**National Cancer Certification Programme**

Catalogue of Requirements for

Comprehensive Cancer Centres and

Oncology Centres

The requirements in this Catalogue are the basis for the certification of Oncology Centres. The requirements to be met by Comprehensive Cancer Centres under the funding programme “Interdisciplinary Comprehensive Cancer Centres” are described in detail in the application documents of German Cancer Aid (DKH). Some of the overall requirements are presented in this Catalogue of Requirements.

**Prepared by the Certification Committee Oncology Centres**

**Comments on the Catalogue of Requirements**

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

|  |  |
| --- | --- |
| Audit year: | **2025** |
| Version: | **M1** |
| Date: | **19.08.2024** |

The changes marked in green in this Catalogue of Requirement (CoR) were decided in 2023 and are valid for all audits carried out from 01.01.2024.

Changes compared to version L1 dated 20 December 2023 are marked in yellow.

Important notice: This translation is for your convenience only. In the event of any discrepancies or divergences in interpretation, the German text is the sole authoritative version..

**Prologue**

This Catalogue of Requirements sets out the clinical care requirements to be met by Oncology Centres and Comprehensive Cancer Centres.

It reflects the achievement of an important objective of the National Cancer Plan, i.e. the care of patients “is possible in line with the same technical and medical quality requirements irrespective of the treatment structure, i.e. irrespective of the facility in which treatment is given […]”P0F[[1]](#footnote-1)P. The basis for this concept is the following definition of certified Centres:

“A Centre is deemed to be a network of qualified and jointly certified, multi- and interdisciplinary, trans-sectoral and, where appropriate, multi-site facilities (hospitals, SHI-authorised medical care, rehabilitation centres) which, if necessary in medical terms, covers, if possible, the entire chain of patient care. Certified facilities are classified in three certification tiers:

* Organ Cancer Centre (C) is a Centre specialising in one organ or one specialty.
* Oncology Centre (CC) encompasses several organs or specialties.
* Comprehensive Cancer Centre (CCC) is an Oncology Centre with research foci.[[2]](#footnote-2)

The 3-tier model of oncological health care structures is implemented by German Cancer Aid and the German Cancer Society (DKG) in a “National Certification Programme”.

This joint Catalogue of Requirements is part of this concept.

The processing of the Catalogue of Requirements by the Centres and the format of the certification procedure/funding programme are unchanged.

For some requirements, there is an addition “G-BA”(Federal Joint Committee) in the first column (e.g. 1.1.4). At these points, parts of the centre guideline are included (<https://www.g-ba.de/richtlinien/117>). The aim is to provide a simple overview of the requirements of the guideline fulfilled by the oncology centres, which can be used by the negotiators.

**Structural requirements / Definitions**

**Levels of competence Oncology Centre**

**Organ Cancer Centre (C)**= Breast cancer, Colon Cancer, Prostate Cancer, Lung Cancer, Skin Cancer, Gynaecological Cancer, Haematological Neoplasms

**Module (M)**= Anal Cancer, Pancreatic Cancer, Gastric Cancer, ~~HCC~~ Liver/ Bile, Oesophageal Cancer, Head and Neck tumours, Neuro-oncological tumours, Paediatric Oncology, Soft tissue Sarcoma, Kidney, Urinary Bladder, Testicles, Penis

|  |  |
| --- | --- |
| **Focus (F)** |  |
| I | ~~Bile ducts,~~ neuroendocrine tumours of the gastrointestinal tract, tumours of the small intestine; |
| IV | Endocrine malignancies (incl. thyroid, adrenal gland, paraganglia, pituitary gland, parathyroid, neuroendocrine tumours) |
| VI | ~~Kidney, urinary bladder,~~ Testicles and Penis |

The tumours listed in Foci I-VI are to be further developed stepwise. Tumours in the Focus List may not be included as Transit (=”T”) but only as a Focus in the scope of the Oncology Centres.

**Transition periods Focus  Module/Centre**

**Testicles**

In audit year 2025, 3 verification levels can still be selected for the testicular cancer (module, transit, focus). In audit year 2026, only the verification levels module and transit are possible.

If certification of the testicular cancer as a transit centre is not possible due to the number of cases, the entity must be marked in the cert-calculator with the verification level “V” (treated, but not in the scope of the Oncology Centre).

* From audit year 2027 onwards, if the “scope of application (min. 50%)”/”scope within range of care provided (min. 70%)” is not met, the certificate of the Oncology Center can be extended by a maximum of 1 year.
* From audit year 2028 onwards, if the “scope of application (min. 50%)”/” scope within range of care provided (min. 70%)” is not met, the certificate of the Oncology Center can be extended by a maximum of 1 year.

With the audit year 2029, all transition periods for the testicular cancer will end.

**Penis**

In the audit years 2025, 2 level of competences can still be selected for the Penis Entity ("Module", "Focus").

In the audit year 2026, only the Module level of competence will be possible.

**Structural requirements / definitions**

**Transit (T)**If a Centre does not as yet fulfil the primary case requirements for a tumour entity to be met by an Organ Cancer Centre (C) or a Module (M), this organ can be certified in a transitory manner (level of competence “Transit”) in the Oncology Centre. The objective of this level of competence is further development into a certified Organ Cancer Centre (C) or Module (M). For the initial certification of an Oncology Centre maximum 2 entities can be in the evidence level “T” (Transit), for the re-certification (3 years after initial certification) only one entity in “T” is permitted. After the second re-certification of the Oncology Centre (6 years after initial certification) no entity is permitted to be labelled in transit.

UAnnex Tumour Entity

In the case of tumour entities that are introduced into the scope of the Oncology Centre as Focus or Transit, the clinics must outline their medical therapy regimens and qualifications for the diagnosis and treatment of the disease on the basis of the template **“Annex Tumour Entity”**.

|  |  |  |
| --- | --- | --- |
|  | Initial certification | Recertification(after 3 years) |
| Number of Organ Cancer Centres (C) and/or Modules (M) | 2 | 3 |
| Scope in line with Certcalculator | >= 50 % | >= 50 % |
| Scope within the range of care provided | >= 70 % | >= 70 % |
| Recognition level of competence “T” | Maximum 2 organs per Centre up to recertification  | Maximum 1 organ per Centre for another 3 years after recertification |

CCCalculation formulae

The following structural requirements are calculated automatically by the “Certcalculator”.

|  |
| --- |
| Scope = C + M + F + T > 50% |
| Range of care provided = C + M + F + T + V |
| Scope within the range of care provided | = | C + M + F + T | > 70 % |
| C + M + F + T + V |

**Structural requirements / Definitions**

Multi-site Oncology Centres

Each clinical site must put in place its own Certcalculator.

In the case of a multi-site Oncology Centre at least one clinical site must fulfil all the requirements for the Certcalculator (number of Centres/Modules, area of application at least 50%, ratio area of application to scope of care provided at least 70%). Exceptions are admissible if all the tumour entities included in the scope of care of a clinical site are treated at one clinical site only. This means for instance: in a two-site Oncology Centre patients with breast cancer are treated at one clinical site only. In these cases the areas of application of the clinical sites can be added together.

Notwithstanding this, the following applies: At least 2 Organ Cancer Centres/Modules must be available at each secondary clinical site. The ratio scope to range of care provided (=70%) must be met separately by each clinical site.

Protection until 31.12.2028 for already certified structures.

**Certcalculator Oncology Centre**

The “Cert-calculator Oncology Centre” is an official part of the certification request and of the Catalogue of Requirements. The scope of the Oncology Centre, combined with the respective levels of competence, is defined in this Cert-calculator. The Cert-calculator is available at [15TUwww.onkozert.de](http://www.onkozert.de/)U15T (section “Oncology Centre”).

|  |  |  |  |
| --- | --- | --- | --- |
| **Tumour entities** | **Newly diagnosed cancers**P**1)** | **Proportion** | **Level of competence /Minimum primary cases****Minimum patient cases** |
| **In** | **C** | **M** | **F** | **T** |
| 1 | **Colon** | 65,390 | 16.27% | 50 | X | X | 25 |
| 3 | **Anal Cancer** 7) | ‘--- 7) | ‘--- 7) |  | 12 |  |  |
| 3 | **Pancreas** | 14,960 | 3.72% | X | 25 | X | 13 |
| 4 | **Gastric**  | 15,870 | 3.95% | X | 30 | --- 3) | 15 |
| 5 | **~~LCC~~** Liver/ Bile | 9,520~~8,020~~ | 2.37%~~2.00%~~ | X | 40~~30~~ | --- 3) | 20~~15~~ |
| 6 | **Oesophagus** | 6,180 | 1.54% | X | X |  | X |
| 7 | **Other gastrointestinal tumours (S1)**(~~bile ducts,~~ neuroendocrine tumours of the gastrointestinal tract, tumours of the small intestine) | 1,800~~3,300~~ | 0.45%~~0.82%~~ | X | X | --- 3) | X |
| 8 | **Endocrine malignancies (S4)**(incl. thyroid, adrenal gland, paraganglia, pituitary gland, parathyroid, neuroendocrine tumours) | 5,870 | 1.46% | X | X | --- 3) | X |
| 9 | **Haematological systemic diseases** | 32,830 | 8,17% | 75 5) | X | --- 3) | 38 5X |
| 10 | **Breast** | 72,180 | 17.96% | 100 | X | X | 50 |
| 11 | **Gynaecological tumours**(cervix, uterus, ovaries incl. BOT, vulva, vaginal tumours, STIC) | 26,280 | 6.54% | 50 | X | X | 25 |
| 12 | **Skin**(invasive malignant melanoma) | 17,800 | 4.43% | 40 | X | X | 20 |
| 13 | **Prostate** | 63,440 | 15.79% | 100 | X | X | 50 |
| 14 | **Penis (S6)** 8) | 950 | 0,24 % |  | 8 | --- 3 |  |
| 15 | **Testicles** | 4.710 | 1,17% | X | 15 | --- 3) | 8 |
| 16 | **Kidney**  | 14,500 | 3.61% | X | 35 4) |  | 18 4) |
| 17 | **Urinary bladder**  | 15,970 | 3.97% | X | 50 |  | 25 |
| 18 | **Soft tissue sarcoma** (incl. GIST) | 5,900 | 1.47% | X | 50 4) |  | 25 4) |
| 19 | **Head/neck tumours**(upper aerodigestive tract, oral cavity, throat, larynx, salivary glands) | 17,130 | 4.26% | X | 75 | X | 37 |
| 20 | **Neuro-oncological tumours** | 10,000 | 2.49% | X | 100 | X | 50 |
|  | **Total** | **401,810** | **100%** |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 21 | **Lung** | 49,530 | 12.33% | 200 | X | X | 100 |
| 22 | **Mesothelioma** | 1,600 | 0.35% |  | 12 6) |  |  |
| 23 | **Paediatric oncology** | 2,170 | 0.54% |  | 30 4) |  | 15 4) |
|  | **Total with lung mesothelioma /****pediatric oncology** | **455.110** | **113.22%** |  |  |  |  |

2) Modified according to the incidences reported by the Robert Koch Institute (RKI) 2008

3)  PAt the present time, no minimum requirements have been defined for the level of competence “S”.

4)  Centre cases (the share in % is only credited to the scope if the minimum target of the centre cases is reached or

exceeded)

5)  Patient cases (the share in % is only credited to the scope if the minimum target of patient cases is reached or exceeded).

6) The Mesothelioma entity is an addendum (A) to the Lung Cancer Center (not a module - M). The mesothelioma entity can only be selected in conjunction with a certified lung cancer center (stand-alone certification or in conjunction with an oncology center is not possible). The mesothelioma entity is not included in cell O53 because it is neither a center nor a module.

7) ~~A reliable indication of the incidence of anal cancer (consisting of C21.1 (anal canal carcinoma) and C44.5 (anal margin cancer, subset “other malignant neoplasms of the skin”) is not yet possible (cf. also explanations of the S3 guideline). A corresponding submission to the DIMDI for clarification has already been made.~~ In order to be able to certify the anal cancer module, it is mandatory that a colorectal cancer centre be certified or be certified for the first time in parallel. Transit status is not possible for anal cancer

8) In order to certify the Penis Cancers Module, a Prostate Cancer Centre must be certified or be initially certified at the same time. Transit status is not possible for Penis Cancer.

**Information on the Oncology Centre (OC)**

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

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

**Network/main cooperation partners**

The (main) cooperation partners of Breast Cancer Centres 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 Oncology Centre
	1. Network structure
	2. Interdisciplinary cooperation
	3. Cooperation with referring physicians and aftercare treatment
	4. Psycho-oncology
	5. Social work and rehabilitation
	6. Patient participation
	7. Study management
	8. Nursing care
	9. General service areas (pharmacy, nutrition counselling, speech therapy…)
2. Organ-specific Diagnostics
	1. Consulting hours
	2. Diagnostics
3. Radiology
4. Nuclear Medicine
5. Surgical Oncology
	1. Multi-organ surgical therapy
	2. Organ-specific surgical therapy
6. Medical oncology / systemic therapy
	1. Medical oncology
	2. Organ-specific systemic therapy
7. Radio-oncology
8. Pathology
9. Palliative Care and Hospice care
	1. Outpatient hospice and palliative care
	2. Inpatient hospice
	3. Palliative ward
10. Tumour Documentation/Outcome Quality

A Development/Networking of Oncological Care

B Requirement to be met by Comprehensive Cancer Centres

The table of contents is standardised for all certification systems of the German Cancer Society. The non-relevant chapters are marked as ‘Not documented’.

Annexes: 1. List of Guidelines

 2. Study organigram/Study list

 3. Matrix tumour documentation

 4. Mailing list/Scientific societies involved

|  |  |
| --- | --- |
| **Centre matrix** | Organ Cancer Centres / Organ Groups |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Colon | Anal Cancer | Pancreas | Stomach | ~~LCC~~ Liver/Bile | Oesophagus | Other gastrointestinal tumours | Endocrine malignancies | Haematological neoplasms | Breast | Gynaecological tumours | Skin | Prostate | Testicles | , Penis | Kidneys | Urinary bladder | Soft tissue sarcomas | Head/neck tumours | Neuro-oncological tumours | Lung/ Mesothelioma | Paediatric oncology | FBREK |
| Level of competence |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| QM system |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1.1 Network structure |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1.2 Interdisciplinary cooperation |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1.3 Cooperation with referring physicians and aftercare treatment |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1.4 Psycho-oncology |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1.5 Social work and rehabilitation |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1.6 Patient survey |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1.7 Study management |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1.8 Nursing care |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1.9 General service areas |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 2 Organ-specific diagnostics |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 3 Radiology |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 4 Nuclear medicine |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 5 Surgical oncology |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 6 Medical oncology |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7 Radio-oncology |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 8 Pathology |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 9 Palliative care / hospice work |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 10 Tumour documentation / Outcome quality |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

|  |  |
| --- | --- |
| Central | “Centrally” managed in the Oncology CentreJoint organisation for various organs and cooperating specialty units |
| Specialty related | Is coordinated by one specialty unit for several organs |
| Organ-specific | Is “independently” managed by one unit of the Oncology Centre “decentralised approach” |
|  | Treatment area is not relevant for corresponding organ or treatment is not provided for one specific organ |
|  Level of competence |  |
| C | Organ Cancer Centre |
| M | Module |
| F | Foci |
| T | Transfer/Transit Centres |
| A | Active treatment but not considered within scope of certification  |
| n | No treatment of this organ in line with the Centre philosophy |

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

| **1.1 Structure of the network** |
| --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 1.1.1 | Centre matrixThe responsibilities for the main requirements are to be specified in the Centre matrix. “Centralised” responsibilityThis means that certain services/requirements of the Organ Cancer Centre or specialty department are provided/met on a centralised basis. “Decentralised” responsibilitySpecific requirements are tackled and met independently of centralised solutions. Mixed “centralised” and “decentralised” forms are possible. |  |
| 1.1.2.a | Steering committee/ Director OCA steering committee is to be set up in which the central responsibilities are organised and monitored. |  |
| 1.1.2.b | A director and deputy director for the Centre are to be appointed in the steering committee. The OC director and his deputy should possess broad clinical experience in the diagnosis, treatment and aftercare of solid tumours as well as in palliative medicine. |  |
| 1.1.2.c | The working methods of the steering committee are defined in standard operating procedures (SOPs). They cover in particular the following:* Selection and appointment of the members (recommendation: directors of the Organ Cancer Centres/Modules and representatives of other specialty units)
* Working methods of the steering committee (decision-making channels)
* Definition of objectives, orientation and further development of the Oncology Centre, drawing up and distribution of a mission statement
* Integration of the Organ Cancer Centres
* Appointment of a central Centre coordinator
* Participation/ tasks of the centralised QM department
* Public relations
* Annual review
* Cooperation with external/national institutions (cancer registries, foundations...)
* Preparation and updating of cooperation agreements for the “centralised responsibilities”
* Implementation of an action plan
* Initiation of quality circles
 |  |
| 1.1.3 | Centre Coordinator – duties* Preparation of steering committee meetings
* Coordination of internal/ external audits
* Monitoring and upholding Technical and Medical Requirements
* Communication interface
* Controlling/monitoring actions initiated by the steering committee
 |  |
| 1.1.4 G-BA | Annual reviewThe following points are to be considered by the steering committee in the annual review:* Definition/evaluation and, if necessary, realignment of objectives
* Individual evaluation of centralised responsibilities (in conjunction with appraisal of objectives)
* Analysis of audit results (internal/ external)
* The annual review is to be documented (incl. updating action plan).
* Compilation of an annual, publicly accessible report that presents and evaluates the results of the oncology centre and its network, identifies suitable improvement measures and presents their implementation. E.g. based on the annual reports of organ cancer centres/modules of the DKG and/ or audit reports.
 |  |
| 1.1.5 | The funding body/bodies of the Centre make sufficient funds/resources available in order to meet the staffing, spatial and material requirements. |  |
| 1.1.6.a | Cooperation agreementsCooperation agreements are to be drawn up with external cooperating partners. They must prove that they meet the corresponding Technical and Medical Requirements of this Catalogue (not every service provider has to be a cooperation partner). The cooperation partners are to be listed in the “master data sheet”. If a cooperating partner of a Centre belongs to a different funding body or is located at a different clinical site, written cooperation agreements are necessary (implementation of the points described in Section 1.1.7 has to be ensured) |  |
| 1.1.6.b | Members of an OC:Cooperation agreements are required for all (registered) members of an Oncology Centre. This applies, for instance, to the following specialty units: Outpatient oncological care, pharmacy, nutrition counselling, genetic counselling, haematology and oncology, hospice, surgical and medical oncology, palliative medicine, pathology, physiotherapy, psycho-oncology, radiology, radio-oncology, pain therapy, spiritual counselling, self-help, social services |  |
| 1.1.6.c | Mandatory members of an OC (= main cooperation partners):Service providers of equal standing who undergo a quality assessment (audit) and whose presence at tumour boards is mandatory.e.g. haematology and oncology, surgical and medical oncology, pathology, radiology, radio-oncology |  |
| 1.1.6.d | A cooperation agreement with a certified Centre for Personalised Medicine should be sought (see also 1.2.12b). If the Centre for Personalised Medicine and the OC are under one sponsorship or at one hospital site, written agreements are not necessary (implementation of the points mentioned under 1.1.7 must nevertheless be ensured). |  |
| 1.1.7 | Cooperation agreements The following points are to be regulated:* Competences and responsibilities
* Description of treatment processes relevant to the Centre taking into account the interfaces
* Undertaking to implement defined guidelines
* Description of cooperation concerning tumour documentation
* Declaration of willingness to cooperate on internal/external audits
* Undertaking to comply with the relevant DKG criteria and to supply the relevant data on an annual basis
* Upholding of medical confidentiality
* Participation in continuing education/specialty training schemes and public relations
* Declaration of consent to be publicly identified as part of the Oncology Centre (e.g. home-page)
 |  |
| 1.1.8 | Tumour board(participation only if stipulated in Section 1.2 Interdisciplinary Cooperation)* Mandatory participation
* Ensuring availability of specialist level
* Participation and voting rules in the case of more than one cooperation partner for each medical specialty (see also provisions “Interdisciplinary Cooperation”)

 Author of the cooperation agreements regarding* “Centralised” responsibilities: steering committee
* “Decentralised” responsibilities: respective specialty unit

 Monitoring/ updatingUp-to-datedness is to be reviewed annually (see also annual review). |  |
| 1.1.9 | QM certificationFor initial certification the OC should have a certified QM system. ~~Approved standards are: ISO 9001, KTQ, proCum Cert, Joint Commission and QEP (practices) and pharmacy-specific QM in cytostatics production (DGOP - German Society for Oncological Pharmaceutics). For pathologies also accreditation according to ISO/IEC17020.~~ |  |
| 1.1.10 | Presentation Organ Cancer Centres, Oncology Centre and CCC The overall structure of the Centres is to be described and publicised (e.g. Internet). This also includes the appointment of all internal/external cooperation partners with the following information:- Name and address of cooperation partner- Contact person with tel./ email details |  |
| 1.1.11 | Centre manualA Centre manual (paper or electronic format) is to be compiled which details how the Technical and Medical Requirements are met (including the standard operating procedures/patient pathways stipulated in the individual sections of the Catalogue of Requirements). A short description is to be included in the Catalogue of Requirements itself with reference to the relevant section in the Centre manual. If the requirements are already described in the existing rules/manuals, then reference is to be made to them in the Catalogue of Requirements.  |  |
| 1.1.12 | Internal auditThe Oncology Centre must undergo an internal audit once a year which will verify fulfilment of the Technical and Medical Requirements. |  |
| 1.1.13 | Continuing education/ specialty training* Events for the exchange of information and for continuing education/specialty training are to be offered twice a year to the cooperation partners of the Oncology Centre.
* This should correspond to some of the requirements to be met by the cooperation partners in respect of continuing education/specialty training.
* Target groups/ dates/ contents/ results and attendance are to be documented and presented in a table, for example. A continuing education/specialty training plan is to be submitted.
* Can be done in conjunction with specialty training for private practitioners.
 |  |

| **1.2 Interdisciplinary cooperation** |
| --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 1.2.1 | The number of patients treated for each tumour entity must be documented. |  |
| 1.2.2 | A central reception point within the OC is desirable. |  |
| 1.2.3 | Tumour boards typesIf there are different types of tumour boards, the differences and specifics (circle of participants, cycle…) are to be described. |  |
| 1.2.4.a | Cycle/ participantsA tumour board must be staged at least once a week. |  |
| 1.2.4.b | All tumour patients are to be presented at the tumour board (organ-specific requirements, Centres, Modules, Foci are to be taken into account). Exceptions are to be explained.If web conferences are used, the sound and documents presented are to be transmitted. There must be provision for each of the main cooperation partners to present his/her own documents/images.For standard questions, documented electronic consent is possible – preferably before the actual tumour board. |  |
| 1.2.4.c | Participation in the conference at a specialist level is mandatory for the following specialties:* Diagnostic, surgical and, if applicable, organ-specific, medical specialty (organ-specific)
* Radio-oncology
* Haematology and oncology
* Radiology
* Pathology
 |  |
| 1.2.4.d | Other disciplines and professional groups are to be involved in the tumour board as required (e.g. pharmacists, surgery, neurosurgery, neurology, orthopaedics, palliative medicine, nuclear medicine, nursing care, psycho-oncology, specialised pain therapy, study coordination). |  |
| 1.2.4.e | If several cooperation partners are named for a specialty, then the presence of a representative is sufficient if a formalised exchange of information has been put in place between them (e.g. through quality circles).Nonetheless, each cooperation partner must attend at least 30 percent of the tumour boards. |  |
| 1.2.4.f | The process of registration, preparation, execution and documentation of the tumour board is to be described in a standard operating procedure (SOP). |  |
| 1.2.5 | Presentation of visual materialPatient-related images (e.g. pathology, radiology) 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.  |  |
| 1.2.6 | Preparation of tumour board* The main patient data are to be summarised in writing in advance and distributed to the participants. Preliminary consideration of suitable study patients is to be undertaken.
* All patients with recurrent symptoms and metastases, who have entrusted the Centre with their care, are to be presented.

 Presentation rates are set for each organ. |  |
| 1.2.7 | Tumour board minutes* The results of the tumour board consist, inter alia, of a written, interdisciplinary therapy plan (“tumour board minutes”).
* The minutes of the tumour board meeting must be part of the patient file and
* The recommendation of the tumour board should also be part of the medical report.
* The “tumour board minutes” should be automatically generated by the tumour documentation system.
 |  |
| 1.2.8 | Tumour board resultsThe patient must be informed about the recommendations of the tumour boardPatient information (case-related):The patient is given* An aftercare plan (if available)/ aftercare pass

 and, on request, the following documents:* tumour board minutes/ therapy plan
* Medical report/ discharge letter
* If relevant, study documentation
 |  |
| 1.2.9 | Participation in the tumour board e as continuing education* One-off binding participation of the following functions/ professional groups in the tumour board ~~is to~~ should be made possible (refresh every three years):
* Assistant staff (MTR (= medical technologists for radiology) ~~MTA, TRA, medical technical/radiology assistants~~…) from radiology, nuclear medicine and radiotherapy
* Staff ~~social services,~~ psycho-oncology and pharmacy
* Participation in the tumour board is recognised as continuing education for the above-mentioned functions/ professional groups.

  |  |
| 1.2.10 | Therapy plan* An individual interdisciplinary therapy plan is to be drawn up for all patients. This also applies to patients not presented at any tumour board.
* A uniform documentation template is recommended for the therapy plan and tumour board minutes.
 |  |
| 1.2.11 | Therapy deviations* In principle, therapy plans and recommendations of the tumour board are binding.
* If any deviations from the original therapy plan or from the Guidelines are observed, they must be recorded and evaluated. Depending on the reason, steps are to be taken to avoid deviations.
* It must be demonstrated (e.g. in the form of a concept) how it is ensured that deviations are recorded. If, at the patient’s request, treatment does not start or is discontinued prematurely (despite an existing indication), this must also be recorded.
 |  |
| 1.2.12.a | Metastasis therapy* At least once pre-therapeutic presentation of all metastasised patients at the tumour board. Objective: e.g., assess metastasis resectability or use local therapy measures or other therapy intervention.
* Description of treatment strategies (with special consideration of oligometastasis) with responsibilities for the various metastasis locations (liver, lung, skeleton, brain…)
* Definition of treatment pathways (patient transfer to another specialty unit, documentation and formalised exchange of information)
 |  |
| 1.2.12.b | For patients with advanced cancer, * who have already undergone guideline-based therapy,
* who, according to the assessment of the clinical parameters, are able to receive molecular-based therapy,
* who agree in principle to a possible therapy based on the molecular findings,

should be referred to a Centres 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. |  |
| 1.2.12.c | Particularly for patients with an advanced diseasea. Validated instruments (MIDOS, IPOS) should be used to record symptoms and distress (see S3 guideline on palliative care).b. Specialised palliative careDetails are to be given in the scope of the OC about how specialised palliative care is integrated into the treatment process (treatment pathway of the S3 guideline). |  |
| 1.2.13.a | Patient pathwaysPatient pathways are to be drawn up for all tumour entities treated in the OC, which chart the procedure from patient admission to the Centre up to the termination of care (special consideration being given to interdisciplinary and trans-sectoral cooperation).  |  |
| 1.2.13.b | Fertility preservation* All patients with a planned fertility-reducing treatment (surgery, radiotherapy, systemic therapy) should be offered information about fertility-preserving measures prior to therapy. The consultation must be documented.
* A description of the procedure with the names of the responsible persons is to be given.
* SOP Fertility Preservation[:](https://ecc-cert.org/certification-system/document-collection/)<https://www.krebsgesellschaft.de/zertdokumente.html>
 |  |
| 1.2.14 | Quality circles (QCs)* Tasks, circle of participants and contents of the quality circles are defined by the steering committee in consultation with the specialist disciplines.
* The mandatory members/main cooperation partners of the OC must take part in or initiate QCs.
* Quality circles are to be held at least three times a year. Oncological topics are one of the foci.
* 1 Morbidity/mortality conferences of the OC/year can ~~are~~ also be recognised as quality circles.
* A list of participants is kept.
* Organisation and documentation by the Centre coordinator or QM officer.
* The quality circles must produce clear results (actions, decisions) which are deemed conducive to significant further development/improvements in the Oncology Centre.

 A quality circle must have been held by the time of initial certification. The results of the quality circle are to be documented. |  |
| 1.2.15 | Centralised list of guidelines/ SOPsA list of guidelines/ SOPs is to be kept (in accordance with Annex 1) which the corresponding specialty unit undertakes to implement. The person responsible for each guideline is to be designated by name in the list.SOPs are updated and concrete diagnostic and therapy instructions, which are based on the S1-S3 Evidence-based guidelines.For entities which do not have respective guidelines, adequate SOPs are to be put in place.SOPs are to be documented for all tumour entities in the area of application.For palliative medicine the SOPs of the leading oncological centre’s network can be used (<http://www.ccc-netzwerk.de/arbeitsgruppen/standard-operating-procedures/netzwerk-sops.html>)  |  |
| 1.2.16 | Tasks of the persons responsible for the guidelines* Monitoring of up-to-datedness and further development
* Presentation of guideline contents to new staff members (description of type of presentation and documentation)
* Monitoring of guideline implementation (e.g. guideline audit, data monitoring)
* Changes to guidelines
* Systematic, timely and verifiable presentation of changes (documented, e.g. as continuing education sessions, quality circles)
* Changes to internal procedures/ specifications resulting from guideline changes
 |  |
| 1.2.17 | 1.2.17 (Symptom) screening in oncological patientsIn order to optimise outpatient and inpatient care, it is recommended that symptoms, stress, consultation and treatment needs be recorded in the form of a basic oncological screening.  The basic screening includes, for example (see SOP at <https://www.krebsgesellschaft.de/zertdokumente.html>): * Screening for psychosocial stress (see section 1.4)
* Symptom screening using validated instruments (e.g. MIDOS/IPOS (see section 9))
* Needs assessment for socio-legal counselling (see section 1.5)
* Screening for malnutrition (e.g. NRS, see section 1.9)
* Screening for geriatric risks for all patients > 70 years of age (e.g. G8)
* Therapeutic movement screening for restrictions in movement and mobility
* Recording the burden on relatives of incurable cancer patients

 The processes and the involvement of the relevant support areas (e.g. nutritional counselling) must be described. Basis for this: "SOP Basic Oncological Screening" at <https://www.krebsgesellschaft.de/zertdokumente.html> |  |

| **1.3 Cooperation with referring physicians and providers of aftercare treatment** |
| --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 1.3.1 | Cooperating referrersAn up-to-date list of cooperating referrers is to be kept. The referrers are to be informed about cooperation within the Oncology Centre with regard to the following: Duties of the Oncology Centre:* Referrers are entitled to attend the tumour board when their patients are presented.
* Referrers are to be given an opportunity to present patients at the tumour board.
 |  |
| 1.3.2 | Contact personsThe contact persons and their function (e.g. telephone, email) are to be made known to the referrers. This may be done in conjunction with the required publication of the cooperation partners.  |  |
| 1.3.3 | Provision of documentsReferrers are to be given the following documents in a timely manner:* Histology
* Tumour board minutes/ therapy plan
* Surgical report (optional)
* Medical report/discharge letter
* Changes to therapy
 |  |
| 1.3.4 | Feedback systemA written procedure for recording, processing and providing feedback on general and case-specific concerns/ questions/ complications by referrers is to be put in place. |  |
| 1.3.5 | Referrer satisfaction survey* A referrer satisfaction survey is to be conducted every three years. The results of this survey are to be evaluated and analysed.
* The referrer satisfaction survey must be available for the first time for the first surveillance audit (one year after initial certification).
 |  |
| 1.3.6 | Continuing education/ specialty trainingAt least two events a year are to be proposed by the Centre for the exchange of experience and training purposes. The contents/ results and attendance are to be documented. |  |

| **1.4 Psycho-oncology** |
| --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 1.4.1 | Psycho-oncology qualifications * Diploma/ Master in Psychology, which qualifies its holder to practice scientifically recognised psychotherapy
* Doctors of Human Medicine,
* Diploma/ Master in Social Pedagogics, which qualifies its holder to practice scientifically recognised psychotherapy

 in each case with specialty training in psychotherapy: behavioural therapy, psychodynamic psychotherapy (analytical psychotherapy and psychology-based psychotherapy), systemic therapy, neuropsychological therapy (for mental disorders due to brain injuries), interpersonal therapy (IPT; for affective disorders and eating disorders), EMDR for the treatment of post-traumatic stress disorders, hypnotherapy for addictive disorders and for psychotherapeutic co-treatment of somatic diseases and with psycho-oncological specialty training (DKG-recognised). Licence to practice: At least 1 person in the psycho-oncological team of the network (inpatient or outpatient) must have a licence to practice (psychological or medical psychotherapist) Protection of existing standards for all who are currently recognised and those who commenced a DKG-recognised psycho-oncological continuing education course by 31 December 2019. Representatives of other psychosocial professions are allowed if they can prove the above-mentioned additional qualifications. This should be evaluated on a case-by-case basis. |  |
| 1.4.2 | Offer and accessEach patient must be promptly offered a psycho-oncological counselling session in the vicinity (must be documented). The threshold to these services must be low.  |  |
| 1.4.3 | Psycho-oncological resourcesIf needed, at least 1 psycho-oncologist with the above-mentioned qualifications is available to the centre (list of names).Organ Cancer Centre/ Module requirements are to be considered separately Recommendation: further resources, if necessary, are to be provided for coordination and scientific tasks (e.g. documentation assistants). |  |
| 1.4.4 | Scope of care provided* ~~The number of patients who receive psycho-oncological care is to be documented.~~
* Psycho-oncological care, in particular for patients with excessive stress in the distress screening, must be presented.
* ~~Consultation frequency and length are to be documented~~.

 For further information, see FAQ.   |  |
| 1.4.5 | Premises A suitable room is to be provided for the psycho-oncological patient consultations. |  |
| 1.4.6 | Organisation chartThe assumption of tasks is to be set out in an organisation chart which contains details, inter alia, of resource availability and local presence. |  |
| 1.4.7.a | Psycho-oncology - Task profileThe psycho-oncological care of patients is to be offered at all stages of treatment (diagnosis, inpatient, post-inpatient). |  |
| 1.4.7.b | Objectives and tasks of care:* Diagnostic clarification after positive screening
* Prevention/ treatment of ensuing psychosocial problems
* Activation of personal coping strategies
* Preservation of quality of life
* Consideration of the social environment
* Organisation of outpatient aftercare through cooperation with outpatient psycho-oncological service providers
* Public relations (patient events, etc.)
* Chairing of psychosocial quality circle
 |  |
| 1.4.7.c | Recommendations:* Staging or coordination of supervision, continuing education/ specialty training for staff members
* Twice yearly discussions between psycho-oncologists, nursing and medical staff
* Regular written and, if necessary, oral feedback on the psycho-oncological activity to the medical staff (e.g. referral report or documentation in the medical record)
* Regular participation in the ward and tumour boards
* Cooperation with the social services and other Centres
* Provision or coordination of interdisciplinary intervention
* The psycho-oncologists should present their work at least twice a year at the tumour board.
 |  |
| 1.4.8 | Documentation and evaluationTo identify treatment needs, screening of psychological strains ~~(see S3 Guideline Psycho-oncology)~~ is required and the results is to be documented.The proportion of patients subjected to distress over-threshold screening should be reported.~~Psycho-oncological care is to be continuously documented and evaluated with the aid of suitable instruments~~.~~Psycho-oncological care must be documented and evaluated on an ongoing basis using suitable instruments (e.g. PO-BaDo).~~ |  |
| 1.4.9 | Continuing education/ specialty training/ supervision* At least one specific continuing education/ specialty training session annually for each staff member (at least one day a year)
* External supervision is to be offered 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 | Social work - Qualifications* Social worker/ social education worker
* Case-by-case examination in line with the instructions of the professional body is possible
* ~~Additional qualifications:~~ ~~Experience in medical/oncological professional field~~
 |  |
| 1.5.2 | ResourcesFor the counseling of patients in the Center there is at least one full-time staff member available for 400 counselled patients (= primary cases, secondary metastasis, recurrence). The HR resources can be kept centrally. An organisation chart must be available. |  |
| 1.5.3 | Offer and accessEvery patient must be offered the possibility of counseling by the social service in all phases of the disease, locally and promptly (proof required). The offer must never be made in a threshold manner. |  |
| 1.5.4 | Scale of patient supportA record must be kept of the number of patients who have received support from the social services. |  |
| 1.5.5 | Premises A suitable room is to be provided for social services counselling. |  |
| 1.5.6 | Organisation chartThe assumption of tasks is to be specified in an organisation chart in which, inter alia, resource availability and local presence are identifiable.  |  |
| 1.5.7 | Counselling topics using the DVSG service catalog and the expert standard PEOPSA (psycho-social initial counseling of oncological patients by social work):* Identification of social, economic and psychological distress
* Initiation of medical rehabilitation measures
* Advice on social law and financial questions (e.g. legislation concerning the severely disabled, wage compensation benefits, pensions, benefit requirements, employee contributions, etc.)
* Help with application procedures
* Advice on outpatient and inpatient care options and help with accessing supportive measures and specialist services
* Support for professional and social reintegration
* Cooperation with social insurance bodies and care providers.
* Discharge management
* Intervention in emergencies
 |  |
| 1.5.8 | Other tasks:* Offer educational/ informational sessions for other disciplines at the Center and/ or patients.
* Public relations and networking
* Participation in multi-professional case discussions, supervision
* Interdisciplinary cooperation, particularly with physicians, nurses, physiotherapists, psycho-oncologists, spiritual counselling, etc.
 |  |
| 1.5.9 | Documentation and evaluationThe activities of social workers are to be documented and evaluated (e.g. Care SD, KIS). |  |
| 1.5.10 | Continuing education/ specialty training* At least one specific continuing education/ specialty training session for each staff member a year (at least one day a year).
* Offer of supervision
 |  |
| 1.5.11 | Choice of rehabilitation centre for each patientIf there is an existing indication the patient should be offered oncological rehabilitation in a consultation. (see also 1.5.7) |  |

| **1.6 Patient participation** |
| --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 1.6.1 | Patient surveys* At least every three years patients are to be given the opportunity to participate once in a patient survey over a period of three months.
* The response rate should be higher than 30% (if lower, the result is to be evaluated).
 |  |
| 1.6.2 | Evaluation of the patient survey* Responsibility for the evaluation is to be specified.
* The evaluation must refer to patients of the Oncology Centre.
* A documented evaluation must be made and is to be presented at the audit.
* Further action is to be determined on the basis of the evaluation.
 |  |
| 1.6.3 | Patient information (general)* The Centre is to present itself and its treatment options as a whole (e.g. in a brochure, patient folder, its website).
* The cooperation partners and contact person are to be designated by name. The available treatments are to be described.
* The range of treatments presented must include: rehab/ post-treatment rehab, self-help, treatment measures and alternatives.
 |  |
| 1.6.4 | Discharge consultationEach patient is given a discharge consultation (short documentation/checklist) during which at least the following subjects are touched on and corresponding information provided:* Therapy plan
* Individual aftercare plan (handing over of aftercare pass)
* ~~If appropriate~~ If available, “Patient guideline” <www.leitlinienprogramm-onkologie.de>, ~~self-help flyer~~

 Patient information should be evidence-based and free of any interests. ~~Brochures~~ Information should therefore preferably be ~~obtained~~ used from the German Cancer Aid, the regional cancer associations, cancer self-help organisations and the Krebsinformationsdienst (Cancer Information Service) |  |
| 1.6.5 | Patient eventThe Oncology Centre is to stage an information event for patients and/or interested parties at least once a year. If possible, in cooperation with self-help groups.If patient events are (co-)financed by industry, this fact including potential conflicts of interest of the speakers must be disclosed. The centre must rule out any direct influence on patients by industry representatives. |  |
| 1.6.6 | Complaints managementFormalised complaints management is in place. The patients are given feedback. Complaints are taken into account for the improvement of procedures. |  |
| 1.6.7.a G-BA | Self-help groupsThe self-help groups and self-help centres, with which the Oncology Centre actively cooperates, are to be designated by name.* A contact person must be designated by name.
* Cooperation must be announced (e.g. on the website), possibly including cooperation with nationwide, entity-specific self-help organisations
* The tasks of the self-help groups may only be carried out by members of the self-help groups.
 |  |
| 1.6.7.b G-BA | Written agreements are to be entered into with the self-help groups. These agreements should be updated at least every 5 years and should encompass the following points:* Access to self-help groups at all stages of treatment (initial diagnosis, hospitalisation, chemotherapy, aftercare…)
* Publication of contact details of self-help groups e.g. in patient brochures, OC website)
* Possibility for self-help groups to display information brochures
* Clinics approach the local self-help groups or the federal associations if information material is required
* Regular provision of premises at the OC for discussions with patients
* Quality circle with participation of representatives from psycho-oncology, self-help groups, social services, spiritual counselling, nursing and medical care.
* Personal discussions between self-help groups and the OC for the purposes of jointly staging or coordinating actions and events. The results of the discussions are to be documented.
* Participation of all medical staff in events of the self-help group
 |  |
| 1.6.8 G-BA | Accessibility* Access to the hospital is basically barrier-free.
* The rooms for patient care and examination must be accessible to people with disabilities.
* The centre shall designate a contact person or competent authority for persons with disabilities and publish this information in the quality report of the approved hospitals pursuant to Section 136b (1) No. 3 SGB V.
 |  |

| **1.7 Study management** |
| --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 1.7.1 | The statements below refer to the following cooperation partners: General remarkEach of the cooperation partners of the Oncology Centre, that offers or conducts studies for tumour patients, must prove that it meets the requirements in this section of the Catalogue. Hence, each cooperation partner from this specialty is to process this section in detail or to make specific statements in this section. |  |
| 1.7.2 | Investigator/ Study leaderTo be designated by name in the “study organisation”. Investigator and study leader may be the same person. Definition investigator* Responsible for conducting the study in accordance with Section 40 Medicinal Products Act (AMG)
* Minimum two years’ experience in clinical drug trials

 Definition study leader* Physician named by the investigator
* Investigator delegates tasks to the study leader
* When a new study leader is appointed, proof of dedicated continuing education in studies is to be provided.
 |  |
| 1.7.3 | Study assistant* A study assistant is to be designated by name in the “study organigram” for “each ongoing study unit” (Annex 2).
* In exceptional situations, this assistant may be actively involved in several parallel studies.
 |  |
| 1.7.4 | Study assistant - qualifications Continuing educationIf possible, specialist medical training (e.g. medical technical assistant, health care assistant/nurse, medical assistant) TrainingDocumentation is to be provided of dedicated training for the study assistant function. At the time of initial certification at least one application for a training course must have been submitted. The course is to be completed within one year. During the training the investigator/study leader must compensate for any qualification deficits.  |  |
| 1.7.5 | Study assistant - tasksThe range of tasks is to be specified in writing (e.g. via job/function descriptions) and may include the following contents:* Conduct of studies together with the investigator
* Recruiting, registering and providing supportive information to patients
* Patient support during the study and in aftercare
* Organisation, coordination of diagnostics, laboratory, sample shipment and test medication
* Collection and documentation of all relevant study data
* Preparation and support for audits and official inspections
* Cover staff rules

The activity of the study assistant can be combined with other activities like tumour documentation.  |  |
| 1.7.6 | Cooperation study assistant - investigatorStudy assistant must have direct access to the investigator or study leader (documented for instance by means of a regular exchange).  |  |
| 1.7.7 | Study secretariatDedicated premises are to be assigned for documentation and document storage activities. |  |
| 1.7.8 | Standard operating procedures (SOPs)The procedures for the acceptance/ initiation of new studies and the conduct of studies are to be specified, including responsibilities. This encompasses for instance:* Selection of new studies incl. approval decisions
* Internal announcement of new studies (updating of study list (see Annex 2), …)
* Qualification of staff members involved
* Study organisation (specifics of support for study patients, documentation…)
* Communication exchange/ distribution of tasks between study secretariat and staff conducting the study
* Method of sharing study results (e.g. staff, patients)
* If drugs are prepared/ manufactured in the pharmacy as part of the study, the pharmacy must be involved prior to initiation
 |  |
| 1.7.9 | Access to studiesAccess to the studies must be possible for patients. The studies conducted at the Oncology Centre are to be listed and, for instance, published on the website (incl. short description of the study). |  |
| 1.7.10 | Assignment to a study* Before participation in a study is recommended to a patient, a patient-related discussion must have taken place in the interdisciplinary tumour board.
* The provisions for study participation are formulated in the organ-specific requirements (Organ Cancer Centre, Module, Focus). 5% of all tumour patients treated in the Oncology Centre should participate in studies.
* *[only relevant for corresponding pilot project in CR GC]* Study patients can be counted for 2 centers, provided that the sending center itself conducts at least one own study for the tumor entity corresponding to the scope of the certificate. If this method of counting is chosen (facultative), the center must show how many patients are brought into its own studies, sent to other centers/clinics for study participation and taken over from other centers/clinics for study participation.
* Study participation is solely deemed to be the inclusion of patients in studies following a positive vote by the ethical committee combined with a study plan (non-interventionist/diagnostic studies are also recognised).
 |  |
| 1.7.11 | Communication of serious events It must be ensured that the corresponding study secretariat is informed immediately of any serious adverse events (SAEs). This presupposes that the study status of each patient is absolutely clear to the specialty department. |  |
| 1.7.12 | If the unit conducting the study is not part of the clinicDocumentation of a written cooperation agreement is to be provided, that ensures compliance with all the Technical and Medical Requirements set out in this section. |  |
| 1.7.13 G-BA | Research activityThe Oncology Centre fulfils at least one of the following requirements for the field of oncology:* Collaboration on guidelines and consensus papers (name and guideline/ consensus paper) and/or
* At least one annual scientific publication (international publication, peer-review procedure) ~~in the field of oncology~~ (name of at least 1 publication with associated centre/ module) and/ or
* Participation in multicentre studies of evidence level Ib or lla
 |  |

| **1.8 Nursing care** |
| --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 1.8.1 | Specialist oncology nurses (with the exception of paediatric oncological care).* At least 2 full-time active specialist oncology nurses must be employed on day duty in the Oncology Centre.
* Specialist oncology nurses must be designated by name.
* Active care by a specialist oncology nurse must be documented in the units in which patients receive inpatient oncology care.
* If no specialist oncology nurse is directly employed in an inpatient oncology unit, a specialist oncology nurse is to be designated by name and his/ her performance of tasks is to be formalised in writing and documented.

 The preconditions for recognition as oncology nursing staff are* Continuing education as oncology nursing staff according to the country-specific regulations
* Or according to the model of the German Hospital Federation (Deutsche Krankenhausgesellschaft e.V. DKG)
* Or Advanced Practice Nurse (Master’s Programme name) plus 2 years’ practical on-the-job experience (equivalent to a full time position) in the oncological sector to be certified.
 |  |
| 1.8.2 | Responsibilities/ tasksPatient-related tasks:* If applicable, (symptom) screening in oncological patients (see section 1.2.17) and specialist assessment of symptoms, side effects and stress/ strain
* Individual derivation of interventions based on the nursing standards
* Conduct and evaluation of nursing and therapeutic measures
* Identification of individual patient-based counselling needs.
* The specialist counselling needs are already to be defined in the nursing concept of the individual Organ Cancer Centres.
* Ongoing information and counselling of patients (and their family members) during the entire course of the disease
* Conduct, coordination and documentation of structured counselling sessions and guidance of patients and family members, if necessary on the basis of the above-mentioned screening/assessment, including other areas of support.
* Participation in the tumour board
* Initiation of and participation in multi-disciplinary case discussions/nursing visits; the aim is to find a solution in complex nursing situations; criteria for the selection of patients are to be laid down; per year and ~~scope of the~~ Oncology Centre ~~at least 12~~ case discussions/nursing visits are to be documented regularly of the Oncology Centre

  Overarching activities:* A nursing concept is to be developed and implemented in which the organ-specific features of oncological nursing care are to be taken into account in the Organ Cancer Centres/ Modules.
* Drawing up of specialist, in-house standards on the basis of (if possible) evidence-based guidelines (e.g. S3 Evidence-based Guideline for Supportive Therapy).
* Offer of consultation/supervision by colleagues
* Networking of specialist oncological nurses in the Oncology Centre, for instance in the joint quality circles
* And, there, organisation of the training plan for the Oncology Centre with its Organ Cancer Centres/ Modules (in line with Section 1.8.5).
* Exchange with all professional groups involved in treatment

 Responsibility for implementing the requirements to be met by the nurse administering chemotherapy (see Section 6.2.3) |  |
| 1.8.3 | InductionThe induction of new staff members is to be done on the basis of an oncological induction catalogue/plan with the participation of the specialist oncology nurse. |  |
| 1.8.4 | Continuing education/ specialty training* A qualification plan for nursing staff is to be presented listing the planned qualification sessions for the period of one year.
* At least one specific continuing education/specialty training session for each staff member (minimum one day a year) if they carry out quality-relevant activities for the Oncology Centre.
 |  |

| **1.9 General service areas (pharmacy** |
| --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 1.9.1 | Pharmaceutical care qualification* Qualified pharmacist
* Desired additional qualifications:

Continuing education/ specialty training approved by the pharmaceutical associations (Apothekenkammern) or DGOP in the field of oncological pharmaceutics |  |
| 1.9.2 | Offer and accessIf required, the pharmacist specialised in oncology is to provide physicians, nursing staff and patients with information and advice (must be documented). |  |
| 1.9.3 | ResourcesAdequate resources are to be assigned to pharmaceutical care and support. |  |
| 1.9.4 | Organisation chartIf pharmaceutical-oncological care and support are provided by external cooperation partners or for several clinical sites and clinic facilities, the performance of tasks is to be laid down in an organisation chart in which, inter alia, resource availability and local processes (deliveries, orders, etc.) are clearly set out. |  |
| 1.9.5 | Pharmacy – task profileObjectives and tasks of pharmaceutical care and support:* Possibility of daily (7d) centralised quality-assured production of the active ingredients needed for intravenous tumour therapy
* Monitoring of stability and compatibility of therapy regimens
* Plausibility analysis of dosage taking into account individual patient laboratory parameters
* Support for risk assessment, staff instruction, decontamination, extravasation and disposal of cytostatic drugs
* Correct reception, storage, production or preparation, distribution and disposal of the test drugs
* Information and advice for physicians, nursing staff and patients by pharmacist if necessary
* Participation in tumour board and meetings of the study centres (in line with section 1.2)

 ~~Recommendations:~~* ~~Pharmacist should regularly take part in the meetings of the study coordination units (quality assurance protocols in oncology)~~
* ~~The pharmacy should present its work to the tumour board at least once a year.~~
 |  |
| 1.9.6 | Documentation and evaluationPharmaceutic support is to be documented and evaluated continuously with the aid of suitable instruments (e.g. computer-aided documentation ~~with Cypro, Zenzy etc~~.). |  |
| 1.9.7 | External approval of a QM system is recommended (e.g. pharmacy-specific QM in cytostatic production (DGOP) |  |
| 1.9.8 | Continuing education/ specialty trainingAt least two dedicated continuing education sessions for each staff member in cytostatic production who carries out quality-relevant tasks for the OC. |  |
| 1.9.9 | Pain therapy* For central areas of the Oncology Centre (operating theatre, medicinal therapy, radiotherapy) a “pain treatment” SOP must be available
* The names of designated contacts for pain therapy/ pain consultations are to be provided
* An information leaflet “Pain therapy” should be available to patients for each area
 |  |
| 1.9.10 | Nutritional counselling* Nutritional counselling must be part of the Oncology Centre. An SOP should be available
* Need for nutritional counselling is to be actively identified and provided for each patient
* The metabolic risk (nutritional risk) should be recorded at the latest on inpatient admission using Nutritional Risk Screening (NRS), for instance in line with Kondrup 2003.
 |  |
| 1.9.11 | Hygiene management* For the scope of the OC physicians and nurses with responsibility for hygiene are to be designated by name.
* Compliance with the central hygiene requirements is to be documented for the individual areas (inter alia operating theatre, therapy).
 |  |
| 1.9.12 | Antibiotic stewardship visits (ABS visits)* A concept for antibiotic stewardship visits (ABS visits) or similar formats must be demonstrated for the scope of the OC.
* The visits should be carried out on a multi-professional basis.
 |  |
| 1.9.13 | The Oncology Centre must provide evidence of a concept for providing information on smoking advice/tobacco cessation. |  |

**2. Organ-specific diagnostics**

| **2.1 Consultation hours** |
| --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 2.1.1 | The requirements concerning the organ-specific consulting hours are contained in the Catalogues of Requirements of the corresponding Organ Cancer Centres/Modules and are to be fully complied with.The departments which treat tumour entities, that are not or cannot be treated in a certified Organ Cancer Centre, must present proof of specialist qualifications and treatment concepts. Organ-specific presentation in accordance with the template “Catalogue of Requirements Oncology Centre – Annex tumour entity” |  |

| **2.2 Diagnostics** |
| --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 2.2.1 | The requirements concerning organ-specific consulting hours are contained in the Catalogues of Requirements of the corresponding Organ Cancer Centres/Modules and are to be fully complied with.The departments which treat tumour entities, that are not or cannot be treated in a certified Organ Cancer Centre, must present proof of specialist qualifications and treatment concepts. Organ-specific presentation in accordance with the template “Catalogue of Requirements Oncology Centre – Annex tumour entity” |  |

**3. Radiology**

|  |
| --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 3.1 | Specialists* At least one radiology specialist
* Written documentation cover staff has same qualifications
* Specialist and cover staff are to be designated by name
 |  |
| 3.2 | Medical technical radiology assistants (MTR(= medical technologists for radiology) ~~MTRAs~~)At least 2 qualified MTR ~~MTRAs~~ must be available |  |
| 3.3 | Radiology methods that must be available: * Conventional x-ray
* Angiography
* Sonography
* Spiral-CT
* MRl (field strength at least 1.5 Tesla)
 |  |
| 3.4 | 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. |  |
| 3.5 | Compilation of resultsThe radiologist’s written report must be available to the attending physicians at the latest 24 hours after the examination. |  |
| 3.6 | Induction of new staff membersSystematic, documented induction of new staff members is to be ensured, which imparts knowledge about the Oncology Centre’s respective field of activity. This induction must take place within three months of commencement of employment. |  |
| 3.7 | Continuing education/ specialty training* A training plan for medical and nursing medical assisting staff is to be presented outlining the planned training sessions for the period of one year.
* At least 1 dedicated continuing education/ specialty training session for each staff member (minimum one day a year) who carries out quality-relevant tasks for the Oncology Centre.
 |  |
| 3.8 | Quality circles* Staff are to stage or take part in at least three quality circles a year in which oncological topics are addressed.
* Scheduling, e.g. in training plan
* Quality circles are to be documented.

 Participation in the quality circles organised centrally by the Oncology Centre is recognised (see “Catalogue of Requirements Section 1.2.14 Interdisciplinary Work”). |  |

**4. Nuclear medicine**

|  |
| --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 4.1 | Specialists in nuclear medicine* At least one specialist for nuclear medicine is available.
* Written documentation that cover staff has same qualifications
* Specialist and cover staff are to be designated by name
 |  |
| 4.2 | MTR ~~Medical technical radiology assistants~~ of nuclear medicineAt least two qualified MTR ~~medical technical radiology assistants~~ of nuclear medicine must be available. |  |
| 4.3 | Nuclear medicine methods that must be available:* Bone scintigraphy (mandatory)

 Optional:* PET-CT, PET-MRI
* Inpatient radionuclide therapy
 |  |
| 4.4 | Standard operating procedures (SOPs)The imaging procedures are to be described and checked once a year to ensure they are up to date. |  |
| 4.5 | Compilation of resultsThe ~~nuclear physician’s~~ nuclear medicine "Scintigraphy" (gamma camera diagnostics) written report must be available to the attending physicians at the latest 24 hours after completion the examination.A period of 24 hours per specialist discipline involved is provided for the preparation of the findings of radiological-nuclear medicine hybrid diagnostics. |  |
| 4.6 | Induction of new staff membersSystematic, documented induction of new staff members is to be ensured, which imparts knowledge about the Oncology Centre’s respective field of activity. This induction must take place within three months of commencement of employment. |  |
| 4.7 | Continuing education/ specialty training* A training plan for medical and nursing staff is to be presented outlining the planned training sessions for the period of one year.
* At least one dedicated continuing education/specialty training session for each staff member (minimum one day a year) who carries out quality-relevant tasks for the Oncology Centre.
 |  |
| 4.8 | Quality circles* Staff are to stage or take part in at least three quality circles a year in which oncological topics are addressed.
* Scheduling, e.g. in training plan
* Quality circles are to be documented.

 Participation in the quality circles organised centrally by the Oncology Centre is recognised (see “Catalogue of Requirements Section 1.2.14 Interdisciplinary Work”). |  |

**5. Surgical oncology**

| **5.1 Multiple organ surgical therapy** |
| --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 5.1.1 | The statements below refer to the following cooperation partners: General remarkEach of the cooperation partners of the Oncology Centre in the field of surgery must prove that it meets the requirements in this section of the Catalogue. Hence, each cooperation partner from this specialty is to process this section in detail or to make specific statements in this section. |  |
| 5.1.2 | Specialists* At least one specialist for visceral surgery Cover staff member with equivalent qualifications is to be designated in writing.
* Specialists are to be designated by name. If necessary documented in a cooperation agreement
 |  |
| 5.1.3 | Availability/ On call* 24h-availability of a surgical specialist including weekends and public holidays
* 24 hour emergency surgical care must be guaranteed
 |  |
| 5.1.4 | Case numbers surgery* The organ-specific requirements are documented in Section 5.2 of the organ-specific Catalogues of Requirements
 |  |
| 5.1.5 | Interdisciplinary approach* For every tumour patient at an advanced stage of disease and/or with remote metastasis, the approach to be adopted is to be planned and documented prior to surgery by the specialist disciplines involved in line with the recommendation of the tumour board.
 |  |
| 5.1.6 | Standard operating procedures (SOPs)* The care concepts for special surgical treatment needs (metastasis, advanced stages of recurrence, etc.) are to be presented (e.g. cooperation urology, neurosurgery, casualty surgery, thoracic surgery, vascular surgery)
* For patients with myelon compression and neurological symptoms, an SOP for "treatment must be established within 24h of suspected diagnosis"
* The interdisciplinary procedure for surgical procedures, bearing in mind the interfaces, must be described, and the concept with corresponding cooperation agreements must be presented at certification
* Post-operative care of patients with intraoperative surgical results
* Options for intensive medical care
* Transfer back to the general ward after treatment by the primary specialty
* Supportive measures in accordance with the guidelines are to be described for the individual therapy concepts and documented in detail for each patient
 |  |

| **5.2 Organ-specific surgical therapy** |
| --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 5.2.1 | The requirements to be met by organ-specific surgical treatment are set out in the Catalogues of Requirements of the corresponding Organ Cancer Centres/Modules and must be met in full.The units which treat tumour entities, that are not or cannot be treated in a certified Organ Cancer Centre, must show proof of specialist qualifications and treatment concepts. Organ-specific presentation in accordance with the template “Catalogue of Requirement Oncology Centres – Annex tumour entity” |  |

**6. Medicinal oncology/ Systemic therapy**

| **6.1 Medical oncology** |
| --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 6.1.1 | The statements below refer to the following cooperation partners: General remarkEach of the cooperation partners (haematologists and oncologists) of the Oncology Centre must prove that it meets the requirements in this section of the Catalogue in the field of medical oncological therapy. Hence, each cooperation partner from this specialty is to process this section in detail or to make specific statements in this section. This also applies when inpatient and outpatient therapy is provided by different cooperation partners (separation inpatient/ outpatient). |  |
| 6.1.2 | It is preferable for systemic therapy to take place in central therapy units with multidisciplinary support. |  |
| 6.1.3 | Medical qualifications * Specialist for internal medicine, haematology and medical oncology
* A cover staff member with the aforementioned qualifications is to be designated by name

 Requirements Eligible for specialty training by the competent medical board in haematology and medical oncology.If there is no eligibility for full specialty training, the provisions in Sections 6.1.4 – 6.1.6 must be complied with. |  |
| 6.1.4 | Cooperation with a unit for allogenic and autologic stem cell transplantation must be documented in the case of the corresponding scope of the OC. If necessary by means of cooperation. A standard operating procedure (SOP) should be available. |  |
| 6.1.5 | Availability/ On call* 24-hour availability of a specialist for internal medicine, haematology and medical oncology including weekends and public holidays
* Arrangements for ward rounds must be in place at the weekend.
* A visitation shift must be set up for the weekend
 |  |
| 6.1.6 | * Beds in a closed inpatient unit for haematological and oncological patients in facilities, which meet the requirements for continuing education facilities for haematology and oncology, must be available at all times (verification via the OC bed plan)
* The isolation and protective isolation of patients must be possible and corresponding measures (e.g. hand disinfection, screening for problematic germs, filters) must be in place (standard operating procedure [SOP]).
* Individual monitoring places or monitors and access to intensive care must be available in the same hospital at all times for oncology patients.
 |  |
| 6.1.7 | Cooperation with specialists for haematology and medical oncology who work with outpatients must be documented (e.g. also via authorisation, multidisciplinary systemic therapeutic unit). |  |
| 6.1.8 | Provision of oncological consultation services for all inpatient departments on site that are involved in tumour therapy.  |  |
| 6.1.9 | The standard operating procedure for using the on-call services of the specialist for internal medicine, haematology and medical oncology for patients who come to the hospital must be described and presented using concrete cases. |  |
| 6.1.10 | Participation in the tumour boardParticipation in the tumour board is mandatory. |  |
| 6.1.11 | Therapy plan/ttumour board minutes* In principle, therapy plans and recommendations of the tumour board are binding and form the basis for treatment.
* Therapy plan/tumour board minutes must be available in the patient-based documentation.
* If there are any deviations from the recommended therapy plan, they are to be presented at the tumour board.
* Supportive measures in accordance with the guidelines are to be described for the individual therapy concepts and documented in detail for each patient.
 |  |
| 6.1.12 | Continuing education/ specialty training:* A training plan for medical and nursing staff is to be presented listing the planned training sessions for the period of one year.
* At least 1 specific continuing education/ specialty training session for each staff member (minimum 1 day a year) who carries out quality-relevant activities for the Oncology Centre.
 |  |
| 6.1.13 | Quality circles* Staff are to stage or take part in at least 3 quality circles a year in which oncological topics are addressed.
* Scheduling, e.g. in training plan
* Quality circles are to be documented

 Participation in the quality circles organised centrally by the Oncology Centre is recognised (see “Catalogue of Requirements 1.2.14 Interdisciplinary Work”). |  |
| 6.1.14 | StudiesIf studies are offered or conducted, the requirements in Section 1.7 Study management are to be fully complied with. |  |
| 6.1.15 | Nursing careFor inpatient care, the nursing care requirements in Section 1.8 Nursing care are to be fully complied with. |  |

| **6.2 Organ-specific systemic therapy** |
| --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 6.2.1 | The statements below refer to the following cooperation partners: General remarkEach of the cooperation partners of the Oncology Centre must prove that it meets the requirements in this section of the Catalogue in the field of medical oncological therapy. Hence, each cooperation partner from this specialty is to process this section in detail or to make specific statements in this section. This also applies when inpatient and outpatient therapy is undertaken by different cooperation partners (separation inpatient/ outpatient). |  |
| 6.2.2 | Conduct of medical tumour therapy (e.g. chemotherapy, antibody therapy, hormone therapy, cellular therapy) Specialist for* internal medicine with the focus designation Haematology and Medical Oncology for the entire spectrum

 For the following specialist disciplines, implementation is exclusively discipline-specific:* Specialist with additional qualification in medicinal tumour therapy (in Modules: implementation in peer-based cooperation with the aforementioned specialists)
* Gynaecology and obstetrics with the sub-speciality gynaecological oncology
* Internal medicine and gastroenterology or internal medicine and pneumology
* Paediatric medicine with the official sub-speciality “Paediatric haematology – Oncology”
* Radiation therapy for implementation of systemic tumor therapy in combination with radiotherapy for solid tumors.

 A representative (the representatives of cooperation) with the aforementioned qualification is (are) to be designated by name.The specialists named here must monitor medical oncological therapy. It is not possible to delegate responsibilities to physicians who do not have the aforementioned qualification. |  |
| 6.2.3 | Specialist nursePrerequisites for specialist nurses responsible for administering chemotherapy:* Inpatient, day patient or clinical-outpatient units in which medical 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.
* Minimum one year professional experience in oncology
* 50 chemotherapy administrations per year (in the case of initial certification an estimate can be made. In subsequent years documentation will have to be provided for the audit.)
* Documentation of training in line with the recommendations of the Conference of Oncological Nursing and Paediatric Nursing Care (KOK) (KOK action recommendation, administration of cytostatic drugs by specialist nurse)
* Active involvement in meeting the requirements for emergency treatment and treatment of comorbidities and secondary diseases

Evidence of the documentation of nursing advice and/or education of patients is to be provided* Documentation of proof of competence to administer chemotherapeutics by the specialists designated in Section 6.2.2.

Documentation of annual training courses that encompass inter alia the contents outlined in Sections 6.2.13 and 6.2.14 is required for proof of competence |  |
| 6.2.4 | Medicinal tumour therapy in the Oncology Centre* The treatment units of the OC, including the associated Organ Cancer Centres and Modules, which carry out the tumour therapy are to be depicted in the centre matrix (page 10)
* Efforts are to be made to put in place treatment units that carry out the central tumour therapy
 |  |
| 6.2.5 | Availability/ On call* 24-hour availability outside of working hours including weekends and public holidays
* Access to therapy data must be possible during 24-hour availability

 Specifics inpatient care* Ward rounds on weekends
 |  |
| 6.2.6 | Case numbers per treatment unit* at least 200 medicinal tumour therapies (cytostatic therapies and/or targeted therapeutic agents and/or antibody/ immunotherapies, no hormone therapies) a year and /or at least 50 with a specific indication (e.g. mammary gland, colorectal….) unless otherwise specified in the organ-specific requirements
* Radiotherapy: at least 50 systemic tumour therapies in combination with radiotherapy for solid tumours
* Calculation method: completed systemic/cytostatic/targeted therapy for each patient (consisting of **several** administration cycles, combination therapies count as 1 therapy). In the case of cross-year therapies, the therapy commenced in the survey year counts. 1 therapy per patient = 1 therapy line per disease per patient
* In the event of shortfall, expertise cannot be documented via cooperation (must be documented by each individual treatment unit).
 |  |
| 6.2.7 | Facilities medical oncological therapy (only outpatient)At least four treatment places for intravenous tumour therapy and blood transfusions in a separate room. |  |
| 6.2.8 | Basic diagnostics laboratoryBasic diagnostics including emergency laboratory must be possible during working hours. If done externally, documentation by means of cooperation agreement. Basic diagnostics laboratory must be available 24h/7d in the Oncology Centre. |  |
| 6.2.9 | Basic diagnostics imaging* 24h daily access to ultrasound diagnosis
* 24h daily access to radiological emergency diagnosis including CT
* Availability of MRI diagnosis

 Documented, where applicable, in a cooperation agreement. |  |
| 6.2.11 | **a)** Uniform standardised regimens for systemic therapies in the OC* The drawing up of/changes to existing therapy regimens must be undertaken by means of regulated approval.
* The antiemetics that correspond to the Guidelines are to be included in the therapy plans.
* In the case of special highly emetogenic/moderately emetogenic therapies, the antiemetic prophylaxis and therapy in line with the Guidelines are to be included in the therapy plan: <http://www.leitlinienprogramm-onkologie.de/leitlinien/supportive-therapie/>, Table 33
* Prior to approval or changes to therapy regimens, the expert opinion of pharmacists have to sought.
* The therapy regimens are to be protected from any unintended changes.
* The therapy regimens are comparable between the outpatient and inpatient units.

 **b)** Individual therapy plan* All systemic therapy must be planned on the basis of a therapy regimen.
* The therapy plans are to be checked and approved.

 **c)** Approval/ administration of therapyTherapy is to be checked on the day of administration, approved for the patient and administration, including time, is to be documented. |  |
| 6.2.12 | Preparation of cytostatic drugs* Drugs are prepared in accordance with statutory provisions (inter alia AMG, AP-BetrO, GMP, GCP, Eudralex (Vol. 10)) in a pharmacy. If it is not part of the facility, a supply agreement must be entered into.
* It must be possible to consult the pharmacist during the period in which therapy is being administered. 24-hour on-call service is required for inpatients.
* Standard operating procedures (SOPs) are to be drawn up.
 |  |
| 6.2.13 | Standard operating procedures* The delegation of physician’s tasks to nurses (inter alia cytostatic administration) must be described.
* All phases of the standard operating procedure for medical oncological therapy (initiation, conduct and termination of therapy) are to be described.
* Supportive measures in accordance with the guidelines are to be described for the individual therapy concepts and documented in detail for each patient.
 |  |
| 6.2.14 | Standards comorbidities and secondary diseasesStandards are to be drawn up * in particular extravasate management (extravasation set and SOP), infections, thromboembolic complications, allergic reactions and procedure for handling a high temperature in neutropenia
* and side effect management in the case of immunological and targeted therapies (e.g. osteoprotection in conjunction with bisphosphonates, RANK ligand antibodies/OMS surgical examination prior to commencement of therapy)

for the prophylaxis/treatment of comorbidities and secondary diseases and training for physicians and nursing staff is to be documented (log). |  |
| 6.2.15 | Emergency treatment* Availability of emergency medical equipment and written flowchart for emergencies.
* Annual training for medical staff in the treatment unit must be documented (contents of e.g. anaphylactic shock, resuscitation, etc.). The training logs are to be documented (training logs with list of participants for the previous 12 months).
 |  |
| 6.2.16 | Case-related information/ dialogue with patientsAdequate information is to be provided for diagnosis and therapy planning and a consultation is to be given. This includes:* Presentation of alternative treatment concepts
* Offer of and assistance in obtaining second opinions
* Discharge consultation as a standard procedure
* Written patient information (information leaflet) inter alia about immunological/targeted therapies and vaccination recommendations in the case of immunosuppression should be handed out to the patients

 Patient consultations are to be documented in medical reports and other protocols/ records. |  |
| 6.2.17 | Information on therapy conduct/ planningAfter each administration of systemic therapy the patient and/ or physician responsible for further treatment is/ are given information about the current status of therapy and future planning (blood tests…), e.g. in an aftercare pass/ therapy Preparation of discharge letterAfter conclusion of systemic therapy (last administration) and/ or a change in therapy and/ or after final staging/ therapy discontinuation, the physician responsible for further treatment or the co-attending physician is given the final report within 7 days. |  |
| 6.2.18 | Induction of new staff membersSystematic, documented induction of new staff members is to be ensured, which imparts knowledge about the Oncology Centre’s respective field of activity. This induction must take place within three months of commencement of employment.The implementation of the induction concept is to be documented (submission of lists of the staff members hired during the previous 12 months). |  |
| 6.2.19 | Continuing education/ specialty training* A training plan for the medical and nursing staff is to be presented listing the planned training sessions for the period of one year.
* At least one dedicated continuing education/ specialty training session for each staff member (minimum one day a year) who carries out quality-relevant activities for the Oncology Centre.
 |  |
| 6.2.20 | Quality circles* Quality circles in which oncological topics are discussed must be conducted or participated in at least 3 times a year
* Scheduling, e.g. in qualification plan
* Minutes of Quality circles are to be taken.

 Participation in the quality circles held centrally at the Oncology Centre is acknowledged at this stage (see "EB 1.2.14 Interdisciplinary cooperation"). |  |
| 6.2.21 | StudiesIf studies are offered or conducted, the requirements in Section 1.7 Study management are to be fully complied with. |  |
| 6.2.22 | Nursing careIf inpatient care is provided, the nursing care requirements in Section 1.8 Nursing care are to be fully complied with. |  |

**7. Radio-oncology**

|  |
| --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 7.0 | The Technical and Medical Requirements to be met by radio-oncology are summarised on a cross-organ basis in the “Catalogue of Requirements Radio-oncology”. Irrespective of the number of Organ Cancer Centres/ Modules that cooperate with a radio-oncology unit, this “Catalogue of Requirements Radio-oncology” is only to be processed once and also only to be updated once every 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. The cross-organ “Catalogue of Requirements Radio-oncology” can be downloaded from <http://www.onkozert.de>. |  |

**8. Pathology**

|  |
| --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 8.0 | The Technical and Medical Requirements to be met by pathology are summarised in a cross-organ manner in the “Catalogue of Requirements Pathology”. Irrespective of the number of Organ Cancer Centres/ Modules that cooperate with a pathology unit, this “Catalogue of Requirements Pathology” is only to be processed once and also only updated once per audit year (objective: no multiple presentations/ on-site inspections within one audit year).  The cross-organ “Catalogue of Requirements Pathology” can be downloaded from <www.onkozert.de>. |  |

**9. Palliative care and hospice care**

|  |
| --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 9.0.0 | **General (applies to sections 9.1-9.3)** |  |
| 9.0.1 | The integration of palliative care into the treatment of patients is to be depicted in an SOP using the treatment path in the S3 Guideline Palliative Medicine. |  |
| 9.0.2 | Applies to patients receiving specialised palliative care. The procedure for recording symptoms using validated instruments (e.g. MIDOS, kPOS) is to be described.  |  |
| 9.1.0 | **Outpatient hospice and palliative care** |  |
| 9.1.1 | Besides general outpatient palliative care, specialised outpatient palliative care services are to be made available or provided in cooperation. The quality indicators of specialised outpatient palliative care (SOPC) are to be described in the following text. Regional and country-specific characteristics are to be considered. If a SOPC structure is currently being put in place, the planned implementation steps (target dates) are to be specified. Specialised outpatient palliative care must be proven to be up and running by recertification either in-house or in cooperation.  |  |
| 9.1.2 | Nursing staffDesignation by name of at least four full-time staff members with palliative care qualifications and experience (Definition palliative care qualification ≥160 hours specialty training according to the curriculum of the German Society for Palliative Medicine (DGP) |  |
| 9.1.3 | Medical staffAt least two physicians with an additional qualification in palliative medicine are to be designated by name:Name:Name: |  |
| 9.1.4 | Care numbers and indicatorsAt least 30 documented palliative patients receiving multi-professional care per year  |  |
| 9.1.5 | Emergency and crisis interventionOn-call emergency and crisis intervention around the clock for patients receiving treatment (including physicians’ house calls): Listing of the telephone number on which patients/family members can reach the specialist outpatient palliative care service 24h/7d. |  |
| 9.1.6 | Supervision/ supervised practice* Supervision and/ or supervised practice in groups and/ or individual discussions for nursing and medical staff are to be proven.
* Minimum requirement 12 hours/ year (must be documented)
 |  |
| 9.1.7 | External quality assuranceParticipation in external quality assurance measures, e.g. national hospice and palliative care register is recommended. |  |
| 9.1.8 | Outpatient hospice work* Proof of cooperation with outpatient hospice services in accordance with Section 39a Social Code V (SGB V) (if available)
* The ways in which patients and family members can reach hospice services and hospice volunteers are to be outlined
 |  |
| 9.2.0 | **Inpatient hospice** |  |
| 9.2.1 | If an inpatient hospice is being set up close to the Centre, the planned establishment steps (target dates) are to be specified. Proof should be provided at recertification that an inpatient hospice is up and running. |  |
| 9.2.2 | Information transfer* Patients and family members must have access to information about the hospice. Contact persons are to be designated by name.
* The formalised transfer of information between the hospice and the cooperation partners concerned is to be described.
* In the event of death, cooperation partners must be informed within three days.
 |  |
| 9.3.0 | **Palliative ward** |  |
| 9.3.1 | The statements below refer to the following cooperation partners: General remarkEach of the cooperation partners of the Oncology Centre must prove that it meets the requirements in this section of the Catalogue for inpatient palliative medical care. Hence, each cooperation partner from this specialty is to process this section in detail or to make specific statements in this section. |  |
| 9.3.2 | If an independent palliative ward is only in the process of being set up, a concept is to be formulated that outlines the resources (personnel/ financial), infrastructure, the requirements listed in Section 9.3 and planned steps for implementation (target dates, cooperation partners). A palliative service in line with the provisions of the OPS (8-982 and 8-98h) (German modification of the International Classification of Procedures in Medicine) must be in place at initial certification. The palliative ward must be shown to be up and running at recertification, where appropriate in cooperation close to the Centre. |  |
| 9.3.3 | Indicators of the palliative ward (separate unit)* Number of beds: ≥5
* New admissions: ≥100 patients/ year
 |  |
| 9.3.4 | Medical directorThe director and his deputy are to be designated by name and their qualifications listed Director: name, qualifications, FTEs (full-time equivalents)Deputy: name, qualifications, FTEs |  |
| 9.3.5 | SpecialistAt least two specialists with an additional qualification in palliative medicine  Resources:0.2 FTE (full-time equivalents) for each serviceable patient bed (Name, scope of position) |  |
| 9.3.6 | Head nurseThe head nurse and his/ her deputy must have a palliative care qualification (definition palliative care qualification: ≥160 hours specialty training in line with the DGP (German Society for Palliative Medicine) curriculum Name:Deputy: |  |
| 9.3.7 | Nursing qualificationMore than 75% of the nursing staff should have the palliative care qualification(definition palliative care qualification: ≥160 hours specialty training, see above) Number of full-time nurses:Of them, number with palliative care qualification: In line with S3 guidelines for palliative medicine:at least 1.2 FTE (full-time equivalents) for each serviceable patient bed |  |
| 9.3.8 | Palliative ward* Setting up of separate ward as a closed-off area
* Meeting and/ or farewell room
* Possibility of accommodation for family members
 |  |
| 9.3.9 | A standard operating procedure (SOP) for patient admission is to be specified in which the following are defined:* Admission criteria which are communicated to the cooperation partners
* Multi-dimensional basic assessment (e.g. core data set of DGP/DHPV (German Society for Palliative Medicine/ German Hospice and Palliative Care Association)
* Documented SOP for implementation of forward care planning
 |  |
| 9.3.10 | Palliative medical therapy planningPlanning of therapy is done for each individual patient and is documented correspondingly |  |
| 9.3.11 | Treatment standards and guidelines concerning other symptomsDefined and recorded symptom registration and treatment procedures are to be documented using patient examples |  |
| 9.3.12 | A standard operating procedure for the discharge of patients is to be establishedThere is systematic documented discharge planning with information of all relevant medical staff  involved (e.g. family physician/ referrer, specialty areas OC)* The information chain in the event of death is formalised (family members, family physician, nursing service, other cooperation partners, etc.)
* In the event of death all cooperation partners are to be informed within three days
 |  |
| 9.3.13 G-BA | There must be an SOP for the reachability and inclusion of the palliative service (recognised by medical service (MD) for billing OPS 8-98h).The multi-professional palliative service must be available for consultations and, where appropriate, for the tumour board.24-hour palliative care at the location of the oncology centre within 30 minutes at the patient's bedside must be guaranteed. |  |
| 9.3.14 | Psychosocial care and other therapeutic methods Qualifications:* Psychologist and/ or social education worker with additional therapeutic training in a guideline-based procedure (psychological psychotherapist, child/ adolescent psychotherapist) or conversational psychotherapist or systemic family therapist and special qualification: advanced palliative care training (DGP) or specialty training psychosocial oncology (DKG)
* Social worker/ social education worker
* Physiotherapist
* Occupational therapist
* Art-music therapist
* Case manager
* Hospital counsellor

 Resources:A total of 0.2 FTEs (full-time equivalents) for each serviceable patient bed  |  |
| 9.3.15 | Multidisciplinary case review* Weekly intervals
* Discussion of the therapy plans of all patients present, documentation of the results (findings, therapeutic goals, changes, measures) on a case-by-case basis (record, therapy plan) and in a discussion-based manner (short protocol)
* A list is to be kept of participants in the discussions with the names of the persons responsible for therapy
* Participation of >75% of all staff members present on the ward, at least one representative from medical, nursing and psychosocial care
 |  |
| 9.3.16 | External quality assuranceParticipation in external quality assurance measures, e.g. DGP and DHPV core data set is recommended. |  |
| 9.3.17 | Public relationsUp-to-date information for patients and family members (e.g. flyers, website) is available. |  |
| 9.3.18 | Continuing education eventAn information/ continuing education event is to be staged at least once a year on palliative medicine. This can be part of a central event of the Oncology Centre.  |  |
| 9.3.19 | Induction of new staff members* Systematic, documented induction of new staff members is to be ensured, which imparts knowledge about the Oncology Centre’s respective field of activity.
* This induction must take place within three months of commencement of employment.
 |  |
| 9.3.20 | Continuing education/ specialty training* A training plan for medical, nursing and psychosocial staff is to be presented listing the planned training sessions for the period of one year.
* At least one dedicated continuing education/ specialty training session for each staff member (minimum one day a year) who carries out quality-relevant tasks for the Oncology Centre.
 |  |
| 9.3.21 | Supervision/ supervised practice* Supervision and/ or supervised practice in groups and/ or individual interviews for all staff members are to be proven.
* Annual plan and lists of participants with a minimum of 12 hours a year for each staff member are to be documented.
 |  |
| 9.3.22 | Quality circles* Staff are to stage or take part in at least three quality circles a year in which oncological topics are addressed
* Scheduling, e.g. in training plan
* Quality circles are to be documented
* Participation in the quality circles organised centrally by the Oncology Centre is recognised (see “Catalogue of Requirements Section 1.2.14 Interdisciplinary Work”).
 |  |
| 9.3.23 | StudiesIf studies are offered or conducted, the requirements in Section 1.7 Study management are to be fully complied with. |  |
| 9.3.24 | **Palliative indicators** (The Centre’s patients are recorded) The indicators must **not** be entered in the Catalogue of Requirements. Please report the respective indicators in the Excel Data Sheet. |  |

**10. Tumour documentation / Outcome quality**

|  |
| --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 10.1 | DKG-certified Organ Cancer Centres/Modules Tumour documentation systemTumour documentation must be in place at the time of initial certification, which contains patient data for a minimum period of three months Name of the tumour documentation system in the cancer registry and/ or CentreA dataset corresponding to the Uniform Oncological Basic Data Set and its modules of the Working Group of German Tumour Centres (ADT) and the Society of the Epidemiological Cancer Registries in Germany (GEKID) must should be used. The Centre must ensure that the data are transferred to the competent cancer registry in a timely manner. Where appropriate, consideration is to be given to existing federal state (Länder) laws for notification deadlines. |  |
| 10.2 | Use of different IT systemsThe system used to determine outcome quality is to be specified for each tumour entity in the “matrix tumour documentation”. |  |
| 10.3 | Data presentation periodThe data are to be presented for the previous calendar year. |  |
| 10.4 | Cooperation with the cancer registry* Cooperation with the responsible section 65c cancer registry is to be documented in a cooperation agreement [Link: Tumorzentren.de](https://www.adt-netzwerk.de/)
* The OncoBox (if available for the corresponding tumour entity) should be completed by the responsible cancer registry. The complete data are to be transmitted in an ongoing manner to the cancer registry
* The presentation of the Catalogue of Requirements and outcome quality should be undertaken by the cancer registry to the extent that this information is of relevance for the cancer registry
* Parallel systems are to be avoided
* Until the responsible cancer registry is able to meet the stipulated requirements, the Oncology Centre is to fall back on supplementary or alternative solutions. The Oncology Centre bears direct responsibility for any external solution that is not working.
 |  |
| 10.5 | Documentation officerAt least one documentation officer is to be designated by name as the person responsible for tumour documentation. Name/function: The documentation officer is responsible for the following tasks:* Ensuring and monitoring the timely, complete and correct transmission and quality of the patient data of relevance for certification by all cooperation partners to the cancer registry
* Providing motivation for cross-sector cooperation between the specialties involved in the cancer registry (pathology findings, radiotherapy and medicinal treatments)
* Qualification and support of staff involved in record keeping
* Regular analysis of the evaluations, particularly over the course of time
 |  |
| 10.6 | Allocation of resourcesThe required staff resources are to be made available for the performance of documentation and data collection tasks (e.g. through a cancer registry (guidance value: 0.5 FTE (full-time equivalents) per 200 primary cases and 0.1 FTE per 200 aftercare cases). |  |
| 10.7 | The tumour documentation system must offer at least the following selection options:* Year of birth
* TNM classification or comparable classifications (e.g. FIGO)
* Types of therapy (surgical therapy, radiotherapy, hormone therapy, immune therapy, chemotherapy)
* Date of recurrence/metastasis
* Deaths
* Follow-up status (last update)
 |  |
| 10.8 | Tumour-specific outcome quality indicators Kaplan-Meier curves:Overall survival (OAS) of all patients in sub-groups by pT categories, stages of local recurrence-free survival of all patients and for sub-groupsMetastasis-free survival of all patients and for sub-groups. Post-progression survival (PPS) Depending on the question, cohorts can be grouped together (e.g. low patient numbers). With higher patient and event numbers the cohorts are to be evaluated separately. For each Kaplan-Meier curve there is also a table with patient numbers and survival data.Detailed organ-specific requirements are compiled in the matrix annex: Outcome quality. |  |
| 10.9 | Data analysis* The presentation of outcome quality (previous section) must be possible at recertification.
* Data in the tumour documentation system are to be analysed at least once a year.
* If benchmarking/ annual report is offered, the results of the benchmarking are to be taken into account in the analysis.
* The results must be discussed in an interdisciplinary fashion. There should be participation in any regional or national networks.
 |  |
| 10.10 | Recording follow-upThe method of collecting follow-up data is to be explained as is the current follow-up status (see outcome matrix specific tumour entity) Functioning cancer registries present follow-up status.Where this option is not available, a regional solution is sought together with the Centres, ADT, DKG and the respective governmental authorities. Follow-up status consists of:Progression (local recurrences, possibly regional lymph node recurrences, remote metastasis, at least the first progression)Secondary malignanciesDeathsCurrently resides at the addressTermination of follow-up (e.g. moves away from the catchment area, federal state) |  |

**A Development/network of oncological care**

|  |
| --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| A1 | ~~Update management:~~* ~~How is the speedy translation of new scientific findings (bearing in mind the existing S3 Guidelines) into clinical practice organised?~~
* ~~How is the access of all patients to the necessary innovative procedures in diagnostics and therapy ensured?~~
 |  |
| A2 | ~~Mandatory statement of the Centres as to how they view their collaboration on the conduct/recruitment of horizontal and vertical studies with the other levels of the 3-tier system (Organ Cancer Centres, Oncology Centres, Comprehensive Cancer Centres)~~* ~~What studies are you currently undertaking?~~
* ~~How do you envisage future collaboration?~~
* ~~How can inclusion in studies be optimised?~~
 |  |
| A3 | ~~Collaboration with the other levels of the 3-tier system.~~ |  |

**B Requirements for top oncology centres**

|  |
| --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| A0 | The Technical and Medical Requirements to be met by the Comprehensive Cancer Centres are summed up in the document “Application Guidelines Oncology Centres of Excellence”. The latest version is available for download at <https://www.krebshilfe.de/forschen/foerderung/ausschreibungen/>.  |  |
| A1 | Internationally competitive and innovative research programmes, most importantly in the area of translational cancer research (‘bench to bedside’). This must include major solid tumours. The number and quality of ongoing peer-reviewed research projects are important. Active participation in local, national or international collaborative research consortia is expected. What measures have been taken to promote the development of scientific excellence and to integrate (translational) research into the different multidisciplinary groups responsible for health care? |  |
| A2 | * What are the most important research pro-grammes/main foci in your Centre? Describe these programmes paying special attention to translational research aspects as well as the integration of both clinicians and scientists engaged in basic research.
* How do these programmes complement each other to reach the scientific goals/visions of your Centre?
* How do the different cancer-related scientific themes of the parent institution fit together with those of the Centre? How do they complement each other?
* How does the Centre contribute to practice-changing developments which lead to more effective cancer prevention, diagnosis and treatment?

 In case of a CCC Consortium, please specify the above points for each partner site. Also, list the measures to establish joint research programs and strategies. |  |
| A3 | Mandatory development and conduct of innovative clinical trials, including investigator initiated trials. The trials must include a reasonable portfolio of the most important cancer entities. The proportion of patients in trials must be close to 90% for paediatric neoplasms, 50% for haematolymphoid and 10% for solid tumours. Availability of a specialised, centrally coordinated clinical trials office for oncology. The office must be involved in the design and management of the clinical trials. Existence of a central early clinical trials unit where all Phase-I/II cancer trials are conducted. |  |
| A4 | Programmes in outcomes research, including tumour epidemiology, and the identification of cancer risks and predictive factors. |  |
| A5 | A comprehensive and centralised tumour bank and biobank with defined quality and documentation standards is expected.Give a summary of the Oncology Centre’s tumour bank/biobank(s) with special consideration of the Centre’s policies for the operation of the biobank and for the use of tumour tissues (project management, standard operating procedures, quality control, connection to clinical documentation system). Are the complete clinical data of each patient accessible? Describe the development of the biobank in recent years with specific reference to the biobank-IT/laboratory information management system (LIMS) and quality management. Include a description of your activities in the field of liquid biobanking. Please comment on the size of the tumor-/biobank (current number of patients whose fresh frozen tissue specimens, formalin-fixed paraffin-embedded (FFPE) specimens, ~~and~~ liquid and living (organoid) samples are stored in the biobank). Describe whether and how the paraffin blocks archive of the Pathology Institute is accessible for projects of the biobank. Describe the degree of centralization/harmonization of the tumor-/biobank(s). Describe your concept of performance measurement of the biobank.In case of a CCC consortium please describe the interconnection of the biobanks between the individual CCC partner sites, particularly by means of IT technology. Also describe how accessibility of samples between the partner sites is guaranteed. Please address the criteria defined in the list of requirements for CCC biobanks (Enclosure ~~1~~ 2 in <https://www.krebshilfe.de/fileadmin/Downloads/PDFs/Foerderung/CCCs_9th_Call/Ausschreibung_und_Leitfaden_9._Call_30.09.21.pdf> Note:Oncology Centres active in the field of translational research are also advised to set up or maintain quality-assured tumour banks and biobanks. |  |
| A6 | ~~Infrastructure~~ Structures which promote~~s~~ interdisciplinary as well as translational research. Core facilities/ technology platforms and shared resources available to the center must be presented. |  |
| A7 | MetricsCatchment area (map, number of inhabitants).Number of all cancer patients treated in the Centre.Number of newly diagnosed cancer patientsNumber of patients enrolled in clinical trialsList of specific clinical trials at the Centre (Investigator Initiated Trials (IIT) and Industry Trials) etc. In case of a CCC Consortium show the data for each CCC site as well as for the total consortium. |  |
| A8 | Fields of specific competence of the Oncology Centre (e.g. rare tumour entities, specific diagnostic or therapeutic options). |  |
| A9 | Multidisciplinary care and research must be supported by an up-to-date and adequate in-formation technology.Describe the information technology structure and systems operated at the Oncology Centre. Please give special consideration to the following points/issues:* clinical information system
* electronic medical record for each patient
* local clinical cancer registry
* documentation of tumor board decisions
* electronic clinical pathways/care plans
* access to information about clinical trials/study management
* biobank IT system
* data warehouse
* user access (Who has access?)
* responsibilities/ support from IT-Department

 In case of a CCC Consortium, please describe how the individual partner sites are interconnected regarding their IT systems. How does your center ensure interoperability with national initiatives (e.g., NCT Program, DKTK, MII, nNGM, DNPM etc.)? |  |
| A10 | **Innovative Therapy Concepts/Precision Medicine**Broad portfolio of innovative diagnostic and clinical therapy programs, including immunotherapy **Patient Engagement/Involvement**Involvement of patient representatives in patient-related aspects of clinical care and in boards/committees of the cancer center, responsible for the conceptual design and assessment of patient care. |  |

| **Annex 1 - List of Guidelines/ SOPs** |
| --- |
| Specialty (field of application) | Guideline designation (incl. version, level of classification S1-3) | SOP designation (incl. version) | Person responsible for guideline / SOP |
| e.g. gynaecology | S3-LL MaCa Version 4.0 |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

| **Annex 2 - Study organigram** |
| --- |
| Unit performing study | Investigator (Section 40 AMG)  | Study leader(if available) | Study assistant  | Contact(email, telephone) |
| e.g. internal medicine |  |  |  |  |
| e.g. radio-oncology |  |  |  |  |
| e.g. oncology 1 practice |  |  |  |  |
| e.g. urology |  |  |  |  |

| **Study list** | Patients included during the period from … to…. | 01.01.24 – 31.12.24 |
| --- | --- | --- |
|  |  |  |  |
| Unit performing the study | Study | Status of studyopen / closed (dd.mm.yy) | Number of patients(during assessment period) |
| e.g. internal medicine  | Study type A | open | 4 |
|  | Study type B | closed (30.09.07) | 5 |
|  |  |  |  |
| e.g. radio-oncology | Study type A | open | 14 |
|  | Study type C | open | 12 |
|  | Study type D | open | 2 |
|  |  |  |  |
| e.g. oncology 1 practice | ….. |  |  |
|  |  |  |  |
|  |  |  |  |
| e.g. urology | ….. |  |  |

| **Annex 3 - Matrix tumour documentation** |
| --- |
| Tumour entity/ies | Specialist unit system support / tumour documentation officer | System designation | Interface clinical cancer registry |
| Breast | Breast Cancer Centre (gynaecology) | Mammasystem5000 | Cancer registry federal state xy |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Annex 4 - Mailing list / Scientific societies involved** (in alphabetical order)

Auditors

Association of German Pathologists - BDP

Association of Haematologists and Oncologists in Private Practice – BNHO

Associations of German Radiotherapists – BVDST

Chairmen of the Committees of the Organ Cancer Centres and Organ Modules

Conference of Oncological Nursing and Paediatric Nursing Care - KOK

German Association of Social Work in Health Care - DVSG

German Cancer Aid - DKH

German Cancer Society – DKG

German Dermatology Society - DDG

German Pathology Society - DGP

German Radiology Society - DRG

German Respiratory Society - DGP

German Society for Coloproctology – DGK

German Society for Digestive and Metabolic Diseases - DGVS

German Society for Ear-Nose-Throat Medicine, Head and Neck Surgery - DGMKG

German Society for Endocrinology – DGE

German Society for General and Visceral Surgery - DGAV

German Society for Gynaecology and Obstetrics – DGGG

German Society for Interventional Radiology and Minimally Invasive Therapy – DeGIR

German Society for Nuclear Medicine - DGN

German Society for Oral and Maxillofacial Surgery - DGMKG

German Society for Orthopaedics and Orthopaedic Surgery - DGOOC

German Society for Palliative Medicine - DGP

German Society for Radio-oncology - DEGRO

German Society for Senology - DGS

German Society for Thoracic Surgery - DGT

German Society of Haematology and Oncology – DGHO

German Society of Plastic, Reconstructive and Aesthetic Surgeons – DGPRÄC

German Society of Urology - DGU

German Surgical Society – DGCH

German Society for Ear, Nose and Throat Medicine, Head and Throat Surgery - DGHNO

German Society for Senology - DGS

House of Cancer Self-Help - Federal Association e.V.

Neuro-oncology Working Group - NOA

Pneumology-Oncology Working Group - POA

Society for Paediatric Oncology and Haematology - GPOH

Spokesperson of the Network of Comprehensive Cancer Centres (CCC)

Working Group for Oncological Rehabilitation and Social Medicine - AGORS

Working group for Social Work in Oncology – ASO

Working Group for Surgical Oncology – CAO

Working Group of German Tumour Centres - ADT

Working Group on Dermatological Oncology - ADO

Working Group on Ear-Nose-Throat Medicine, Oral and Maxillofacial Surgical Oncology - AHMO

Working Group on Gynaecological Oncology - AGO

Working group on hereditary tumour diseases – AET

Working Group on Internal Oncology – AIO

Working Group on Oncological Pathology - AOP

Working Group on Oncological Pharmacy - OPH

Working Group on Oncological Thoracic Surgery - AOT

Working Group on Oncology - ABO

Working Group on Paediatric Oncology - APO

Working Group on Palliative Medicine - APM

Working Group on Prevention and Integrative Oncology - PRIO

Working Group on Psycho-Oncology - PSO

Working Group on Radiological Oncology - ARO

Working Group on Supportive Measures in Oncology – AGSMO

Working Group on Surgical Oncology - ACO

Working Group on Tumour Classification in Oncology – ATO

Working Group on Uro-oncology - AUO

**Annex 5 - Data Sheet** – Certcalculator

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 Catalouge of Requirement.

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

1. <http://www.bmg.bund.de/fileadmin/dateien/Downloads/N/Nationaler_Krebsplan/Ziel_5-Nationaler_Krebsplan.pdf> [↑](#footnote-ref-1)
2. <http://www.bmg.bund.de/fileadmin/dateien/Downloads/N/Nationaler_Krebsplan/Ziel_5-Nationaler_Krebsplan.pdf> [↑](#footnote-ref-2)