of ops [3)] colon ≥ 15	Number of ops [3)] rectum ≥ 10	Location/hospital [4)]

1) Prerequisite for senior colorectal surgeon (described acc. to EB 5.2.5): positive qualification assessment by OnkoZert and appointment by the CrCC (max. 1 senior colorectal surgeon per centre)
2) 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 EB)
3) There are no demands on the annual expertise for senior colorectal surgeons
4) Relevant in the case of centres with several locations or if a surgeon is regularly active as a surgeon at several locations/hospitals (operative expertise must be documented separately for each location/hospital)

6. Medical/ Internal oncology

6.1 Haematology and oncology

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	The questionnaires of the organ cancer centres and oncological centres have a standardised table of contents. The present chapter does not issue technical requirements for Colorectal cancer centres.		

6.2 Organ-specific oncologic pharmacotherapy

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
6.2.1	Specialist's qualifications Specialist in internal medicine and haematol-		

6.2 Organ-specific oncologic pharmacotherapy

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	ogy/oncology, or specialist in internal medicine and gastroenterology, or specialist in radiotherapy The radiation oncologist can conduct chemotherapy in the context of radio-chemotherapeutic approaches. A stand-in 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 without the above-mentioned qualification.		
6.2.2	Specialised Nurses Requirements for the specialised nurse responsible for administering chemotherapy: • At least 1 year of professional experience in oncology • At least 50 chemo therapy applications (estimations possible for initial certification, proof must be provided in the following years) • Proof of training according to the recommendations of the KOK (Handlungsempfehlungen der KOK, Applikation von Zytostatika durch Pflegefachkräfte (Recommendations of the Conference of Oncological Nurses and Children's Nurses on the Application of Cytostatic Agents by Nursing Personnel)) • Active integration in the implementation of requirements for the emergency treatment and therapy of comorbid conditions and sequelae. • The provision of advice and/or information to the patient by nurses must be documented.		
6.2.3	On-call service/availability medical staff • Must be reachable 24-hours a day outside of working hours, including weekends and public holidays • Access to the therapy data must be possible during 24-hour 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 proof the expertise in a cooperation (every treatment unit needs to proof it´s qualification 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: laboratory		

6.2 Organ-specific oncologic pharmacotherapy

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	Basic diagnostics including laboratory for emergencies must be possible 24 hours. If internal not possible, proof of external cooperation agreement for 24 hrs. laboratory.		
6.2.7	Basic diagnostics: imaging Cooperation for emergency and routine diagnostics in sonography and radiology. If imaging is not possible 24 hours, proof of a cooperation agreement for 24 hours emergency diagnostics.		
6.2.8	Definition and presentation of indicators (see annex) • Adjuvant chemotherapy: colon (UICC stage III) (quality indicator derived from the guideline) • Neoadjuvant chemotherapy: rectum (UICC stage II and III) (quality indicator derived from the guideline)		
6.2.9	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.		
6.2.10	Procedures for systemic therapy • The creation of therapy procedures and the modification of existing ones must be regulated by a release system. • The pharmacist can be consulted before the therapy procedures are released 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 plan of a systemic therapy must be made according to a therapy procedure. • The therapy planning must be reviewed and released.		
6.2.11	Preparation of cytostatics • Cytostatics are produced in a pharmacy in line with the legal requirements (e.g. AMG, GMP, GCP, Eudralex (vol. 10)). If this pharmacy does not belong to the Centre, a supply contract must be concluded. • 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. • Procedure descriptions on manufacturing must be drawn up.		

6.2 Organ-specific oncologic pharmacotherapy

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
6.2.12	Process descriptions • All phases of the procedure to be followed for drug-based oncological therapy (beginning, 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-centred manner.		
6.2.13	Standards on concomitant and secondary diseases Standards must be drawn up for treating concomitant and secondary diseases, in particular extravasation, infections and thromboembolic complications.		
6.2.14	Emergency treatment Emergency equipment and a written plan of procedure must be available for emergency situations.		
6.2.15	Information for/dialogue with the patient In view of the diagnosis and the therapy planning, sufficient information must be conveyed and an appropriate dialogue must be conducted. This includes: • The description of possible treatment concepts • Offering and arranging for a second opinion • Discharge consultation as a standard procedure The general way in which information is provided and the dialogue conducted must be described. They are to be documented in relation to the patient in the doctor's report and in minutes taken/notes.		
6.2.16	Information on the implementation and planning of therapy Every time a systemic therapy is applied, the patient and/or the follow-up doctors are subsequently informed about the current therapy status and the further planning (blood tests,...), e.g. via an aftercare pass. Writing doctor's letters After completion of the systemic therapy (final application), the follow-up or attending doctor receives the final report within 7 days.		
6.2.17	On-the-job training for new members of staff Familiarising new members of staff must follow a systematic, documented system that teaches knowledge on the Centre in relation to the staff's respective scope of activity. This familiarising process must be carried out within 3 months after employment begins.		

6.2 Organ-specific oncologic pharmacotherapy

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
6.2.18	Further/advanced training: • A plan for the further qualification of physicians, nursing and other staff members is to be submitted in which the qualification measures for the coming year are described. • At least 1 specific further/additional training measure per staff member per year (duration > 0.5 days per year), to the extent that the staff member performs tasks relevant to the quality of the Colorectal cancer centre		

7. Radiation oncology

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
7.0	Alternatively, the requirements for radiation oncology can be set forth in the “Questionnaire on Radio-oncology”. This is recommended especially when the provider of radiation oncology is designated as a cooperation partner for additional certified organ cancer centres (one description for multiple organs). In this case, the “Catalogue of requirements on Radio-oncology” serves as an annex to this questionnaire and is, therefore, to be submitted along with it. The catalogue of requirements “Radio-oncology” can be downloaded under http://www.onkozert.de/praxen_kooperationspartner.htm.		
7.1	Specialists. • At least two specialists • Specialists are to be designated by name In combined therapies (e.g. percutaneous radiation/brachytherapy/IORT, simultaneous radiochemotherapy), medical and medical-physical responsibility must not change. If a change in this responsibility is unavoidable for organisational reasons, the treatment plan must be agreed by all responsible caregivers prior to treatment and be signed by them.		
7.2	Medical physicist • At least one medical physicist must be available in the department on workdays • Medical physicists and their backups are to be designated by name • A back-up plan must be formulated in writing		
7.3	Medical-technical radiology assistant (MTRAs) • At least two qualified MTRAs must be available per accelerator • 2 MTRAs must be present per linear accelerator during radiotherapy • A back-up plan must be formulated in writing		
7.4	Accessibility/obligation to be on call A specialist in radiation therapy must be present		

7. Radiation oncology

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	during working hours and have 24/7 on-call duty outside of working hours (including weekends and holidays), if necessary via cooperation		
7.5	Required technical equipment and radiation treatment plan/techniques • One accelerator with >= 6 MV photons with at least 6-15 MeV electrons • Description of the technical equipment • A contingency plan (tandem solution) formulated in writing Radiation treatment planning: • Therapy simulator or virtual simulation • Planning CT • 3D radiation treatment planning system		
7.6	Vacant (table of contents unchanged, therefore not deleted)		
7.7	On-site inspection by medical authorities (according to Art. 83 of the Radiation Protection Ordinance) • The assessment by the medical authorities must correspond with Category I (no defects), II (low-degree defect, new on-site inspection in 2 years) or degree III (once only). • Any deficiencies determined must be eliminated. • The medical authorities must be informed of the participation in an oncological centre or an organ cancer centre and of the corresponding quality requirements before the on-site inspection.		
7.8	Waiting time • Period between patient's first contact and the initial presentation: < 10 Days • Period between the initial presentation and beginning of treatment, provided there are no medical reasons to the contrary: < 4 weeks • The actual overall treatment time should not exceed the prescribed overall treatment time by more than 10%. Interruptions in radiotherapy for medical reasons or by the patient constitute exceptions • The waiting periods are to be surveyed by random sampling and statistically assessed (recommendation: assessment period 4 weeks per year).		
7.9	Consultation hours • It must be ensured that every patient is presented to a physician before the beginning of a radiation treatment series • At least one additional contact with a physician must be documented at the radiotherapy facility during a radiation treatment series		
7.10	Case-related information/dialogue with the patient In view of the diagnosis and therapy planning,		

7. Radiation oncology

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	sufficient information must be conveyed and a consultation with the physician must be held. This includes: • Structured information regarding the indication, effects, adverse effects and course of therapy • Presentation of alternative treatment concepts • Offer and arrangement of second opinions • Discharge consultations as a standard procedure • The patient must be provided with written information on what precautions to take during and after radiotherapy. All discussions with patients are to be documented for each individual patient.		
7.11	Documentation/tumour monitoring • The doses that are prescribed are to be recorded according to the guidelines. A documented reason must be given for deviations from the prescribed dose. • Support measures in keeping with the guidelines are to be described for individual therapy concepts and documented in detail in relation to the individual patient.		
7.12	Radiation processes The specifications of the radiation protection laws and the “Guideline for Radiation Protection in Medicine” must be implemented.		
7.13	Simultaneous chemoradiotherapy The procedure for sequential/simultaneous chemoradiotherapy has to be described. If the radiation oncologist does not perform the simultaneous chemoradiotherapy him/herself, the responsibilities for the treatment of side effects, interruptions of radiotherapy, dose specification and dose reductions must be clearly defined beforehand. The joint treatment plan must also be signed by a specialist in radiotherapy in every case. Treatment documentation: Blood-count checks and laboratory tests must be documented by the radiation oncologist during radio-chemotherapy.		
7.14	Palliative radiotherapy • In cases of palliative radiotherapy, the intention of the therapy (local control or solely to alleviate symptoms) must be documented. • Palliative medical measures, as well as the development of symptoms and adverse effects, must be described especially in relation to therapy concepts intended to alleviate symptoms and documented in relation to the individual patient. • Simultaneously administered pharmacother-		

7. Radiation oncology

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	apy (e.g. pain or tumour-specific therapy) must be documented.		
7.15	Follow-up care The process of tumour-specific follow-up care must be described (taking the "Guideline for Radiation Protection in Medicine" into consideration). This means: • Appointment schedule/reminder (follow-up care calendar) • Type of documentation Information regularly relayed to the centre's internal tumour documentation system in cases of recurrences, metastases or death of the patient		
7.16	Treatment plan/minutes of the tumour board • In principle, therapeutic procedures should be in accordance to the treatment plans and/or recommendations by the tumour board. • Any deviations from the recommended therapy plan must be presented to the tumour board and must be documented in the patient´s record.		
7.17	Further/additional training: • A plan for the further qualification of the physicians, nursing and other staff is to be submitted in which the qualification measures planned for the coming year are described. • At least one further/additional training measure per staff member per year (duration > 0.5 days per year), to the extent that the staff member performs tasks relevant to the quality of the Colorectal Cancer Centre		

8. Pathology

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
8.0	Alternatively, the requirements for pathology can be described in the "Questionnaire Pathology". This is recommended especially when the provider of pathology services is also designated as a cooperation partner by other organ cancer centres (one description for multiple organs). In this case the "Catalogue of requirements Pathology" must be included as an annex to this questionnaire and is, therefore, to be submitted along with it. The "Catalogue of requirements Pathology" can be downloaded under http://www.onkozert.de/praxen_kooperationspartner.htm.		
8.1	Specialists • At least 2 qualified specialists for pathology		

8. Pathology

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	• The specialists are to be designated by name Specialists (director and at least 1 other specialist).		
8.2	Medical-technical assistants (MTAs) A sufficient number of qualified MTAs must be available.		
8.3	Number of cases: Pathological Institute At least 15,000 histological (incl. cytological) examinations per year (case numbers, documentation via journal entry number) • At least 50 examined colon/rectum biopsies • At least 50 examined colon/rectum specimens		
8.4	Procedures that must be available • Immunohistochemical examinations • In-situ hybridisation • Molecular pathology These special services can only be delegated to pathological institutes. The institutes should have a recognised QM system or a valid accreditation or be able to document successful participation in round robin tests.		
8.5	Autopsies The CrCC must be fully able to perform autopsies in-house without restriction. Proof of an autopsy room must be provided.		
8.6	Frozen section analysis (cryosection) • The technical and organisational prerequisites for frozen section analysis must be fulfilled. • An operational cryostat must be available • Virtual slide telepathology is not acceptable		
8.7	Retention time • Archiving of paraffin blocks ≥ 10 years, • Retention of wet tissue ≥ 4 weeks. • Cryopreservation should also be possible		
8.8	External quality assurance Regular (every 2 years) successful participation in external quality-assurance measures (e.g. QUIP), especially interlaboratory tests (e.g. RAS testing if performed at the CrCC) or peer review processes • Facilitation of a second consultant opinion at the request of the hospital or the patient or when a final assessment is not possible. • The external assessment and approval of a QM system is recommended.		
8.9	Parameters for frozen sections Time required and time measured from arrival in pathology (in min.) to announcing the result (benchmark max. 30 minutes) Evaluation of time needed: min./max./range figure		
8.10	Pathology reports		

8. Pathology

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	Pathology reports for the macroscopic report and the microscopic examination must contain 100% of the information required by the guideline. The following information is required: • Site • Tumour type acc. to WHO classification • Tumour invasion depth (pT classification) • Status of the regional lymph nodes (pN classification) • Number of lymph nodes analysed • Number of lymph nodes affected • Grading • The pathologist must always indicate the resection edges and the minimum safety distance (quality indicator derived from the guideline); (deviations must be explained). • R classification • Lymph/blood-vessel invasion • TME quality (quality indicator derived from the guideline)/CRM quality • Degree of tumour regression in the case of neoadjuvant therapy (optional).		
8.11	Time until histological result • Biopsy specimens/polyps: max. 3 working days • Surgical specimens max. 5 working days		
8.12	Microsatellite instability If the examination is not conducted directly by the pathologist, a cooperation agreement must be concluded.		
8.13	Lymph nodes • At least 12 lymph nodes must be examined in the surgical specimen (quality indicator derived from the guideline) The lymph nodes must be examined in accordance with the guideline "Recommendations on the pathological-anatomical diagnosis of colorectal carcinoma" issued by the Professional Association of German Pathologists and the German Society for Pathology.		
8.14	Further training • A plan for the further qualification of physicians is to be submitted in which the measures planned for the coming year are described. • At least 1 specific further/additional training measure per staff member per year, to the extent that the staff member performs tasks relevant to the quality of the Colorectal Cancer Centre.		

9. Palliative care and hospice work

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	

9. Palliative care and hospice work

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
9.1	Palliative care • Cooperation agreements with various providers of specialised in- and outpatient palliative care and inpatient hospices must be documented. Regional concepts (on basis of 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 paths of access and the palliative medical care must be described (SOP, structure and process).~~ • 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 symptoms and stress of patients on a palliative ward, validated screening tools (e.g. MIDOS, iPOS) should be used repeatedly. • The access to the palliative care can be offered at the same time as the tumour-therapy. The procedures in the centre are to be described in SOP. • The number of primary cases with terminal illness has to be documented. • ~~Standards (e.g. interdepartmental) for the care of terminally ill patients and ethical guidelines must be described and adhered to.~~ Colour legend: Deletion from /addition to version dated 15 October 2015		
9.2	Supportive therapy and alleviation of symptoms in palliative care • The options for supportive/palliative inpatient therapy must be described (process description/algorithm). • A pain therapist must be available. Pain therapy procedures (algorithm) must be described and verified for the documented cases during the period under examination • Access to nutritional counselling must be described • Access to psycho-oncological and psychosocial care as well as to spiritual counselling must be described. • A cooperation agreement must be signed when required services are provided by cooperation partners		

10. Tumour documentation/outcome quality

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
10.1	Tumour documentation system A system of tumour documentation that contains patient data for a period of at least 3 months must be in place at the time of initial certification Name of the centre's tumour documentation system or of the responsible cancer registry The dataset used must correspond with the basic dataset used by the Arbeitsgemeinschaft Deutscher Tumorzentren (Working Group of German Tumour Centres or ADT).		
10.2	Period represented by the data The data must represent the whole of the previous calendar year		
10.3	Cooperation with the cancer/tumour registry • The data must be transmitted to the cancer registry continuously and completely. • The requirements for the quality of the results and the tumour documentation should be fulfilled by the cancer/tumour registry. • For as long as the responsible clinical cancer registry is unable to fulfil the requirements, supplementary or alternative solutions should be employed by the Colorectal Cancer Centre.		
10.4	Documentation commissioner At least 1 documentation commissioner must be designated as the person responsible for tumour documentation. The documentation commissioner is responsible for the following: • Ensuring and monitoring the rapid, complete and correct compilation of patient data • Qualification and support of the personnel responsible for data collection • Regular compilation of assessments		
10.5	Provision of resources: Sufficient resources must be provided for the collection of data and other documentation tasks. Benchmark for the definition of resources Per 200 primary cases (per annum): 0.5 FTE Per 200 follow-up cases: additional 0.1 FTE		
10.6	Selection options The following selection options must be given in the tumour documentation system: • Year of birth/age • Diagnosis (TNM classification, etc.) • Status: palliative, curative • Forms of therapy (surgery, chemotherapy, radiation therapy, study participation) • Date of the recurrence/metastases		

10. Tumour documentation/outcome quality

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
	• Survival data (5 years)		
10.7	Indicators on outcome quality/scope of follow-up data: • Overall survival by stage • Relapse-free survival by stage and type of surgery • Distant-metastasis-free survival by stage • Survival after relapse by stage Development of follow-up data must be shown for each patient.		
10.8	Record of follow-up It has to be described how the follow-up data are collected. Follow-up data must be collected at least 1 x per year for each patient covered by the tumour documentation system. The relevant figures must be made available for the first time 1 year later at the 1st surveillance audit. Data to be collected via: • Residents' registration office • Clinical/population-based cancer registry • Follow-up - at the hospital - from cooperation partners - from referrers - follow-up coordination offices • Writing to patients Mortality must be determined before a letter is written to the patients (consideration for family members) Evaluation/preparation of the data The necessary data can be collected by different methods. The Centre must also be able to submit a summary evaluation of the follow-up data in order to gain certification.		
10.9	Evaluation of the data • Data in the tumour documentation system must be evaluated and analysed at least 1 x per year • The data published in the quality report pursuant to section 137 of the German Social Security Code (SGB V) must be checked for comparability and a corresponding evaluation presented. • In cases of participation in benchmarking, the results of the benchmarking are to be taken into consideration during the analysis. • Concrete action must be taken on the basis of the analysis. • Discussion of the results must be interdisciplinary.		

10. Tumour documentation/outcome quality

Chapt.	Requirements	Comments by the Colorectal Cancer Centre	
10.10	Demands on following up the patients covered in the outcome-quality matrix	From 1 Jan. 2012	
	Minimum requirement for successful recertification.	≥ 80%	
	Recertification or maintenance of certification only on certain conditions (e.g. shorter period of validity, concept for raising the response rate, etc.)	60 – 79%	
	Recertification or maintenance of certification not issued.	< 60%	

Indicator 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. The EXCEL template must not be changed.

The EXCEL template is available for download at www.krebsgesellschaft.de and www.onkozert.de.

Period	General information for processing the Annex • The actual figures (no estimates) must 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 in an item, it must give an explanation at the appropriate point in the questionnaire	Definition of periods for first certifications • At the time of the first certification, data must be available at least for a 3-month period (ideally for a full year); data on primary cases (EB 5.2.4), operations per surgeon (EB 5.2.5) and experience of examiners (EB 2.2.1) are always required for a full year • If a shorter period than a full calendar year is shown, this period must not be more than 4 full months in the past (relative 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 sums of the primary-case types mentioned below. • A malignant diagnosis (adenocarcinoma) must have been given • Demands on the tumour conference, tumour documentation and follow-up apply in full Primary case types • Only endoscopic • Operative • Palliative (not operative) • Watch and wait (not operative curative, not endoscopic)	Primary case definition (only endoscopic) • No additional removal of tumour by surgery • Time of counting = endoscopic ablation • ~~OPS 5-482ff = endoscopic primary case: rectum (incl. full-wall excision)~~ Primary case definition (operative) • Malignant first diagnosis of rectum (up to 16cm 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 operative) • No surgical tumour removal planned • Time of counting = date of the histological finding Primary case definition watch and wait • In the case of watch and wait patients these are newly diagnosed rectal carcinomas which, after radiotherapeutical and/or chemotherapeutical pre-treatment and full clinical remission, are not surgically treated initially*. If these pa-	The following (among other things) are not recognised as operative 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)) • Relapse • Metastatic surgery

	tients undergo secondary surgery in the event of tumour recurrence or for other reasons, they are counted as primary surgical cases. ~~in the same interval, they cannot be counted as a new primary case.~~ • Time of counting: Histological result ~~* within 6 months after start of therapy.~~	

Colour legend: Deletion from /addition to version dated 15 October 2015.
Colour legend: Primary case definition watch and wait modified to version dated 14 July 2016.

