**Catalogue of Requirements Radio-oncology**

This "Catalogue of Requirements (CR) Radio-oncology" sets out the requirements which must be met by the cooperation partner radio-oncology in Oncology Centres and/or Organ Cancer Centres certified by the German Cancer Society (*Deutsche Krebsgesellschaft* – DKG). The Catalogue of Requirements Radio-oncology is, therefore, an annex to the Catalogue of Requirements Oncology Centres and the organ-specific Catalogues of Requirements.

In principle, in addition to the requirements listed here, the requirements laid down in the Guidelines on the Radiation Protection Act (*Strahlenschutzverordnung* – StrlSchV) (RS ll 4 – 11432/1) must also be met. Particular attention must be paid to the staffing and technical requirements.

|  |  |
| --- | --- |
| Name of the department/doctor's surgery1) |  |
| Head of department/doctor's surgery |  |
| Contact certification |  |
| Address |  |
| Tel. |  |
| Email |  |

|  |  |
| --- | --- |
| 1) | Definition clinical site: The clinical site is determined by the address. 1 clinical site is 1 cooperation partner of the Centre, irrespective of any existing different organisational/legal forms (doctor's surgery, part of the clinic, medical centres…). In the registration as a cooperation partner only 1 name may be used (artificial name possible from a combination of the legal forms). |

**Scope of radio-oncology (clinical site-related)**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | OC |  | MHNT |  | MPED |  | MNOC |  | MSAR |  | BC |  | GC |  | CC |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | MA |  | ML |  | MG |  | MP |  | ME |  | HC |  | SC |  | LC |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | PC |  | MB |  | MT |  | MK |  | MPEN |  |  |  |  |  |  |

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| --- | --- | --- |
| **Preparation / Updating of the Catalogue of Requirements Radio-**  **oncology** |  |  |
| **List of Abbreviations**   * **Oncology Centre** = OC; **Visceral Oncology Centre** = VC; **Uro-oncology Centre** = UC * **Organ Cancer Centres:** BC = Breast Cancer Centre, CC = Colorectal Cancer Centre, GC = Gynaecological Cancer Centre,HC= Centre for Haematological Neoplasia, SC = Skin Cancer Centre, LC = Lung Cancer Centre, PC= Prostate Cancer Centre * **Modules:** MA = Anal Cancer Centre, MHNT = Head and Neck Tumour Centre, ML = Liver Cancer Centre, MG = Gastric Cancer Centre, MNOC = Neuro-oncology Centre, MP = Pancreatic Cancer Centre, MPED = Paediatric Cancer Centre, ME = Esophageal Cancer Centre, MSAR = Soft Tissue Sarcoma Centre, MB = Bladder Cancer Centre, MT = Testicular Cancer Centre, MK = Kidney Cancer Centre, MPEN = Penis Cancer Centre | | |

**Entry into force on 18 December 2023**

This Catalogue of Requirements (CR) is binding for all audits conducted from 1 January 2023. The changes made to the version valid in the audit years 2022 are highlighted in "green" in this Catalogue of Requirements.

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**Multi-site radio-oncology (network structure)**

The Catalogue of Requirements refers to 1 clinical site. Radio-oncology departments that have several clinical sites (= network) must complete a Catalogue of Requirements for each clinical site. It is possible to define a main clinical site of the network which presents the central regulations. The secondary clinical sites can refer to these central regulations in their Catalogue of Requirements. It may be the case that not all clinical sites in a surgery network are cooperation partners of the Centre/Centres. These clinical sites do NOT have to process the Catalogue of Requirements. Each individual clinical site must meet the requirements. Any exceptions are to be indicated.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Clinical site of a network |  |  | yes |  |  | no | If "no", then the following information is not relevant. |

|  |  |
| --- | --- |
| Name of the network |  |

|  |  |
| --- | --- |
| Comments on the network (optional) |  |

|  |  |  |  |
| --- | --- | --- | --- |
| No. | Name of the clinical sites in the network which participate in the certification system 2) | Address (house number, street, postal code and place) | Number accelerators |
| 1 |  |  |  |
| 2 |  |  |  |
| 3 |  |  |  |
| 4 |  |  |  |
| 5 |  |  |  |

2) If there is a main clinical site, it should be mentioned first.

**Structural data on the clinical site**

**A. Organisational structure (multiple responses possible)** 3)

|  |  |  |
| --- | --- | --- |
|  |  | Independent clinic department |
|  |  |  |
|  |  | (sub-area) medical centre |
|  |  |  |
|  |  | Doctor's surgery |

3) Mixed forms 🡪 Multiple responses possible; indicate lead organisation structure with an "X" and other structural forms with an "n"

**Structural data on the clinical site**

**B. QM proof of the clinical site** (if available)

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

**C. Inpatient care (if available)**

|  |  |
| --- | --- |
|  | Own ward |
|  |  |
|  | Co-use of ward |

**D. Linear accelerator at the clinical site**

|  |  |  |
| --- | --- | --- |
| No. | Designation of equipment accelerator (company) | Year installed |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |
| 4 |  |  |
| 5 |  |  |
| 6 |  |  |

|  |  |  |
| --- | --- | --- |
| No. | Name planning system | Assignment accelerator (number from above table |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |

**E. Types of therapy at the clinical site**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Intensity Modulated Radiotherapy (IMRT) |  | Brachytherapy |
|  |  |  |  |
|  | Image Guided Radiotherapy (IGRT) |  | Stereotactic radiotherapy |
|  |  |  |  |
|  | Others |  |  |

**Structural data on the clinical site**

**F. Systemic tumor therapy in combination with radiotherapy for solid tumors**

see also Sections 7.12 and 6.2 of the tumour-specific CR

|  |  |
| --- | --- |
|  | Systemic tumor therapy solely by radiooncology for the following organs: |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | OC |  | MHNT |  | GC |  | CC |  | MPED |  | MG |  | MP |  | ME |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | MB |  | MSAR |  | MNOC |  | LC |  | MA |  |  |  |  |  |  |

|  |  |
| --- | --- |
|  | Systemic tumor therapy solely by cooperation partner  Cooperating partner performssystemic tumor therapy for the following organs with no involvement of radio-oncology (= the cooperation partner is responsible for implementing Section 6.2 of the Catalogue of Requirements): |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | OC |  | MHNT |  | GC |  | CC |  | MPED |  | MG |  | MP |  | ME |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | MB |  | MSAR |  | MNOC |  | LC |  | MA |  |  |  |  |  |  |

|  |  |
| --- | --- |
|  | In cooperation  Systemic tumor therapy is performed for the following organs in cooperation with other specialist departments (e.g. involvement haematology/oncology, use of outpatient day clinic): |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | OC |  | MHNT |  | GC |  | CC |  | MPED |  | MG |  | MP |  | ME |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | MB |  | MSAR |  | MNOC |  | LC |  | MA |  |  |  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Systemic tumor therapy (multiple mentions possible) |  | outpatient |  | inpatient |

| **7.1** **Interdisciplinarity** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Radio-oncology |  |
|  | Cooperation agreement  When the cooperation partners of a Centre work under a funding body or at a clinical site, no written agreements are needed (nonetheless the implementation of the following points must be ensured).  The following points are to be dealt with:  (see also "Template Cooperation Agreement")   * Description of the treatment processes of relevance for the Centre bearing in mind the interfaces * Obligation to implement indicated guidelines * Description of cooperation on tumour documentation * Declaration of willingness to cooperate on internal/external audits * Undertaking to comply with the relevant DKG criteria and the annual submission of the relevant data * Upholding of medical confidentiality * Participation in continuing education/specialty training schemes and public relations work * Declaration of consent to be publicly identified as part of the Oncology Centre (e.g. homepage) |  |  |
|  | Tumour board   * Mandatory participation * Ensuring availability of specialist * Participation and consensus provisions in the case of more than 1 cooperation partner for each specialty (see also provisions "Interdisciplinary cooperation") |  |  |
|  | Web/Online conference  If web conferences are used, the sound and documents presented are to be transmitted. Radio-oncology must be able to present its own documents/images. |  |  |
|  | Therapy plan/tumour board minutes   * In principle, the therapy plans and recommendations of the tumour board are the basis for treatment. * The therapy plan/tumour board minutes must be available in the documentation for each patient. * If there are any deviations from the recommended therapy plan, they are to be presented at the tumour board and documented in the patient’s medical record. |  |  |
|  | Interdisciplinary cooperation   * The standard operating procedure for the prompt exchange of information (e.g. on applied cycles/doses, side effects during therapy) between the attending specialties is to be documented (e.g. medical report, short protocoll, CTC notification)   In the case of combination therapies toxicities, in particular CTC Grades lll/IV, are to be notified immediately. |  |  |
|  | Organ-specific features |  |  |
| BC/GC  CC/MP  MG/ML  ME/MA  LC  PC/MK  MH/MB  MPEN | Cooperation agreement  The following points are to be regulated:  24-hour availability, e.g. for emergency interventions  (in accordance with Section 7.8 - Radiotherapy processes) |  |  |
|  | Changes compared to version of 28.09.2022 |  |  |

| **7.2** **Accelerators** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Radio-oncology |  |
|  | **Oncology Centres**   * 2 accelerators in the OC   At clinical sites with 1 accelerator, which are part of a network, the special characteristics listed in Section 7.4 are to be borne in mind. |  |  |
|  | **Organ Cancer Centres / Modules**  1 Accelerator |  |  |

| **7.3** **Number of radiotherapy treatments** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Radio-oncology |  |
|  | Calculation method expertise  When a patient is given several radiotherapy series with his/her own radiotherapy plan (e.g. bilateral breast carcinoma, 2 tumours), they can be counted more than once.  They are assigned to the calendar year on the basis of the date of the first radiotherapy treatment. |  |  |
|  | Number of complete radiotherapy series for tumour patients (not restricted to the Centre's patients). | Information in the table "Complete radiotherapy series" (at the end of this Section) |  |
|  | **Oncology Centres**  A complete radiotherapy series must be documented for at least 800 tumour patients. Of them, at least 200 patients must be treated in the Oncology Centre. |  |  |
|  | Clinical site of a network with 1 accelerator  Complete radiotherapy series with at least 400 tumour patients; of them at least 100 patients must be treated in the Oncology Centre. |  |  |
|  | **Organ-specific characteristics** |  |  |
| MA | At least 6 patients treated with anal cancer / year |  |  |
| MHNT | At least 30 treated HNT patients/year  Network structure see Section "7.4 Network" |  |  |
| MPED  Old: 7.7 | ~~5 completed radiotherapy series/year for paediatric patients are to be documented. Patients referred for proton therapy can be included.~~  A reference radiotherapy consulting session should be organised and documented.  The number of paediatric patients who have completed a radiotherapy series must be recorded.  ~~Details of number:~~ |  |  |
| LC | Number of radiotherapy treatments per radiotherapy treatment unit  Primary treatment:   * ≥50 patients with a lung cancerwho are given thoracic radiotherapy   Total number:   * ≥100 patients with a lung cancerwho receive a complete radiotherapy series in a curative, palliative or metastatic situation.   Network structure see Section "7.4 Network" |  |  |
| PC | Expertise radiotherapy prostate cancer   * Definitive or post-operative (adjuvant or salvage) radiotherapy: at least 50 cases/year   For 25-49 cases the following applies: at least 75 definitive or post-operative radiotherapy treatments in the 5 years prior to the audit   * Precondition: In the audit report recommendation for the issuing/maintenance of the certificate without any constraints   Network structure see Section "7.4 Network" |  |  |
| MSAR | Number of radiotherapy sessions for each treatment unit  At least 20 treated patients/year with sarcoma |  |  |
|  | Changes compared to version of 28.09.2022 | |  |

Number of complete radiotherapy series (not restricted to the Centre's patients)

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Clinical site  Radio-oncology | BC | GC | CC | MG | MP | ML | ME | HC | SC | MHNT | MPED | LC | MNOC | PC | MSAR |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Clinical site  Radio-oncology | MK | MB | MA | MT | MPEN | Other |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

Changes compared to version of 28.09.2022

|  |  |  |  |
| --- | --- | --- | --- |
| **7.4** **Networks of radio-oncological institutes/doctor's surgeries** (if relevant)  If the requirements in Section 7.2 "Oncology Centre: 2 accelerators" or in Section 7.3 "Number of radiotherapy treatments" are not met independently, then alternatively compliance can be proven by meeting the following requirements. | | | |
| Section | Requirements | Explanatory remarks Radio-oncology |  |
| New | * Minimum for each tumour entity  At least 10 patients with one tumour entity a year with a complete radiotherapy series for each institution/clinical site/doctor's surgery (case number for the respective Organ Cancer Centre/Module). |  |  |
|  | * In a network at least two specialists must work in each clinical site. |  |  |
|  | * Specialists in the doctor's surgeries/institutes which are part of the network work on the basis of foci, i.e. all patients with a disease are treated by a dedicated team. |  |  |
|  | * Specialisation based on division of labour of specialists in various tumour entities must be documented. |  |  |
|  | * A specialist exchange between specialists is formalised and documented. |  |  |
|  | * Accelerators are compatible with each other and calibrated to a joint planning system. The radiation parameters are available in a joint planning system. |  |  |
|  | * The network partners have uniform radio-oncological Standard Operating Procedures (SOPs). |  |  |
|  | * A contingency plan must be implementable by the end of the next working day. The utilisation of the linear accelerators must set aside capacity for contingency plans. |  |  |
|  | * Distance from the clinical site to the Centre:   maximum 45 km |  |  |
|  | * The clinical sites in the network have a joint ownership structure (simple cooperation models are not sufficient). |  |  |

| **7.5** **Specialists** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Radio-oncology |  |
|  | **Oncology Centres**  At least three specialists  The requirements of *the Radiation Protection Ordinance (Strahlenschutzordnung* - StrlSchV) are to be taken into account.  Network structure  Special characteristics see rules in 7.4 |  |  |
|  | **Organ Cancer Centres / Modules**  At least two specialists |  |  |
| MPED  Old: 7.3 Section 5(3) | * At least 2 radiotherapy specialists who are the contacts for paediatric oncology. * All paediatric oncology cases are to be treated by these stipulated contacts with paediatric expertise.   The names of the specialist, substitute staff member and department are to be given. |  |  |
|  |  |  |  |

**Details of the specialists radiotherapy**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name, first name | Title | Specialist (S) | Full-time or  part-time as % | Organ Cancer Centres/Modules 4) |
|  |  |  |  |  |
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| 4) | A specialist may not work in more than three different Organ Cancer Centres/Modules; Visceral Oncology Centre: counts once (colorectal,anal, HCC, gastric, pancreas and oesophageal cancer or prostate, kidney, urinary bladder, testicles, penis ); junior doctors may not represent an Organ Cancer Centre/Module |

Changes compared to version of 28.09.2022

| **7.6** **Medical Physics Expert (MPE)** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Radio-oncology |  |
| Old: 7.2 | **Oncology Centres**   * At least 3 MPEs are available to the OC on working days. The requirements of the Radiation Protection Ordinance (StrlSchV) are to be met. * A MPE (Medical Physics Expert) may not work in more than three Organ Cancer Centres/Modules.   Name of MPE: |  |  |
| Old: 7.2 | **Organ Cancer Centres / Modules**   * At least one MPE is available to the department on working days. * Cover staff rules must be formulated in writing.   Name of MPE (including cover staff replacement): |  |  |

| **7.7** **Medical technical radiology assistants (MTRAs)** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Radio-oncology |  |
| Old: 7.3 | * 2 MTRAs must be present for each linear accelerator during radiotherapy. * Cover staff rules must be formulated in writing. |  |  |
|  | Name: |  |  |

| **7.8** **Radiotherapy processes** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Radio-oncology |  |
|  | Radiotherapy processes  The instructions in radiation protection legislation and the "Guidelines on Radiation Protection in Medicine" ("*Richtlinie Strahlenschutz in der Medizin*") are to be followed. |  |  |
|  | Contingency plan  Contingency plan formulated in writing (network see also Section 7.4). |  |  |
|  | Combination therapies  In the case of combination therapies (e.g. percutaneous radiotherapy/brachytherapy/IORT, simultaneous radio-chemotherapy) the medical and medical-physical responsibility should not change. If a change in this responsibility is essential for organisational reasons, the therapy plan must be agreed and signed by all responsible healthcare professionals prior to the commencement of treatment. |  |  |
|  | On-site inspection by the medical authority (pursuant to Section 83 Radiation Protection Ordinance [StrlSchV])   * The assessment by the medical authority must correspond to level 1 (no deficiencies), 2 (minor deficiencies, renewed on-site inspection in two years' time) or once only level 3. * Documentation off the elimination of detected deficiencies must be provided. |  |  |
|  | Documentation/Tumour control   * The relevant radiation data (single dose, total dose, total treatment time) are to be recorded in line with the Guidelines.  Any deviation from the prescribed dose must be justified and documented. * Supportive measures in accordance with the Guidelines are to be described for the individual therapy concepts and documented in detail for each patient. |  |  |
|  | Availability/On-call  Presence of one specialist for radiotherapy during working hours, 24-hour on-call service outside working hours, if necessary through cooperation (including weekends and public holidays) |  |  |
|  | **Oncology Centres**   * Oncology Centres must have a written concept for emergency radiotherapy and timely radiotherapy for relief of symptoms in palliative patients. * In the case of patients with compression of the myelon and neurological symptoms a therapy plan must be drawn up within 24 hours of the suspected diagnosis. |  |  |
|  | **Organ-specific characteristics** |  |  |
| GC | The patient should be treated in just one Gynaecological Cancer Centre. |  |  |
| HC | * Centres for haematological neoplasia must have written down a concept for emergency radiation and prompt radiation therapy to alleviate symptoms in palliative care patients. |  |  |
| MHNT | Any supportive treatment options must be presented; measures for/in the case of dental reconstruction; nutritional deficiency; mucositis; behaviour in the case of neutropaenia; thrombocytopaenia; sepsis. |  |  |
| MPED | Treatment is given in line with the standards of the protocols of the latest therapy optimisation studies including reference recommendations and the latest registry recommendations. |  |  |
|  | Conduct of therapy   * The option of therapy under anaesthetic/sedation must be possible.   The anaesthetic/sedation must be administered by a specialist for anaesthetics or a specialist for paediatric medicine with additional training in intensive medicine. |  |  |
| MSAR | Any supportive treatment options must be outlined: measures for/in the case of dental reconstruction, nutritional deficiencies, mucositis, behaviour in the case of neutropaenia, thrombopaenia, sepsis, cystitis (in the case of radiotherapy in the region of the bladder). |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **7.9** **Radiotherapy planning** | | | |
| Section | Requirements | Explanatory remarks Radio-oncology |  |
|  | * Therapy simulator or virtual simulation * CT planning * 3D and IMRT radiotherapy planning system * Access to magnetic resonance imaging (not for LC) * Optional: Integration of PET into therapy planning (not a requirement for BC/LC) |  |  |
|  | * Integration of PET or PET-CT data into the radiotherapy planning system (optional) * MRI for radiotherapy planning (optional, NOC mandatory) * 4D computer tomography for radiotherapy planning (optional) |  |  |
| BC | Not a requirement |  |  |

| **7.10** **Radiotherapy techniques** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Radio-oncology |  |
|  | Techniques that must be available:   * Image-Guided Radiation therapy (IGRT) * Intensity Modulated Radiotherapy (IMRT, optional: BC) * 3D-compliant radiotherapy |  |  |
|  | **Organ-specific characteristics** |  |  |
| BC | Boost irradiation   * for patients ≤ 50 years * for patients> 51 years only with increased local relapse risk (G3, HER2-positive, tripelnegative,> T1) |  |  |
|  | Fractionation  If indicated, the radiation should be performed hypofractionated. |  |  |
| CC | Patients in whom downsizing is the goal can also be given short-term radiation with a longer interval of up to 12 weeks to surgery (with and without neoadjuvant chemotherapy). |  |  |
| HC | * Involved-site (IS) - radiotherapy * Involved-field (IF) - radiotherapy * Craniospinal radiotherapy * Whole body radiation (only available for patients with allogeneic stem cell transplantation)   Optional:   * Radiation with deep inspiration in mediastinal lymphomas * Volumetric modulated radiation therapy (VMAT) |  |  |
| SC | Special radiotherapy techniques: stereotactic radiotherapy, whole skin radiotherapy (optional, possibly in cooperation). |  |  |
| LC | * Special radiotherapy techniques: extracranial and intracranial stereotactic radiotherapy; consideration of respiratory motion through suitable techniques * Whole brain irradiation alone should be avoided as initial therapy in patients in good general condition and with 1 to 4 stereotaxable brain metastases. |  |  |
|  | * Breath-triggered radiotherapy (optional) |  |  |
| MNOC | Techniques that must be available:   * Fractionated stereotactic radiotherapy * Intensity-Modulated Radiotherapy (IMRT) * Methods for stereotactic one-off radiotherapy * Craniospinal radiotherapy |  |  |

| **7.11** **Brachytherapy** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Radio-oncology |  |
| GC | * Intracavity brachytherapy * Interstitial brachytherapy with the insertion of needles into the parametrium (optional) * CT-aided radiotherapy planning with supine applicator with fusion of the MRI images * 3D radiotherapy planning system (recommended) * Access to an MRI should be ensured particularly for brachytherapy planning. * MRI-aided radiotherapy planning with supine applicator (recommended) * In primary therapy of the cervix carcinoma, brachytherapy is an integral part of the overall concept and must be guaranteed, in cooperation if necessary |  |  |
| GC | Cervix:   * Brachytherapy as IGABT * MRI of pelvic region before radiotherapy and before brachytherapy is started * for MRI planning: apply 40-50Gy in 3-5 fractions using the HDR or PDR method * EQD2 in the Tm area at least 85Gy (percutaneous + brachytherapy) * Total treatment duration (tele- and brachytherapy): 45-50 calendar days   Endometrium:   * The target volume should comprise max. the prox. third of the vaginal stump * Vaginal brachytherapy alone: 15-25 Gy in 3-4 fractions using HDR brachytherapy (PORTEC II: 3 x 7.0 Gy in 5mm tissue depth 1x/W); equivalent dose regimens are 4 x 6.0 Gy or 5 x 5.0 Gy 1-2 weekly. * Vaginal brachytherapy as a boost after percutaneous radiotherapy: 8-11 Gy in 2-3 fractions (usually 2x 5.0 Gy) at the end of percutaneous radiotherapy |  |  |
| MHNT | * The brachytherapy option should be available or ensured through cooperation. * 3D radiotherapy planning system (recommended) |  |  |
| LC | Brachytherapy (possibly in cooperation) |  |  |
| PC | Expertise brachytherapy (optional)   * LDR brachytherapy (permanent seed implants) * HDR brachytherapy   Expertise LDR/HDR must be documented in accordance with the decision of 18 June 2015 of the Federal Joint Committee (*Gemeinsamer Bundesausschuss* - G-BA) (guidance value without consideration of special regulations is one-off documentation of at least 100 therapies conducted within the last 5 years). |  |  |
| ME | * The brachytherapy option must be available or ensured through cooperation * 3D radiotherapy planning system |  |  |
| MPED | In the case of brachytherapy by radiotherapy:  Indication of the number of therapies carried out. |  |  |
|  | Changes compared to version of 28.09.2022 |  |  |

| **7.12** **Systemic tumor therapyby radio-oncology** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Radio-oncology |  |
|  | If radiotherapy carries out performs a drug oncological therapy for an entity, the provisions in Section 6.2 of the respective organ-specific Catalogue of Requirements apply in addition. |  |  |
|  | Implementation of systemic tumour therapy using radiation therapy in combination with radiotherapy for solid tumours |  |  |
|  | Case numbers per treatment unit   * At least 50 systemic tumour therapies in combination with radiotherapy for solid tumoursif not otherwise specified in the organ-specific requirements. * Calculation method: completed systemic / cytostatic / targeted therapy for each patient (consisting of **several** cycles or applications, combined therapies count as one therapy). For therapies extending over a year, the therapy started in the indicator year counts. 1 therapy per patient = 1 therapy line per disease per patient. * In the event of a shortfall, expertise cannot be proven via cooperation (must be proven by each individual treatment unit). | Case numbers in the table at the end of the chapter |  |
|  | The standard operating procedure for sequential/simultaneous radio-chemotherapy is to be described. |  |  |
|  | Treatment documentation for systemic tumour therapy in combination with radiotherapy for solid tumours:   * The side effects are to be recorded and evaluated. * Blood count monitoring and laboratory tests must be recorded by the radio-oncologist |  |  |
|  | If the radio-oncologist does not personally carry out the systemic tumor therapy, then the staff members responsible for dealing with side effects, breaks in radiotherapy, dose specification and dose reduction must be clearly identified beforehand. In each case the joint therapy plan must be signed by the specialist for radiotherapy, too. |  |  |
|  | **Organ-specific characteristics** |  |  |
| LC | When performing simultaneous thoracic radio-chemotherapy through radiotherapy:  At least 30 lung cancer patients with simultaneous thoracic radio-chemotherapy/year |  |  |
| MHNT | At least 15 HNT patients with radio-chemotherapy in the radio-oncological department. |  |  |
| MSAR | At least 30 patients with radio-chemotherapy in the radio-oncology department (not limited to patients with a sarcoma). |  |  |

Systemictumor therapiescarried out by radio-oncology in combination with radiotherapy for solid tumors (not limited to patients of the Centre)

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| Clinical site Radio-oncology | MHNT | MPED | MNOC | MSAR | BC | GC | CC | MA | ML | MG | MP |
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| Clinical site Radio-oncology | ME | HC | SC | LC | PC | MB | MT | MPEN | Others |
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Changes compared to version of 28.09.2022

| **7.13** **Palliative radiotherapy** | | | |
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| Section | Requirements | Explanatory remarks Radio-oncology |  |
|  | * In the case of palliative radiotherapy, the therapeutic goal (local control or solely symptom alleviation) is to be documented. * Palliative medical measures, progress of symptoms and side effects are to be described and documented for each patient particularly in the case of therapeutic concepts for symptom alleviation. * Simultaneous medicinal therapy (e.g. pain, tumour-specific therapy) is to be documented. |  |  |

| **7.14** **Consulting hours/Waiting times** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Radio-oncology |  |
|  | Consulting hours   * Each patient is to undergo a medical consultation prior to the commencement of radiotherapy. * During a radiotherapy series at least one documented contact with a doctor is to be ensured in the radiotherapy unit carrying out the treatment. |  |  |
|  | Waiting times   * Time between patient registration and first presentation < 10 days * Time between first presentation and commencement of treatment if there are no medical contraindications: < 4 weeks * The actual total treatment time should not exceed the prescribed treatment time by more than 10%. Medically justified or patient-justified breaks in radiotherapy are exceptions. * The waiting times are to be recorded on a random basis and statistically evaluated (recommendation: evaluation period 4 weeks a year). |  |  |

| **7.15** **Case-related information/Dialogue with patient** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Radio-oncology |  |
|  | Adequate information must be provided about diagnosis and therapy planning and a consultation is to be given. This includes *inter alia*:   * Structured explanation of indication, action, side effects, treatment schedule * Presentation of alternative treatment concepts * Offer of and aid in obtaining second opinions * Discharge consultation as a standard procedure * Patients must be given written patient information about behaviour during and after radiotherapy.   Patient consultations are to be documented for each patient. |  |  |
|  | **Organ-specific characteristics** |  |  |
| BC | Patients must be given written patient information about behaviour during and after radiotherapy and rehabilitation. |  |  |
| LC | Patients must be given written patient information about behaviour during and after radiotherapy, in particular information about programmes on giving up smoking is to be provided. |  |  |
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| **7.16** **Induction, continuing education/specialty training** | | | |
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| Section | Requirements | Explanatory remarks Radio-oncology |  |
|  | Continuing education/specialty training   * A training plan for medical, nursing and other staff is to be presented listing the planned training sessions for the period of one year. * At least 1 dedicated continuing education/specialty training session for each staff member who carries out quality-relevant activities for the Centre. |  |  |
|  | **Oncology Centres**  Minimum continuing education/specialty training for each staff member and year: at least 1 day |  |  |
|  | Systematic, documented induction of new staff members is to be ensured, which imparts knowledge about the Oncology Centre's respective field of activity.  This induction must take place within three months of commencement of employment. |  |  |
|  | **Organ Cancer Centres / Modules**  Minimum continuing education/specialty training for each staff member and year: at least 0.5 days |  |  |

| **7.17** **Quality circles** | | | |
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| Section | Requirements | Explanatory remarks Radio-oncology |  |
|  | * Quality circles, in which oncological topics are addressed, are to be staged at least 3 times a year. * Scheduling, e.g. in training plan * Minutes of quality circles are to be taken.   Participation is to be documented in total and not for each individual organ; quality circles can be interdisciplinary, for a specific organ and/or trans-organ in nature (central quality circles of the Oncology Centre are, for instance, recognised pursuant to the CR OC Section 1.2.14). |  |  |

| **7.18** **Cross-sectional areas** | | | |
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| Section | Requirements | Explanatory remarks Radio-oncology |  |
|  | Radio-oncology must take into account the implementation of the requirements from the sections  1.4 Psycho-oncology  1.5 Social services  1.7 Study management  1.8 Nursing care  for the patients treated (by using the existing structures of the Centre or its own organisation). |  |  |

| **7.19** **Aftercare** | | | |
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| Section | Requirements | Explanatory remarks Radio-oncology |  |
|  | The process for the tumour-  (radiotherapy-)specific aftercare is to be described (bearing in mind the Guidelines "Radiation protection in medicine"). This includes:   * Appointment/reminder (aftercare pass) * Type of documentation * Formalised notification of the respective in-house tumour documentation system in the event of recurrences, metastases and death of patients. |  |  |

| **7.20** **Tumour documentation** | | | |
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| Section | Requirements | Explanatory remarks Radio-oncology |  |
|  | Assignment Centre / patient  The documentation must contain clear, evaluable information on whether the patient is a Centre patient and to which Centre this patient has been assigned. |  |  |
|  | Follow-up data  Follow-up data that have been obtained in radio-oncology are to be notified systematically to the Centre. The follow-up data of the radio-oncological patients available to the Centre should be used by radio-oncology to improve quality. |  |  |
|  | Side effects  It must be possible to systematically record side effects on the organ level that have been identified. These records should be evaluated and analysed on an annual basis (e.g. in a quality circle). |  |  |