**Catalogue of Requirements for Uro-oncology Centres**

**of the German Cancer Society**

**Prepared by the Certification Commission Uro-oncological Centre/ Prostate Cancer Centers of the DKG**

**Chairmen of Certification Commission:** Prof Dr M. Burchardt, Prof Dr J. Fichtner

**Members (in alphabetical order):**

ACO Working Group on Surgical Oncology

ADT Working Group German Tumour Centres

AET Hereditary Tumour Diseases Working Group

AGORS Working Group Rehabilitation and Social Medicine

AIO Working Group on Internal Oncology

AOP Working Group on Oncological Pathology

AOT Working Group for Oncological Thoracic Surgery

APM Working Group Palliative Medicine

ARO Working Group on Radiological Oncology

ASO Working Group on Social Work in Oncology

ATO Working Group Tumour Classification in Oncology

AUO Working Group on Urological Oncology

BDP Federal Association of German Pathologists

BDU Professional Association of German Urologists

BNHO Professional Association of Practising Haematologists and Oncologists

BPS Prostate Cancer Self-help Group

BVDST Professional Association of German Radiation Therapists

CAO Working Group Oncology

DeGIR German Society of Interventional Radiology and Minimal-invasive Therapy

DEGRO German Society for Radio-oncology

DGfN German Society for Nephrology

DGHO German Society for Haematology and Oncology

DGN German Society for Nuclear Medicine

DGP German Society of Pathology

DGT German Society for Thoracic Surgery

DGU German Society for Urology

DRG German Radiological Society

DVSG German Association for Social Work in Health Care

dvta German Association of Technical Assistants in Medicine

FgSKW, Professional association for stoma, continence and wound care (formerly DVET)

German Foundation for Young Adults with Cancer

GTCSG German Testicular Cancer Study Group

IABC Interdisciplinary Bladder Carcinoma Working Group of the DKG e.V.

IAG-N Interdisciplinary Working Group on Renal Cell Carcinoma

KOK Conference on Oncological Nursing and Paediatric Nursing Care

OPH Working Group Oncology Pharmacy

PRIO Working Group on Prophylaxis and Integrative Medicine in Oncology

PSO Working Group on Psychological Oncology

Auditors

Self-help group “Das Lebenshaus e.V.”

ShB Bladder Cancer Self-Help Association

S3 Guideline Germ cell tumours of the testicle

S3 Guideline Penile carcinoma

S3 Guideline Prostate carcinoma

S3 Guideline Renal cell carcinoma

GS3 Guideline Bladder carcinoma

Permanent guests:

* OncoSuisse

**Comments on the Catalogue of Requirements**

The Catalogue of Requirement and its appendices are binding for all centres.

|  |  |
| --- | --- |
| Audit year: | **2025** |
| Version: | **P1** |
| Date: | **18.09.2024** |

The changes marked in green in this Catalogue of Requirement (CoR) were decided in 2024 and are valid for all audits carried out from 01.01.2025.

Incorporated:

* S3 guideline "Early detection, diagnosis and treatment of the various stages of prostate cancer"
* S3 guideline "Early detection, diagnosis, treatment and aftercare of bladder cancer"
* S3 guideline "Diagnosis, treatment and aftercare of germ cell tumours of the testicle"
* S3 guideline "Diagnosis, treatment and aftercare of renal cell carcinoma"
* S3-GL Diagnostics, therapy and aftercare of penile carcinoma

This Catalogue of Requirements is based on the TNM classification of malignant tumours, 8th edition 2017 as well as the ICD classification ICD-10-GM 2024 (DIMDI) and the OPS classification OPS 2024 (DIMDI).

|  |  |
| --- | --- |
| Colour legend | "black" .... relevant for all organs |
|  | only relevant for "Prostate" |
|  | only relevant for "Kidney" |
|  | only relevant for "Bladder" |
|  | only relevant for "Testicles" |
|  | only relevant for "Penis" |

**Prologue**

In the certified Centres, interdisciplinary, interprofessional and transsectoral networks are established that cover the entire care chain from the patient's perspective[[1]](#footnote-1) . Clinical work is based on the content of evidence-based guidelines. A series of uro-oncological guidelines with the associated quality indicators were published via the [oncology guideline programme](http://www.leitlinienprogramm-onkologie.de/). Based on these guidelines, the certification commission (see title page) has drawn up the content to be used in the Uro-oncology Centre.

In order to facilitate practical implementation and reduce the number of survey forms and audit procedures, the individual tumour entities (definition "Scope" on page 2) have been combined under the umbrella of the "Uro-oncology Centre" (UOC). The Centres can independently define the scope of the Centre according to their own specialisation and expertise.

Certification for penile cancer is only possible together with certification as a Prostate Cancer Centre.

An UOC fulfils at least the requirements (according to the definition "Scope" on page 2) for

1 Prostate Cancer Centre + 1 other tumour entity (bladder, testicles, kidney). A prostate cancer centre and a Penile Cancer Centre together do not form a Uro-Oncology Centre.

Irrespective of this, certification of an independent Prostate Cancer Centre is still possible.

Certification takes place during an audit, regardless of the number of modules selected. It is possible to change the scope at a later date. The scope of validity is shown on the certificate.

For single Prostate Cancer Centers, the fulfillment of the requirements must be presented in the Catalouge of Requirment for Uro-Oncology Centers/Prostate Cancer Centers (the separate Catalouge of Requirment for Prostate Cancer Centers is no longer available). Requirements marked with “UC” in the “Section.” column are relevant for all organs and thus apply to both Uro-Oncological Centers and singular Prostate Cancer Centers.

**Information on the Uro-Oncology Centre (UC)**

|  |  |
| --- | --- |
| Centre |  |
| Director Centre |  |
| Coordinator of the Centre |  |

|  |  |
| --- | --- |
| Clinical site 1 (hospital/place) |  |
|  |  |
| Clinical site 2 (hospital/place) |  |

**Centre’s area of application:**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Prostate |  | Kidney |  | Bladder |  | Testicles |  | Penis |  |

**Network/main cooperation partner**

The (main) cooperation partners of Uro-Oncology Centers are registered in a Master Data Sheet with the certification agency OnkoZert. All information about this registration is published on [www.oncomap.de](http://www.oncomap.de). The Centre is obliged to report all new and also all no longer valid cooperations. Any other updates (e.g. changes to management, contact data.) must be indicated in the corrected master data sheet in the run-up to the annual surveillance audit. The master data sheet for the registration of cooperation partners can be obtained from OnkoZert.

**Table of contents**

1. General information about the Centre

1.1. Structure of the network

1.2. Interdisciplinary cooperation

1.3. Cooperation between referring physicians and aftercare

1.4. Psych-oncology

1.5. Social work and rehabilitation

1.6. Patient participation

1.7. Study management

1.8 Nursing Care

1.9 General care areas (pharmacy, nutritional counselling, speech therapy, ...)

1. Organ-specific diagnostics and therapy
   1. Consultation hour
   2. Diagnostics procedures
2. Radiology
3. Nuclear medicine
4. Surgical Oncology
   1. General-organ surgical therapy
   2. Organ-specific surgical pncology
5. Medicinal/internal oncology
   1. Haematology and oncology
   2. Organ-specific oncologic pharmacotherapy
6. Radio-oncology
7. Pathology
8. Palliative Care and Hospice Work
9. Tumour Documentation/Outcome Quality

Attachments to the Catalouge of Requirements

Data sheet - Prostate (Excel template)

Data sheet - Kidney (Excel template)

Data sheet - Bladder (Excel template)

Data sheet - Testicles (Excel template)

Data sheet - Penis (Excel template)

**1. General information on the Uro-Oncology Centers**

| **1.1 Structure of the network** | | |
| --- | --- | --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 1.1.1.a - PC, Mk, MB, MT, MPEN | **Centre Director**  The following functions must be specified by name:   * Director(s) of the Centre ((max. 2 directors per Centre, one of whom is the designated contact person) * Centre Coordinator     Coordination - Tasks   * Coordination of internal/external audits * Monitoring and ensuring the fulfilment of technical requirements * Communication interface * Control/monitoring of interdepartmental actions |  |
| 1.1.1.b - PC, Mk, MB, MT, MPEN | **Co-operation partner**    Main co-operation partners and treatment partners can be part of a clinic or independent practices.    Main cooperation partner   * Urology * Radiotherapy * Internal oncology * Pathology * Radiology     Co-operation partner   * Psycho-oncology * Social service * Stoma therapy (bladder) * Nuclear medicine * Pain therapy * Self-help group * Palliative medicine * Laboratory medicine * Human genetics (for kidney) * Nephrology (kidney) * Nutritional counselling     Specialist disciplines to be consulted according to ASV-RL (cooperation agreement not necessary, e.g. SOP instead)   * Vascular surgery * Gastroenterology * Cardiology * Neurology * Visceral surgery * Gynaecology/Gyn. Oncology * Thoracic surgery * Physiotherapy * Optional for testicles: Andrology     Cooperation with Centres for Personalised Medicine  A cooperation agreement with a certified Centre for Personalised Medicine should be sought (CPM) (see also 1.2.7). If the CPM and the UC are under the same sponsorship or at the same clinical location, written agreements are not necessary (implementation of the points mentioned under 1.1.4 must nevertheless be ensured). |  |
| 1.1.1.c - PC, Mk, MB, MT, MPEN | The Centre's management structures, QM responsibilities and network coordination must be clearly defined.   * Rules of procedure (regulate the relationship between the main cooperation partners) * Job description QMB * Job description coordination     The Director of the Centre ensures the implementation of standards and legal regulations. |  |
| 1.1.1.d - PC | **Cooperation models**   * Within a Centre, cooperation between up to 2 surgical urologies is possible if each surgical urology performs its primary surgical cases independently. The number of primary cases must then be at least 200 * Within a Centre, cooperation of up to 2 radiotherapies is possible if each radiotherapy proves its expertise independently.     If a clinic management represents 2 departments, the performance indicators must be provided separately for each department.    Prerequisite for all co-operation models:   * Identical Centre name * Joint tumour board * Prior structural assessment by OnkoZert required |  |
| 1.1.2 - PC, Mk, MB, MT, MPEN | The Centre has defined a clear mission statement and quantitative quality targets.  Interdisciplinarity and evidence-based medicine are clearly reflected in the statements and are comprehensible in practice.  The basic orientation of the Centre is known to the employees and is implemented. |  |
| 1.1.3 - PC, Mk, MB, MT, MPEN | The achievement of quality targets is measured. The results are subjected to a documented evaluation.  In annual quality planning under the responsibility of   * Centre management * Coordination * QM representative   (BÄK, DIN, DGQ or equivalent)  clear strategies are defined that promote the achievement of objectives.  The QM officer can also perform the same role in other organ cancer Centres. |  |
| 1.1.4 - PC, Mk, MB, MT, MPEN | **Co-operation agreements**  A cooperation agreement must be concluded with the treatment partners involved. These partners must demonstrably fulfil the relevant technical requirements of the Catalogue of Requirement.  The co-operation partners must be listed in the "Master Data Sheet" (administration via OnkoZert). The agreements must be reviewed annually by the Centre to ensure that they are up to date.  If the cooperation partners of a centre work under one sponsorship or at one clinic location, written agreements are not necessary (implementation of the following points must nevertheless be ensured).    The following points are to be regulated:   * Mandatory participation in the pre-therapeutic conference/tumour board * 24/7 availability of the main clinical cooperation partners at the centre: urologists, radiologists, haemato-oncologists * Description of the treatment processes relevant to the centre, taking into account the interfaces * Obligation to implement recognised guidelines (S3 guidelines) * Description of cooperation and interfaces * Description of the collaboration with regard to tumour documentation * Declaration of willingness to cooperate with regard to internal/external audits * Declaration of commitment to comply with the DKG criteria and the annual provision of the relevant data * Declaration of consent by the treatment partner to be publicly identified as part of the centre (e.g. homepage) * Compliance with confidentiality * Participation in further training measures and public relations work |  |
| 1.1.5.a - PC, Mk, MB, MT, MPEN | **Contact person of the Centre**  The Centre's contact persons at the clinic location and for the individual cooperation partners must be named and announced (e.g. on the Internet). In medical areas, responsibilities must be defined at specialist level.    Treatment partners who have agreed to cooperate with the Centre in writing are referred to as cooperation partners of the Centre. If there is no such written agreement, these service providers and treatment partners may also treat patients of the Centre. However, they may not refer to themselves as cooperation partners or part of the certified Centre. |  |
| 1.1.5.b - PC, Mk, MB, MT, MPEN | **Representation of the Centre**  The structure of the Centre must be presented in its entirety and made public (e.g. Internet). This also includes the naming of all internal/external co-operation partners with the following information:   * Name, address of the co-operation partner   Contact person with phone/e-mail contact. |  |
| 1.1.6 - PC, Mk, MB, MT, MPEN | **Strategic planning/reporting**  It is recommended that an annual review be carried out at management level, in which the following aspects, for example, are considered:   * Target definition/assessment, realignment of targets if necessary * Consideration of audit results (internal/external) * Human resources for Centre management (coordination) * Public Relations/Pat.information * Tumour documentation/outcome quality     The provider(s) of the Centre provide(s) sufficient financial means/resources to meet the personnel, spatial and material requirements. |  |
| 1.1.7 - PC, Mk, MB, MT, MPEN | **Patient Pathways**  Overarching patient pathways must be defined in which the relevant medical guidelines are reflected.  The patient pathways take into account the interdisciplinarity of the Centre and the networking with the practices.  Paths are to be defined for:   * Prevention and diagnostics * Therapy * Aftercare * Rehabilitation * Palliation   Patient pathways can be summarised in a QM manual, for example. |  |
| 1.1.8 - PC, Mk, MB, MT, MPEN | **Internal audits**  Internal audits must be carried out at least once a year and documented by means of audit reports. The internal audit must be carried out for the first time prior to initial certification. |  |

| **1.2 Interdisciplinary cooperation** | | |
| --- | --- | --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 1.2.1.a - PC, Mk, MB, MT, MPEN | **Number of cases in the Centre**  Definition of Centre case   * all patients with initial diagnosis, localised and/or metastatic, as well as all patients with recurrence or secondary metastasis who are presented at the centre or the TC and receive essential parts of the therapy there (surgery, radiotherapy, systemic therapy, watchful waiting, active surveillance, etc.) * Patients and not stays and not operations * Patient can only be counted as a Centre case for 1 centre * Patients who are only presented for a second opinion or consultation are not taken into account. * Interdisciplinary therapy plan must be available * Prostate: Counting time is the time of (first) presentation at the centre; * Penile carcinoma: the time of (first) presentation at the centre is counted * For the other entities, the counting time is the time of diagnosis (date of biopsy) * Histological findings must be available * Complete recording in the tumour documentation system     Definition of primary case (subset of Centre case):   * Patients with primary disease (incl. primary M1)     For further explanations see FAQ. |  |
| 1.2.1.b - PC | Primary cases of prostate cancer per year  > 100 primary cases per year |  |
| 1.2.1.c - Mk | The Centre must treat 35 patients per year with a diagnosis of kidney cell carcinoma (ICD-10 C64)    For further information, see FAQ |  |
| 1.2.1.d - MB | The Centre must treat 50 patients per year with a **primary** diagnosis of bladder cancer and/or its precursors (ICD-10 C67, D09.0, D41.4)    Definition:  Carcinomas and precursors (non-invasive papillary carcinoma, carcinoma in situ) are counted; papillomas are not counted |  |
| 1.2.1.e - MT | The Centre must treat 15 patients per year with a primary diagnosis of   * a germ cell tumour of the testicle including its precursors (germ cell neoplasia in situ) or * a germline/stromal tumour of the testis or * of an extragonadal germ cell tumour (see diagnosis list in the Data Sheet) |  |
| 1.2.1.f - MPEN | The Centre must treat 8 patients per year with a first diagnosis of penile carcinoma and/or its precursors (ICD-10 C60, D07.4).    This also includes patients who are referred to the Centre after local therapy (surgical, laser) for lymph node diagnostics (MIL [modified inguinal lymphadenectomy], DSNB [dynamic sentinel lymph node biopsy]) or lymph node therapy and, if necessary, adjuvant therapy as part of primary therapy. |  |
| 1.2.2 - PC | Referral of patients with prostate cancer to the Centre:  It must be described how a patient can be presented at the Centre for a pre-therapeutic conference and on what basis, if applicable, a special consultation is carried out (contract doctor, personal authorisation, institute authorisation, polyclinic authorisation).    Primary referral to main cooperation partner   * Referral of the patient to a main cooperation partner in the Centre * Create treatment plan based on available findings (biopsy, PSA, therapy proposal) by service provider * Offer and conduct a patient discussion (interdisciplinary discussion if necessary)   - Supplement treatment plan  - No interdisciplinary discussion desired --> Allocation of surgery appointment / radiotherapy planning |  |
| 1.2.3 - PC | Interdisciplinary discussion (optional)  Interdisciplinary consultations should be offered for patients of a PCA Centre.   * Participants: Patient + radiotherapist + urologist * Result: Update of treatment plan     Number of interdisciplinary consultations (patients) |  |
| 1.2.4.a - PC | **Pre-therapeutic conference**   * The pre-therapy conference must take place at least once a week at specialist level for the purpose of therapy planning. * The responsibilities for preparation, implementation and follow-up must be defined (see 1.2.6) * Participation rate of the specialisations > 95 % |  |
| 1.2.4.b - PC | * Participants: Urologist and radiotherapist * To be presented: All primary cases without prim. M1 |  |
| 1.2.4.c - PC | Special features Pre-therapeutic conference:   * The physical presence of the participants is only mandatory in unclear cases. Otherwise, telephone coordination or online validation is sufficient. The use of video conferencing systems is preferable to telephone conferences. * Demonstration of imaging material - Patient-related image material (e.g. pathology, radiology) must be available at the conference for advanced tumours and suitable technical equipment must be available for the presentation of the image material. Computerised presentation is sufficient. * If a radiotherapist cooperates with several urological clinics, this radiotherapy department must independently present all primary cases that are treated with curative intent (see def. section 7) at the corresponding Centre. For this purpose, the radiotherapy department compiles a list of all prostate cancer patients presented for radiotherapy, in which a centre assignment is made (Centre certified, certification in preparation, no Centre). The presentation rate of 90% must be achieved separately in all cooperating centres. Proof of presentation must be provided in accordance with the requirements described here. This patient allocation is also relevant for tumour documentation. |  |
| 1.2.4.d - PC | Procedure of the pre-therapeutic conference   * Referral of patient to a service provider of the Centre * All parameters must be recorded in advance by the responsible service provider in the "Treatment plan" template * All cases must be recorded in a list * Presentation of patient in the conference   Coordination of parameters and supplementation of treatment plan   * Notification of results within 10 working days via treatment plan to referring physician, patient and any physician named by him (e.g. copy of the treatment plan) by the physician to whom the patient was primarily presented. |  |
| 1.2.5.a - PC, Mk, MB, MT, MPEN | **Tumour board**   * The tumour board must be held weekly at specialist level for the purpose of therapy planning. * The responsibilities for preparation, implementation and follow-up must be defined * Participation rate of the specialisations > 95 %     For further explanations, see FAQ |  |
| 1.2.5.b - PC | Participants:   * Urology * Radiotherapy * Haematology/Internal Oncology * If the haematologist/oncologist is unable to attend the conference, the urologist responsible for chemotherapy (qualification in accordance with Section 6.2) may represent him/her in exceptional cases. * Pathology * Radiology * Nuclear medicine     To be presented:  o All primary cases with histology worthy of discussion (≥ pT3a, and/or R1, and/or pN+); generally no binding obligation for other patients undergoing primary radiotherapy or curative surgery.  o All patients with recurrences or metastases  o At least 10 patients with castration-resistant prostate cancer/year    For further explanations see FAQ |  |
| 1.2.5.c - Mk | * Participants: Urology, Radiology, Internal Oncology, Pathology * Radiotherapy should be included if there is a special indication (e.g. distant osseous metastasis) * Nephrology must be involved if there is a special indication * If the internal oncologist is unable to attend the conference, he/she can be represented by the urologist responsible for chemotherapy (qualification according to section 6.2). * To be presented: Patients with locally advanced tumour (≥ cT~~3~~ 4/pT4 and/or c/pN+), patients with R1 resection, patients with ≥ intermediate-high risk, patients with rare histology (i.e. non-clear cell and/or papillary and/or chromophobe kidney carcinoma), pat. evidence of hereditary genesis, patients with initial diagnosis of distant metastases and/or recurrence. |  |
| 1.2.5.d - MB | * Participants: Urology, Radiotherapy, Radiology, Internal Oncology, Pathology * If the internal oncologist is unable to attend the conference, he/she can be represented by the urologist responsible for chemotherapy (qualification according to section 6.2). * To be presented: Cases after TUR-B (at least T1 high-grade, T2) and cases after cystectomy (at least R1 u/o N+) as well as patients with initial diagnosis of distant metastases (including primary M1) u/o recurrences after TUR-B (at least T1 high-grade u/o Cis) ~~and~~ and/or after cystectomy (at least R1 u/o N+). |  |
| 1.2.5.e - MT | Participants:   * Urology, internal ~~or urological oncology~~ (qualification see section 6.2), radiotherapy, pathology, radiology * If the internal oncologist is unable to attend the tumour board, s/he can be represented by the urologist responsible for chemotherapy (qualification according to section 6.2) * if required: visceral/thoracic surgery, nuclear medicine, andrology     To be presented:   * postoperative all patients with initial diagnosis of a germ cell tumour * all patients with (gonadal/extragonadal) germ cell tumours who have a residual tumour after chemotherapy * Pre-therapeutically all patients with * Recurrence and/or new distant metastases * primary chemotherapy * extragonadal germ cell tumour |  |
| 1.2.5.f - MPEN | Participants:   * Urology * Haematology/internal oncology * If the haematologist/oncologist is unable to attend the conference, the urologist responsible for chemotherapy (qualification in accordance with Section 6.2) may represent him/her in exceptional cases. * Pathology * Radiology * Radiotherapy     To be presented:   * all patients with indication for multimodal therapy (cT4 and/or cN3) * all patients with invasive carcinoma ≥ pT1b before invasive LN diagnostics (dynamic sentinel lymph node biopsy [DSNB, OPS 5-401.51/.52/.53, 5-401.a1/.a2/a3 ] or modified inguinal lymphadenectomy [MIL, OPS 5-402.4/.9]) * all patients after (radical/therapeutic) inguinal and/or pelvic lymphadenectomy (OPS 5-404.d-h, 5-406.4, 5-407.2/.3/.4) * all patients with progression, patients with initial diagnosis of distant metastasis and/or recurrence |  |
| 1.2.5.g - PC, Mk, MB, MT, MPEN | Associated specialist areas (e.g. psycho-oncologist, social work, nursing) and specialists working in the palliative situation (neurology, neurosurgery, surgery, pain therapy, orthopaedics, etc.) should be included in the tumour board as required.    If several cooperation partners are named for a specialisation, the presence of a representative is sufficient if a regulated exchange of information has been established between them (e.g. via quality circles).  Each cooperation partner must participate in at least 30% of the tumour boards (cooperating urological practices 4 times a year). |  |
| 1.2.6.a - PC, Mk, MB, MT, MPEN | **General requirements pre-therapeutic conference/ tumour board**  The following applies to all pre-therapeutic conferences/tumour boards at the Centre: |  |
| 1.2.6.b - PC, Mk, MB, MT, MPEN | **Coordination with the signaller**  Any differences or ambiguities in relation to the information provided by the referrer must be clarified directly and personally with the referrer. |  |
| 1.2.6.c - PC, Mk, MB, MT, MPEN | **General information on the treatment plan**  The result of the tumour board consists, among other things, of a written, interdisciplinary treatment plan ("minutes of the pre-therapeutic conference/tumour board"). It must be part of the patient file and can also constitute the doctor's letter.  The treatment plan should be generated automatically from the tumour documentation system.  The patient will receive a copy of the treatment plan on request. |  |
| 1.2.6.d - PC, Mk, MB, MT, MPEN | **Preparation for the tumour board**  The essential patient data must be summarised in writing in advance and distributed to the participants. A preliminary assessment of suitable study patients must be carried out.    A written interdisciplinary treatment plan must be drawn up for patients who are not presented at the pre-therapeutic conference/tumour board. |  |
| 1.2.6.e - MT | In preparation for the tumour board, it should be clarified whether a discussion about fertility preservation has been held with the patient. |  |
| 1.2.6.f - PC, Mk, MB, MT, MPEN | **Demonstration of imaging material** Patient-related image material (e.g. pathology, radiology) must be available at the pre-therapeutic conference/tumour board - if available and relevant to the issue - and suitable technical equipment must be available for the presentation of the image material. Computerised presentation is sufficient.    Web/online conference  If web conferences are used, sound and the documents presented must be transmitted. Each cooperation partner must have the opportunity to present documents/image material independently. |  |
| 1.2.6.g - PC, Mk, MB, MT, MPEN | **Logging**  The result of the pre-therapeutic conference/tumour board consists of a written, interdisciplinary protocol (also referred to as a "treatment plan"). |  |
| 1.2.6.h - PC, Mk, MB, MT, MPEN | **Therapy deviation**   * The therapeutic procedure should be based on the treatment plans or recommendations of the pre-therapeutic conference/tumour board. * If deviations from the original treatment plan or deviations from the guidelines are identified, these must be recorded and evaluated. Depending on the cause, measures must be taken to avoid deviations. * It must be explained (e.g. in the form of a concept) how it is ensured that deviations are recorded. * If a therapy is not started at the patient's request (despite an existing indication) or is cancelled prematurely, this must also be recorded. |  |
| 1.2.6.i - PC, Mk, MB, MT, MPEN | **Participation in pre-therapeutic conference/tumour board as further training**  ~~For~~ The following functions/professional groups should attend ~~one-time mandatory participation~~ in the tumour board once ~~must be made possible~~ (refresher every 3 years)   * Assistance personnel (MTR, TRA, ...) from the fields of radiology, nuclear medicine and radiotherapy * Staff, ~~social services,~~ psycho-oncology and pharmacy * Participation in the tumour board is recognised as further training for the above-mentioned functions/professional groups. |  |
| 1.2.7 - PC, Mk, MB, MT, MPEN | **Metastasised tumours**  Procedures for the care (diagnosis/therapy) of patients with PSA (prostate only)/ with metastasis must be described (presentation of patient pathways - a written procedure for systemic therapy in metastasised patients must be available).    For patients with advanced cancer,   * who have already undergone guideline-based therapy, * who are able to receive molecular-based therapy according to the assessment of the clinical parameters, * who agree in principle to a possible therapy based on the molecular findings, should be referred to a Centre for Personalised Medicine. The prerequisite for this is the existence of a tumour board decision from an organ-specific centre. The MTB recommendation will be made available to the referring Centre. |  |
| 1.2.8 - PC, Mk, MB, MT, MPEN | **Morbidity/mortality conferences**   * Invited participants are the participants of the tumour board. * Conference can be scheduled to coincide with the pre-therapeutic conference/tumour board conference. * A list of participants will be kept. * M&M conferences must be held at least twice a year. * Cases with a special or improvable course (e.g. ≥ grade 3 CTC) should be discussed. Patients  who have died postoperatively/interventionally must always be discussed. * M&M conferences must be recorded.     For further information, see FAQ |  |
| 1.2.9 - PC, Mk, MB, MT, MPEN | **Quality circle**   * The tasks, participants and content of the quality circles must be defined. * Quality circles must be held at least 3 times a year in which uro-oncological topics are considered as one of the focal points. * A list of participants will be kept. * All main cooperation partners take part in the quality circles. The group of participants can be supplemented, for example, by practising physicians.   If main cooperation partners do not participate in the Centre's quality circles, then these main cooperation partners must independently provide evidence of quality circles to the required extent (combination possible).   * Organisation and recording by the coordinator or QM officer. * The quality circles must produce clear results (actions, decisions) that appear suitable for a significant further development/improvement of the centre. * A quality circle must have taken place at the time of initial certification. The result of the quality circle must be recorded.     Possible topics:   * Analysing the quality of results (benchmarking) * Interdisciplinary training * Interdisciplinary case discussion * Structural improvements to the centre * Public relations |  |
| 1.2.10 - PC, Mk, MB, MT, MPEN | **Further training**   * Further training events must be offered at least twice a year for the network of the Uro-oncology Centre (possibly also following MM conferences/Q-circles). * Content/results and participation must be recorded. A training plan must be submitted. |  |
| 1.2.11 - PC, Mk, MB, MT, MPEN | **Events of the Centre**  Each main cooperation partner must take part in at least 2 events at the Centre. The following are recognised:   * Q-Circle * Morbidity/mortality conference * Further training |  |

| **1.3 Cooperation with referring physicians and providers of aftercare treatment** | | |
| --- | --- | --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 1.3.1 - PC, Mk, MB, MT, MPEN | **Co-operating referring physicians** (integrated care):  A list of cooperating referring physicians (e.g. urologists, general practitioners) must be kept. Referrers can present patients independently at the pre-therapeutic conference/tumour board (e.g. in case of suspected recurrence).  Referrers must be informed about these options.    General Remarks:  Of course, there are also urologists who are not co-operation partners and only refer patients for diagnostics and therapy, for example. |  |
| 1.3.2 - PC | **Referral of the patient to the Centre:**  It must be described how a patient can be presented at the Centre for a pre-therapeutic conference and on what basis, if applicable, a special consultation is carried out (contract doctor, personal authorisation, institute authorisation, polyclinic authorisation).    Reference to CR 1.2.2 possible |  |
| 1.3.3 - PC, Mk, MB, MT, MPEN | **Provision of documents**  The urologist or radiotherapist is responsible for preparing the medical letter for the patients assigned to them.  The referring physician, the patient and each physician named by the referring physician must be provided with the collected documents ≤ 2 working days after they are available:   * Histology * Tumour board protocol/treatment plan, if applicable * Changes to the therapy if necessary |  |
| 1.3.4 - PC, Mk, MB, MT, MPEN | **Contact person**  The Centre's contact persons must be made known to referring physicians according to their function (e.g. telephone, e-mail). This can be mapped with the required publication of the cooperation partners. |  |
| 1.3.5 - PC, Mk, MB, MT, MPEN | **Feedback system**  A written procedure must be set up for the co-treating physicians to record, process and provide feedback on general and case-related concerns / questions from the main referring physicians. |  |
| 1.3.6 - PC, Mk, MB, MT, MPEN | **Further training**  The Centre must offer further training events for doctors at least twice a year. The content/results and participation must be recorded. |  |
| 1.3.7 - PC, Mk, MB, MT, MPEN | **Referrer satisfaction survey**   * A referrer satisfaction survey must be carried out every 3 years. The results of this survey must be evaluated and analysed. A cross-departmental survey can be recognised. * The referrer satisfaction survey must be available for the first time for the 1st surveillance audit (1 year after initial certification). |  |
| 1.3.8 - PC, Mk, MB, MT, MPEN | **Tumour documentation / follow-up**   * The co-operation with referring physicians during aftercare must be described. * The requirements for this are shown under "10 Tumour documentation". |  |

| **1.4 Psycho-oncology** | | |
| --- | --- | --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 1.4.1 - PC, Mk, MB, MT, MPEN | **Psycho-oncology - Qualification**   * Diploma/Master's degree in psychology that qualifies for a scientifically recognised psychotherapy method, * Doctors of human medicine, * Diploma/Master's degree in social pedagogy that qualifies for a scientifically recognised psychotherapy method     Each with at least 1 further psychotherapeutic training course: behavioural therapy, psychodynamic psychotherapy (analytical psychotherapy and depth psychology-based psychotherapy), systemic therapy, neuropsychological therapy (for psychological disorders caused by brain injuries), interpersonal therapy (IPT; for affective disorders and eating disorders), EMDR for the treatment of post-traumatic stress disorders, hypnotherapy for addiction disorders and for the psychotherapeutic co-treatment of somatic illnesses.    and psycho-oncological training (DKG-recognised).    Grandfathering for all those who are currently recognised and those who have started DKG-recognised psycho-oncological training by 31 December 2019.    Licence: At least 1 person in the psycho-oncological team of the network (inpatient or outpatient) must be licensed (psychological or medical psychotherapist)    Representatives of other psychosocial professions may be authorised if they can provide proof of the above-mentioned additional qualifications. A case-by-case assessment is required for this.    For further information, see FAQ |  |
| 1.4.2 - PC, Mk, MB, MT, MPEN | **Psycho-oncology - services and access**  Every patient must be offered the opportunity of a psycho-oncological consultation in a timely and appropriate manner. The offer must be low-threshold.    For further information, see FAQ |  |
| 1.4.3 - PC, Mk, MB, MT, MPEN | **Psycho-oncology resources**  At least 1 psycho-oncologist with the above-mentioned qualifications is available to the Centre (by name). |  |
| 1.4.4.a - PC, Mk, MB, MT, MPEN | **Scope of supply**  Psycho-oncological care, in particular for patients with high levels of distress in the distress screening, should be presented.    For further information, see FAQ |  |
| 1.4.4.b - PC, Mk, MB, MT, MPEN | The frequency and duration of conversations must be recorded |  |
| 1.4.5 - PC, Mk, MB, MT, MPEN | **Premises**  A suitable room must be provided for psycho-oncological patient consultations. |  |
| 1.4.6 - PC, Mk, MB, MT, MPEN | **Organisation chart**  The performance of tasks is to be regulated by an organisational plan in which, among other things, the availability of resources and the local presence can be seen. |  |
| 1.4.7.a - PC, Mk, MB, MT, MPEN | **Psycho-oncology - Tasks**  Psycho-oncological care for patients must be offered in all phases of care (diagnosis, inpatient, post-inpatient).    Goals and tasks of support:   * Diagnostic clarification after positive screening * Prevention/treatment of secondary psychosocial problems * Activation of personal coping resources * Maintaining the quality of life * Consideration of the social environment * Organisation of further outpatient care through cooperation with outpatient psycho-oncological service providers * Public relations work (patient event, etc.) * Management of the psychosocial quality circle |  |
| 1.4.7.b - PC, Mk, MB, MT, MPEN | Also recommended:   * to offer and coordinate the implementation of supervision and further education and training programmes for employees. * a twice-yearly meeting between psycho-oncologists and the nursing and medical staff * regular written and, if necessary, verbal feedback on psycho-oncological activities to the medical practitioners (e.g. consultation report or documentation in the medical file) * Regular participation in ward conferences and tumour boards * Cooperation with social services and other Centres * Offer and coordination of interdisciplinary intervention programmes |  |
| 1.4.7.c - PC, Mk, MB, MT, MPEN | The psycho-oncologists should present their work at least twice a year at the tumour board. |  |
| 1.4.8 - PC, Mk, MB, MT, MPEN | **Documentation and evaluation**  To identify the need for treatment, it is necessary to carry out a screening for psychological stress (e.g. see indicator "Psycho-oncological distress screening") and to document the result. The proportion of patients subjected to distress over-threshold screening should be reported. |  |
| 1.4.9 - PC, Mk, MB, MT, MPEN | **Training/further training/supervision**   * At least 1 specific training programme per employee per year (at least 1 day per year). * External supervision must be provided on a regular basis (recommendation: twice a month). |  |

| **1.5 Social work and rehabilitation** | | |
| --- | --- | --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 1.5.1 - PC, Mk, MB, MT, MPEN | **Social work - qualification**   * Social worker / social pedagogue * Individual case reviews in accordance with the guidelines of the professional association are possible * ~~Additional qualification~~ * ~~Experience in the medical/oncological field~~ |  |
| 1.5.2 - PC, Mk, MB, MT, MPEN | **Social Services - Resources:**  A minimum of 1 staff member is available to advise patients in the Centre for 400 patients (not cases) advised in the Centre (= primary cases, secondary metastases, recurrences). The personnel resources can be provided centrally; an organisational plan must be available. |  |
| 1.5.3 - PC, Mk, MB, MT, MPEN | **Social work - offer and access**  Every patient must be offered the opportunity to receive counselling from the social services in all phases of the illness in a timely and appropriate manner (proof required). The offer must be low-threshold. |  |
| 1.5.4 - PC, Mk, MB, MT, MPEN | **Scope of patient care**  The number of patients who have received care from social services must be documented and analysed. |  |
| 1.5.5 - PC, Mk, MB, MT, MPEN | **Premises**  A suitable room must be provided for social counselling work. |  |
| 1.5.6 - PC, Mk, MB, MT, MPEN | **Organisation chart**  The performance of tasks is to be regulated by an organisational plan in which, among other things, the availability of resources and the local presence can be seen. |  |
| 1.5.7.a - PC, Mk, MB, MT, MPEN | **Contents of the counselling**  using the DVSG service catalogue and the expert standard PEOPSA (initial psychosocial counselling of oncological patients by social work):   * Identification of social, economic and psychological emergencies * Initiation of medical rehabilitation measures * Advice on social law and economic issues (e.g. severe disability law, wage replacement benefits, pensions, benefit requirements, personal contributions, etc.) * Support with application procedures * Advice on outpatient and inpatient care options and referral to support services and specialist services * Support with professional and social reintegration * Cooperation with service providers and service providers * Discharge management * Intervention in emergencies |  |
| 1.5.7.b - PC, Mk, MB, MT, MPEN | Further tasks:   * Offer further training/information events for other disciplines at the Centre and/or patients. * Public relations and networking * Participation in multi-professional case discussions, supervision * Interdisciplinary co-operation, in particular with doctors, nurses, physiotherapists, psycho-oncologists, pastoral care, etc. |  |
| 1.5.8 - PC, Mk, MB, MT, MPEN | **Documentation and evaluation**  The activities of the social workers must be documented (e.g. CareSD, HIS) and evaluated. |  |
| 1.5.9 - PC, Mk, MB, MT, MPEN | **Training/further education**   * At least 1 specific training programme per employee per year (at least 1 day per year). * Offer of supervision |  |
| 1.5.10 - PC, Mk, MB, MT, MPEN | **Patient-related selection of rehabilitation facilities**  Patients should be offered oncological rehab during the consultation if this is indicated. (see also 1.5.7). |  |

| **1.6 Patient participation** | | |
| --- | --- | --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 1.6.1 - PC, Mk, MB, MT, MPEN | **Patient surveys:**   * At least every 3 years over a period of 3 months, all primary-case inpatients (surgical) must have the opportunity to participate in the patient survey. * The response rate should be higher than 30% (action must be taken if lower). * The survey can take place during or after the hospital stay. |  |
| 1.6.2 - PC, Mk, MB, MT, MPEN | **Evaluation of patient survey:**   * Responsibility for the evaluation must be assigned. * The evaluation must refer to the Centre's patients. * A recorded evaluation must be made and presented during the audit. * Further action is to be determined on the basis of the evaluation. |  |
| 1.6.3 - PC, Mk, MB, MT, MPEN | **Patient information (general):**   * The Centre should present itself and its treatment options as a whole (e.g. in a brochure, patient folder, on the homepage). * The co-operation partners and their contact persons must be named. The treatment programme must be described. * The treatment programme presented must include Rehab / AHB, self-help, treatment measures and alternatives. |  |
| 1.6.4 - PC, Mk, MB, MT, MPEN | **Discharge consultation**  A discussion is held with each patient on discharge in which the following topics are addressed and relevant information is provided: e.g. disease status, treatment planning, aftercare, personalised long-term aftercare plan (Testicular Cancer Survivorship Plan (testicles only)),supportive measures (e.g. rehabilitation, medical supply Centre, psychosocial services). Information provided e.g. uro-oncological patient guidelines via https://[www.leitlinienprogramm-onkologie.de/german-guideline-program-in-oncology](https://www.leitlinienprogramm-onkologie.de/german-guideline-program-in-oncology) |  |
| 1.6.5 - PC, Mk, MB, MT, MPEN | **Patient information (case-related):**  The patient is actively offered the provision of the following documents.  The patient will receive the following documents on request:   * The tumour board report/therapy plan * Medical report/discharge report * Aftercare plan / aftercare pass * Study documents, if applicable |  |
| 1.6.6 - PC, Mk, MB, MT, MPEN | **Event for patients**  The Centre must hold an information event for patients and/or interested parties at least once a year.  If patient events are (co-)financed by industry, this fact, including potential conflicts of interest of the speakers, must be revealed. The Centre must exclude any direct influence on patients by industry representatives.    For further information, see FAQ |  |
| 1.6.7 - PC, Mk, MB, MT, MPEN | **Complaints management**  An official procedure for complaint management is in place. The patients are given feedback. Complaints are taken into account in the improvement process. |  |
| 1.6.8 - PC, Mk, MB, MT, MPEN | **Self-help groups**  The self-help groups with which the Centre actively cooperates must be named. Written agreements must be made with the self-help groups, which should include the following points:   * Access to self-help groups in all phases of therapy (initial diagnosis, hospitalisation, chemotherapy, ....) * Announcement of contact details of self-help groups (e.g. in patient brochures, homepage of the Centre) * Possibilities Display of information brochures from self-help groups * Regular provision of rooms at the centre for patient consultations * Quality circles involving representatives from psycho-oncology, self-help groups, social work, pastoral care, nursing and medicine. * Personal discussions between self-help groups and the centre with the aim of organising joint activities and events or coordinating them with each other. The result of the discussion must be recorded. * Participation of nursing/medical staff in events organised by the self-help group |  |

| **1.7 Study management** | | |
| --- | --- | --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 1.7.1 - PC, Mk, MB, MT, MPEN | **Access to studies**  Patients must have access to studies. The studies conducted at the Centre must be listed and published, e.g. on the homepage (including a brief description of the study). |  |
| 1.7.2 - PC, Mk, MB, MT, MPEN | **Study representative**  Study representative physician must be named    Study assistant/ study nurse   * One study assistant per "conducting study unit" must be named in the "study organisation chart". * This can be active for several "performing study units" in parallel. * Study assistance should be available at the time of initial certification. * Proof of the training programme for study assistants should be available as a qualification. |  |
| 1.7.3 - PC, Mk, MB, MT, MPEN | **Study assistance - Tasks**  The range of tasks must be defined in writing (e.g. via job/function description) and may include the following contents, among others:   * Conducting studies together with the doctor in charge of the study * Patient care during the study and in aftercare * Organisation, coordination of diagnostics, laboratory, sample dispatch and test medication * Collection and documentation of all study-relevant data * Preparation and monitoring of audits and inspections by authorities * The work of a study assistant can be combined with other activities such as tumour documentation. |  |
| 1.7.4 - PC, Mk, MB, MT, MPEN | **Process description**  The processes including responsibilities must be defined for the initiation of new studies and the implementation of studies. This includes, for example   * Selection of new studies incl. approval decision * Internal announcement of new study (update of study list, ...) * Study organisation (special features of student support, documentation, ...) * Type of disclosure of study results (e.g. MA, Pat.) |  |
| 1.7.5.a - PC, Mk, MB, MT, MPEN | **Share of study pat.**  Initial certification: at least 1 patient in studies  after 1 year: at least 5 % of primary cases    Only the inclusion of patients in studies for which a valid ethics vote can be presented counts as study participation.    The requirement applies per tumour entity.    For further information, see FAQ |  |
| 1.7.5.b - PC, Mk, MB, MT, MPEN | Only the inclusion of patients in studies with an ethics vote counts as study participation (non-interventional/diagnostic studies and prevention studies, health services research are recognised, biobank collections are excluded).    All study patients can be taken into account for the calculation of the study quota (proportion of study patients in relation to the primary case number of the Centre)  General requirements for the definition of study quota:   * Patients can be counted once per study, time: date of patient consent (exception: CPM patients, see FAQ document) * Study patients can be counted for 2 centres, provided that the sending centre itself conducts at least one study for patients of the centre (per tumour entity). If this counting method is chosen (optional), the centre must show how many patients are included in studies in its own centre, sent to other centres/clinics for study participation and transferred from other centres/clinics for study participation - see also Excel template Data Sheet. * Patients in the palliative and adjuvant situation can be counted, no restriction of stages. * Patients who are enrolled in several studies at the same time can be counted more than once.     For further explanations see FAQ. |  |
| 1.7.6 - PC, Mk, MB, MT, MPEN | **Cooperation with external bodies**  If the initiation or implementation of the study is not (in part) carried out by the main cooperation partners, this must be clearly regulated in a cooperation agreement. |  |

| **1.8 Nursing care** | | |
| --- | --- | --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 1.8.1 - PC, Mk, MB, MT, MPEN | **Oncological specialist nurses**   * There must be at least 1 active oncology specialist nurse (1 full time) on day duty at the Centre. * Specialist oncological nurses must be named. * In areas where patients are cared for, evidence must be provided that an oncological nurse is employed. * The fulfilment of duties/representation must be regulated and documented in writing.     For initial certification, at least one application for training as an "oncological nurse" must be submitted. In this case, it must be explained how the "responsibilities / tasks" described below will be performed during the training programme. During the training phase, it is recommended to enter into cooperation with an already trained oncological nurse who will accompany the performance of tasks during the training phase. After 3 years, the oncological specialist nurse must provide proof of training.    The prerequisite for recognition as an oncological specialist nurse is the   * Further training as an oncological nurse in accordance with the respective state regulations * or the model for a state regulation of the German Hospital Federation (DKG) * or Advanced Practice Nurse (Master's degree) plus 2 years of practical uro-oncological work experience (full time equivalent in inpatient, day-care or outpatient clinics) |  |
| 1.8.2 - PC, Mk, MB, MT, MPEN | **Responsibilities / Tasks**  Patient-related tasks:   * Specialist assessment of symptoms, side effects and stress * Individualised derivation of interventions from nursing standards * Implementation and evaluation of nursing and therapeutic measures * Determination of individual patient-related counselling needs. * The Centre's care concept must already define the specialist advice required * Continuous information and counselling of the patient (and their relatives) throughout the course of the illness * Implementation, coordination and verification of structured counselling sessions and guidance for patients and relatives; according to the concept, these can also be carried out by other experienced nursing staff with oncological expertise. * Participation in the tumour board (according to section 1.2) is desirable * Initiation of and participation in multi-professional case discussions/care visits; the aim is to find solutions in complex care situations; criteria for the selection of patients must be defined; ~~at least 12~~ case discussions/care visits must be regularly demonstrated per year and centre     Superordinate activities:   * A care concept must be developed and implemented in which the organ-specific characteristics of oncological care in the prostate cancer/Uro-Oncological Centre are taken into account. * Creation of specialised, in-house standards on the basis of (if possible) evidence-based guidelines (e.g. S3-GL Supportive). * Offer of collegial counselling/supervision * Networking of oncology nurses in a joint quality circle and participation in the quality circle of the prostate cancer/Uro-Oncological Centre. * Interdisciplinary exchange with all professional groups involved in the treatment       Responsibility for implementing the requirements for the nurse administering chemotherapy (see section 6.2.3) |  |
| 1.8.3 - PC, Mk, MB, MT, MPEN | **Nursing concept**  A nursing concept that takes specific aspects of oncological care into account is to be developed and implemented. |  |
| 1.8.4 - PC, Mk, MB, MT, MPEN | **Induction**  The induction of new staff members must be undertaken on the basis of a specialist oncological induction catalogue/plan with the participation of the specialist oncology nurse. |  |
| 1.8.5 - PC, Mk, MB, MT, MPEN | **Continuing education**   * A qualification plan for the nursing staff must be submitted in which the qualifications planned for a one-year period are presented. * At least 1 specific training/ further training per employee per year (at least 1 day per year), provided that the employee performs quality-relevant activities for the Centre. |  |
| 1.8.6 - MB | **Postoperative care**   * Stoma care (where applicable) must be regulated in a procedure description |  |
| 1.8.7 - MB | Recognised training in stoma therapy:   * Recognised are further training courses of the FgSKW to become a nursing expert for stoma, continence and wounds with a scope of further training of 720 hours or other comparable further training courses. * At least one application for "Stoma therapy" training must be submitted for initial certification. In this case, it must be explained how the "responsibilities / tasks" described below will be performed during the training programme. * During the training phase, it is recommended to enter into cooperation with an already trained oncological nurse who will accompany the performance of tasks during the training phase. * Proof of stoma therapy must be provided after 3 years.     Definition of the tasks of stoma therapy   * Pre-inpatient, pre-operative and post-inpatient guidance, counselling and training for patients and relatives * Participation in preoperative labelling (or regulated exchange of information) * If necessary, hold a stoma consultation |  |

| **1.9 General service areas (pharmacy** | | |
| --- | --- | --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 1.9.1 - PC, Mk, MB, MT, MPEN | **Supportive therapy**   * The options for supportive therapy must be described for all therapy stages (process description/algorithm). * A pain therapist must be named and be available to patients as a fixed contact person for consultations. * Patients undergoing outpatient treatment should be informed about social work counselling and access to psycho-oncological care, and a permanent contact person should be available. * Access to pastoral care is to be described * In the case of execution via co-operation partners, a co-operation agreement must be concluded for the aforementioned requirements. * Nutritional counselling must be part of the PC/UC, an SOP should be available * The need for nutritional counselling must be actively determined and implemented in relation to the patient * The metabolic risk ("nutritional risk") should be recorded at the latest on admission to hospital using Nutritional Risk Screening (NRS), e.g. according to Kondrup 2003. |  |

**2. Organ-specific diagnostics**

| **2.1 Consultation hours** | | |
| --- | --- | --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 2.1.1 - PC, Mk, MB, MT, MPEN | **Number of physicians/specialists** working for the Centre in the field of urological diagnostics   * At least 1 urology specialist named per tumour entity * A specialist may be appointed for several tumour entities * Specialists must be named |  |
| 2.1.2 - PC, Mk, MB, MT, MPEN | **Waiting times according to indication**  < 2 weeks wait for an appointment  < 2 weeks wait for an appointment for ultrasound-directed punch biopsy  < 2 weeks Presentation at pre-therapeutic tumour board or tumour board.    In total, the period for consultation on the treatment recommendation must not exceed 6 weeks |  |
| 2.1.3 - PC, Mk, MB, MT, MPEN | **Waiting times during consultation hours**  Requirement: < 60 min    Waiting times for an appointment  Requirement: < 4 weeks    Waiting times should be recorded on a random basis and statistically analysed (recommendation: evaluation period of 4 weeks per year). |  |
| 2.1.4 - PC, Mk, MB, MT, MPEN | Procedure descriptions of the relevant processes in the field of urological diagnostics must be available. These include   * Diagnostics incl. notification of findings (incl. patients with (local) recurrence and/or distant metastasis) * Therapy planning (preoperative time) * (Pre-)inpatient admission * Collaboration with other cooperation partners (especially external) * Preparation of patients for the tumour board     Sufficient resources must be available for the execution of the processes. |  |
| 2.1.5.a - Mk | **Detection of hereditary burden and Genetic counselling**  Patients suspected of having hereditary kidney cell carcinoma should be advised of the possibility of genetic counselling  The checklist for recording a hereditary burden can be downloaded under this [link](https://www.krebsgesellschaft.de/zertdokumente.html?file=files/dkg/deutsche-krebsgesellschaft/content/pdf/Zertifizierung/Erhebungs-und-Kennzahlenboegen/Fragebogen%20Heredita%CC%88res%20Nierenzellkarzinom_v4.1%20220316.pdf&cid=86235) |  |
| 2.1.5.b - MT | **Fertility preservation**   * All patients with a suspected germ cell/strand tumour should be offered cryopreservation of spermatozoa before the start of therapy (before ablatio testis, at the latest before chemotherapy or radiotherapy).   The discussion must be documented.   * A procedure description with the names of those responsible must be provided. * The SOP Fertility Preservation can be downloaded from the following link:   [www.krebsgesellschaft.de/zertdokumente.html](www.krebsgesellschaft.de\zertdokumente.html) |  |
| 2.1.6 - PC, Mk, MB, MT, MPEN | **Continuing education/specialty training**   * A training plan for medical staff (physicians, nurses, technicians, etc.) must be submitted * The qualification plan must set out the qualifications planned for a one-year period. * Annual scope of at least 1 specific further training course per employee (at least 1 day per year), provided they perform quality-relevant activities for the Centre. * If relevant content is covered in the 6 further training courses required by the oncology agreement for uro-oncology, these can be credited here (in part). |  |
| 2.1.7 - PC, Mk, MB, MT, MPEN | Equipment description and list of all ultrasound equipment used for diagnostics in the Centre (the possibility of transrectal sonography must be given) |  |

| **2.2 Diagnostics** | | |
| --- | --- | --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 2.2.1 - PC | * In principle, the laboratory should be accredited for the parameters total PSA and free PSA and have the corresponding certificate from the DAR (German Accreditation Council). * If the laboratory is not accredited, the following conditions/requirements must be met. |  |
| 2.2.2 - PC | **Laboratory management**   * Specialist in laboratory medicine * or clinical chemist * or urology specialist with laboratory qualification * or Master of Science Biotechnology      * A substitution arrangement with appropriate qualifications is in place. * It must be possible for the clinicians at the PC to consult with the laboratory management every working day. * A medical specialist or the laboratory management carries out the medical validation of the laboratory findings. |  |
| 2.2.3 - PC | **Medical-technical assistants (MTL):**   * The analyses are only carried out by qualified medical-technical assistants. * The technical validation of the measurement results is carried out by MTL. |  |
| 2.2.4 - PC | **Parameters:**   * Mandatory daily determination of total PSA (tPSA) * Optional daily determination of free PSA (fPSA) and calculation of the PSA quotient or optional daily determination of complexed PSA (cPSA). * Optional determination of ultra-sensitive PSA |  |
| 2.2.5 - PC | **Internal laboratory quality assurance:**   * According to the guidelines of the German Medical Association. |  |
| 2.2.6 - PC | **Diagnostics manufacturers and analyser systems:**   * No specifications regarding the selection of diagnostics manufacturers and the analyser system used. * When changing manufacturers, the comparability of the measurements must be determined by means of parallel analyses (old/new system) or analyses of reference samples. |  |
| 2.2.7 - PC | **Findings:**   * Cumulative transmission of findings must be possible * Specification of the cut-off value * Specification of the PSA quotient * Specification of age-appropriate reference intervals |  |
| 2.2.8 - PC | * Successful participation in 4 proficiency tests per year for total PSA and free PSA (verification). * Standardised pre-analysis, analysis and post-analysis according to established SOPs. |  |
| 2.2.9.a - PC | **Biopsies**   * The correct indication for TRUS biopsy of the prostate must be demonstrated. * At least 20% of patients with punch biopsies must be positive. * At least 10 punch biopsy cylinders, each at least 1 cm long, must be taken.     An evaluation must be submitted.    For further information, see FAQ. |  |
| 2.2.9.b - Mk | **Biopsies**   * The biopsy should be performed as a punch cylinder biopsy. * At least 2 biopsies should be taken under ultrasound or CT control |  |
| 2.2.10 - MB | **Urine diagnostics**  The following urine diagnostics must be possible:   * Urine microscopy/ microbiological examination * Urine cytology incl. fluorescence in situ hybridisation (FISH) or immunocytology |  |

**3. Radiology**

|  | | |
| --- | --- | --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 3.1 - PC, Mk, MB, MT, MPEN | **Specialists**   * At least 1 specialist in radiology * Substitution regulation with the same qualification must be documented in writing * Specialist and representative must be named |  |
| 3.2 - PC, Mk, MB, MT, MPEN | **Medical technologists in radiology (MTR) of radiology**   * At least 2 qualified MTRs must be available and named |  |
| 3.3.1 - PC, Mk, MB, MT, MPEN | **Methods/devices to be provided**   * Conventional X-ray * Spiral CT for staging distant metastases * Sonography (including the option of transrectal sonography) * MRI for staging |  |
| 3.3.2 - PC | (if possible and obligatory if available as a health insurance benefit: mp-)MRI for detection: device specification according to PI-RADS v2.1 (1.5 or 3 Tesla) |  |
| 3.3.3 - MB | * CT urography |  |
| 3.3.4 - Mk | * Whole-body CT (low dose)   or   * Whole-body MRI (possibly via co-operation) |  |
| 3.4 - PC, Mk, MB, MT, MPEN | Imaging for staging and reporting on the same or following working day must be guaranteed. |  |
| 3.5 - PC | Quality standards mpMRI  The currently valid quality standards of the DRG/BDR must be taken into account when performing mpMRI (Franiel T, et al. DOI 10.1055/a-1406-8477). The implementation must be described. |  |
| 3.6 - PC, Mk, MB, MT, MPEN | **Radiology process descriptions (SOPs)**  The imaging procedures must be described and checked once a year to ensure that they are up to date. |  |
| 3.7.1 - PC, Mk, MB, MT, MPEN | **Creation of findings**  The written findings must be submitted to the co-treating physicians no later than 48 hours after the examination. |  |
| 3.7.2 - PC | The MRI of the prostate must be standardised, e.g. according to the recommendations of the European Consensus Meeting. |  |
| 3.8 - PC, Mk, MB, MT, MPEN | **Further education**   * A qualification plan for medical and other staff (MTR) must be submitted, in which the qualifications planned for a one-year period are presented. * At least 1 specific training course per employee per year (duration > 0.5 days), provided that the employee performs quality-relevant activities for the Centre. |  |
| 3.9 - PC, Mk, MB, MT, MPEN | **Availability**  Presence of a radiology specialist during working hours, 24-hour availability outside working hours, if necessary via cooperation (including weekends and public holidays) |  |

**4. Nuclear medicine**

|  | | |
| --- | --- | --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 4.1.1 - PC, Mk, MB, MT, MPEN | **Specialists in nuclear medicine:**   * At least 1 specialist in nuclear medicine is available * Substitution regulation with the same qualification must be documented in writing * Specialist and representative must be named |  |
| 4.1.2 - Mk, MB, MT, MPEN | Radiologists with additional training in nuclear medicine diagnostics are also recognised as specialists |  |
| 4.2 - PC, Mk, MB, MT, MPEN | **MTR of nuclear medicine:**  At least 2 qualified MTRs must be available and named |  |
| 4.3.1 - PC, Mk, MB, MT, MPEN | **Methods**  Description of the imaging methods available in the department.  Obligat:   * Bone scintigraphy (kidney, bladder, testicles: possibly in co-operation) * FDG-PET/CT (penile carcinoma) |  |
| 4.3.2 - PC | Optional:   * PSMA-PET hybrid imaging * Inpatient radionuclide therapy |  |
| 4.4 - PC, Mk, MB, MT, MPEN | **Process descriptions (SOPs)**  The imaging procedures in nuclear medicine must be described and reviewed once a year to ensure that they are up to date. |  |
| 4.5 - PC, Mk, MB, MT, MPEN | **Creation of findings**  The written findings of the nuclear medicine "scintigraphy" (gamma camera diagnostics) must be available to the co-treating physicians no later than 24 hours after completion of the examination. A time period of 24 hours per specialist discipline involved is provided for the preparation of the findings of hybrid diagnostics. |  |
| 4.6 - PC, Mk, MB, MT, MPEN | **Further education**   * A qualification plan for medical and other staff (MTR) must be submitted, in which the qualifications planned for a one-year period are presented. * At least 1 specific training course per employee per year (duration > 0.5 days), provided they perform quality-relevant activities for the Centre. |  |

**5. Surgical oncology**

| **5.1 Multiple organ surgical therapy** | | |
| --- | --- | --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 5.1.1 - PC, Mk, MB, MT, MPEN | Catalogue of Requirements of the Organ Cancer Centres and Oncology Centres have a uniform table of contents.  This section does not contain technical requirements for Uro-Oncology Centres. |  |

| **5.2 Organ-specific surgical therapy** | | |
| --- | --- | --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 5.2.1.a - PC | **Surgical expertise prostate**  Number of prostatectomies as part of uro-oncological operations/year/Centre (related to primary cases and patients with new recurrence)   * 50-74 prostatectomies:   If only 1 surgeon is appointed, then appointment of a 2nd surgeon is necessary  until the next audit (qualification CR 5.2.6)   * ≥ 75 prostatectomies => nomination of at least 2 surgeons     Prostatectomies:   * Radical prostatectomy (primary intervention) * Radical cystoprostatectomy for bladder carcinoma AND PCa (primary intervention) * Radical cystoprostatectomy for prostate carcinoma (primary intervention) * Radical prostatectomy (recurrence therapy) - Salvage prostatectomy     Indication of prostatectomies in basic data  (Excel template)    For 25-49 prostatectomies: Case-by-case decision; the audit report must contain a recommendation to maintain the certificate without restriction (including ≥ 100 primary cases)    Naming of surgeons  in table Prostate surgeons    For further information, see FAQ. |  |
| 5.2.1.b - Mk | **Surgical expertise in kidney ~~cell carcinoma~~**   * At least 30 partial kidney resections and/or nephrectomies (OPS 5-553, 5-554) of **malignant kidney tumours ~~carcinoma~~**/year/Centre (= carcinomas (ICD-10 C 64,C65) are counted)     Data Sheet Kidney  (Excel template; Basic Data)    For further information, see FAQ. |  |
| 5.2.1.c - MB | **Bladder surgical expertise**   * 20 cystectomies (OPS 5-576) for bladder carcinoma/year/Centre (= carcinomas (ICD-10 C 67, D09.0, D41.4) are counted) * Likewise front /complete exenteration (OPS 5-687.0, 5-687.2) in patients with bladder carcinoma (ICD-10 C67, ~~D09.0, D41.4~~) and patients with any C-diagnosis.     Data Sheet Urinary bladder (Excel template; Basic Data)    For further information, see FAQ. |  |
| 5.2.1.d - MPEN | **Surgical expertise penis**   * 4 resections (OPS 5-640.2, 5-641, 5-642) in connection with ICD 10 C60/ D07.4 per year and * 3 inguinal/pelvic lymphadenectomies (OPS 5-401.51/.52/.53, 5-401.a1/.a2/a3, 5-402.4/.9, 5-404.d-h, 5-406.4, 5-407.2/.3/.4) in conjunction with ICD 10 C60 /D07.4 per year |  |
| 5.2.1.e - MB | **White light cystoscopy**    Requirement Implementation:   * Specialist for urology     The following diagnostics must be made possible:   * Flexible or rigid cystoscopy * Fluorescence-assisted cystoscopy (hexylaminolaevulinate) (see also section 5) * Biopsy     **Techniques**   * Fluorescence-assisted TUR-B (with hexylaminolaevulinate) must be made possible * In the context of a transurethral bladder resection, the following findings should be described in the surgical report: estimated size of the tumour (in cm), location and number of tumours, appearance of the tumour and the presence of other mucosal abnormalities     For further information, see FAQ. |  |
| 5.2.2 - MB | **Instillation therapy**  The following techniques must be available/enabled:   * Chemotherapy early instillation * Instillation therapy with Bacille-Calmette-Guerin (BCG) |  |
| 5.2.3 - PC, Mk, MB, MT, MPEN | **Bed capacity**  must be sufficient for the inpatient care of patients at the Centre.  Description of the   * Equipment of the patient rooms * Special features of the department |  |
| 5.2.4 - PC, Mk, MB, MT, MPEN | **Surgical capacity**  At least 1 operating theatre must be regularly available for uro-oncological operations. |  |
| 5.2.5 - PC, Mk, MB, MT, MPEN | **Nursing staff capacity**  In the inpatient, surgical area of the Centre, one registered nurse must always be available per shift. |  |
| 5.2.6 - PC, Mk, MB, MT, MPEN | **Postoperative care**  Care in the following areas must be regulated in a procedure description:   * Intensive medical care * Physiotherapy * Postoperative pain therapy * The possibility of 24-hour emergency surgical care must be guaranteed     **Emergency treatment**   * Availability of emergency equipment and written emergency plan. |  |
| 5.2.7 - PC, Mk, MB, MT, MPEN | **Specialists for the Uro-Oncology Centre**  At least 2 medical specialists working for the centre in accordance with the staffing plan (can also be surgeons). The medical specialists must be named. |  |
| 5.2.8.a - PC, Mk, MB, MT, MPEN | **Surgeons**   * Each Centre patient must be operated on by one of the named surgeons (or as part of a teaching assistantship).     Assistance  Recognition as an assistant is only possible if this takes place as part of training (no parallel recognition of cases with 2 surgeons). |  |
| 5.2.8.b - PC | **Prostate surgeons**    Expertise per surgeon   * Every prostate surgeon must provide evidence of at least 25 prostatectomies per year or 75 prostatectomies in 5 years. For initial certification, this number must be proven in the year prior to the initial certification (extract from the clinic information system). * Description of the special qualification (training) of prostate surgeons via curricula.   + Radical prostatectomy (retropubic, perineal or laparoscopic)   + Nerve-sparing radical prostatectomy   + Removal of the pelvic lymph nodes (including extended-field lymphadenectomy)   + Transurethral palliative therapy of prostate carcinoma (in particular transurethral resection of the prostate)   + Monitoring of complications after surgery   + Metastatic surgery   + At least 1 dedicated prostate training event for each surgeon each year (length > 0.5 day)     Naming of surgeons in table Prostate surgeons  (at the end of the sectopm)    For further information, see FAQ. |  |
| 5.2.8.c - PC | **Authorisation of new surgeons**  First appointment as prostate surgeon: at least 100 radical prostatectomies as first surgeon (extract from the clinic information system or submission of certificates). |  |
| 5.2.8.d - Mk | **Kidney surgeons**   * At least 2 kidney surgeons must be named (surgeons can also be prostate/ bladder/testicle/penile surgeons)     **Expertise per surgeon**   * At least 15 partial kidney resections and/or nephrectomies (=OPS: 5-553, 5-554), of **malignant kidney tumours ~~carcinoma~~**//year (= carcinomas (ICD-10 C 64, C65) are counted)     Named in table "Kidney surgeons"  ( at the end of this section) |  |
| 5.2.8.e - Mk | **Authorisation of new surgeons**   * In the last 3 years, a cumulative total of at least 40 kidney partial resections and/or nephrectomies for **malignant kidney tumours ~~carcinoma~~** (ICD-10 C 64, C65) as the primary surgeon (extract from the clinic information system or submission of certificates). |  |
| 5.2.8.f - MB | **Bladder surgeons**   * At least 2 bladder surgeons must be named (surgeons can also be prostate/kidney/testicle/penile surgeons)     **Expertise per surgeon**   * 10 cystectomies (OPS 5-576) for bladder carcinoma/year (= carcinomas (ICD-10 C 67, D09.0, D41.4)) are counted) * Likewise, front / complete exenterations (OPS 5-687.0; 5-687.2) in patients with bladder cancer (ICD-10 C67~~, D09.0, D41.4~~) and patients with any C-diagnosis     Named in table "Bladder surgeons"  ( at the end of this section) |  |
| 5.2.8.g - MB | **Authorisation of new operators**   * At least 30 cumulative cystectomies for bladder cancer (ICD -10 C67, D09.0, D41.4) in the last 3 years as first surgeon (extract from the hospital information system or submission of certificates). * Likewise, front / complete exenterations (OPS 5-687.0; 5-687.2) in patients with bladder cancer (ICD-10 C67, ~~D09.0, D41.4~~) and patients with any C-diagnosis |  |
| 5.2.8.h - MT | **Testicle surgeons**   * At least 2 testicular surgeons must be named (surgeons can also be prostate/kidney/bladder/penile surgeons)     **Expertise per surgeon**   * 3 (nerve-sparing) retroperitoneal (paraaortic, paracaval) lymphadenectomies (OPS 5-404.d/e, 5-407.2) per year     For further information, see FAQ. |  |
| 5.2.8.i - MT | **Authorisation of new surgeons**  In the last 3 years cumulatively 9 retroperitoneal (paraaortic, paracaval) lymphadenectomies as first surgeon (extract from the clinic information system or submission of certificates).    For further information, see FAQ. |  |
| 5.2.8.j - MPEN | **Penis surgeons**   * At least 2 penis surgeons must be named (surgeons can also be prostate/bladder/testicle/kidney surgeons)     **Expertise per surgeon:**   * at least 6 resections in the last 3 years (OPS 5-640.2, 5-641, 5-642) in conjunction with ICD 10 C60/ D07.4) and * at least 4 inguinal/pelvic lymphadenectomies in the last 3 years (OPS 5-401.51/.52/.53, 5-401.a1/.a2/a3, 5-402.4/.9, 5-404.d-h, 5-406.4, 5-407.2/.3/.4) in conjunction with ICD 10 C60 /D07.4     Naming of surgeons in the penile surgeons table (at the end of the section) |  |
| 5.2.8.k - MPEN | **Authorisation of new surgeons**   * at least 4 resections (OPS 5-640.2, 5-641, 5-642) in conjunction with ICD 10 C60/ D07.4) and * at least 4 inguinal/pelvic lymphadenectomies (OPS 5-401.51/.52/.53, 5-401.a1/.a2/a3, 5-402.4/.9, 5-404.d-h, 5-406.4, 5-407.2/.3/.4) in conjunction with ICD 10 C60 /D07.4 |  |
| 5.2.9 - PC | **Nerve-preserving surgery**  More than 80% of patients defined as suitable for nerve preservation undergo nerve-preserving surgery. The intraoperative assessment by the surgeon must be taken into account. |  |
| 5.2.10 - PC, Mk, MB, MT, MPEN | **Information / dialogue with patients:**  With regard to diagnosis and treatment planning, sufficient information must be provided and a dialogue must be conducted. This includes, among other things   * Presentation of alternative treatment concepts. * Offer and ~~provision~~ support in obtaining second opinions. * Dismissal interviews as standard.     The manner in which information is provided and the dialogue is to be described in general terms. This must be documented in the patient's medical notes and protocols/records. |  |
| 5.2.11 - PC, Mk, MB, MT, MPEN | The following **quality-determining processes** are to be described with details of responsibilities:   * Perioperative management * Discharge management * Operative management (operating theatre procedures, reprocessing material, documentation) * Postoperative pain therapy * Emergency care (e.g. haemorrhage) including deployment planning of qualified personnel (duty rota/call service)     Sufficient resources must be available for the execution of the processes. |  |
| 5.2.12 - PC, Mk, MB, MT, MPEN | **Continuing education/specialty training**   * A qualification plan for the medical and nursing staff must be submitted in which the qualifications planned for a one-year period are presented. * At least 1 specific training/ further training per employee per year (at least 1 day per year), provided that the employee performs quality-relevant activities for the Centre |  |

**6. Medicinal oncology/ Systemic therapy**

| **6.1 Medical oncology** | | |
| --- | --- | --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 6.1.1 - PC, Mk, MB, MT, MPEN | Catalogue of Requirements of the Organ Cancer Centres and Oncology Centres have a uniform table of contents.  This section does not contain technical requirements for Uro-Oncology Centres. |  |

| **6.2 Organ-specific systemic therapy** | | |
| --- | --- | --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 6.2.1 - PC, Mk, MB, MT, MPEN | **Medical qualification**  The physician performing the procedure must fulfil the following criteria:   * Specialist in internal medicine and haematology and oncology   or   * Specialist for radiotherapy   or   * Specialist for urology     Requirements for urology specialists   * until MWBO 2018: + additional qualification in medical tumour therapy; alternatively: participation in the "Oncology Agreement" Appendix 7 to the Federal Coverage Agreements in regional implementation and * 5 years of experience in drug-based tumour therapy for uro-oncological diseases (proof)     The specialists named here must actively carry out the drug-based tumour therapy. It is not possible to delegate responsibilities to doctors without the above-mentioned qualifications.    For further information, see FAQ. |  |
| 6.2.2 - PC, Mk, MB, MT, MPEN | **General requirements**   * A deputising arrangement must be available in writing (specialist with the same qualification). * The medical specialists must be named. |  |
| 6.2.3 - PC, Mk, MB, MT, MPEN | **Specialised nurses**   * Requirements for the specialised nurse responsible for administering chemotherapy * Inpatient, day patient or clinical-outpatient units in which medicinal oncological therapy is carried out by non-medical staff must be under the specialist supervision of a specialist oncology nurse. This rule does not apply to cooperating practices. * At least 1 year of professional experience in oncology * 50 chemotherapy administrations/year (estimations possible for initial certification, documentation must be provided in the following years) * Documentation of training according to the recommendations of the KOK (*Handlungsempfehlungen der KOK, Applikation von Zytostatika durch Pflegefachkräfte* (Recommendations of the Conference of Oncological Nursing and Paediatric Nursing Care, administration of cytostatic agents by specialist nurses) * Active integration in the implementation of requirements for the emergency treatment and therapy of comorbidities and secondary diseases. * The provision of advice and/or information to the patient by nurses must be documented. |  |
| 6.2.4 - PC, Mk, MB, MT, MPEN | **On call/availability of medical staff**   * 24-hour outside normal working hours including weekends and public holidays * During 24-hour availability, access to therapy data must be possible. |  |
| 6.2.5.a - PC, Mk, MB, MT, MPEN | **Case numbers per treatment unit/partner**  The department carrying out the work must fulfil the following criteria:    Counting method:  Systemic (= cytostatic therapies and/or targeted therapeutics and/or AK/immune therapies) therapy per patient (consisting of **several** cycles or applications, combination therapies count as 1 therapy). For therapies spanning several years, the therapy started in the audit year counts. 1 therapy per patient = 1 therapy line per disease per patient. In the event of a shortfall, expertise cannot be verified via collaborations (to be verified individually by each treatment unit).     * At least 200 systemic therapies (cytostatic therapies and/or targeted therapeutics and/or AK/immune therapies, no hormone therapies) per year (for different tumour types) * incl. 5 patients with metastasised prostate carcinoma and/or kidney and/or bladder and/or testicular carcinoma/year (depending on the area of application) * Number of cases reflects the expertise of the treatment unit and is not limited to Centre patients; instillation or hormone therapies cannot be counted     **OR** |  |
| 6.2.5.b - PC | * 20 urological patients with chemotherapy/year (including docetaxel) * 5 patients with metastasised prostate carcinoma/year (may be a subset of the 20 patients) |  |
| 6.2.5.c - Mk | * 20 urological patients with systemic therapy/year * 5 patients with kidney carcinoma (may be a subset of the 20 patients) |  |
| 6.2.5.d - MB | * 20 urological patients with systemic therapy/year * 5 patients with bladder carcinoma (may be part of the 20 patients) |  |
| 6.2.5.e - MT | * 20 urological patients with systemic therapy/year * 5 patients with germ cell/strand tumour (may be part of the 20 patients) |  |
| 6.2.5.f - MPEN | * 20 urological patients with systemic therapy/year |  |
| 6.2.6 - PC, Mk, MB, MT, MPEN | **Implementation of system therapy**  ~~Chemotherapy~~ Systemic therapy usually takes place on an outpatient basis or as part of a day clinic (also interdisciplinary). There is the option of inpatient treatment in the event of complications or in palliative care (written co-operation). |  |
| 6.2.7 - PC, Mk, MB, MT, MPEN | **Process descriptions:**   * The procedure for ~~chemotherapy~~ systemic therapy must be described for all phases (start of therapy, implementation of therapy and completion of therapy). * Guideline-compliant supportive measures must be described for the individual therapy concepts and documented in detail for each patient |  |
| 6.2.8 - PC, Mk, MB, MT, MPEN | **Structural data per treatment unit**   * Number of outpatient therapy places * Number of inpatient therapy places |  |
| 6.2.9 - PC, Mk, MB, MT, MPEN | **Basic diagnostics laboratory**  Basic diagnostics including emergency laboratory must be possible 24 hours a day (if necessary via cooperation) |  |
| 6.2.10 - PC, Mk, MB, MT, MPEN | **Basic diagnostics Imaging**   * Cooperation for sonographic and radiological emergency and routine diagnostics (possibly via cooperation) |  |
| 6.2.11 - PC, Mk, MB, MT, MPEN | **Standards Concomitant and secondary diseases**  Standards must be drawn up for the treatment of concomitant and secondary diseases, in particular the treatment of extravasations, infections and thromboembolic complications. |  |
| 6.2.12 - PC, Mk, MB, MT, MPEN | **Emergency treatment**  Availability of emergency equipment and written emergency plan. |  |
| 6.2.13 - PC, Mk, MB, MT, MPEN | **Cytostatic preparation**   * Production takes place in a pharmacy in compliance with the legal requirements (including AMG, APBetrO, GMP, GCP, Eudralex (Vol. 10)). If this is not part of the organisation, a supply contract must be concluded. * Consultation with the pharmacy must be possible during the time the therapy is being administered. 24-hour on-call service required for inpatients. * Process descriptions for production must be drawn up. |  |
| 6.2.14 - PC, Mk, MB, MT, MPEN | **Palliative therapy**   * A written concept for palliative therapy is available. |  |
| 6.2.15 - PC, Mk, MB, MT, MPEN | **Information for/dialogue with the patient**  With regard to diagnosis and treatment planning, sufficient information must be provided and a discussion must be held. This includes, among other things   * Presentation of alternative treatment concepts * Offer and ~~provision~~ of services: support in obtaining second opinions. * Dismissal interviews as standard * The manner in which information is provided and the dialogue is to be described in general terms. This must be documented in the patient's medical notes or other protocols/records. |  |
| 6.2.16 - PC, Mk, MB, MT, MPEN | **Systemic therapy regimens**   * The drawing up of /changes to existing therapy regimens must be undertaken by means of regulated approval. * Prior to approval or changes to therapy regimens, the expert opinion of pharmacists can be sought. * The therapy regimens are to be protected from any unauthorised changes. * The therapy regimens are comparable between the outpatient and inpatient units.     Therapy plans   * Each systemic therapy is to be planned on the basis of a therapy regimen. Therapy planning is to be checked and approved. |  |
| 6.2.17 - PC, Mk, MB, MT, MPEN | **Further education**   * A qualification plan for the medical (medical, nursing, technical...) staff must be submitted, in which the qualifications planned for a one-year period are presented. * Annual scope of at least 1 specific further training course per employee (at least 1 day per year), provided that the employee performs quality-relevant activities for the Centre.     If relevant content is covered in the 6 further training courses required by the oncology agreement for uro-oncology, these can be credited here (in part). |  |

**7. Radio-oncology**

|  | | |
| --- | --- | --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 7.0 - PC, Mk, MB, MT, MPEN | The Technical and Medical Requirements for radio-oncology are summarised in the “Catalogue of Requirements Radio-oncology” in a cross-organ manner. Irrespective of the number of Organ Cancer Centres/Modules that cooperate with a radiology unit, this “Catalogue of Requirements” is only to be processed once and also only updated once each audit year (objective: no multiple presentations/on-site inspections within one audit year). The “Catalogue of Requirements Radio-oncology” is, therefore, an annex to this Catalogue of Requirements.    Download the cross-organ "Catalouge of Requirement of Radio-oncology" at <https://ecc-cert.org/> or <www.onkozert.de>. |  |

**8. Pathology**

|  | | |
| --- | --- | --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 8.0 - PC, Mk, MB, MT, MPEN | The Technical and Medical Requirements for pathology are summarised in the “Catalogue of Requirements Pathology” in a cross-organ manner. Irrespective of the number of Organ Cancer Centres/Modules that work together with a pathology department, this “Catalogue of Requirements” is only to be processed once and also only updated once per audit year (goal: no multiple presentations/on-site inspections within one audit year). The “Catalogue of Requirements Pathology” is, therefore, an annex to this Catalogue of Requirements.    Download the cross-organ "Catalogue of Requirements for Pathology" at <https://ecc-cert.org/>[l](www.krebsgesellschaft.de\zertdokumente.html) or <www.onkozert.de>. |  |

**9. Palliative care and hospice care**

|  | | |
| --- | --- | --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 9.1.1 - PC, Mk, MB, MT, MPEN | * Cooperation agreements with cooperation partners in specialised inpatient and outpatient palliative care and inpatient hospices must be demonstrated. Regional concepts for the integration of palliative care must be described on the basis of the treatment pathway for patients and relatives from the S3 guideline on palliative care (Fig. 3, p. 174), naming all parties involved. * A physician with additional training in palliative medicine must be available for consultation and, if necessary, for participation in tumour boards. * The group of patients with incurable cancer has to be informed about palliative care options at an early stage (SOP). * To identify the need for treatment, it is necessary to carry out a screening to record symptoms and stress (see S3 guideline Palliative Care) (MIDOS or IPOS). * Access to the palliative care can be offered at the same time as tumour therapy.The procedures in the Centre are to be described in a standard operating procedure (SOP). |  |
| 9.1.2 - Mk, MB, MPEN | * The number of primary cases with incurable cancer must be documented. |  |

**10. Tumour documentation / Outcome quality**

|  | | |
| --- | --- | --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 10.1 - PC, Mk, MB, MT, MPEN | **Tumour documentation system**  A tumour documentation system that contains patient data for a period of at least 3 months must be in place at the time of initial certification.    The primary cases of the Centre must be registered in one central tumour documentation system (separate systems for urology/radiotherapy are not permitted).    Name of the Centre’s tumour documentation system in the cancer registry and/or Centre. |  |
| 10.2 - PC, Mk, MB, MT, MPEN | **Period covered by the data**  The data must cover the entire previous calendar year. |  |
| 10.3 - PC, Mk, MB, MT, MPEN | **Tumour documentation requirements**  A data set must be used in line with the Uniform Basic Oncological Data Set and its modules of the Working Group of German Tumour Centres (ADT) and the Association of Population-based Epidemiological Cancer Registries in Germany (GEKID).    The Centre must ensure that data are passed on promptly to the competent cancer registry. Any existing state laws on reporting deadlines must be observed. |  |
| 10.4 - PC, Mk, MB, MT, MPEN | **Cooperation with cancer registry**   * Cooperation with the competent 65c cancer registry is to be documented on the basis of the cooperation agreement [Link Tumorzentren.de](https://www.adt-netzwerk.de/) * The OncoBox should be filled by the responsible cancer registry (prostate). The full data must be transmitted to the cancer registry on an ongoing basis. * The presentation of the Data Sheet and outcome quality are to be ensured via the cancer registry to the extent that the data concern cancer registration. * Until the competent cancer registry can fulfil these requirements, the Centre must use supplementary or alternative solutions. The Centre is responsible in the event of a non-functioning external solution. If the responsible cancer registry is unable to provide the follow-up data, the cancer registry and centre should explain in writing why the data cannot be provided     For further information, see FAQ. |  |
| 10.5 - PC, Mk, MB, MT, MPEN | **Documentation officer:**  At least 1 documentation officer must be named who is responsible for the tumour documentation.    The documentation officer is responsible for the following tasks:   * Ensuring and monitoring the timely, complete and correct transmission and quality of certification-relevant patient data by all cooperation partners to the cancer registry. * Qualification and support of the staff responsible for data collection * Regular analysis of the evaluations particularly over the course of time |  |
| 10.6 - PC, Mk, MB, MT, MPEN | **Provision of resources:**  The necessary personnel capacity should be provided to carry out the documentation tasks and to record the data (e.g. by a cancer registry) (guideline: 0.5 FTE per 200 primary cases and 0.1 FTE per 200 follow-up cases). |  |
| 10.7 - PC, Mk, MB, MT, MPEN | **Selection options**  The following selection options must at least be available in the tumour documentation system:   * Vintages * TNM classification and prognostic factors * Forms of therapy (surgical therapy, radiotherapy, hormone therapy, immunotherapy, chemotherapy) * Date of recurrence/metastasis * Deaths * Follow-up status (last update) |  |
| 10.8.1 - Mk, MB, MT | **Tumour-specific indicators for outcome quality**  Kaplan-Meier curves:   * Overall survival (OAS) for all patients in subgroups according to pT categories, c+p stages * Local recurrence-free survival for all operated patients and for subgroups * Survival from progression (PDS)     Each Kaplan-Meier curve also includes a table with patient numbers and survival data. |  |
| 10.8.2 - PC | **Tumour-specific indicators for outcome quality**  1. Recurrence-free survival by stage (Kaplan-Meier curves)  Definition of biochemical recurrence:  a. After radical prostatectomy, a PSA value of > 0.2 ng/ml confirmed in at least two measurements (2 weeks apart)  b. After radiotherapy alone, a PSA increase of > 2 ng/ml confirmed in at least two measurements (2-3 months apart) via the post-interventional PSA nadir.  2. Overall survival by pT categories, stage (Kaplan-Meier curves)  3.  EPIC-26 incl. additional questions    Patient questionnaire with EPIC-26 incl. additional questions must be available at the time of initial certification. |  |
| 10.9 - PC, Mk, MB, MT, MPEN | **Analysing the data**   * The presentation of the quality of results (above point) must be possible for the recertifications * Data in the tumour documentation system must be evaluated at least once a year according to the relevant indicators * If a benchmarking/annual report is offered, the results of the benchmarking must be included in the analysis * The discussion of the results must be interdisciplinary; if regional or supra-regional networks exist, they must be involved. |  |
| 10.10 - PC, Mk, MB, MT, MPEN | **Follow-up recording**  Describe how the follow-up data is obtained and what the current follow-up status is (see prostate results matrix)  Functioning cancer registries represent the follow-up status.  Where this is not possible, a regional solution will be sought together with the Centres, the ADT, the DKG and the respective government authorities.    The follow-up status includes   * Progression (local recurrence, regional lymph node recurrence if applicable, distant metastases, at least the first progression in each case) * Secondary malignancies * Deaths * lives at the current address * Cessation of follow-up (e.g. moving out of the catchment area, federal state) |  |
| 10.11.1 - PC | Requirements for the follow-up of patients included in the quality of outcomes matrix   (valid as of the 1st OC after recertification)    Since 01.01.2013 |  |
| 10.11.2 - PC | Minimum requirement for successful recertification.    ≥ 80 % |  |
| 10.11.3 - PC | Recertification or maintenance of certification only possible with conditions (e.g. reduced period of validity, concept for increasing the response rate, ...)    60 - 79 % |  |
| 10.11.4 - PC | Recertification or maintenance of certification not given.    < 60 % |  |
| 10.11.5 - MB | Follow-up  No follow-up data are to be collected for stage 0 a/is (Ta/Tis-N0-M0). |  |

**Data Sheet**

A Data Sheet (EXCEL template) is available for presenting the Basic Data, indicators and other data from the Centre. The Data Sheet is an appendix to the Catalogue of Requirement.

The EXCEL template can be downloaded from <http://ecc-cert.org/> and [www.onkozert.de](http://www.onkozert.de/)

|  |  |  |
| --- | --- | --- |
| **Period** | General remarks for processing the annex   * the actual values must be stated (no estimates) * Data must always relate to a calendar year * Data must not be older than 1 year (data from 2017 is not acceptable for an audit in 2021) * If the "target requirements" are not met in one point, an explanation must be provided at the appropriate point in the data collection form | Definition of initial period certifications   * At the time of initial certification, data must be available for a period of at least 3 months (ideally a whole year); for the information on primary cases/centre cases (CR 1.2.1) and operations per surgeon (CR 5.2.7), data is always required for a whole year. * unless a complete calendar year is depicted, the period must not be more than 4 full months in the past (based on the certification date) * the selected period must consist of whole months (if possible, select complete quarters) |

1. [https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3\_Downloads/N/Nationaler\_Krebsplan/Nationaler\_Krebsplan-Zieluebersicht.pdf](https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/N/Nationaler_Krebsplan/Nationaler_Krebsplan-Zieluebersicht.pdf%20)  [↑](#footnote-ref-1)