**Catalogue of Requirements for Prostate Cancer Centres**

All of the Requirements for Prostate Cancer Centres are laid down in this Catalogue. The certification of

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

**Developed by the DKG (German Cancer Society) Certification Commission for Prostate Cancer** **Centres**

**Chairman** Prof. Dr. Martin Burchardt; Prof. Dr. Jan Fichtner

**Members (in alphabetical order):**

ADT Working Group German Tumour Centres

AIO Working Group on Internal Oncology

AOP Working Group on Oncological Pathology

APM Working Group Palliative Medicine

ARO Working Group on Radiological Oncology

ASO Working Group on Social Work in Oncology

ASORS Working Group for Supportive Care in Oncology, Rehabilitation and Social Medicine

AUO Working Group on Urological Oncology

BDP Federal Association of German Pathologists

BNHO Professional Association of Practising Haematologists and Oncologists

BPS Prostate Cancer Self-help Group

CAO Working Group Oncology

CAO-V Working Group on Surgical Oncology – Visceral Surgery

DeGIR German Society of Interventional Radiology and Minimal-invasive Therapy

DEGRO German Society for Radio-oncology

DGHO German Society for Haematology and Oncology

DGN German Society for Nuclear Medicine

DGP German Society for Palliative Medicine

DGP German Society of Pathology

DGU German Society for Urology

DKG German Cancer Society

DRG German Radiation Society

DRG German Radiological Society

DVDST Professional Association of German Radiotherapist

DVPZ Umbrella Organisation of Prostate Cancer Centres

DVSG German Association for Social Work in Health Care

dvta German Association of Technical Assistants in Medicine

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

**Valid from 09 November 2018**

This Catalogue of Requirements (CR) is binding for all audits from 1 January 2019. All changes to the previously

applicable versions of this Catalogue (audit year 2018) are marked in green.

Changes from 25.01.2019

All changes to the previously applicable version from 09.11.2018 are marked in yellow. In the following chapter changes were made 1.1.1, 1.2.10 and 1.8.6

The Catalogue takes account of

* the evidence-based “Guideline on the early detection, diagnosis and treatment of the different stages of prostate carcinoma” (Germany)

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

**Information on the Prostate Cancer Centre**

|  |  |
| --- | --- |
| Prostate Cancer Centre (PCC) |  |
| Director of the Centre |  |
| Coordinator of the Centre |  |

**QM system certification**

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| --- | --- | --- | --- | --- |
| QM system certification |  | Yes |  | no |

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

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

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

**Network/main cooperation partners**

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

**Preparation/Update**

The electronically generated questionnaire serves as the basis for the PCC's certification. The information provided here has been checked for accuracy and completeness.

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| The data on outcome quality are for the calendar year  |  |

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| Date on which the questionnaire was prepared/updated |  |

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**1.** **General information on the Prostate Cancer Centre**

| **1.1 Network structure**  |
| --- |
| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 1.1.1 | **Cooperation partners**~~A Prostate Cancer Centre consists of:~~Main cooperation partners and treatment partners can be part of a clinic or separate practices.Main cooperation partners ~~Service provider l~~* Urology
* Radiotherapy

~~Service provider ll~~* ~~Haematology/~~Internal oncology
* Pathology
* Radiology
* ~~Nuclear medicine~~

Cooperation partners* Psycho-oncology
* Social services
* Nuclear medicine
* Pain therapy
* Self-help group
* Palliative medicine
* Laboratory medicine
* Rehabilitation medicine

Specialties to be brought in according to the Ordinance on Outpatient Specialist Medical Care (ASV-RL) (cooperation agreement not required, instead for instance standard operating procedure [SOP])* Vascular surgery
* Gastro-enterology
* Cardiology
* Neurology
* Visceral surgery
* ~~Gynaecology/Gyn. oncology~~
* Thoracic surgery
* Physiotherapy

Colour legend: Changes vis-à-vis version of 06.10.17Colour legend: Changes vis-à-vis version of 09.11.18 |  |  |
| **Centre Director**The persons holding the following positions are to be designated by name:* Director(s) of the Centre ((max. 2 directors per Centre, one of whom is the designated contact person)
* Centre Coordinator

Centre Coordinator – tasks* Coordination internal/external audits
* Monitoring of Technical and Medical Requirements and ensuring compliance with them
* Communication interface
* Control/supervision of cross-specialty activities

Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| The management structures of the Prostate Cancer Centre, QM responsibilities and network coordination must be clearly defined.* Rules of procedure (regulates relations between the care providers)
* Job description (Quality Manager)
* Job description (Network Coordinator)

This applies in particular to cooperative Prostate Cancer Centres The management of the Prostate Cancer Centre ensures the implementation of standards and legal regulations. |  |  |
|  | Cooperation models* A collaboration between up to 2 surgical urological units within a Centre is possible if each surgical urological unit separately documents its surgical primary cases. The number of primary cases must then be at least 200.
* Collaboration between up to 2 surgical radiotherapy units within a Centre is possible if each radiotherapy unit separately documents its expertise.

If a hospital director represents 2 departments, the performance indicators must be calculated separately for each department.Precondition for all cooperation models:* Identical Centre name
* Joint tumour conference
* Prior structural evaluation by OnkoZert
 |  |  |
| 1.1.2 | The Prostate Cancer Centre has defined a clear mission statement and quantitative quality targets.Interdisciplinarity and evidence-based medicine are unequivocally reflected in its statements and in its practical work.The Prostate Cancer Centre's fundamental orientation is known to the staff and is being implemented. |  |  |
| 1.1.3 | Quality target achievement is measured. The results are subject to documented evaluation.Clear strategies to promote target achievement are defined ~~with the involvement of all care providers I. i~~n an annual quality plan under the responsibility of* the Director(s) of the Centre
* the Coordinator of the Centre
* the Quality Manager

The Quality Manager can also take on the same function in other Organ Cancer Centres.Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 1.1.4 | Cooperation agreements~~Cooperation agreements must be concluded with every care provider according to CR 1.1.1. The Prostate Cancer Centre must check the topicality of the agreements every year.~~A cooperation agreement must be signed with cooperating treatment partners. It must be documented that these agreements comply with the Technical and Medical Requirements in the Catalogue of Requirements. The cooperation partners are to be listed in the "master data sheet" (administration by OnkoZert). The agreements are to be examined annually by the Prostate Cancer Centre to ensure they are up to date.~~In the agreements with the main treatment partners~~ The following points are to be regulated: * Binding participation in the ~~post-therapeutic~~ pre-therapeutic conference/tumour conference
* ~~Ensuring availability~~
* 24h/7d availability of main clinical cooperation partners in the Centre: urologists, radiologists, haematologist-oncologists
* Description of the treatment processes of relevance for the Prostate Cancer Centre bearing in mind the interfaces
* Obligation to implement indicated Guidelines (S3 Guideline)
* Description of cooperation and interfaces
* Description of cooperation on tumour documentation
* Declaration of willingness to cooperate on internal/external audits
* Commitment to comply with the relevant criteria laid down in the Specialist Requirements for Prostate Cancer Centres (*Fachliche Anforderungen an Prostatakrebszentren* – FAP) and the annual submission of the relevant data
* Declaration of consent of the treatment partner to be publicly identified as part of the Prostate Cancer Centre (e.g. homepage)
* Upholding of confidentiality
* Participation in specialty training programmes and public relations work

Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 1.1.5 | ~~Agreements with other treating partners:~~~~Written agreements must be signed with the following treating partners declaring their willingness to cooperate:~~* ~~Laboratory medicine~~
* ~~Psycho-oncology~~
* ~~Social services~~
* ~~Self-help groups~~
* ~~Physiotherapy~~
* ~~Hospice/palliative medicine~~
* ~~Rehabilitation medicine~~

~~The agreements with the treating partners should regulate the following points:~~* ~~Participation in further-training courses and public-relations work~~
* ~~Description of cooperation and interfaces~~
* ~~Form of mutual communication~~
* ~~Compliance with the confidentiality obligation~~

Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 1.1.6 | Contact persons of the Prostate Cancer Centre:The contact persons of the Prostate Cancer Centre at the hospital site and for the individual partners must be designated by name and made public (e.g. on the Internet). In medical fields, responsibilities at the specialist level must be defined.~~Care providers and other~~ Treatment partners that have agreed a form of cooperation with the Centre in writing are referred to as cooperation partners of the Centre. In the absence of such a written agreement, these care providers and treating partners can also care for Centre patients, but they may not refer to themselves as cooperation partners or as part of the certified Centre.Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| new | **Presentation of the Centre**The overall structure of the Centre is to be presented and made public (e.g. Internet). This also involves providing the names of all internal/external cooperation partners with the following details:* Name, address of cooperation partner

Cooperation partner with tel./email contact detailsColour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 1.1.7 | **Strategy planning/reporting**An annual review at management leveI is recommended in which the following aspects, for instance, are examined:* Definition/evaluation and, if appropriate, realignment of goals
* Consideration of audit findings(internal/external)
* Human resources for Centre management(Centre Coordinator)
* Public relations work/Patient information
* Tumour documentation/Outcome quality

The organisation(s) supporting the Prostate Cancer Centre provide sufficient financial and other resources to meet its requirements in terms of HR, premises and supplies/equipment. Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 1.1.8 | Patient pathwaysOverarching patient pathways must be defined in line with the relevant medical guidelines.The patient pathways take into account the Centre's interdisciplinarity and networking with practice-based physicians.Pathways must be laid down for:* Prevention and diagnosis
* Therapy
* Follow-up
* Rehabilitation
* Palliation

Patient pathways can be summarised in a QM manual, for example.Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 1.1.9 | ~~Proof of QM system~~* ~~The urology unit, as a care provider I, should show proof of a certified QM system.~~
* ~~If the radiotherapy unit, as a care provider I, exercises an active management or control function, radiotherapy should also show proof of a certified QM system.~~
* ~~Recognised QM certifications include ISO 9001, KTQ, proCum Cert and Joint Commission.~~
* ~~Scope of QM certification~~~~The QM system does not need to cover the complete urology or radiotherapy operation, but the processes relevant for the Prostate Cancer Centre.~~

Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 1.1.10 | Internal auditsInternal audits must be carried out at least annually and be documented through the submission of audit reports. An internal audit must be conducted for the first time prior to initial certification. |  |  |
| 1.1.11 | ~~Malpractice~~* ~~The certifier must be informed in detail, prior to certification, of any treatment errors established by a court of law or determined out-of-court (by a medical expert/conciliation commission)~~*~~.~~*
* ~~A later certification must examine in particular the actions/reactions of the Centre as a result of such a process.~~
* ~~The period presented is the calendar year relevant to the audit.~~
* ~~Non-compliance will be rated as a deviation.~~

Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |

| **1.2 Interdisciplinary cooperation**  |
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| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 1.2.1 | Number of cases in a CentreDefinition of “Centre case”:* All patients with a primary diagnosis, localised and/or metastatic or recurrence or metastasis, who are presented in the Centre or at the tumour board and receive essential elements of the treatment there (surgery, radiotherapy, systemic therapy, watchful waiting active surveillance, etc.)
* Patients and not stays or surgical procedures
* A patient as a “Centre case” can only be counted for 1 Centre; ~~patients seeking a second opinion are not counted~~
* Patients, who are only presented for the purposes of seeking a second opinion or for the purposes of consultation, are not counted.
* Interdisciplinary therapy plan must be available
* Time of counting is the (first) presentation in the Centre
* Histology report must be available.
* Complete recording in the tumour documentation system

Definition primary case (subset Centre case):* Patient with initial disease (incl. primary M1)

Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 1.2.2 | Referral of patients with prostate cancer to the Centre:A description must be given of how a patient in the Prostate Cancer Centre can be presented at the pre-therapeutic conference and on what basis a special consultation (with the patient) might be held (SHI-authorised physician, personal authorisation, authorisation by institute or policlinic).Primary referral to ~~care provider~~ main cooperation partner* Referral of the patient to ~~a care provider~~ the main cooperation partner at the Centre
* Care provider compiles a therapy plan on the basis of the available findings (biopsy, PSA, IIEF, ICS, therapy suggestion)
* Offer and conduct a patient meeting (if necessary an interdisciplinary meeting)- supplement the therapy plan- if no interdisciplinary meeting desired 🡪 provide surgery date/radiotherapy plan

Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 1.2.3 | Interdisciplinary meeting (optional) Interdisciplinary meetings should be offered for patients of a PCC centre.* Participants: patient + radiotherapist + urologist
* Result: update of the therapy plan

Number interdisciplinary meetings (patients) |  |  |
| 1.2.4a) | Pre-therapeutic conference* The pre-therapeutic ~~interdisciplinary~~ conference ~~of the care providers I (diagnostic/operative urologist and radiotherapist)~~ must take place at least once a week at the specialist level for the purpose of therapy planning.
* The responsibilities for preparation, implementation and follow-up must be laid down (see 1.2.6)
* > 95% of the patients hospitalised with the care providers must be presented at the pre-therapeutic conference.

Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
|  | * Participants: urologist and radiotherapist
* The following are to be presented: All primary cases with no primary M1

Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
|  | Special features pre-therapeutic conference:* Physical presence of the participants only mandatory in unclear cases. Otherwise, telephone coordination is sufficient. Use of video-conferencing systems is preferable to conference calls.
* Presentation of visual materialPatient-related images (e.g. pathology, radiology) on advanced tumours must be available at the conference, and suitable technical equipment must be provided for the presentation of the visual material. Computer-aided presentation is sufficient.
* If a radiotherapist cooperates with several urological clinics, then this radiotherapy unit must nevertheless present all primary cases who undergo irradiation with a curative intention (see def. Section 7). In addition, the radiotherapy unit must compile a list of all prostate carcinoma patients presented in relation to radiotherapy which classifies the patients according to categories (certified centre, centre with certification in preparation, no centre). A presentation rate of 90% must be reached. The presentation must be documented according to the requirements described here. This patient allocation is also of relevance for tumour documentation.

Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| b) | Sequence of the pre-therapeutic conference* The patient is admitted to a care provider of the Prostate Cancer Centre.
* All parameters must be recorded beforehand by the responsible care provider using the "therapy plan" template.
* All cases must be recorded in a list.
* The patient is presented at the conference; parameters are synchronised; the therapy plan is supplemented.
* Physician to whom the patient was primarily presented announces the result within 10 working days via therapy plan to referrer, patient and every physician named by the patient (e.g. copy of the therapy plan).
 |  |  |
| 1.2.5a) | Tumour board:* The tumour conference must be held ~~at least every 4~~ once a month on the specialist level for the purposes of therapy planning.
* The responsibilities for preparation, conduct and follow-up are to be laid down.
* Participation rate of specialties > 95 %

participants:* Urology (~~diagnostic + surgical)~~
* radiotherapy)
* ~~Haematologist/oncologist~~ Haematology/internal oncology
* If the haematologist-oncologist cannot take part in the conference, s/he can be represented by the urologist responsible for chemotherapy (qualification in line with Section 6.2).
* Pathology

Patients to be discussed:* All primary cases with a histology requiring discussion (>pT3a, R1, pN+); generally, no binding obligation for other patients primarily receiving radiotherapy or who underwent curative surgical interventions
* All recurrences or metastatic patients

At least 10 patients with castration-resistant prostate cancer per yearColour legend: Changes vis-à-vis version of 06.10.17 |  |  |
|  | Non-compulsory participation (not four times a year)* Nuclear medicine
* Radiology

Associated specialist fields (e.g. psycho-oncology, social work, nursing care) and disciplines actively involved in palliative care (neurology, neurosurgery, surgery, pain therapy, orthopaedics, etc.) should be incorporated into the tumour board as required.If several cooperation partners are named for one discipline, the presence of one representative is sufficient if a formalised exchange of information has been set up between them (e.g. via quality circles).Nonetheless, each cooperation partner must attend at least 30% of the tumour conferences (four times a year).  |  |  |
| 1.2.6a) | **General requirements pre-therapeutic conference/tumour conference**The following applies to all pre-therapeutic conferences/tumour conferences of the Centre:Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| b) | **Presentation rates tumour conference**Target value: ≥ 90% for initial certification≥ 95% after 1 yearColour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| c) | **Coordination with referring physicians** Differences or ambiguities compared to the information provided by the referrer must be clarified directly and personally with the referring physician. |  |  |
| d) | **General information on the therapy plan:**The outcome of the pre-therapeutic conference consists, *inter alia*, of a written, interdisciplinary therapy plan ("minutes of the pre-therapeutic conference"/tumour board). It must be part of the patient's records and can simultaneously serve as the medical report.The "minutes of the pre-therapeutic conference" should be automatically generated from the tumour documentation system.The patient can be given a copy of the therapy plan on request.Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| e) | **Preparation tumour conference**The main patient data are to be summed up in writing beforehand and distributed to the participants. A pre-appraisal of suitable study patients is to be undertaken. |  |  |
|  | A written interdisciplinary therapy plan must be compiled for patients who are not presented at the ~~tumour board~~ pre-therapeutic conference.Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| f) | Presentation of visual material:Patient-related images (e.g. pathology, radiology) – if any exist and are relevant for the issue to be discussed – must be available at the ~~post~~ pre-therapeutic conference/tumour board, and suitable technical equipment must be available to present the visual material. Computer-aided presentation is sufficient.Web/online conferenceIf web conferences are held, the sound and the material presented must be transmitted. Care must be taken to ensure that every main cooperation partner is able to present documents and images.Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| g) | Minutes:The outcome of the pre-therapeutic conference/tumour board consists, *inter alia*, of a written, interdisciplinary therapy plan ("minutes of the tumour board"). If any deviations from the original therapy plan or from the Guidelines are observed, they must be recorded and evaluated. Depending on the reasons, steps are to be taken to avoid such deviations.It, at the patient’s request, treatment does not start or is discontinued prematurely (despite an existing indication), this must also be recorded. Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| h) | **Therapy deviation*** The therapeutic procedure should be oriented towards the therapy plans or recommendations of the pre-therapeutic conference/tumour conference.
* If any deviations from the original therapy plan or from the Guidelines are observed, they must be recorded and evaluated. ~~Measures to avoid any deviations in future must be taken and recorded.~~ Depending on the cause, avoidance measures are to be taken.
* If, at the patient’s request, treatment does not start or is discontinued prematurely (despite an existing indication), this must also be recorded.

Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| i) | **Participation pre-therapeutic conference/tumour conference as continuing education**For the following functions/professional groups, participation in the tumour conference is to be made possible:* Assistant staff (MTA, TRA, ...) from the fields of radiology and radiotherapy
* Staff members social services and psycho-oncology
* Specialist oncology nurse and at least 2 nurses for each treatment unit

Participation in the pre-therapeutic conference/tumour conference is recognised as continuing education for the aforementioned functions/professional groups.Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 1.2.7 | Metastatic prostate carcinomaThe procedure for diagnosing/treating patients with PSA/metastasis (the patient pathways have to be described – a written procedure for systemic therapy of metastatic prostate carcinoma must be available). |  |  |
| 1.2.8 | Morbidity/mortality conference * The participants in the tumour board are the invited participants.
* The conference can be staged on the same date as the pre-therapeutic conference/tumour conference.
* A list of participants must be kept.
* ~~Morbidity~~ M&M conferences are to be held at least twice a year.
* Cases with a special history or a history that could be improved are to be discussed (e.g. grade 3 CTC). All patients who died after surgery/intervention must be discussed.
* Minutes must be taken of the M&M conferences.

Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 1.2.9 | Quality circle* The tasks, participants and contents of the quality circles must be laid down.
* At least 4 3 quality circles must be held every year focusing in particular on prostate-specific topics.
* A list of participants must be kept.
* All ~~care providers~~ main cooperation partners participate in the quality circles. Practice-based physicians, for example, can be added to the group of participants. Any main cooperation partners ~~care providers~~ that do not take part in the Centre's quality circles must show that they have held the required number of quality circles themselves (combinations possible).
* Organisation and the taking of minutes are the responsibility of the Centre Coordinator or Quality Manager.
* The quality circles must lead to unequivocal results (actions, decisions) which seem likely to significantly develop/improve the Prostate Cancer Centre.
* A quality circle must have taken place by the time of initial certification. Minutes of the quality circle must have been taken.

Possible topics:* Analysis of outcome quality (benchmarking)
* Interdisciplinary continuing education/specialty training
* Interdisciplinary case reviews
* Structural improvements to the Centre
* Public relations

Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 1.2.10 | **Continuing education/specialty training*** Continuing education/specialty training events are to be offered for the network of the Prostate Cancer Centre ~~Uro-oncology~~ ~~Centre~~ at least twice a year (where appropriate also after the MM conferences/quality circles).
* Contents/results and participation are to be recorded. A continuing education/specialty training plan is to be presented.

Colour legend: Changes vis-à-vis version of 06.10.17Colour legend: Changes vis-à-vis version of 09.11.18 |  |  |
| 1.2.11 | **Events of the Centre**Each main cooperation partner must participate in at least two of the Centre's events. The following are recognised:* Quality circles
* Morbidity/mortality conference
* Continuing education/specialty training

Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |

| **1.3** **Cooperation with referring physicians and aftercare treatment** |
| --- |
| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 1.3.1 | Cooperating referrers (integrated care):A list of cooperating referrers (urologists, general practitioners) must be kept up to date. Referring physicians can present patients to the pre-therapeutic conference/tumour board independently (e.g. suspected recurrence). The referring physicians must be informed about these possibilities.General note:There are, of course, also urologists who are not ~~care providers II~~ cooperation partners and for instance only refer patients for diagnosis and therapy.Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 1.3.2 | Referral of the patient to the PCC Centre:A description has to be given of how a patient in the Prostate Cancer Centre can be presented to the pre-therapeutic conference and on what basis (if necessary) a special consultation (with the patient) might be held (SHI-authorised physician, personal authorisation, authorisation by institute or polyclinic).Reference to Section 1.2.2 CR possible |  |  |
| 1.3.3 | Providing documents The urologist or radiotherapist is responsible for drawing up the medical reports for the patients assigned to him/her.≤ 2 working days after the collected documents are ready, the following must be made available to the referring physician, the patient and every physician named by the patient:* Histology
* If appropriate, the minutes of the tumour conference/therapy plan
* If applicable, changes to therapy
 |  |  |
| 1.3.4 | Contact persons Referring physicians must be provided with relevant information regarding the contact person at the Prostate Cancer Centre (e.g. telephone, e-mail). This can be done by means of the required publication of the cooperation partners.Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 1.3.5 | Feedback systemA written procedure for the co-attending physicians must be in place for collecting, processing and responding to feedback from the referring physician on general and case-specific issues/questions/complications. Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 1.3.6 | Specialty training The Prostate Cancer Centre must offer physicians specialty training courses at least twice a year. The contents, results and participants must be recorded. |  |  |
| 1.3.7 | Referrer satisfaction survey* Every three years, a referrer satisfaction survey must be conducted. The result of this survey are to be evaluated and analysed. A cross-department survey may be conducted.
* The first satisfaction survey of referring physicians must be completed by the time of the first surveillance audit (1 year after the initial certification).
* Colour legend: Changes vis-à-vis version of 06.10.17
 |   |  |
| 1.3.8 | Tumour documentation/follow-up* Cooperation with the referrers during the follow-up must be described.
* The relevant requirements are described in Section 10 Tumour documentation.
 |  |  |

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

In each case with additional training in psychotherapy and specialty training in psycho-oncology. (see below) (must be documented) Representatives of other psychosocial professions (such as qualified social pedagogues, social workers etc.) can be accredited when they can provide proof of the additional qualifications cited above. In such cases an individual examination is required. The provision of psycho-oncological care by social services, self-help groups or spiritual counsellors is insufficient. Recognised continuing education/specialty training includes: “Specialty Training in Psycho-social Oncology” offered by the PSO or dapo or other adequate specialty training schemes with > 100 teaching units.  |  |  |
| 1.4.2 | Psycho-oncology – Availability and access Every patient must have prompt access in the vicinity to psycho-oncological counselling (must be documented). The threshold to these services must be low. |  |  |
| 1.4.3 | Psycho-oncology resourcesAt least ~~0.5~~ 1 psycho-oncologist should be available to the Centre (to be designated by name).Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 1.4.4 | Scope of care provided* The number of patients who have received psycho-oncological counselling must be recorded by the psycho-oncologist.
 | Enter the value for the indicator in Section 11 Quality Indicators |  |
|  | * Frequency and length of counselling sessions must be recorded.
 |  |  |
| 1.4.5 | PremisesA suitable room must be made available for psycho-oncological patient sessions. |  |  |
| 1.4.6 | Organisation chartTo the extent that psycho-oncological care is provided by external cooperation partners or for a number of clinical sites or hospital facilities, the provision of services is to be regulated in an organisation chart displaying information that includes details of the availability of resources and local presence. |  |  |
| 1.4.7 | Psycho-oncology – responsibilities Psycho-oncological care should be offered to patients at all stages of care (diagnosis, inpatient, post-inpatient). Goals and responsibilities of care:* Prevention/treatment of subsequent psycho-social problems
* Activation of personal resources for coming to terms with the situation
* Maintaining quality of life
* Consideration of the social context
* Organisation of subsequent outpatient care through cooperation with providers of outpatient psycho-oncological services

Public relations work (scheduled events for patients, etc.) |  |  |
| Also recommended are:* Supervision, continuing education and specialty training for staff
* A conceptual discussion twice a year between psycho-oncologists, nursing and medical staff
* Regular written and, if needed, oral feedback to the physician in charge of treatment regarding psycho-oncological activities (e.g. in a consultant’s report or documentation in the medical file).
* Participation in tumour boards as required
* Close cooperation with social services
 |  |  |
| Psycho-oncologists should present their work within the Centre at least ~~once a~~ twice a year.Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 1.4.8 | Documentation and evaluationA screening process on psycho-social stress is recommended to identify the need for treatment (e.g. *Screeningverfahren in der Psychoonkologie* ("Screening Procedures in Psycho-oncology") by P. Herschbach, J. Weis, Berlin 2008, DKG e.V.).Psycho-oncological counselling must be continuously documented and evaluated using appropriate instruments, e.g. Basic Documentation for Psycho-Oncology (PO-BaDo). |  |  |
| 1.4.9 | Continuing education/specialty training* At least 1 dedicated continuing education/specialty training course for each employee each year (at least 1 day per year).
* Regular external supervision must be possible.
 |  |  |

| **1.5** **Social work and rehabilitation** |
| --- |
| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 1.5.1 | Qualification of social services:Social worker/social pedagogue Resources:For patient counselling at least one full-time staff member is available in the Centre for 400 counselling sessions (= primary cases, secondary metastasis, recurrence). The staff resources can be grouped centrally. An organisation chart must be available. |  |  |
| 1.5.2 | Social services Every patient must have prompt access in the vicinity to social service counselling at all stages of the disease (must be documented). The threshold to these services must be low.A record must be kept of the number of patients who receive social service counselling.Colour legend: Changes vis-à-vis version of 06.10.17 | Enter the value for the indicator under “11. Quality Indicators” |  |
| 1.5.3 | Scope of services providedA record must be kept of the number of patients who receive social service counselling.  |  |  |
| 1.5.4 | Premises:A suitable room must be made available for social service counselling. |  |  |
| 1.5.5 | Organisation chart:If social services are provided for a number of departments or clinical sites or in the form of outpatient counselling, the provision of these services must be regulated in an organisation chart delineating the availability of resources and local presence.  |  |  |
| 1.5.6 | Counselling topics:* Identification of social, economic and psychological crises
* Initiation of medical rehabilitation measures
* Advice on financial questions and social law (particularly with regard to medical/occupational rehabilitation, disability law, benefits in lieu of pay, retirement benefits etc.)
* Help with applications
* Advice on outpatient and inpatient care options and referring of patients to support and specialist services
* Support with occupational and social reintegration
* Cooperation with social insurance bodies and care providers
* Intervention in crisis situations
 |  |  |
| Further tasks:* Public relations and networking
* Participation in department conferences and tumour boards, supervision, continuing education
* Interdisciplinary cooperation, especially with physicians, nurses, physiotherapists, psycho-oncologists, spiritual counsellors etc.
* Documentation of activities
 |  |  |

| **1.6 Patient participation** |
| --- |
| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 1.6.1 | 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% ~~50%~~ (action must be taken if lower).
* The survey can take place during or after the hospital stay.

Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 1.6.2 | Evaluation of the patient survey:* Responsibility for the evaluation must be assigned.
* The evaluation must be in relation to the patients of the Prostate Cancer Centre.
* A documented evaluation must take place at least once a year.
* Further action is to be determined on the basis of the evaluation.
 |  |  |
| 1.6.3 | Patient information (general)* The Prostate Cancer Centre must present itself and the treatment options comprehensively (e.g. in a brochure, patient folder or on a website).
* The cooperation/treatment partners must be designated by name along with their contact details. The treatment options must be described.
* The options presented must include rehabilitation/aftercare treatment, self-help, treatment measures and alternatives.
 |  |  |
| 1.6.4 | Discharge consultation Each patient is given a discharge consultation during which the following topics are mentioned and the corresponding information is provided: e.g. disease status, therapy planning, aftercare, supportive measures (e.g. rehab, medical supplies, psychosocial services). Information available e.g. "Patients' guideline on prostate cancer 1 and 2" (in German) see [www.leitlinienprogramm-oncology.de](http://www.leitlinienprogramm-onkologie.de/) |  |  |
| 1.6.5 | Patient information (case-related):The patient should be given the following documents:* The tumour board report/therapy plan
* Medical report/discharge report
* Aftercare plan/aftercare calendar
* Study documentation (if applicable)
 |  |  |
| 1.6.6 | Programmes for patientsAt least once a year the Prostate Cancer Centre must hold scheduled events for patients and/or interested parties. |  |  |
| 1.6.7 | Complaints managementA system of formalised complaints management must be in place. Patients must be given feedback. Complaints are taken into account for the improvement of procedures.  |  |  |
| 1.6.8 | Self-help groupsThe self-help groups with which the Prostate Cancer Centre actively cooperates are to be identified by name. Written agreements must be signed with the self-help groups; they should cover the following:* Access to self-help groups at all stages of therapy (initial diagnosis, inpatient treatment, chemotherapy, …)
* Publication of contact details for the self-help groups (e.g. in patient brochures, website)
* Space for self-help groups to display their brochures
* Regular provision of space at the Prostate Cancer Centre for discussions with patients
* Quality circle with participation of representatives of psycho-oncology, self-help groups, social services, spiritual counselling, nursing and medical staff
* Personal discussions between self-help groups and the Prostate Cancer Centre with the goal of jointly staging and coordinating activities and events. The results of the discussions are to be documented.
* Participation of staff physicians in events staged by self-help groups
 |  |  |

| **1.7 Study management** |
| --- |
| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 1.7.1 | StudiesAccess to studiesThe patients must have access to studies. The studies conducted at the Prostate Cancer Centre must be compiled in a list and this list should be available to the patients e.g. on the website (incl. a short description of the study)Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 1.7.2 | Study leaderThe physician who serves as the study leader must be designated by name. Study assistant/study nurse* A study assistant is to be designated by name for each “unit conducting studies” in the organisation chart for studies.
* The same assistant can act on behalf of a number of “units conducting studies” in parallel.
* Study assistants should be available at the initial certification.
* A certificate on the training course for study assistants should be submitted as documentation of qualifications.
 |  |  |
| 1.7.3 | Study assistant – responsibilitiesThe spectrum of responsibilities must be laid down in writing (e.g. in a job description) and can include the following:* Cooperation with the physician commissioned to conduct the study
* Looking after patients during the study and aftercare
* Organising and coordinating diagnostic and laboratory measures, the investigational medicinal product and the sending of samples
* Collection and documentation of all data relevant to the study
* Preparing and overseeing the audit and inspections by authorities
* The study assistant’s activities can be combined with other activities such as tumour documentation.
 |  |  |
| 1.7.4 | Procedure description:The standard operating procedures (SOPs) for beginning/initiating new studies and for conducting studies (including responsibilities) must be laid down. This comprises for example:* Selecting new studies incl. approval decision
* Internal announcement of new studies (updating study list, etc.)
* Study organisation (special features, supervision, study patients, documentation, etc.)
* How study results are announced (e.g. staff, patients)
 |  |  |
| 1.7.5 | Proportion of study patientsInitial certification: at the time of initial certification ≥ 1 patient must already have been recruited for studies After 1 year: at least 5% of primary casesOnly patients recruited for studies with a positive vote by the ethics committee are counted as study participants. | Enter the value for the indicator under “11. Quality Indicators” |  |
|  | In the event of non-compliance the Centre must meet the following requirements: The Centre must give the reason for non-compliance as well as any steps taken to promote participation in the studies.Only patients recruited for studies with a positive vote by the ethics committee count as participants (non-interventional/diagnostic studies are also recognised).All study patients can be included when calculating the study rate (proportion of study patients in relation to all primary cases at the Centre).* Patients can be counted once per study; the relevant date is the date of patient consent.
* Patients in palliative and adjuvant situations can be counted, no limitation on stages.
* Patients who are recruited for a number of studies in parallel can be counted more than once.
 |  |  |
| 1.7.6 | Cooperation with external bodies:If the study is not initiated or implemented (in parts) by the ~~care providers I~~ main cooperation partners, this must be clearly regulated via a cooperation agreement.Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |

**List of studies**1)

|  |  |  |
| --- | --- | --- |
| Responsiblecooperation partner 2) | Study name | Number of Centre’s patients recruited in 20183) |
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|  |  |  |
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|  |  |  |
|  |  |  |
|  |  |  |
|  | Numerator: Indicator No. 6 “study rate” |  |

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

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

3) Only those patients who are “Centre patients” and were recruited in 2018 to the study can be counted as “study patients”

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

| **1.8 Nursing Care** |
| --- |
| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 1.8.1 | Specialised oncological nurses* At least one full-time specialist oncology nurse must ~~be active~~ work on day duty in the Centre.
* The specialist oncology nurses must be designated by name.
* In areas in which patients are treated, the activity of a specialist oncology nurse is to be documented.
* The performance of tasks/cover staff arrangements are to be laid down in writing and documented.

At the time of initial certification, the previous submission of at least one application for training as an “oncological nurse” is required. In this case, it must be explained how the “responsibilities/tasks” described in the following are to be performed during the training period. Cooperation with previously trained oncological nurses, who provide support in performing tasks, is recommended during the training phase. After 3 years, an oncological nurse must be documented. ~~Training of oncological nurses~~~~According to the outline of an ordinance formulated for the Länder by the Deutsche Krankenhausgesellschaft e.V. (German Hospital Society) or the laws of the Land in question or as an academically trained nurse (Master of Oncology).~~ The precondition for recognition as a specialist oncology nurse is: * Continuing education specialist oncology nurse in line with the respective federal state regulations
* or the Model Federal State Ordinance of the German Hospital Federation (*Deutsche Krankenhausgesellschaft e.V.* - DKG)
* or Advanced Practice Nurse (master title) plus 2 years’ practical oncological occupational experience (full-time equivalent)

Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 1.8.2 | Patient-related tasks:* Specialist evaluation of symptoms, side-effects and stress/strain
* Individual determination of interventions on the basis of nursing standards
* Conduct and evaluation of nursing and therapeutic measures
* Identification of individual patient-based need for counselling.
* The need for specialist counselling is to be defined already in the nursing concept of the Prostate Cancer Centre
* Ongoing provision of information to and counselling of patients (and their family members) throughout the entire course of the disease and conduct, coordination and documentation of structured counselling sessions and instructions to patients and their family members. In line with the concept these activities may also be carried out by other long-serving specialist nurses with specialist oncological expertise.
* Need-based participation in the tumour board
* Initiation of and participation in multi-professional case discussions/nursing visits. The objective is to find solutions in complex nursing situations. Criteria for the selection of patients are to be laid down. At least 12 case discussions/nursing visits are to be documented for each year and Centre

Overarching activities:* A nursing concept is to be developed and implemented in which the organ-specific aspects of oncological nursing care are taken into account in the Prostate Cancer Centre.
* Drawing up of specialist in-house standards based (if possible) on evidence-based guidelines (e.g. S3-LL Supportive)
* Offer of consultation/supervision by colleagues
* Networking between oncology nurses in a joint quality circle and participation in a quality circle in the Prostate Cancer Centre.
* Interdisciplinary exchange with all professional groups involved in treatment
* Responsibility for implementing the requirements for the specialist nurse who administers chemotherapy (see Section 6.2.2)

Colour legend: Changes vis-à-vis version of 06.10.17 |   |  |
| 1.8.3 | Nursing conceptA nursing concept that takes specific aspects of oncological care into account is to be developed and implemented.  |  |  |
| 1.8.4 | 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.Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 1.8.5 | Continuing educationA plan for the continuing education of the nursing staff is to be submitted in which the training measures for the coming year are described.At least one dedicated continuing education measure for each staff member each year (at least 1 day per year) who carries out quality-relevant tasks for the Centre. |  |  |
| ~~1.8.6~~ | **~~Post-operative care~~*** ~~Stoma care (where relevant) is to be laid down in a standard operating procedure (SOP).~~

Colour legend: Changes vis-à-vis version of 09.11.18 |  |  |

| * 1. **General service areas**
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| --- |
| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 1.9.1 | Supportive therapy * The possibilities for supportive therapy (procedure details/algorithm) at every stage of the therapy have to be described.
* A pain therapist must be designated by name and be available as a fixed contact person for consultations.
* For inpatient care it is necessary to provide information about social work counselling services and access to psycho-oncological care. The responsible person must be designated by name.
* Access to chaplain services has to be described.
* If these services are provided by cooperation partners, a cooperation agreement for the above-mentioned requirements must be concluded.
 |  |  |

**2** **Organ-specific Diagnostics**

| **2.1 Consulting hours** |
| --- |
| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 2.1.1 | Number of physicians/specialists working for the Prostate Cancer Centre in the field of urological diagnostics* At least 1 specialist for urology
* Specialists have to be designated by name

Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 2.1.2 | Waiting times for special consulting hours* < 2 week wait for an appointment
* < 2 week wait for an appointment for punch biopsy

Presentation at pre-therapeutic conference < 2 weeksAltogether, it should take no longer than 6 weeks to discuss the therapy recommendation of the pre-therapeutic conference with the patient during the consulting hours. |  |  |
| 2.1.3 | Waiting times during consulting hoursRequirement: < 60 min Waiting times for an appointmentRequirement: < 4 weeksThe waiting times must be determined by random checks and statistically evaluated (recommendation: an evaluation period of 4 weeks a year). |  |  |
| 2.1.4 | Standard operating procedures (SOPs) for the relevant processes in the field of urological diagnosis must be available. They include *inter alia*:* ~~Prostate~~Diagnosis incl. notification of results (incl. pat. with (local) recurrence and/or remote metastasis)
* Therapy planning (timing pre-operative)
* (Pre-)inpatient admission
* Collaboration with other cooperation partners (mainly external)
* Preparation of patients for the tumour conference

Sufficient resources must be available to conduct the SOPs.Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 2.1.5 | Continuing education/specialty training* A training plan for medical staff (physicians, nurses, technicians, etc.) must be submitted showing the training measures planned for a one-year period:
* Each year at least 1 dedicated continuing education/specialty training course (at least 1 day per year) for each employee who is responsible for quality-relevant work at the Centre.

If the content required by the 6 training units relevant to prostate carcinoma according to the Oncology Agreement is covered, this content can be credited (in part). |  |  |

| **2.2 Diagnostics** |
| --- |
| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 2.2.1 | The laboratory should in principle be accredited for the parameters "total PSA" and "free PSA" and be able to submit the appropriate certificate of the German Accreditation Council (DAR). If the laboratory is not accredited, the following conditions/requirements must be met. |  |  |
| 2.2.2 | Laboratory management:* Specialist in laboratory medicine
* or clinical chemist
* or specialist in urology with medical knowledge in laboratory medicine
* Cover staff arrangements are in place with the corresponding qualifications.
* Consultation with the specialist must be possible within one working day for the clinicians of the PCC.
* A specialist is in charge of the medical validation of the laboratory findings.
 |  |  |
| 2.2.3 | Medical-technical laboratory assistants (MTLAs)* The analyses are only conducted by qualified MTLAs.
* The MTLAs carry out the technical validation of the measurement results.
 |  |  |
| 2.2.4 | Parameters:* Mandatory determination of total PSA (tPSA) within one working day
* Optional determination of free PSA (fPSA) and calculation of the PSA quotient within one working day, or optional determination of complexed PSA (cPSA) within one working day.
* Optional determination of ultra-sensitive PSA
 |  |  |
| 2.2.5 | Internal quality assurance in the laboratory:* According to the Guidelines of the German Medical Association.
 |  |  |
| 2.2.6 | Manufacturers of diagnostic agents and analysis systems:* No requirements regarding choice of manufacturers of diagnostic agents or the analysis system used
* When there is a change in manufacturer, the comparability of the measurements must be determined based on parallel analyses (old/new system) or analyses of retained samples.
 |  |  |
| 2.2.7 | Findings:* Cumulative communication of results must be possible
* Information on the cut-off value
* Information on the PSA quotient
* Information on age-appropriate reference intervals
 |  |  |
| 2.2.8 | * Successful participation in 4 interlaboratory tests per year on total PSA and free PSA (proof).
* Standardised pre-analytics, analytics and post-analytics according to compiled SOPs.
 |  |  |
| 2.2.9 | Description of equipment and list of all ultrasound devices used for prostate diagnosis in the Prostate Cancer Centre (transrectal ultrasound option must be available). |  |  |
| 2.2.10 | BiopsyThe correct indication for TRUS biopsy of the prostate must be shown.* At least 20% of the patients with punch biopsies must test positive.
* At least 10 punch biopsy cylinders at least 1 cm in length must be taken.

An evaluation must be submitted. |  |  |

| **3** **Radiology** |
| --- |
| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 3.1 | Specialists.* At least 1 specialist in radiology
* Cover staff arrangements with the same qualifications must be documented in writing.
* The specialists and their cover staff are to be designated by name.
 |  |  |
| 3.2 | Radiology technicians (MTRAs) * At least 2 qualified radiology technicians must be available and designated by name.
 |  |  |
| 3.3 | Radiology methods/devices to be offered* Conventional X-ray
* Spiral CT for remote metastasis staging
* Ultrasound (including transrectal ultrasound scan)
* MRI for staging, MRI for detection: technical specification in accordance with PI-RADS v2.0 (1.5 or 3 Tesla).

Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 3.4 | Imaging for staging and the report on findings must be guaranteed on the same or next working day. |  |  |
| 3.5 | Standard operating procedures for radiology (SOPs)The imaging SOPs are to be described and checked once a year to ensure they are up to date.  |  |  |
| 3.6 | Writing findingsThe radiologist's written report must be available to the attending physicians no later than 48 hours after the examination.The MRI of the prostate must be appraised in a standardised way, e.g. according to the recommendations of the European Consensus Meeting. |  |  |
| 3.7 | Continuing education/specialty training* A training plan for physicians and other staff members (radiological technicians) must be submitted in which the training measures for the coming year are described
* Each year at least 1 dedicated continuing education/specialty training course (lasting > 0.5 day) for each employee who is responsible for quality-relevant work at the Centre.
 |  |  |

| **4** **Nuclear Medicine**  |
| --- |
| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 4.1 | Specialists in nuclear medicine:* At least 1 specialist in nuclear medicine is available
* Cover staff arrangements with the same qualifications must be documented in writing
* Qualified specialists and their cover staff must be designated by name
 |  |  |
| 4.2 | MTRAs for nuclear medicine:At least 2 qualified medical-technical radiology assistants (MTRAs) must be available and designated by name. |  |  |
| 4.3 | Methods:The imaging methods available in the department have to be describedMandatory:* Bone scintigraphy

Optional:* PET and PET-CT
* Inpatient radionuclide therapy
 |  |  |
| 4.4 | Standard operating procedures (SOPs)The imaging SOPs in nuclear medicine are to be described and checked once a year to ensure they are up to date. |  |  |
| 4.5 | The written findings report must be available to the attending physicians no later than 24 hours after the examination. |  |  |
| 4.6 | Continuing education/specialty training* A training plan for physicians and other staff members (radiology assistants) is to be submitted in which the training measures planned for the coming year are described.
* At least 1 unit of prostate-cancer dedicated continuing education/specialty training for each staff member (duration > 0.5 days) who carries out quality-relevant tasks for the Prostate Cancer Centre.
 |  |  |

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| **5** **Surgical Oncology** |
| **5.1 Multi-organ surgical therapy** |
|  | The questionnaires of the Organ Cancer Centres and Oncology Centres have a standardised table of contents.This section does not specify any Technical and Medical Requirements for Prostate Cancer Centres. |  |  |

| **5.2 Organ-specific surgical therapy** |
| --- |
| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 5.2.1 | Surgical expertiseNumber of prostatectomies during uro-oncology surgical procedures per year in the Centre (not relative to primary cases)* ~~25-49 prostatectomies:~~ ~~One surgeon designated (see CR qualification 5.2.6); Prerequisite: Recommendation on the issuance/renewal of a certificate in the audit report without any restriction.~~
* 50-74 prostatectomies: If only one surgeon is designated, a second surgeon needs to be designated by the next audit. (see CR Section 5.2.6)
* ≥ 75 prostatectomies => designation of at least two surgeons

Prostatectomies:* Radical prostatectomies (as primary intervention): counts for Data Sheet
* radical cystectomy with bladder cancer AND prostate carcinoma (primary intervention)
* radical cystectomy with prostate carcinoma (primary intervention)
* Radical prostatectomies (treatment of recurrences) - salvage prostatectomy

Information on prostatectomies in basic data(Excel spreadsheet)* For 25-49 prostatectomies: individual case decision. The audit report must contain a recommendation for maintaining the certificate without any constraints (*inter alia* ≥ 100 primary cases).

Designation of surgeons by name Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 5.2.2 | Bed capacitymust be sufficient for the inpatient care of patients of the Prostate Cancer Centre. Description of:* equipment in the patient rooms
* special features of the department
 |  |  |
| 5.2.3 | Surgical capacityAt least 1 operating theatre must be regularly available for prostate operations.Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 5.2.4 | Nursing staff capacityOne graduate nurse must always be available per shift in the inpatient surgical unit of the Prostate Cancer Centre.Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 5.2.5 | **Post-operative care**Care in the following units is to be laid down in a standard operating procedure (SOP):* Intensive care
* Physiotherapy
* Post-operative pain management
* Possibility of emergency surgical care must be guaranteed 24h/7d.

**Emergency treatment*** Available emergency equipment and written action plan for emergencies

Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 5.2.5 | Specialists for the Prostate Cancer CentreAt least 2 specialists working for the Prostate Cancer Centre according to the organisation chart (can also be surgeons at the same time). Specialists must be designated by name. |  |  |
| 5.2.6 | Prostate surgeons1. Every prostate patient must be operated on by one of the named prostate surgeons (or by a trainee under his/her supervision).
2. First appointment as prostate surgeon: has performed a minimum of 100 radical prostatectomies as first surgeon (extract from the hospital information system or by presenting certificates).
3. Continuation: Each prostate surgeon must prove that s/he performs at least 25 prostatectomies per year or 75 prostatectomies in 5 years. For initial certification this number must be documented in the year before the initial certification (extract from the hospital information system).

AssistanceApproval of assistance only within training (primary cases cannot be counted for both/two surgeons).Designation of surgeons by name  |  |  |
| 5.2.7 | Prostate surgeonsDescription of the prostate surgeons' specific qualifications (training) 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)
 |  |
| 5.2.8 | **Post-operative morbidity**All revision surgeries due to intra- or post-operative complications within the first 90 days after surgeryDescription of the surgeriesRevision surgeries: e.g. post-operative haemorrhage, intestinal injury, endoscopic treatment of anastomotic stricture, lymphocele drainage if there is a risk of thrombosis, ureteral injury, others | Enter the value for the indicator under “Quality Indicators” |
| 5.2.9 | **Nerve-sparing operation**More than 80% of the patients defined as suitable, who have asked for a nerve-sparing procedure, are given nerve-sparing surgery.Patients with an IIEF value of at least 22/25 are assessed as pre-operatively potent. This group of patients represents the basis for evaluating postoperatively potent patients (IIEF value: at least 22/25), if they are given unilateral and bilateral nerve-sparing surgery. |  |
| 5.2.10 | **Information/dialogue with patients:**Sufficient information must be provided on diagnosis and therapy planning, and a dialogue must take place. This encompasses *inter alia*:* Presenting alternative treatment concepts
* Offering and arranging second opinions
* Discharge consultations as a standard procedure.

The type and manner of information provision and dialogue have to be described in general terms. This has to be documented in medical reports and minutes/records for each patient. |  |
| 5.2.11 | The following quality-relevant SOPS with details of responsibilities must be described:* Perioperative management
* Discharge management
* Operative management (operation sequences, recycling of material, documentation)
* Post-operative pain therapy
* Emergency care (e.g. bleeding) including shift planning for qualified staff (duty roster/on-call rota).

Sufficient resources must be available to carry out the procedures.Colour legend: Changes vis-à-vis version of 06.10.17 |  |
| 5.2.12 | **Continuing education/specialty training*** A training plan for medical and nursing staff is to be presented listing the planned training courses for the period of one year.
* Every year at least 1 dedicated continuing education/ specialty training course for each staff member (at least 1 day a year) who carries out quality-relevant activities for the Centre.

Colour legend: Changes vis-à-vis version of 06.10.17 |  |

Prostate surgeons (see CR 5.2.6)

|  |  |  |  |
| --- | --- | --- | --- |
| Name | 2018 |  | Only to be completed if number of prostatectomies < 25 |
|  | 2017 | 2016 | 2015 | 2014 | 5 years2014 - 2017 |
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| **6.** **Medical/ Internal Oncology** |
| **6.1 Haematology and oncology** |
|  | The questionnaires of the Organ Cancer Centres and Oncology Centres have a standardised table of contents.This section does not specify any Medical and Technical Requirements for Prostate Cancer Centres. |  |  |

| **6.2** **Organ-specific oncologic pharmacotherapy**  |
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| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 6.2.1 | **Specialist’s qualifications:**Specialist in internal medicine, haematology and oncology ~~and~~ or specialist in radiotherapy or specialist in urologyRequirements for urology specialist* Further qualification in medical tumour therapy; alternative: participation in the "Oncology Agreement", Annex 7 to the Federal Collective Agreements, regional implementation and
* 5 years’ experience in medical tumour therapy of prostate carcinoma (documentation)

The specialists designated here must actively carry out the drug-based tumour therapy. Responsibility must not be delegated to physicians who do not have the above-mentioned qualification.Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 6.2.2 | General requirements* Cover staff arrangements must be detailed in writing (specialist with the same qualifications).
* The specialists must be designated by name.
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| 6.2.3 | Specialised nursesRequirements 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
* ~~At least~~ 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.

Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 6.2.4 | **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.

Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 6.2.5 | Qualifications of the treatment unit The executing department must meet the following criteria:1. 20 urological patients with chemotherapy per year (including docetaxel)
2. 5 patients with metastatic, prostate carcinoma per year
3. Case number reflects the expertise of the treatment unit and is not restricted to Centre patients. Instillation or hormone therapies cannot be counted

or1. at least 200 ~~chemotherapies~~ systemic therapies (cytostatic therapies and/or targeted therapeutics and/or antibody/immunotherapies) annually (for different types of tumours)
2. incl. 5 patients with metastasised prostate carcinoma and/or kidney urinary bladder carcinoma/year (depending on area of application) ~~(may be subsets of 200 patients)~~

Calculation method: ~~Chemotherapy~~ Systemic (= cytostatic therapies and/or targeted therapeutics and/or antibody/immunotherapies) therapy for each patient (consisting of **several** cycles or administrations, combination therapies count as 1 therapy). In the case of cross-year therapies, the therapy commenced in the survey year counts. In the event of a shortfall, expertise cannot be documented via cooperation (must be documented for each separate treatment unit).Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 6.2.6 | **Administration of systemic therapy**Chemotherapy is usually given on an outpatient basis or in a day clinic (also interdisciplinary). Inpatient treatment of complications or palliation is possible (written cooperation). Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 6.2.7 | **SOP descriptions*** All phases of the standard operating procedure (SOP) to be followed for drug-based oncological therapy (beginning, implementation and conclusion of therapy) must be described.
* Supportive measures in line with the Guidelines for the individual therapeutic concepts must be described and documented in detail for each patient.
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| 6.2.8 | **Structural details of each treatment unit*** Number of outpatient therapy places
* Number of inpatient therapy places

Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 6.2.9 | **Basic diagnosis laboratory*** Basic diagnosis including emergency laboratory must be possible 24h/7d.

Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 6.2.10 | **Basic diagnosis medical imaging*** Cooperation for ultrasound and radiological emergency and routine diagnosis (where appropriate through cooperation)

Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 6.2.11 | **Standards for concomitant and secondary diseases**Standards must be drawn up for treating concomitant and secondary diseases, in particular extravasation, infections and thromboembolic complications.  |  |  |
| 6.2.12 | **Emergency treatment**Emergency equipment and a written plan of procedure must be available for emergency situations. |  |  |
| 6.2.13 | Preparation of cytostatics* ~~Preparation~~ Production is undertaken with consideration of ~~all~~ statutory provisions (*inter alia* Medicinal Products Act (AMG), Ordinance on the Operation of Pharmacies (APBetrO), GMP, GCP, Eudralex (volume 10)) in a pharmacy. If it is not part of the facility, a care agreement must be entered into.
* It must be possible to speak to the pharmacy during the period in which therapy is administered. 24-hour on-call service is required for inpatients.
* Standard operating procedures (SOPs) are to be drawn up for production.

Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 6.2.14 | **Palliative care**A written plan exists for palliative therapy.Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 6.2.15 | **Information for/dialogue with the patient** Based on the diagnosis and the therapy planning, sufficient information must be conveyed and an appropriate dialogue must be conducted. This includes:* a description of possible treatment options
* offering and arranging a second opinion
* a discharge consultation as a standard procedure

The general way in which information is provided and the dialogue conducted must be described. This is to be documented for each patient in a medical report and in minutes taken/notes.  |  |  |
| 6.2.16 | **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.

Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
| 6.2.17 | Continuing education/specialty training:* A plan for the further qualification of physicians, nurses and other staff members is to be submitted in which the training measures for the coming year are described.
* At least 1 dedicated continuing education/specialty training measure every year for each staff member (at least 1 day a year) who carries out quality-relevant tasks for the Prostate Cancer Centre

If the content required by the 6 training units relevant to prostate carcinoma according to the Oncology Agreement is covered, this content can be credited (in part). |  |  |

| **7 Radio-oncology** |
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| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 7.0 | 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 cross-organ “Catalogue of Requirements Radio-oncology” at [www.onkozert.de](http://www.onkozert.de). |  |  |

| **8** **Pathology** |
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| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 8.0 | 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 cross-organ “Catalogue of Requirements Pathology” at [www.onkozert.de](http://www.onkozert.de). |  |  |

| **9 Palliative Care and Hospice Work** |
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| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 9.1 | Palliative care* Cooperation agreements with various providers of specialised inpatient and outpatient palliative care, palliative medical consulting services, inpatient hospices and palliative wards must be documented. Regional concepts (based on the treatment path of the Evidenced-based Guideline: Palliative care for patients with incurable cancer, short version 1.1 – May 2015) for integrating palliative care must be described and the participants designated.
* A physician with additional training in palliative medicine must be available for consultation and, if necessary, for participation in tumour boards.
* The group of patients with incurable cancer ~~with castration-resistant prostate carcinoma (CRPC)~~ has to be informed about palliative care options at an early stage (SOP).
* In order to identify the symptoms and stress experienced by these patients, validated screening tools (e.g. MIDOS, iPOS) should be used on an ongoing basis.
* 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).
* ~~The number of primary cases with castration-resistant prostate carcinoma must be documented.~~

Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |

| **10** **Tumour Documentation/Outcome Quality** |
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| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 10.1 | Tumour documentation systemA 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 | Period covered by the dataThe data must cover the entire previous calendar year. |  |  |
| 10.3 | Tumour documentation requirementsA 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 laws for notification deadlines of the federal states (*Länder*) are to be complied with. |  |  |
| 10.4 | Cooperation with the cancer registry* Cooperation with the competent 65c cancer registry is to be documented on the basis of the cooperation agreement [Link tumour centres.de](http://www.tumorzentren.de/tl_files/dokumente/Kooperationsvereinbarung%20ADT_DKG_07.07.2015%20.docx)
* The OncoBox should be fed with data from the competent cancer registry. The 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 Prostate Cancer Centre is to fall back on additional or alternative solutions. The Prostate Cancer Centre bears responsibility for an external solution that is not working.
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| 10.5 | Documentation officerAt least 1 documentation officer must be designated as the person responsible for tumour documentation. Name/function:The documentation officer is responsible for the following tasks: * Qualification and support of the staff responsible for data collection
* Regular analysis of the evaluations particularly over the course of time
 |  |  |
| 10.6 | Provision of resources:Sufficient resources must be provided for the collection of data and other documentation tasks.Benchmark for the definition of resourcesPer 200 primary cases (a year): 0.5 FTEPer 200 follow-up cases: additional 0.1 FTE |  |  |
| 10.7 | Selection optionsThe following selection options must be available in the tumour documentation system: * Year of birth
* TNM classification and prognosis factors
* Types of therapy (surgery, radiotherapy, hormone therapy, immunotherapy, chemotherapy)
* Date of recurrence/metastasis
* Mortalities
* Follow-up status (last update)
 |  |  |
| 10.8 | Tumour-specific indicators of outcome quality1. Relapse-free survival by stage (Kaplan-Meier curves) Definition of biochemical recurrence:  a. After radical prostatectomy a PSA level > 0.2 ng/ml confirmed in at least two measurements (2 weeks apart) b. After radiotherapy only, a PSA increase > 0.2 ng/ml above the post-interventional PSA nadir confirmed in at least two measurements (2-3 weeks apart).2. Overall survival by pT categories, stage (Kaplan-Meier curves)3. Record IIEF, ICIQ, LQ and state of health (patient's questionnaire: [www.onkozert.de/hinweise\_zertifizierung\_patientenfragebogen\_prostata.htm](http://www.onkozert.de/hinweise_zertifizierung_patientenfragebogen_prostata.htm))~~Age groups can be summarised (e.g. if patient numbers are low). Where patient and event numbers are larger, the age groups should be evaluated separately.~~ ~~A table with the patient figures and the survival data also belongs to each Kaplan-Meier curve.~~~~An initial evaluation on outcome quality in relation to the parameters defined in the Annex must be available 1 year after first certification; it must be updated annually.~~~~A process description for the collection, evaluation and analysis of the patient questionnaire for IIEF, ICIQ, quality of life and state of health must be available at the first certification~~Colour legend: Changes vis-à-vis version of 06.10.17 |  |  |
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| 10.9 | **Evaluation of data*** Depiction of outcome quality (see above point) must be possible for recertifications.
* Data in the tumour documentation system are to be evaluated at least once a year in line with the corresponding indicators.
* If benchmarking/annual report is proposed, the benchmarking results are to be included in the analysis.
* The results must be discussed in an interdisciplinary manner and within any regional or national networks.
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| 10.10 | **Record of follow-up**A description is to be given of how the follow-up data are collected and what the current follow-up status is (see outcome matrix).Functioning cancer registries show follow-up status.Where this is not an option, joint work is being done on a regional solution together with the centres, the ADT, the DKG and the respective government authoritiesThe follow-up status includes:Any progressions (local recurrences, any regional lymph-node recurrences, remote metastases, at least the first progression)Secondary malignant tumoursDeathsCurrently resides at the addressTermination of follow-up (e.g. patient has moved away from the catchment area, federal state) |  |  |
| 10.11 | Demands on following up the patients covered by the tumour documentation system |  | From 1 Jan. 2013 |  |  |
| Minimum requirement for successful recertification. |  | ≥ 80% |  |
| Recertification or maintenance of certification only subject to certain conditions (e.g. shorter period of validity, concept for raising the response rate, etc.) |  | 60 – 79% |  |
| Recertification or maintenance of certification not issued. |  | < 60% |  |

**Data Sheet/Outcome quality matrix**

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

The EXCEL template can be downloaded at [www.krebsgesellschaft.de](http://www.krebsgesellschaft.de) and [www.onkozert.de](http://www.onkozert.de).

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| **Period** | General information for processing the annex* The actual figures (no estimates) are to be given.
* Data must normally refer to a calendar year.
* Data must not be more than 1 year old (Data from 2015 are not acceptable for an audit in 2018).
* if the "target values" are not achieved for one item, an explanation must be given in the appropriate section in the Catalogue of Requirements
 | Definition of period for initial certification* At the time of initial certification, data must be available at least for a 3-month period (ideally for an entire year); in the case of information on primary cases/Centre cases (CR1.2.1) and surgical procedures per surgeon (CR 5.2.8), the data for an entire year are always needed
* If a full calendar year is not depicted, the period may not date back more than 4 full months beforehand (based on the certification date).
* The period selected must consist of whole months (if possible select whole quarters)
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Colour legend: Changes vis-à-vis version of 06.10.17