**Catalogue of Requirements for**

**Skin Cancer Centres**

**of the German Cancer Society (*Deutsche Krebsgesellschaft* - DKG)**

**Prepared by the DKG Certification Committee Skin Cancer Centres**

**Expert groups involved (in alphabetical order)**

Chair: PD Dr. Carmen Loquai, Prof. Dr. Wolfgang Tilgen

* ADH – Working Group on Dermatological Histology
* ADO – Working Group on Dermatological Oncology
* ADT – Association of German Tumour Centres
* AET – Working Group on Hereditary Tumour Diseases
* Working Group on Ear, Nose and Throat Medicine, Oral and Maxillofacial Oncology – AHMO
* AIO – Working Group for Internal Oncology
* AOP – Working Group for Oncological Pathology
* OPH – Working Group on Oncological Pharmacy
* APM – Working Group for Palliative Medicine
* PRIO – Working Group for Prevention and Integrative Oncology
* PSO – Working Group for Psycho-Oncology
* ARO – Working Group for Radio-Oncology
* ASO – Working Group for Social Work in Oncology
* ASORS - Working Group for Supportive and Rehabilitation Oncology
* AUO – Working Group for Radio-Oncology
* BDC – Association of German Surgeons (BDC)
* BVDD – Association of German Dermatologists
* BVDST – German Professional Association of Radiation Therapists
* BNHO – Association of Practice-based Haematologists and Oncologists in Germany
* BDP – Association of German Pathologists
* CAO – Surgical Working Group for Oncology
* CAO-V – Surgical Working Group for Oncology - Visceral Surgery
* DDG – German Dermatology Society
* DeGIR – German Society for Interventional Radiology
* DGPRÄC – German Society of Plastic, Reconstructive and Aesthetic Surgeons
* DGCh – German Society of Surgery
* DGDC – German Society of Dermatosurgery
* DGHNO – German Society for Ear, Nose and Throat Medicine, Head and Throat Surgery
* DGHO - German Association of Haematology and Oncology
* DGNC – German Society of Neurosurgery
* DGN – German Society of Nuclear Medicine
* DGP – German Society of Palliative Medicine
* DGP – German Society of Pathology
* DEGRO – German Society of Radio-Oncology
* DOG – German Ophthalmology Society
* DRG – German X-Ray Society
* DÖSAK – German-Austrian-Swiss Working Group for Tumours of the Jaws and Facial Regions
* DVSG – German Association of Social Work in Health Care
* KOK – Conference on Oncological and Paediatric Oncological Care
* NOA – Neuro-oncology Working Group
* OPS – Seminar for Oncology patients Berlin-Brandenburg
* Skin Cancer Network Germany e.V.
* S3 Guideline Melanoma

**Entry into force on 03 September 2021**

This Catalogue of Requirements (CR) is binding for all audits conducted from 01.01.2021. The changes made to the version valid in audit year 2019 are highlighted in "turquoise" in this Catalogue of Requirements.

Consideration was given to:

* S3 Guideline "Melanoma Diagnosis, Therapy and Aftercare"; Quality indicators

The Catalogue of Requirements is based on the TNM classification of malignant tumours, 8th edition 2017, the ICD classification ICD-10-GM 2021(DIMDI) and the OPS classification 2021 (DIMDI).

**Details about the Skin Cancer Centre**

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| Skin Cancer Centre (SCC) |  |
| Director Skin Cancer Centre |  |
| Centre Coordinator |  |

**QM system certification**

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| --- | --- | --- | --- | --- |
| QM system certification |  | yes |  | no |

**Network/Main cooperation partners**

The Centre's cooperation partners are registered in a master data sheet with OnkoZert. The details in the master data sheet are published on [**www.oncomap.de**](http://www.oncomap.de/). Any new or no longer valid cooperation is to be notified immediately to OnkoZert, outside the certification period, too. Other updates (e.g. changes to management, contact data) are to be indicated in the corrected master data sheet in the run-up to the annual surveillance audit. The master data sheet with the registered cooperation partners can be requested from OnkoZert as a file.

**Preparation / Update**

The electronically generated Catalogue of Requirements serves as the basis for the certification of the Skin Cancer Centre. The details provided there have been checked for correctness and completeness.

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| The data refer to the calendar year |  |

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| Preparation/update date of the Catalogue of Requirements |  |

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Annexes to the Catalogue of Requirements

Data Sheet (Excel template)

# General details about the Centre

| * 1. **Structure of the network**
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| Section | Requirements | Explanatory remarks by the Skin Cancer Centre |  |
| 1.1.1 | Cooperation agreementsA written cooperation agreement is to be entered into with cooperating treatment partners (main cooperation partners/cooperation partners). Documentation must be provided that they meet the appropriate Technical and Medical Requirements of the Catalogue of Requirements (not every service provider has to be a cooperation partner as well). The (main) cooperation partners are to be listed in the "master data sheet" (administered by OnkoZert).  |  |  |
| Main cooperation partnersDermatologists, surgeons and/or representatives of regionally active surgical specialty(e.g. ear, nose and throat [ENT] medicine, oral and maxillofacial surgery [OMS], plastic surgery), internal oncologists, radiologists, radiotherapists |  |
| Cooperation partners (external cooperation also possible)Mandatory* The names of at least 1 representative from OMS, ENT and/or plastic surgery
* Nuclear medicine
* Neurosurgery
* Pathology
* Surgery (general and/or visceral)
* Psycho-oncology
* Social work
* Self-help associations
* Pastoral care
* Palliative network

Optional* Dermatohistology
* Urology
* Ear, nose and throat medicine
* Oral and maxillofacial surgery
* Genetic counselling (*inter alia* familial melanomas, Gorlin-Goltz syndrome, XP)
* Laboratory (with interlaboratory experiment certificate)
* Plastic surgery
* Thoracic surgery
* Gynaecology
 |  |
| 1.1.2 | Cooperation agreementsIf the cooperation partners of a Centre work under a funding body or at a clinic location, written agreements are not necessary. (Nonetheless the implementation of the following points must be ensured). The following points are to be regulated:* Description of the treatment processes of relevance for the Centre bearing in mind the interfaces
* Obligation to implement indicated Guidelines
* Description of cooperation on tumour documentation
* Declaration of willingness to cooperate on internal/external audits
* Undertaking to comply with the relevant criteria laid down in the Specialist Requirements for Skin Cancer Centres (*Fachliche Anforderungen für Hautkrebszentren* – FAH) and the annual submission of the relevant data
* Upholding of medical confidentiality
* Participation in specialty training programmes and public relations work
* Declaration of consent to be publicly identified as part of the Centre (e.g. homepage)

Tumour conference(only to the extent that participation is required under "1.2 Interdisciplinary cooperation")* Binding participation on invitation, where appropriate separately for each tumour entity (melanoma, epithelial tumours, cutaneous lymphomas, rare skin tumours, etc.)
* Ensuring availability specialist level
* Participation and consensus provisions in the case of more than 1 cooperation partner for each specialty (see also provisions "Interdisciplinary cooperation")
 |  |  |
| 1.1.3 | Primary cases* Cases with malignant epithelial tumours (excl. *in situ* tumours) for each year: ≥ 100 patients (details Data Sheet)
* Cases with invasive malignant melanoma for each year: ≥ 40 patients (details Data Sheet)

Cases with cutaneous lymphoma and rare malignant skin tumours (angiosarcoma, Merkel, DFSP) are recorded in the Data Sheet.Definition primary case:* Patients (not stays and not surgical interventions, not aftercare patients, not recurrences) newly diagnosed with skin cancer during the calendar year
* A second tumour of another entity that presented during the calendar year is recorded as another primary case.
* Histopathology report must be available.
* Case can only be counted for 1 Centre Therapy planning (interdisciplinary tumour conference) and therapy conduct through the Centre (main therapy).

Exception: In the treatment of cutaneous lymphomas/sarcomas and cooperation with a corresponding certified centre or module, primary or patient cases can be counted for both partners. In a cooperation agreement or SOP, it must be defined which treatment sections are provided by which cooperation partner. The cooperating centres must be named.* The time of counting is the time of the histolopathological confirmation of diagnosis

Colour legend: Change compared to version as of 09.09.2019 | Details Data Sheet(= Excel template) |  |
| 1.1.4 | Contact partners of the Skin Cancer CentreThe names of the contact partners of the Skin Cancer Centre at the clinic location and of the individual treatment partners are to be given and published (e.g. on the Internet). In medical areas the responsibilities on the specialist level are to be defined. |  |  |

| * 1. **Interdisciplinary cooperation**
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| --- |
| Section | Requirements | Explanatory remarks by the Skin Cancer Centre |  |
| 1.2.1a) | CycleThe tumour conference must be held regularly, at least twice a month.Web/Online conferencesIf web conferences are used, it must be possible to transmit the sound and documents presented. The main cooperation partner must have an opportunity to present its own documents/images. |  |  |
| b) | Participants in the skin tumour conferenceFor the following specialties participation by specialists in the tumour conference is mandatory and to be documented in a list of participants:* Dermatologist
* Radiologist
* Radiotherapist
* Surgeon(organ-specific/oncological)
* Internal oncologist

If the internal oncologist cannot participate in the conference, he /she may in exceptional cases be represented by the specialist responsible for the chemotherapy (qualification according to chapter 6.2). |  |  |
| * Optionally, associated specialist groups (e.g. dermatohistology, pathology, psycho-oncology, nursing care, neurology, neurosurgery, surgery, plastic surgery, pain therapy, ENT, OMS, nuclear medicine, urology, gynaecology *inter alia*) are to be included in the tumour conference (recommendation: regular invitation, targeted participation).
* If several treatment partners are indicated for a specialty, then the presence of one representative is sufficient as long as the formalised exchange of information between the partners has been put in place (e.g. via quality circles).
 |  |
| c) | Preparation tumour conferenceThe main patient data are to be summed up in writing prior to the conferences and distributed to the participants.  |  |  |
| d) | Demonstration imaging materialPatient-related imaging material (radiological/histopathological/photographic) must be available at the tumour conference and suitable technical equipment must be provided to present this material. |  |  |
| e) | MinutesThe results of the tumour conference consist, *inter alia*, of a written, multiprofessional, interdisciplinary treatment plan (documented for instance in the tumour conference minutes). The distribution of the treatment plan to the individual treatment partners (incl. referrers) is to be ensured. |  |  |
| f) | Tumour conferenceIrrespective of the stage and tumour entity, the following are to be presented:* All problem cases
* All patients with an interdisciplinary issue
* Switch in therapy with deviation from specified treatment pathways

The presentation of the remaining patients in the specialised consultation hours/tumour conferences is to be defined via binding internal SOPs.Colour legend: Change compared to version as of 09.09.2019 |  |  |
|  | In principle, patients with the following conditions are to be presented: * Malignant melanoma from stage IIC,
* Malignant melanoma and stage shift/recurrence
* Extracutaneous melanoma
* Cutaneous lymphoma from stage IB
 |  |  |
|  | * Problem cases with malignant, epithelial tumours (BCC, SCC) with an interdisciplinary issue: for instance complicated localisation, spread/infiltration (e.g. *Ulcus rodens*, *Ulcus terebrans*), metastasised tumours, immunosuppressed patients
* All rare malignant skin tumours (*inter alia* Merkel carcinoma, DFSP, MFH, leiomyosarcomas, Kaposi's sarcoma, angiosarcoma): irrespective of the stage

Colour legend: Change compared to version as of 09.09.2019 |  |  |
| g) | Treatment pathwaysIn-house interdisciplinary treatment pathways elaborated for the individual tumour entities with definition of the problem cases (based on the Guidelines) must be drawn up. |  |  |
| 1.2.2 | Treatment plan* For every patient a treatment plan, if possible interdisciplinary, is to be drawn up which is given to the patient if requested. This also applies to patients who have not been presented at any tumour conference.
* A uniform documentation template is recommended for the treatment plan and the tumour conference minutes. The treatment plan can be part of the tumour conference minutes.
 |  |  |
| 1.2.3 | Morbidity/mortality (MM) conferencesAt the regular MM conferences the complications and risks of the therapies conducted are analysed and discussed in an ongoing manner in order to further reduce therapeutic risks and keep them to a minimum. Ethical issues can also be discussed at these conferences. * The invited participants are the participants in the tumour conference and the referrers.
* The MM conference can be timed to coordinate with the tumour conference or with events for referrers.
* Cases with both a negative and a positive course are to be presented.
* MMs are to be conducted and minuted at least once a year.
 |  |  |
| 1.2.4 | Therapy conduct/recommendationThe tumour conference is to be informed of any deviation in the conduct of therapy from the original therapy recommendation. The reasons for the changes and new therapy are to be documented. |  |  |
|  | Documented stating of reasons:* Patient's wish
* Physician's wish
* Side effects/morbidity

If a therapy is not started at the patient's request (despite an existing indication) or is terminated prematurely, this must also be recorded.Colour legend: Change compared to version as of 09.09.2019 |  |  |
| 1.2.5new | Participation in tumour conference as further trainingFor the following functions/professional groups, a one-time obligatory participation in the tumour conference is to be made possible (refresher every 3 years):* Assistant staff (MTA, TRA, ...) from the fields of radiology, nuclear medicine and radiotherapy.
* Staff from nursing, social services and psycho-oncology.
* Participation in the tumour conference is recognised as further training for the above-mentioned functions/professional groups.

Colour legend: Change compared to version as of 09.09.2019 |  |  |
| ~~1.2.5~~1.2.6 | Patients with local recurrence/metastasesThe standard operating procedures (SOPs) for recording patients with local recurrence/metastasis are to be described (presentation of the patient pathways). Colour legend: Change compared to version as of 09.09.2019 |  |  |
| ~~1.2.6~~1.2.7 | Quality circles* The Centre's main treatment partners must stage joint quality circles at least once a year at which topics specific to the Skin Cancer Centre are addressed.
* Scheduling, e.g. in training plan
* Minutes of quality circles are to be taken.
* Cooperation partners: regular invitation, optional participation

Colour legend: Change compared to version as of 09.09.2019 |  |  |

| * 1. **Cooperation referrers and aftercare**
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| Section | Requirements | Explanatory remarks by the Skin Cancer Centre |  |
| 1.3.1 | Cooperating referrersAn up-to-date list is to be kept of the main cooperating referrers. The referrers are to be informed about cooperation within the Skin Cancer Centre with regard to the following details:Obligations of the Skin Cancer Centre* Referrers are entitled to attend the tumour conference.
* Referrers are to be given the opportunity to present patients.
 |  |  |
| 1.3.2 | Medical reportsMedical reports are to be sent to the referrers in a timely manner. Medical reports must contain the histology report, surgical procedure and the results of the tumour conference ("therapy plan"). |  |  |
| 1.3.3 | Feedback systemA written procedure for the recording, processing and feeding back of the general and case-related concerns/questions of the main referrers is to be put in place.The Skin Cancer Centre's contacts are to be made known to the referrers in line with their function (e.g. telephone number, email). |  |  |
| 1.3.4 | Cooperation referrersA description is to be given of cooperation with the referrers. |  |  |
| 1.3.5 | Referrer satisfaction surveyA 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) and its content must refer to the Skin Cancer Centre.A focus on the main referrers is recommended. |  |  |
| 1.3.6 | Continuing educationEvents for the exchange of experience and continuing education events are to be proposed at least once a year by the Skin Cancer Centre. Contents and participation are to be recorded. |  |  |

| * 1. **Psycho-oncology**
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| Section | Requirements | Explanatory remarks by the Skin Cancer Centre |  |
| 1.4.1 | Psycho-oncology qualifications* ~~Qualified psychologists or~~
* ~~physicians~~
* Graduate psychologists/ Master's degree in psychology qualifying for a scientifically recognised psychotherapy procedure, or
* Doctors of human medicine,
* Diploma/ Master in Social Pedagogy qualifying for a scientifically recognised psychotherapy procedure.

~~with psychotherapeutic and psycho-oncological specialty training (see below) (Proof of competence required)~~each with at least 1 psychotherapeutic further training: behavioural therapy, psychodynamic psychotherapy (analytical psychotherapy and depth psychology-based psychotherapy), systemic therapy, neuropsychological therapy (for mental disorders caused by brain injuries), interpersonal therapy (IPT; for affective disorders and eating disorders), EMDR for the treatment of post-traumatic stress disorders, hypnotherapy for addictive disorders and for psychotherapeutic co-treatment of somatic illnesses and psycho-oncological training (DKG-recognised).Licensing: At least 1 person in the psycho-oncological team of the network (inpatient or outpatient) must be licensed (psychological or medical psychotherapist).Protection of the status quo for all those who are currently approved as well as those who have started a DKG-approved psycho-oncological further training by 31.12.2019.The representatives of other psychosocial professional groups ~~(like qualified pedagogues, social workers, etc.)~~ can be approved on presentation of the above-mentioned additional qualifications. This requires a case-by-case assessment.~~The assumption of psycho-oncological tasks by the social services, self-help groups or pastoral care is not sufficient.~~~~Psycho-oncological continuing education~~ ~~"Specialty training in psychosocial oncology" recognised by the PSO (Working Group for Psycho-Oncology or~~ *~~dapo~~* ~~(German Working Group for Psychosocial Oncology) or other adequate continuing education with a volume of > 100 teaching units~~ Colour legend: Change compared to version as of 09.09.2019 |  |  |
| 1.4.2 | Psycho-oncology – Offer and access Each patient must be offered the option of psycho-oncological counselling in a timely manner in the vicinity (proof required). The offer must be made in a low-threshold manner. |  |  |
| 1.4.3 | Psycho-oncology resourcesBased on demand, at least 1 psychooncologist with the above-mentioned qualifications is available to the center.Colour legend: Change compared to version as of 09.09.2019 |  |  |
| 1.4.4 | Scope of treatmentThe number of patients who have had psycho-oncological care is to be recorded.The frequency of the sessions is to be recorded. |  |  |
| 1.4.5 | RoomsA suitable room is to be provided for psycho-oncological patient sessions. |  |  |
| 1.4.6 | Organisation plan~~If psycho-oncological care is provided by external cooperation partners or for several clinical sites and clinic facilities,~~ ~~t~~The performance of tasks is to be laid down in an organisation plan that contains details, *inter alia*, of the availability of resources and local presence.Colour legend: Change compared to version as of 09.09.2019 |  |  |
| 1.4.7 | Psycho-oncology – tasks profileThe psycho-oncological care of patients is to be offered at all stages of care (diagnosis, inpatient, post-inpatient).Goals and tasks of care:* Diagnostic clarification after positive screening
* Prevention/treatment of resulting psychosocial problems
* Activation of personal coping mechanisms
* Maintenance of quality of life
* Consideration of social environment
* Organisation of further outpatient care through cooperation with outpatient psycho-oncological service providers
* Public relations (patient event or the like)
* Leadership of the psychosocial quality circle

Colour legend: Change compared to version as of 09.09.2019 |  |  |
|  | The following are also recommended:* ~~Provision of supervision, continuing education and initial training schemes for staff~~
* to offer or coordinate the implementation of supervision, further education and training courses for staff members
* Twice yearly discussions between psych-oncologists and the nursing and medical area;
* the regular written and, where appropriate, oral feedback on psycho-oncological activities to the medical staff (e.g. through a referral report or documentation in the medical record);
* Regular participation in ward conferences and tumour conferences;
* ~~Close~~ ~~c~~Cooperation with the social services and other centres
* Offering or coordinating interdisciplinary intervention services
* The psycho-oncologists should present their work at least twice a year in the context of ~~at~~ the tumour ~~conferences~~ board. ~~or as part of a quality circle.~~

Colour legend: Change compared to version as of 09.09.2019 |  |  |
| 1.4.8 | Documentation and evaluation~~To identify mental strain screening must be undertaken (instrument S3 Guideline Psycho-Oncology) and the outcome is to be documented.~~To identify the need for treatment, it is necessary to carry out a screening on psychological stress (see S3 guideline on psycho-oncology).Screening should be conducted for patients with melanoma, recurrence/remote metastases and rare tumours.Psycho-oncological care is to be documented and evaluated in an ongoing manner using suitable instruments ~~(e.g. Basic Documentation for Psycho-Oncology - PO-BaDo).~~Colour legend: Change compared to version as of 09.09.2019 |  |  |
| 1.4.9 | Continuing education/specialty training/supervision* At least 1 dedicated continuing education/specialty training session a year for each staff member (at least 1 day a year)
* External supervision is to be made possible on a regular basis (Recommendation: 2x monthly)

Colour legend: Change compared to version as of 09.09.2019 |  |  |

| * 1. **Social work and rehabilitation**
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| Section | Requirements | Explanatory remarks by the Skin Cancer Centre |  |
| 1.5.1 | Social work - qualifications* Social workers/social pedagogues
* Individual case examinations according to the guidelines of the professional society are possible
* Additional qualifications

Experience in the medical/oncological fieldColour legend: Change compared to version as of 09.09.2019 |  |  |
| 1.5.2 | ~~Offer and access~~~~Each patient must be offered the option of counselling by social services at all stages of the disease in a timely manner in the vicinity (documentation required). The offer must be made in a low-threshold manner.~~ResourcesFor the counselling of patients in the centre, at least 1 fulltime staff member is available for 400 counselling sessions with patients of the centre (= primary cases, secondary metastases, recurrences). The personnel resources can be provided centrally; an organisational plan must be available.Colour legend: Change compared to version as of 09.09.2019 |  |  |
| 1.5.3 | ~~Resources~~~~Adequate resources are to be made available for social work. (at least 1 full-time staff member for 400 counselling sessions for patients of the Centre (= primary cases, secondary metastasis, recurrence). The staff resources can be made available centrally.~~Offer and accessEvery patient must be offered the possibility of counselling 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.Colour legend: Change compared to version as of 09.09.2019 |  |  |
| 1.5.4 | Scale patient careThe number of patients counselled by social services is to be documented and evaluated. |  |  |
| 1.5.5 | RoomA suitable room is to be provided for social counselling work. |  |  |
| 1.5.6 | Organisation plan~~If the social service provides its services for several specialty units,~~ tThe carrying out of tasks is to be laid down in an organisation plan that contains details, *inter alia*, of the availability of resources and local presence.Colour legend: Change compared to version as of 09.09.2019 |  |  |
| 1.5.7 | Contents of counselling using the DVSG service catalogue and the expert standard PEOPSA (psycho-social initial counselling of oncological patients by social work):* Identification of social, economic and mental health emergencies
* Start of medical rehabilitation measures
* Advice on social law and economic issues (e.g. severely disabled persons' legislation, wage replacement benefits, pensions, benefit requirements, co-payments, etc.)
* Support for submitting applications
* Advice on outpatient and inpatient care treatment options and referral to support schemes and specialised services
* Support for professional and social reintegration
* Cooperation with service funding agencies and service providers
* Discharge management
* Intervention in emergencies

Colour legend: Change compared to version as of 09.09.2019 |  |  |
| 1.5.8 | Further tasks:* Offer training/information events for other disciplines of the centre and/or patients.
* Public relations and networking
* Participation in ~~ward and tumour conferences~~ multiprofessional case consultations, supervision
* Interdisciplinary cooperation particularly with physicians, nursing staff, physiotherapists, psycho-oncologists, pastoral services *inter alia*

Colour legend: Change compared to version as of 09.09.2019 |  |  |
| 1.5.9 | Documentation and evaluation* The activity of the social workers is to be documented (e.g. ~~Lexsoft, ISH-med, case groups of the German Association of Social Work in Health Care [DVSG] for social work in the health care system~~ Care SD, KIS) and evaluate.
* ~~Evaluation is recommended~~

Colour legend: Change compared to version as of 09.09.2019 |  |  |
| 1.5.10 | Continuing education/specialty training* At least 1 dedicated continuing education/specialty training course for each staff member every year (at least 1 day a year)
* Offer of supervision

Colour legend: Change compared to version as of 09.09.2019 |  |  |

| * 1. **Patient involvement**
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| Section | Requirements | Explanatory remarks by the Skin Cancer Centre |  |
| 1.6.1 | Patient surveys* A survey of patients of the Skin Cancer Centre over a period of at least three months must be conducted every three years.
* The return rate should be more than 40 % (steps to be taken if this rate is not reached)
 |  |  |
| 1.6.2 | Evaluation patient survey* Responsibility for the evaluation is to be specified. The evaluation must encompass the patients of the Skin Cancer Centre.
* A minuted evaluation must take place.
* Actions are to be laid down on the basis of the evaluation.
 |  |  |
| 1.6.3 | Patient information (general)* The Skin Cancer Centre should give a full presentation of itself and its treatment options (e.g. brochure, patient folder, homepage).
* The cooperation/treatment partners are to be named with details of the contacts. A description is to be given of the treatment on offer.
* The presented treatment offering must encompass: Rehabilitation/post-hospital rehabilitation, access to psycho-oncology, self-help, treatment measures and alternatives
 |  |  |
| 1.6.4 | Consultation about the impact of the diseaseEach patient is given a consultation on discharge or at the first outpatient appointment during which the following topics are addressed and information is provided: e.g. disease status, prognosis, therapy planning, aftercare, supportive measures (e.g. rehabilitation, psychosocial offering). Information provided e.g. <https://www.leitlinienprogramm-onkologie.de/patientenleitlinien/melanom/> |  |  |
| 1.6.5 | Patient information (case-related)Every patient is given a copy of the final medical report. It contains information on histology, tumour stage, planned aftercare and any therapy. |  |  |
| 1.6.6 | Event for patients The Skin Cancer Centre should stage a regular information event for its patients. |  |  |
| ~~1.6.8~~1.6.7 | Self-help groupsThe self-help groups, with which the Skin Cancer Centre actively cooperates, are to be named. If there are no local tumour-related self-help groups, then contacts to national or cross-organ self-help groups are to be organised. Written agreements with the self-help groups should be entered into and updated at least every 5 years which cover the following points:* Personal discussions between the self-help groups and the Skin Cancer Centre with a view to jointly staging or mutually agreeing on actions and events. The results of the discussions are to be recorded.
* Involvement of medical staff in the events of the self-help group
* Reference to the work of the self-help groups at all stages of treatment (initial diagnosis, hospitalisation, chemotherapy...)
* Provision of contact data of self-help groups (e.g. in patient brochures, homepage of the SCC)
* Options to display information brochures of self-help groups
* Quality circles with the participation of representatives of psycho-oncology, self-help groups, social services, pastoral care, nursing care and medicine
* A contact person for self-help should be named
* A room should be made available for the meetings of the self-help groups.

Colour legend: Change compared to version as of 09.09.2019 |  |  |

| * 1. **Study management**
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| --- |
| Section | Requirements | Explanatory remarks by the Skin Cancer Centre |  |
| 1.7.1 | It must be possible for patients to access studies. The studies conducted at the Skin Cancer Centre are to be listed (e.g. homepage) and patients should be able to access this list and a short description of the studies. |  |  |
| 1.7.2 | Responsibilities studiesA study manager is to be named for the Skin Cancer Centre. If several treatment partners are involved in conducting studies, then the activities are to be coordinated by the study manager. |  |  |
| 1.7.3 | Study nurseA study nurse/study assistant should be available for initial certification (mandatory after 3 years). The study nurse/study assistant is responsible for the care, documentation and administration of study patients of the Skin Cancer Centre- He/she must document the above-mentioned activity and the Skin Cancer Centre must make sufficient capacities available (activity can also be carried out in conjunction with other functions). |  |  |
| 1.7.4 | Description of standard operating procedures (SOPs)The SOPs including responsibilities are to be described for the taking on/initiation of new studies and the conduct of studies (information, conduct and aftercare). |  |  |
| 1.7.5 | Share study patients (malignant melanoma stages lll-IV).1. Initial certification:At the time of initial certification ≥ 1 patients must have been included in studies.2. After 1 year: The names of at least 5% of patients should be included in studies.All study patients can be taken into account when calculating the study rate.Only the inclusion of patients in studies with an ethical vote counts as study participation.Exclusive biobank collections are excluded.Colour legend: Change compared to version as of 09.09.2019 | Details Data Sheet(= Excel template) |  |
| 1.7.6 | Cooperation with external facilitiesCooperation with external facilities on studies is to be regulated in cooperation agreements. |  |  |

**List of studies****malignant melanoma**1)

|  |  |  |  |
| --- | --- | --- | --- |
| Responsible cooperation partner 2) | Name of the study | Type of study | Number centre patients recruited in 2020 3) |
| interventional | non interventional |
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| Numerator Indicator No. 6 "Study participation" |  |

1) The list of studies must be processed. It is not possible to refer to the Catalogue of Requirements of the Oncology Centre.

2) Responsible cooperation partners: Study unit/specialty unit managing the study (e.g. department for radio-oncology, joint haematology/oncology practice Dr Smith …) Designation cooperation partners identical to details on www.oncomap.de, if listed

3) Only those study patients can be counted who are listed as Centre patients in the Centre and who were included in the study in 2021 (no double counting of study patients in more than 1 Centre).

| * 1. **Nursing care**
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| Section | Requirements | Explanatory remarks by the Skin Cancer Centre |  |
| 1.8.1 | Specialist oncology nurses* At least 1 specialist oncological nurse must be actively employed on day duty in the Skin Cancer Centre.
* The names of specialist oncology nurses are to be provided.
* In departments where patients are treated, the activity of one specialist oncological nurse must be proven.
* The specialist oncological nurse performs patient-related and higher-level activities (see below)
* The implementation of tasks / substitution must be regulated in writing and proven accordingly.

Prerequisite for the recognition as oncological specialist nurse is the* Specialty training oncology nurse in line with the respective federal state regulations
* or in line with the model of the federal state ordinance of the German Hospital Federation (*Deutsche Krankenhausgesellschaft e.V.* – DKG
* or Advanced Practice Nurse (Master's degree) plus 2 years of practical work experience (full-time equivalent) at the Skin Cancer Center.
 |  |  |
| 1.8.2 | Subject-specific, nursing, patient-related tasks for example:* Subject-related assessment of symptoms, side effects and strains
* Individual conclusion for intervention based on nursing standards
* Implementation and evaluation of nursing and therapeutic measures
* Determination of individual patient-related counselling needs.
* As part of the nursing concept of the Skin Cancer Center, the subject-specific need for counselling must already be defined
* Continuous information and counselling to the patient (and their relatives) throughout the course of the disease
* Implementation, coordination and proof of structured counselling sessions and guidance of patients and relatives; in line with the concept, these can also be carried out by other experienced nurses with longstanding oncological expertise.
* Participation in the tumour board ~~is desirable~~ (according to chapter 1.2)~~.~~
* Initiation of and participation in multiprofessional case discussions / nursing visits; the aim is to find solutions in complex nursing situations; Criteria for selecting patients should be defined; At least 12 case reviews / nursing visits per year and per center must be proven

Subject-specific higher-level nursing activities:* A nursing concept is to be developed and implemented which includes the organ-specific features of the oncological nursing care at the skin cancer center.
* Establishment of subject-specific in-house standards based on (if possible) evidence-based guidelines (e.g., S3-LL supportive).
* Offer of collegial counselling / supervision
* Networking of oncological nurses in a common quality circle and participation in the quality circle of the skin cancer center.
* Interdisciplinary exchange with all professional groups involved in the treatment

Responsibility for the implementation of the requirements for the specialist nursing staff applying chemotherapy (see chapter 6.2.2)Colour legend: Change compared to version as of 09.09.2019 |  |  |
| 1.8.3 | Induction of staffThe induction of new staff members must be done on the basis of an oncological induction document / plan with the participation of specialist oncological nursing staff. |  |  |
| 1.8.4 | Continuing education and specialty training* A training plan for nursing staff is to be presented listing the planned qualification sessions for the period of one year.
* At least 1 dedicated continuing education/specialty training course for each staff member (at least 1 day a year) who carries out quality-relevant activities for the Centre.
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| * 1. **General service areas (pharmacy, nutritional counselling, speech therapy...)**
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| Section | Requirements | Explanatory remarks by the Skin Cancer Centre |  |
| 1.9.1 | The Catalogues of Requirements of the Organ Cancer Centres and Oncology Centres have a uniform table of contents. For the Skin Cancer Centres this section does not specify any Technical and Medical Requirements. |  |  |

# Organ-specific diagnostics

| * 1. **Consulting hours**
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| Section | Requirements | Explanatory remarks by the Skin Cancer Centre |  |
| 2.1.1 | Information/dialogue with the patient Adequate information on diagnosis, prognosis and treatment planning must be provided in accordance with the current state of medical knowledge. ~~about diagnosis and therapy planning and a dialogue is to be entered into~~. This includes *inter alia*:* Information consultation about preventive health care, diagnosis, prognosis, therapy, ~~and~~ aftercare and self-examination
* Possibility of participating in clinical studies
* Presentation of ~~alternative~~ further treatment concepts
* Offer and sourcing of psychosocial ~~support~~ care
* Offer and sourcing of second opinions

A general description is to be given of the way in which information is provided and the dialogue organised. This is to be documented for each patient in medical reports and minutes/records.Colour legend: Change compared to version as of 09.09.2019 |  |  |
| 2.1.2 | Skin tumour consulting hourOn what basis is a special consulting hour held? (Participating physician, personal authorisation, institute authorisation, ~~polyclinic authorisation~~, university outpatient clinic, ambulatory specialist care, medical centre)Staff resources: * at least 2 specialists in dermatology
* Presentation at the consultation is possible by all cooperation partners of the centre.
* All skin tumour patients with increased complexity are to be diagnosed and treated on an interdisciplinary basis.
* The specialists are to be named.
* The specialists named here must be actively involved in the skin tumour consultation.

Colour legend: Change compared to version as of 09.09.2019 |  |  |
| 2.1.3 | FrequencyThe skin tumour consulting hour must be staged at least once a week and cover the following topics:* Skin cancer detection
* guideline-based full body inspection
* Dermoscopy
* Preparation of skin cancer report (BK 5103)
* Therapy planning
* Aftercare
* Surgical advice
* Advice about risk factors and familial predisposition
* Advice about benign skin tumour diseases and precancerous lesions

If appropriate, the topics can be covered in special, separate consulting hours.Colour legend: Change compared to version as of 09.09.2019 |  |  |
| 2.1.4 | Waiting timesHow long are the waiting times * during the consulting hours:

< 60 min target value* for an appointment for first presentation (melanoma, lymphoma, rare, highly malignant skin tumours): < 2 weeksAll other tumours: < 4 weeks
* for an appointment for an outpatient, instrument-based examination (no aftercare patients): < 2 weeks

The waiting times are to be recorded in a representative random sample and statistically evaluated once a year. |  |  |
| 2.1.5 | Repeat presentation of patient is to be organised in the event of therapeutic side effects. |  |  |

| * 1. **Diagnostics**
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| Section | Requirements | Explanatory remarks by the Skin Cancer Centre |  |
| 2.2.1 | Lymph node sonography* Number of lymph node sonographies
* Only ultrasound devices with a frequency of ≥ 7.5 MHz are to be used for lymph node diagnosis.
 |  |  |

| Radiology |
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| Section | Requirements | Explanatory remarks by the Skin Cancer Centre |  |
| 3.1 | Specialists* For X-ray diagnosis, CT and MRI at least 2 specialists
* The names of the specialists are to be provided.
* Qualification of specialists is to be documented with regard to the activity for the Skin Cancer Centre or the local interdisciplinary tumour centre.
 |  |  |
| 3.2 | CT/MRIAccess to the CT/MRI examinations is to be ensured. If CT/MRI is not possible at the clinical site of the Skin Cancer Centre, then access elsewhere has to be regulated in a cooperation agreement. |  |  |
| 3.4 | DiagnosisThe written report of the radiologists must be available to the co-attending physicians at the latest 1 day after the test. |  |  |
| 3.5 | Continuing education/specialty training* A training plan for medical and nursing staff is to be presented listing the planned training courses for the period of one year.
* Every year at least 1 dedicated continuing education/specialty training course for each staff member (at least 0.5 days/year) who carries out quality-relevant activities for the Centre.
 |  |  |

| Nuclear medicine |
| --- |
| Section | Requirements | Explanatory remarks by the Skin Cancer Centre |  |
| 4.1 | Specialists* at least 2 specialists
* The names of the specialists are to be provided.
* The qualification of specialists is to be documented with regard to the activity for the Skin Cancer Centre or the local interdisciplinary tumour centre.
* Radiologists with the corresponding expert knowledge are also recognised as specialists.
 |  |  |
| 4.2 | Procedures that are to be made available in nuclear medicineOptional:PET and PET-CT |  |  |
| 4.3 | Continuing education/specialty training* A training plan for medical and nursing staff is to be presented listing the planned training courses for the period of one year.
* Every year at least 1 dedicated continuing education/specialty training course for each staff member (at least 0.5 days/year) who carries out quality-relevant activities for the Centre.
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# Surgical oncology

| * 1. **Cross-organ surgical therapy**
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| Section | Requirements | Explanatory remarks by the Skin Cancer Centre |  |
| 5.1.1 | The Catalogues of Requirements of the Organ Cancer Centres and Oncology Centres have a uniform table of contents. For the Skin Cancer Centres this section does not specify any Technical and Medical Requirements. |  |  |

| * 1. **Organ-specific surgical therapy**
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| Section | Requirements | Explanatory remarks by the Skin Cancer Centre |  |
| 5.2.1 | Description of the unit (e.g. number of beds, facilities in the patients' rooms, special features of the department, nursing staff ratio) |  |  |
| 5.2.2 | Operating theatre for skin tumour interventions:Number of operating theatres regularly available for skin tumour surgery at least 1 operating theatre |  |  |
| 5.2.3 | Surgeons in the Skin Cancer CentreThe following sub-areas are to be taken into account:1. Excision of primary tumours with safety margin
2. Micrographically controlled surgery
3. Sentinel node biopsy (SNB)
4. Lymph node dissections
5. Metastasis surgery
6. Plastic surgical wound closure
 |  |  |
| On 1: Excision of primary tumours with safety margin (details of malignant melanoma, DFSP, Merkel cell carcinoma, sarcoma)* The names of at least two specialists (surgeons) are to be provided.
 |  |
| On 2: Micrographically controlled surgery * The names of at least two surgeons are to be given.
 |  |
| On 3: Sentinel node biopsy (SNB) * The names of at least 2 surgeons, including at least 1 specialist for dermatology or general surgery and 1 specialist for ENT, OMS, plastic surgery, gynaecology are to be provided.
* For SNB in the head and neck area, proof must be provided of cooperation with a partner specialising in ENT, maxillofacial surgery and/or plastic surgery. The cooperation must be described in a cooperation agreement or SOP.
* For each surgeon at least 50 SNB surgical interventions are to be documented (overall experience, not restricted to malignant skin tumours). 30 out 50 SNB surgical interventions must be carried out as the first surgeon.
* Number of patients who have undergone a surgical intervention with SNB, at least 20/year, of which 10/named surgeon not restricted to malignant skin tumours)
* Every patient who receives an operation with SNB must be operated on directly by a designated surgeon with the above-mentioned expertise or under his or her supervision (second surgeon).

Colour legend: Change compared to version as of 09.09.2019 |  |
| On 4: Systematic complete regional lymph node dissection * The names of at least 2 surgeons, including at least 1 specialist for dermatology or general surgery and 1 specialist for ENT, OMS, plastic surgery are to be provided. Depending on the centre, other disciplines (e.g. gynaecology) can also be involved.
* At least 30 systematic dissections for each surgeon are to be documented. Of them 50% may have been undertaken as a teaching assistant

Colour legend: Change compared to version as of 09.09.2019 |  |
| On 5: Metastasis surgery (separately for thoracic, visceral, neurosurgery, orthopaedics/trauma surgery, ENT/OMS and plastic surgery)* For metastasis surgery, cooperations with the indicated specialties are to be documented and the interfaces (communication, participation tumour conference, etc.) are to be described.
 |  |
|  | On 6: Plastic surgical wound closure/dressing* The names of at least 2 surgeons, including at least 1 specialist, are to be provided.
 |  |  |
| 5.2.4 | Documentation detection rate SNBThe clinical detection rate is to undergo regular quality control (at least once a year) and discussed in an interdisciplinary round. |  |  |
| 5.2.5 | Systematic lymphadenectomyLymph node dissection must be done systematically and oriented towards anatomical-morphological guide structures which are to be clearly described in the surgical report. In this context a minimum number of 6 lymph nodes to be examined for each region should not be undercut (in line with UICC, TNM classification of malignant tumours). Inguinal, iliac-obturator, axillary and cervical regions are to be considered separately as lymph node regions.The requirements for and qualifications of the surgeon are outlined in Section 5.2.3. |  |  |
| 5.2.6 | Continuing education/specialty training* A training plan for medical, nursing and other staff is to be presented listing the planned training courses for the period of one year.
* Every year at least 1 dedicated continuing education/specialty training course for each staff member (at least 0.5 days/year) who carries out quality-relevant activities for the Centre.
 |  |  |

# Medicinal / Internal Oncology

| * 1. **Haematology and oncology**
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| Section | Requirements | Explanatory remarks by the Skin Cancer Centre |  |
| 6.1.1 | The Catalogues of Requirements of the Organ Cancer Centres and Oncology Centres have a uniform table of contents. For the Skin Cancer Centres this section does not specify any Technical and Medical Requirements. |  |  |

| * 1. **Organ-specific medicinal oncological therapy**
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| Section | Requirements | Explanatory remarks by the Skin Cancer Centre |  |
| 6.2.1 | Specialists* at least 1 specialist for dermatology with the additional designation medicinal tumour therapy and 1 specialist for internal medicine and haematology and oncology or
* 2 specialists for internal medicine and haematology and oncology
* The names of the specialists are to be provided.
* The specialists named here must be actively involved in medicinal oncological therapy.
 |  |  |
| 6.2.2 | Specialist nurse/ specialist medical assistantInpatient, day-patient or outpatient departments in which medicinal oncological therapies are carried out by non-medical staff must be under the professional supervision of an oncological specialist nurse. Cooperating practices are not affected by this regulation.Requirements for a specialist nurse administering chemotherapy under medical supervision:* at least 1 year's professional experience in oncology
* 50 parenteral systemic therapies (for initial certification an estimate is possible, in the ensuing years documentation must be provided.)
* documentation of training in line with the recommendations of the Conference of Oncological Nursing and Paediatric Nursing Care (*Konferenz Onkologischer Kranken- und Kinderkrankenpflege* - KOK) (KOK recommended actions, administration of cytostatics by specialised nurses)
* active involvement in the implementation of the requirements to be met by emergency treatment and therapy of comorbidities and secondary diseases
* nursing counselling and/or education of the patient is to be documented.
 |  |  |
| 6.2.3 | Qualifications of treatment unit/partnerIn the case of skin tumour patients:Every year at least 50 systemic therapies (cytostatic therapies and/or targeted therapeutics and/or anticoagulant/immune therapies).Calculation method: systemic/cytostatic/targeted therapy for each patient (consisting of **several** cycles or applications, combination therapies count as one therapy) In the case of cross-year therapies, the therapy commenced in the survey year counts. Possible cooperation with treatment partners where there is no proof of competence:* Haematology/Oncology:

Documentation of 200 cross-organ cytostatic therapies* Conduct of systemic therapy for skin tumour patients in a medical centre or a multidisciplinary systemic therapeutic unit:

200 cross-organ cytostatic/targeted therapies of which at least 15 cytostatic/targeted in skin tumour patients. The head of this unit bears the main responsibility for the therapy. |  |  |
| 6.2.4 | Chemotherapy outpatient/inpatientIt must be possible for chemotherapy to be offered in both an outpatient and inpatient setting. |  |  |
| 6.2.5 | Options to be provided that correspond to the current level of knowledge: for instance * Immune therapy
* Supportive therapies("palliative medicine")
* Cytostatic therapy
* Target therapy
* Other systemic therapies, e.g. ECP
* Systemic PUVA therapy for lymphomas

General chemotherapy* Cytostatics workplace (in line with the statutory guidelines) if necessary
* Professional waste disposal
* 24-hour on-call service
 |  |  |
| 6.2.6 | Rooms chemotherapy* Description rooms for outpatient chemotherapy
* Number of places
 |  |  |
| 6.2.7 | Treatment plan/tumour conference minutes* In principle, the treatment plans and recommendations of the tumour conference are binding and constitute the basis for treatment.
* The treatment plan/tumour conference minutes must be available in the documentation for each patient.
* If there are any deviations from the recommended treatment plan, then they are to be presented at the tumour conference.
 |  |  |
| 6.2.8 | Systemic therapy regimens* The drawing up of/changes to existing therapy regimens must be undertaken by means of regulated release.
* Prior to release or changes to therapy regimens, the expert opinion of pharmacists can be sought.
* The therapy regimens are to be protected from any unauthorised changes.
* The therapy regimens are comparable between the outpatient and inpatient units.

Therapy plans* All systemic therapy must be planned on the basis of a therapy regimen.
* The therapy plans are to be checked and released.
 |  |  |
| 6.2.9 | Standards comorbidities and secondary diseasesStandards are to be drawn up for the treatment of comorbidities and secondary diseases, in particular for the treatment of paravasates, infections and thromboembolic complications. |  |  |
| 6.2.10 | Emergency treatmentAvailable emergency equipment and written emergency plan |  |  |
| 6.2.11 | Supportive/palliative therapyA description of the options of supportive/palliative inpatient therapy is to be given (SOP description/algorithm).Supportive measures in accordance with the guidelines are to be described for the individual therapy concepts and documented in detail for each patient. |  |  |
| 6.2.12 | Pain therapy* A pain therapist must be available.
* The standard operating procedure (SPO) for pain therapy (algorithm) is to be described.
 |  |  |
| 6.2.13 | Information/dialogue with the patient With regard to diagnosis, prognosis and therapy planning, sufficient information is to be provided about the current medical level of knowledge. This includes *inter alia*:* Information consultation about preventive health care, diagnosis, prognosis, therapy and aftercare
* Possibility of participating in clinical studies
* Presentation of alternative treatment concepts
* Offer and sourcing of psychosocial care
* Offer of and aid in obtaining second opinions
* A general description is to be given of the way in which information is provided and the dialogue organised. This is to be documented for each patient in medical reports and minutes/records.
 |  |  |
| 6.2.14 | Standard operating procedures (SOPs)The standard operating procedures for all systemic therapies are to be described for all phases (start, conduct and conclusion of therapy). |  |  |
| 6.2.15 | Continuing education/specialty training* A training plan for medical and nursing staff is to be presented listing the planned training courses for the period of one year.
* Every year at least 1 dedicated continuing education/specialty training course for each staff member (at least 0.5 days/year) who carries out quality-relevant activities for the Centre.
 |  |  |

| Radio-oncology |
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| Section | Requirements | Explanatory remarks by the Skin Cancer Centre |  |
| 7.0 | The Technical and Medical Requirements to be met by radio-oncology are summed up in the "Catalogue of Requirements Radio-Oncology" in a cross-organ manner. Independently of the number of Organ Cancer Centres / Modules, which work with a radio-oncology unit, this "Catalogue of Requirements Radio-Oncology" is only to be processed once and also only updated once for each audit year (goal: no multiple presentations or on-site inspections within one audit year). The "Catalogue of Requirements Radio-Oncology" therefore constitutes an annex to this Catalogue of Requirements.Download cross-organ "Catalogue of Requirements" from [www.krebsgesellschaft.de/zertdokumente.html](http://www.krebsgesellschaft.de/zertdokumente.html) and [www.onkozert.de](http://www.onkozert.de/). |  |  |

| Pathology |
| --- |
| Section | Requirements | Explanatory remarks by the Skin Cancer Centre |  |
| 8.0 | The Technical and Medical Requirements to be met by pathology are summed up in the "Catalogue of Requirements Pathology" in a cross-organ manner. Independently of the number of Organ Cancer Centres / Modules, which work with a pathology, this "Catalogue of Requirements Pathology" is only to be processed once and also only updated once for each audit year (goal: no multiple presentations or on-site inspections within one audit year). The "Catalogue of Requirements Pathology" therefore constitutes an annex to this Catalogue of Requirements.Download cross-organ "Catalogue of Requirements" from [www.krebsgesellschaft.de/zertdokumente.html](http://www.krebsgesellschaft.de/zertdokumente.html) and [www.onkozert.de](http://www.onkozert.de/).For Skin Cancer Centres which cooperate in line with the master data sheet with a cooperation partner for the specialty "dermatohistology", the following requirements must be processed by the cooperation partner "dermatohistology", if appropriate (e.g. autopsies are not to be processed). For Centres that only cooperate with pathologists, the cross-organ Catalogue of Requirements is to be processed. |  |  |
| 8.2 | Dermatohistological/pathological experience* Every year at least 250 histologies of malignant skin tumours (not only primary cases)
* Assessment of lymph nodes (all tumour entities): Every year at least 100 histologies of lymph nodes

(After a lymphadenectomy (LAD) the lymph nodes must be examined by a pathology specialist. If necessary, this can also be done within the framework of a second diagnosis by a specialist in dermatology with an additional qualification in dermatohistology. Sentinel for skin tumours: Assessment by dermatology specialist with the additional designation "dermatohistology" or pathology specialist)Colour legend: Change compared to version as of 09.09.2019 |  |  |
| 8.3 | Specialists* The names of at least 1 dermatology specialist with the additional qualification "dermatohistology" and 1 pathology specialist

or* 2 pathology specialists
 |  |  |
| 8.5 | MTAsA sufficient number of qualified MTAs/medical technical assistants must be available. |  |  |
| 8.6 | Procedures that must be available* Immunohistochemical tests
* Molecular pathology

These special services may only be commissioned externally from Pathology Institutes which are to be named on submission of a cooperation agreement. The institutes should have a recognised QM system or valid accreditation or document successful participation in interlaboratory experiments. |  |  |
| 8.7 | AutopsiesWithin the Centre the unlimited possibility of carrying out of autopsies must be possible and promoted. An autopsy room must be documented (possibly in cooperation). |  |  |
| 8.8 | Interfaces* The technical and organisational preconditions for frozen sections must be in place for each surgical location.
* Remote frozen segment diagnosis is not permitted.
 |  |  |
|  | Parameter frozen sectionsTime needed (in minutes) and time point measured from arrival in pathology to communication of the result (guidance value maximum 30 minutes)Evaluation of time needed: min / max / range value |  |  |
| 8.10 | Storage times* Archiving paraffin blocks ≥ 10 years
* Storage fresh material ≥ 4 weeks after reception
* Cryopreservation should be possible.
 |  |  |
| 8.11 | Diagnostic reportsDiagnostic reports must contain all the information stipulated in the Guidelines for macroscopic and microscopic assessments (in particular: histological type according to the current WHO classification, grade, TNM stage, R classification). |  |  |
|  | Additional information melanoma:* Tumour density according to Breslow, ulceration, optional: mitosis rate with a tumour density < 1 mm according to the AJCC staging system ~~2009~~ 2017.
* Histopathological specificities like possible association with a melanocytic nevus, a regression zone, morphological specificities (e.g. desmoplastic melanoma parts) and vessel infiltration

Colour legend: Change compared to version as of 09.09.2019 |  |  |
| 8.12 | 8.12 Lymph nodes (LN)* All lymph nodes in the surgical specimen are to be examined macroscopically and microscopically.
* Deviations from the minimum numbers in the Guidelines are to be discussed on an interdisciplinary level.
* The lymph nodes must be examined in line with the guidelines.
* The localisation of the lymph node (at least regional versus distance from the tumour) is to be indicated.
* The following information should be included in the histopathological report on the sentinel lymph node:

o detection of nevus or melanoma cellso in the case of melanoma cells, indication of prognostically important parameters (e.g. according to GL: largest diameter of the largest tumor cell accumulation, maximum penetration depth of melanoma cells into the lymph node parenchyma, invasion of melanoma cells into the lymph node capsule or capsule rupture, localisation of melanoma cells in perinodal lymph vessels)o largest diameter of the micrometastasis |  |  |
|  | Pro region a minimum of 6 lymph nodes are to be examined. |  |  |
| 8.13 | Resection~~/safety~~ margin |  |  |
|  | Details of the resection margins are always to be provided by the dermatohistologist/pathologist (deviations are to be justified).Colour legend: Change compared to version as of 09.09.2019 |  |  |
| 8.14 | Regular successful participation in external quality assurance measures (examples QUIP, benchmarking, external quality circles) annually, e.g. section seminars |  |  |
|  | Consultative second opinionFacilitation of consultative second opinions when asked by clinic or patient or when definitive assessment is not possible. |  |  |
| 8.15 | Quality circles* Quality circles, in which oncological aspects are addressed, are to be staged at least three times a year.
* Scheduling, e.g. in training plan
* Minutes of quality circles are to be taken.

Participation is to be proven in total and not for each individual organ; quality circles can be interdisciplinary, for a specific organ and/or trans-organ in nature (central quality circles of the Oncology Centre are, for instance, recognised pursuant to CR OC Section 1.2.14). |  |  |
| 8.16 | Continuing education* A training plan for medical staff is to be presented listing the planned training courses for the period of one year.
* At least 1 dedicated continuing education/specialty training course for each staff member who carries out quality-relevant activities for the Centre.
 |  |  |

| Palliative care and hospice work |
| --- |
| Section | Requirements | Explanatory remarks by the Skin Cancer Centre |  |
| 9.1 | Palliative care* Documentation is to be provided of cooperation agreements with service providers offering specialist outpatient and inpatient palliative care and inpatient hospices. Regional care concepts for the integration of palliative care are to be described on the basis of the treatment pathway for patients and family members from the S3 Guidelines Palliative Medicine (Figure 3, p. 174) with the names of all involved persons.
* A physician with the additional designation palliative medicine must be available for consultations and, where applicable, tumour conferences.
* The group of target patients for specialised palliative-medical support offers is to be defined (SOP).
* For patients looked after in the Centre symptoms and strains are to be repeatedly recorded using validated tools (e.g. MIDOS, iPOS).
* The access to palliative care can be offered in parallel to tumour-specific therapy. The procedure in the Centre is to be described in an SOP.
* The number of primary cases with incurable cancer is to be documented.
 |  |  |

| Tumour documentation / Outcome quality |
| --- |
| Section | Requirements | Explanatory remarks by the Skin Cancer Centre |  |
| 10.1 | Tumour documentation systemTumour documentation, which contains the patient data for a minimum period of 3 months, must be in place at the time of initial certification.Name of the tumour documentation system in the cancer registry and/or Centre.  |  |  |
| 10.2 | Period covered by the dataThe full data are to be presented for the respective last calendar year. |  |  |
| 10.3 | Requirements to be met by tumour documentationA data set in line with the Uniform Oncological Basic Data Set and its modules of the Working Group of German Tumour Centres (ADT) and the Association of Population-based Cancer Registries in Germany (GEKID) must be used.The Centre must ensure that data are transferred to the competent cancer registry in a timely manner. Any existing regional laws for notification deadlines are to be complied with. |  |  |
| 10.4 | Cooperation with cancer registry* Cooperation with the competent 65c cancer registry is to be documented on the basis of the cooperation agreement t[(www.tumorzentren.de](http://www.tumorzentren.de/))
* The full data are to be made available to the cancer registry in an ongoing manner.
* The presentation of the Data Sheet and outcome is to be ensured via the cancer registry to the extent that this information is of relevance for the cancer registry.
* Parallel systems are to be avoided.
* As long as the competent cancer registry is unable to meet the requirements imposed, the Centre is to use additional or alternative solutions. The Centre is responsible in the event of a non-functioning external solution.
 |  |  |
| 10.5 | Documentation officerThe name of at least 1 documentation officer is to be given who is responsible for the tumour documentation.Name/Function:The documentation officer has the following tasks:* Ensuring and monitoring the timely, full, complete and correct transfer and quality of the patient data that are relevant for certification by all cooperation partners to the cancer registry.
* Motivation of trans-sectoral cooperation with participating specialty units in the cancer registry (pathology reports, radiotherapy and medicinal treatments)
* Qualification and support for the staff involved in data collection
* Regular analysis of evaluations particularly over the course of time.
 |  |  |
| 10.6 | Provision of resourcesThe required staff capacity should be made available for the carrying out of documentation tasks and the collection of data (for instance by a cancer registry) (~~e.g.~~ Indicative value: for each 200 primary cases 0.5 full-time position and for each 200 aftercare cases 0.1 full-time position).Colour legend: Change compared to version as of 09.09.2019 |  |  |
| 10.7 | The following selection options must be possible at least for the tumour documentation system:* Years of birth
* TNM classification or comparable classifications and prognosis factors
* Forms of therapy (surgical therapy, radiotherapy, immunotherapy, chemotherapy)
* Date of recurrence/metastasis
* Deaths
* Follow-up status (latest update)
 |  |  |
| 10.8 | Tumour-specific indicators of outcome qualityThe recording of survival data is optional. Missing Kaplan-Meier curves should not lead to a deviation by the Centre.The tumour documentation/matrix **must** be undertaken for the malignant melanoma stages I to IV in line with the TNM 8th edition (primary cases, no stage shifts).After 3 years in addition for rare tumours (cutaneous lymphomas from stage llb, angiosarcoma, Merkel cell carcinoma, DFSP).Kaplan-Meier curves only malignant melanoma * Overall survival (OS) and progression-free survival (PFS)

Organ-specific detailed requirements are compiled in the annex to the matrix outcome quality |  |  |
| 10.9 | Evaluation of the data* The presentation of outcome quality (previous point) must be possible for the recertifications.
* The data in the tumour documentation system are to be evaluated at least once a year in line with the corresponding indicators.
* If benchmarking/annual report are offered, the benchmarking results are to be taken into account in the analysis.
* The results must be discussed in an interdisciplinary manner and in a network with other Skin Cancer Centres.
 |  |  |
| 10.10 | Recording follow-upDetails are to be given of how aftercare data are collected and what the current follow-up status is (see outcome matrix) |  |  |

**Data sheet**

A structured Data Sheet is available to Centres to record the indicators and data on outcome quality. This Data Sheet also contains an automatic evaluation of data quality. Only those presentations of indicators are eligible for certification which are undertaken on the basis of the Data Sheet made available by OnkoZert. No changes may be made to the data sheet.

The data sheet can be downloaded from [www.krebsgesellschaft.de](http://www.krebsgesellschaft.de/) and [www.onkozert.de](http://www.onkozert.de/).