**Catalogue of Requirements**

**Lung Cancer Centres**

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

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

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

Chairs: Prof. Dr. H. Hoffmann, Prof. Dr. N. Reinmuth

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| ACO – Association of Surgical OncologyADT - Association of German Tumour CentresAIO - Working Group for Internal OncologyAGORS – Working Group of Rehabilitation and Social MedicineAOP - Working Group for Oncological PathologyOPH – Working Group of Oncological PharmacyAOT - Working Group for Oncological Thoracic SurgeryAPM - Working Group for Palliative MedicinePSO - Working Group for Psycho-OncologyARO - Working Group for Radio-OncologyASO - Working Group for Social Work in OncologyAGSMO - Working Group for Supportive Measures in OncologyBVDST - German Professional Association of Radiation TherapistsBNHO - Association of Practice-based Haematologists and Oncologists in GermanyBDP – Association of German Pathologists BDP - Federal Association of Pneumologists in GermanyCAO - Surgical Working Group for OncologyDeGIR – German Association of Interventional Radiology DGHO - German Association of Haematology and OncologyDGN – German Association of Nuclear Medicine DGP - German Society for Palliative MedicineDGP - German Society for PathologyDGP - German Respiratory SocietyDEGRO - German Society for Radiation OncologyDRG - German X-Ray SocietyDGT - German Society of Thoracic SurgeryDVSG - German Association of Social Work in Health CareKOK - Conference on Oncological and Paediatric Oncological CareNOA - Neuro-oncology Working GroupPOA - Pneumological-Oncological Working GroupSHL – Self-helping Group Lung Cancer**Entry into force on 31 August 2022**This Catalogue of Requirements (CR) is binding for all audits conducted from 1 January 2023. The changes made to the version valid in the audit year 2022 are highlighted in "green" in this Catalogue of Requirements.Consideration was given to:Interdisciplinary S3 Guidelines of the German Respiratory Society (DGP) and the German Cancer Society (DKG) "Prevention, Diagnosis, Therapy and Aftercare of Lung Carcinomas"The basis for the Catalogue of Requirements is the TNM Classification of malignant tumours, 8th edition 2017 as well as the ICD classification ICD-10-GM 2022 (DIMDI) and the OPS classification OPS 2022 (DIMDI) |

**Mesothelioma units**

**Entry into force on 31.08.2022**

Note: Certified mesothelioma units can optionally be located at certified lung cancer centres as a supplementing unit. In the case of supplementary certification, the certificate as a mesothelioma unit also expires if the certificate as a certified lung cancer centre is lost. The mesothelioma-specific additions to the survey form and the data sheet for mesothelioma units were developed in consultation with the German Social Accident Insurance (DGUV).

Color legend "black": relevant for lung cancer centers

 "pink": only relevant for mesothelioma units

**Details of the Lung Cancer Centre**

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| Name of Lung Cancer Centre (LC) |  |
| Director of Lung Cancer Centre |  |
| Centre Coordinator |  |

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|  |  |  | This Catalogue of Requirements is valid for |
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| Clinical site 1 (hospital/clinic) -Thoracic surgery |  |  |  |  |  |
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| Clinical site 2 (hospital/clinic) -Pneumology |  |  |  |  |  |
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| Clinical site 3 (hospital/clinic) -Pneumology |  |  |  |  |  |
| only for cooperating LCs |  |  |  |  |  |

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| Certification as a mesothelioma unit |  | yes |  | no |

**QM system certification**

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| QM system certification |  | yes |  | no |

**Network/Main cooperation partners**

The cooperation partners of the centre are registered with OnkoZert in a so-called master sheet. The information contained therein is published at www.oncomap.de. New or no longer valid cooperations are to be communicated by the centres to OnkoZert immediately, even outside the certification period. Other updates (e.g. change of director/coordinator, contact details) must be notified in advance of the annual surveillance audits in the form of the corrected master sheet. The master sheet with the registered cooperation partners can be requested from OnkoZert as a file.

**Compilation / Update**

The electronically generated Catalogue of Requirements serves as the basis for the certification of the Lung Cancer Centre. The correctness and completeness of the information contained therein have been verified.

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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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(Excel template)

Color legend "black": relevant for lung cancer centers

 "pink": only relevant for mesothelioma units

**1.** **General details of the Lung Cancer Centre**

| **1.1**  **Structure of the network** |
| --- |
| Section | Requirements | Explanatory remarks of the Lung Cancer Centre |  |
| 1.1.1 | The management structures of the Lung Cancer Centre and QM responsibilities and Centre coordination are to be clearly defined.* Procedural rules
* Job description - Quality management officer
* Job description Centre coordinator

This applies in particular to cooperative Lung Cancer Centres.The procedural rules describe the management structures of the LC and set out the services of thoracic surgery, pneumology and, where appropriate, haematology/oncology (see also the contents of the partnership agreements of the main treatment partners). |  |  |
|  | The main treatment partners of the LC are:* Pneumology
* Thoracic surgery
* Internal oncology / haematology-oncology or pneumology with corresponding expertise (in line with the agreement in the procedural rules)
* Radiotherapist
* Pathologist
* Radiologist
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|  | The position of head of the Lung Cancer Centre is normally assumed by the head of the disciplines pneumology or thoracic surgery. A rotating head is recommended.The head of the Lung Cancer Centre ensures the implementation of standards and statutory regulations. |  |  |
|  | The discipline pneumology is represented by a pneumology department (or area with a focus on pneumology) with at least two full-time or an equivalent number of part-time pneumology specialists. If a clinic head represents two departments, the performance numbers must be listed for and met separately by each department. |  |  |
|  | The discipline thoracic surgery is represented by a thoracic surgery department (or area with a focus on thoracic surgery) with at least two full-time or an equivalent number of part-time thoracic surgery specialists.If a clinic head represents two departments, the performance numbers must be listed for and met separately by each department (with due consideration of the cooperation models.) |  |  |
|  | Cooperation modelsCooperation thoracic surgery* Within an LC, cooperation between several clinics for thoracic surgery is possible if each thoracic surgery clinic independently generates its surgical case numbers.

Further cooperation possibilities, if the following conditions are fully met:1. one of the thoracic surgery departments must independently fulfil the number of surgical cases (main location), the 2nd (and possibly max. 3rd) department (secondary location) at least 40 anatomical lung resections ~~50% (>= 38 anatomical lung resections)~~2. the thoracic surgery departments of the secondary locations are under the same medical management as the main location (already implemented for at least 3 months when the application is submitted)3. all anatomical resections (OPS: 5-323 to 5-328, for ~~each ICD-10 C diagnosis, including ICD-10 C34~~ ICD-10 C.34.0 – 9, C78.0 at all locations must be performed by thoracic surgeons named in 5.2.3.4. a 24h/7d on-call service for thoracic surgery specialists must be ensured for all locations.5. the distance of the secondary locations to the main location must not exceed 45 km (special evaluation possible).6. a thoracic surgeon of the main site named in 5.2.3 must participate in the tumour conference(s) of the other site(s) (video conferences are possible up to 2x/month) (see requirements below) and maintain a pre- and post-operative consultation hour thereColour legend: Changes vis-à-vis version from 09.07.2020 |  |  |
|  | Independent Lung Cancer Centre –Cooperation thoracic surgeryA Centre with >200 primary cases and fewer than 75 anatomical lung resections can become an independent Centre when it cooperates with an existing LC, i.e. patients undergo surgery in the thoracic surgery unit of an independent certified Lung Cancer Centre.* All surgical cases of a Centre with < 75 surgeries must be operated on in the cooperating thoracic surgery unit.
* The cooperating thoracic surgery unit must assign the surgical cases to the Centres.
* Patients who do not undergo surgery in the cooperating thoracic surgery unit are not patients of the Centre.
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|  | Precondition for multi-location cooperation models:* At least 1x/month a joint tumour board (TB). In the other weeks, site-specific TB, in which all requirements for theTB must be fulfilled (= among other things, all main treatment partners present according to CoR 1.2).
* The technical requirements and performance indicators must be fulfilled and demonstrated individually for each site.
* Common tumour documentation system
* -Patients must be fully documented at the site or assigned to the site responsible for presentation at the tumour board.
* Prior structural evaluation ~~OnkoZert~~ is required before the certificate is issued.
* Number of cooperating thoracic surgeons/pneumologists: max. 3 pneumologists and 3 thoracic surgeons

Colour legend: Changes vis-à-vis version from 09.07.2020 |  |  |
|  | A clinic for thoracic surgery or a pneumology department can be involved in two independent LCs when the required thoracic surgery/pneumology case numbers can be met separately by each LC and when there is a clear assignment of the patients to the respective Centres. |  |  |
|  | It must be proven that, as a rule, the department for thoracic surgery actually operates on all patients with the corresponding indication in the cooperating pneumology departments. |  |  |
| 1.1.2  | Written agreements (cooperation agreements) are to be entered into with the main cooperation partners (with the exception of pneumology and thoracic surgery and possibly haematology/oncology – they set out their services in the procedural rules). The agreements are to be examined annually by the Lung Cancer Centre to ensure they are up to date.The following points are to be dealt with in the agreements with the main cooperation partners:* Binding participation in the tumour conference
* Ensuring availability
* Description of the treatment processes of relevance for the Lung Cancer 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 of the Technical and Medical Requirements to be met by Lung Cancer Centres and with the annual submission of the relevant data
* Declaration of consent of the treatment partners to be publicly identified as part of the Lung Cancer Centre (e.g. homepage)
* Other disciplines/specialties, e.g. nuclear medicine, psychosocial oncology or others can be called in when necessary.
* 24-hour availability of the main clinical cooperation partners (thoracic surgery, radiotherapy, pneumology, haemato-oncology, if applicable), e.g. for emergency interventions.

Colour legend: Changes vis-à-vis version from 09.07.2020 |  |  |
| 1.1.3 | Agreements with other treatment partners:Written agreements are to be entered into for the following treatment partners in which a willingness to engage in cooperation is declared:* Psycho-oncology
* Nuclear medicine
* Social services
* Advice for smokers / smoking cessation
* Physiotherapy
* Hospice/palliative medicine
* Neurosurgery

The following points are to be dealt with, amongst other things, in the agreements with the cooperation partners:* Participation in specialty training programmes and public relations work
* Description of cooperation and interfaces
* Type of reciprocal communication
* Upholding of medical confidentiality

If the treatment partner comes under the disciplinary jurisdiction of the LC, a written agreement is not required. |  |  |
| 1.1.4 | Further cooperations Cooperation with the National Genomic Medicine Network should be considered. |  |  |
| 1.1.5 | The Lung Cancer Centre has a clear mission statement and quantitative quality goals.Interdisciplinarity and evidence-based medicine are clearly reflected in its statements and are visible in practice.The fundamental orientation of the Lung Cancer Centre is known to and implemented by its employees. |  |  |
| 1.1.6 | The achievement of quality goals is measured. The results undergo documented evaluation.Clear strategies, which encourage the achievement of goals, are defined in the annual quality plans under* the responsibility of the Centre head and
* Centre coordination.
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| 1.1.7 | Contact partners of the Lung Cancer CentreThe names of the contact partners of the Lung Cancer Centre at the clinical site and for the individual cooperation 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. |  |  |
| 1.1.8 | The funding body/bodies of the Lung Cancer Centre make sufficient funds / resources available in order to meet the staffing, spatial and material requirements |  |  |
| 1.1.9 | Standard Operating Procedures (SOPs) must be defined for patients in which the relevant medical guidelines are set out. Regular checks should be made to ensure they are up to date.The SOPs take into account the interdisciplinarity of the Centre and the networking with practice-based physicians.Pathways are to be specified for:* Diagnostics
* Therapy
* Aftercare
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| ~~1.1.10~~ | ~~The LC should have a certified QM system (ISO 9001, KTQ, PCC, JC etc.) which is continuously developed.~~Colour legend: Changes vis-à-vis version from 09.07.2020 |  |  |

| **1.2** **Interdisciplinary cooperation** |
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| Section | Requirements | Explanatory remarks of the Lung Cancer Centre |  |
| 1.2.1 | The Lung Cancer Centre must treat at least 200 patients a year with a primary diagnosis of "lung cancer" in its own Centre. Definition primary cases of lung cancer of the Centre:* All patients with newly diagnosed lung cancer, who are presented to the Centre or the tumour conference, and receive large parts of their treatment there.
* A patient can only be counted as a primary case for 1 Centre; pretreated patients or patients seeking a second opinion are not counted.
* Patients (not stays, not surgery)
* Complete recording in the tumour documentation system
* Pathology report must be available (ICD, C34.0-34.9)
* The time of counting is the time of the pathological confirmation of diagnosis
* Patients with no pathological confirmation of diagnosis may be counted if (all of the following apply):
* Solitary pulmonary nodule, suspected malignoma
* FDG-PET positive
* Documented size progression over course of time (at least 8 weeks)
* High risk for patients through pathological confirmation
* Presentation tumour conference and indication radiotherapy without pathological confirmation
* Time of counting is date of presentation tumour conference
* A primary case with synchronous treatment of bronchial carcinomas (independent of the side or lobe localisation)
* Two primary cases with metachronous treatment of bronchial carcinomas, if these occur on different sides (not counted as a second primary case is the occurrence in different lobes on the same side)
* Synchronous tumour in another tumour entity can be counted as a primary case for each tumour entity

**With additional certification as a mesothelioma unit:**The centre must treat at least 12 patients per year with the primary diagnosis according to ICD-10 C45.0 (mesothelioma of the pleura) and/or C45.2 (mesothelioma of the pericardium). If patients with the primary diagnosis C45.1 (mesothelioma of the peritoneum) are also treated, cooperation with a certified colorectal cancer centre must be ensured.Definition of primary case of mesothelioma of the centre:* All patients with newly diagnosed malignant mesothelioma who present at the centre or the tumour board and receive essential parts of the therapy there.
* Patients can only be counted as primary cases for 1 centre; pre-treated patients or patients for a second opinion can only be counted as primary cases for 1 centre or patients for a second opinion are not counted.
* Patients (not stays, not operations)
* Complete recording in the tumour documentation system
* Pathological findings must be present (ICD C45.0, C45.1, C45.2). A cytological diagnosis alone is only sufficient in justified exceptional cases.
 | Details in the Data Sheet: Basic data / Indicator 1 (Excel template)Indicator 1a and 1b - mesotheliom |  |
|  | Therapy discontinuations:Can be counted in the case of first treatment as a primary case. Are to be entered in the tumour documentation system. Number of patients is to be indicated. Not recognised when the patient has switched to another Centre after diagnosis or before the commencement of treatment |  |  |
| 1.2.2 | The thoracic surgery department must prove at least 75 anatomical lung resections a year in patients with ~~a c-~~diagnosis ICD-10 C.34.0 – 9, C78.0 (Def. surgical spectrum CR 5.2.2).Colour legend: Changes vis-à-vis version from 09.07.2020 | Details in the Data Sheet: Basic data / Indicator 11a and 11b - lung(Excel template) |  |
| 1.2.3a) | CycleThe tumour conference must be held at least once a week.Web/online conference* If web conferences are used, it must be possible to transmit the sound and documents presented. It must be possible for each main cooperation partner to present its own documents/imaging material.
* Telephone conferences with no imaging material are not an option.
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| b) | Participants tumour conferenceThe main treatment partners (Section 1.1.1.) attend each tumour conference. Participation must be proven, for instance in a list of participants.Palliative physicians should regularly attend the tumour conference.In line with needs, associated specialty units (e.g. psycho-oncology, nursing care) and other specialties (neurology, neurosurgery, surgery, pain therapy, orthopaedics, etc.) are to be included in the tumour conference. |  |  |
| c) | Preparation tumour conferenceThe main patient data are to be summed up in writing prior to the conferences and distributed to the participants.A pre-appraisal of suitable study patients is to be undertaken. |  |  |
| d) | Demonstration imaging materialAny existing patient-related imaging material (e.g. pathology, radiology) of relevance for the question in hand, must be available at the conference and suitable technical equipment must be provided for the presentation of this material. |  |  |
| e) | MinutesThe results of the tumour conference consist, *inter alia*, of a written, interdisciplinary treatment plan ("Minutes tumour conference"). The treatment plan must be made available to the conference participants and to care and specialty units responsible for further treatment. It must be part of the patient’s medical record.Dissenting decisions are documented. Responsibility for treatment lies with the attending physician. |  |  |
| 1.2.4 | Tumour conferenceAll patients, who come to the Centre with a first manifestation, a new recurrence or remote metastasis, must be presented at the pretherapeutic tumour conference and/or in the tumour conference after conclusion of primary therapy.**In case of additional certification as a mesothelioma unit:**Patients with newly diagnosed mesothelioma are to be presented to the tumour board as frequently as possible, both pre-therapeutically and post-operatively.Colour legend: Changes vis-à-vis version from 09.07.2020 |  |  |
|  | Oligometastasis in NSCLC Definition of oligometastasis:The stage of oligometastasis is characterized by limited metastasis, in which local ablative therapy of all tumour sites in addition to system therapy pursues a curative therapeutic goal. A limited number of metastases on imaging is used as a surrogate for a limited metastatic capacity. The definitions of oligometastatic NSCLC vary between a solitary distant metastasis according to stage M1b of the UICC classification (8th ed) and a maximum of 3-5 distant metastases as inclusion criteria of prospective studies. The majority of the evidence is based on patients with a maximum of two distant metastases, which should form the basis for the indication of a local ablative therapy in combination with an adequate system therapy of oligometastatic NSCLC.(Consultation version of the S3-LL Lung Cancer, version 2.01 (05/2022); Recommendation 8.131)* For oligometastasised patients, information must be available for the pre-therapeutic tumour conference:
	+ number of metastatic foci
	+ metastasis localisation
	+ largest diameter of organ metastases
* Depending on the location of the metastases, the specialist disciplines neurosurgery, trauma surgery/orthopaedics and/or visceral surgery/urology must be included in the decision-making process, interventional radiology (participation at the tumour conference or consultation)
* The disciplines consulted should work in a cooperating certified centre (e.g. NCC, CRCC, PCC or OCC)

Colour legend: Changes vis-à-vis version from 09.07.2020 |  |  |
| 1.2.5 | Pretherapeutic tumour conference* Primary cases
* Local recurrence/distant metastases
 | Indicator 2a (Excel template)Indicator 2b (Excel template) |  |
|  | Indication conference* In Centres with >500 primary cases, the pre-therapeutic tumour conference can be conducted as an indication conference.
* Participants: Pneumology/haematology-oncology, thoracic surgery, radiology. Optional: Radiotherapist, palliative medicine
 | Indicator 2a (Excel template) |  |
| 1.2.6 | Tumour conference after surgical therapy (to examine the indication for adjuvant therapy) | Indicator 3 (Excel template) |  |
| 1.2.7 | Conduct/recommendation of therapyIf, in the course of therapy, there is a deviation from the original therapy recommendation, the case must be presented again at the conference. The reasons for the change and the amended therapy are to be documented. |  |  |
| 1.2.8 | Therapy planningOn request, the patient is given the minutes of the tumour conference. Alternatively, a separate record can be made for the patient. |  |  |
| 1.2.9 | Quality circles* Quality circles, in which lung aspects are addressed as one of the foci, are to be conducted at least 3 times a year.
* Participants: mandatory for all main treatment partners; other partners of the Centre (nursing care, psycho-oncology, etc.) are to be invited in line with the topics to be discussed (at least once a year).
* Minutes of quality circles are to be taken.
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| 1.2.10 | Morbidity conferences* The invited participants are the participants in the tumour conference and referrers.
* The dates of these conferences can be timed to coordinate with the tumour conference or with events for referrers.
* At least 2 morbidity conferences are to be held every year and at least 3 cases are to be presented at each conference.
* Cases presenting a special development in the course of the disease or cases in need of improvement are discussed.
* Minutes of morbidity conferences are to be taken.
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| 1.2.11 | For the group of patients with foreseeable limited life expectancy, a written, structured concept of care and communication should be developed at the centre and presented at the audit. If necessary, taking into account the chapter Advanced Care Planning of the S3-GL Lung or Palliative.(Groups with foreseeably limited life expectancy: among others M1-patients SCLC/NSCLC without treatable molecular alteration and progression after failure of the first line of system therapy) |  |  |

| **1.3** **Cooperation with referring physicians and providers of aftercare treatment** |
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| Section | Requirements | Explanatory remarks of the Lung Cancer Centre |  |
| 1.3.1 | Cooperating referrers A list is to be kept of cooperating main referrers. Referrers may independently present patients (e.g. suspected recurrence). The referrers must be informed of these options. |  |  |
| 1.3.2 | ContactsThe Centre's contacts are to be given to the referrers in line with their function (e.g. telephone number, email). |  |  |
| 1.3.3 | Medical reportsMedical reports are to be given to the referrer, the patient (if he/she wishes) and each physician indicated by him/her. Medical reports must contain the pathology report, surgery report and the results of the tumour conference.After preparation of the report, the referrer should have timely access (< 2 days) to the surgery report, the histological results and the minutes of the tumour conference. |  |  |
| 1.3.4 | 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. |  |  |
| 1.3.5 | Referrer satisfaction surveyEvery three years a referrer satisfaction survey is to be conducted. The results of this survey are to be evaluated and analysed. The results must be available for the 1st surveillance audit. |  |  |
| 1.3.6 | Continuing educationThe Lung Cancer Centre must propose continuing education evens for physicians at last twice a year. Contents/results and participation are to be recorded. |  |  |

| **1.4** **Psycho-oncology** |
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| Section | Requirements | Explanatory remarks of the Lung Cancer Centre |  |
| 1.4.1 | Psycho-oncology qualifications* Qualified psychologist /Master in Psychology, which qualifies for a scientifically recognised psychotherapy procedure or
* Physicians
* Diploma / Master's degree in social pedagogy, which qualifies for a scientifically recognised psychotherapy procedure

with at least 1 psychotherapeutic specialty training: behavioural therapy, psychodynamic psychotherapy (analytical psychotherapy and psychotherapy based on depth psychology), systemic therapy, neuropsychological therapy (for psychological disorders caused by brain injuries), interpersonal therapy (IPT; for affective disorders and eating disorders), EMDR for the treatment of post-traumatic stress disorders, hypnotherapy for addiction disorders and for psychotherapeutic co-treatment for somatic disordersand psycho-oncological continuing education (acknowledged by the German Cancer Society - DKG)Protection of the status quo for all those who are currently recognised and those who have begun a DKG-recognised psycho-oncological further training course by 31.12.2019.Licence to practise: At least 1 person in the psycho-oncological team of the network (inpatient or outpatient) must be licensed (psychologicalor medical psychotherapist)The representatives of other psychosocial professional groups can be approved on presentation of the above-mentioned additional qualifications. This requires a case-by-case assessment~~.~~The process of patient care in the centre (screening, evaluation of screening results, care) must be demonstrated in the audit based on examples. |  |  |
| 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.Documentation and evaluation~~Psycho-oncological treatment is to be documented and evaluated in an ongoing manner using suitable instruments (e.g. Basic Documentation for Psycho-Oncology - PO-BaDo).~~ To identify treatment needs, screening of mental strain must be undertaken (indicator “psycho-oncological distress-screening” ~~instrument e.g. see S3 Guidelines Psycho-Oncology~~), and the result is to be documented. The proportion of patients overstressed in distress screening should be presented.Scope of treatmentPsycho-oncological care, in particular for patients with excessive stress in the distress screening, must be presented.~~Patients who have received psycho-oncological support are to be documented. The frequency and duration of the sessions is to be recorded.~~Colour legend: Changes vis-à-vis version from 09.07.2020 |  |  |
| 1.4.3 | Psycho-oncology resourcesNeeds-based, at at least 1 psycho-oncologist with the above qualifications is available to the Centre (name to be given)~~.~~ |  |  |
| 1.4.4 |  PremisesA suitable room is to be provided for psycho-oncological patient consultations. |  |  |
| 1.4.5 | Organisation planIf psycho-oncological care is provided by external cooperation partners or for several sites and clinic facilities, 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. |  |  |
| 1.4.6 | Psycho-oncology – tasksThe psycho-oncological care of patients is to be offered in all stages of care (diagnosis, inpatient, post-inpatient).Goals and tasks of care:* 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)
* Provision of supervision, initial and continuing education for staff
 |  |  |
|  | The following are also recommended:* 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 cooperation with the social services;
* the psycho-oncologists should present their work at least twice a year at the tumour conferences.
 |  |  |
| 1.4.7 | Continuing education/supervision* At least 1 dedicated continuing education course a year for each staff member (at least 1 day a year)
* External supervision is to be made possible on a regular basis.
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| **1.5**  **Social work and rehabilitation** |
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| Section | Requirements | Explanatory remarks of the Lung Cancer Centre |  |
| 1.5.1  | Qualifications social work* Social workers/social pedagogues
* Individual case examinations according to the specifications of the professional society are possible
* Additional qualification: Experience in the medical/oncological field

Resources: For patient counselling in the Centre at least 1 full-time staff member is available for 400 counselled patients (not cases) of the Centre (primary cases, secondary metastasis, recurrence). The personnel resources can be grouped centrally, an organisation plan must be available.Premises:A suitable room is to be provided for social counselling work.Organisation plan: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. |  |  |
| 1.5.2 | Social work – Offer and accessEach patient must be offered the option of counselling by the social services at all stages of the disease in a timely manner in the vicinity (proof required). The offer must be made in a low-threshold manner Counselling social services:The number of patients who have received support from the social services is to be documented and evaluated. |  |  |
|  | Number of patients who received counselling from the social services. | Indicator 5 (Excel template) |  |
| 1.5.3 | Tasks of psychosocial counsellingTopics of counselling using the DVSG catalogue of services and the expert standards PEOPSA (Psychosocial Initial Counselling of Oncological Patients by Social Work* Identification of social, economic and mental health emergencies
* iInitiation of medical rehabilitation measures
* Advice on social law and economic issues (e.g. severely disabled persons' legislation, wage replacement benefits, pension, benefit requirements, co-payments, etc.)
* Support with application procedures
* Advice on outpatient and inpatient treatment options
* Referral to support offerings, specialised services, care services
* Support for professional and social reintegration
* Cooperation with service funding agencies and service providers, counselling centres
* Discharge management
* Intervention in emergencies
* Help with transfer to/placing in palliative care facilities and hospice care (outpatient / inpatient)
 |  |  |
| 1.5.4 | Further tasks:* Offering further education/ information events for other disciplines of the Centre and/or patients
* Multi-professional cooperation particularly with physicians, nursing staff, psychologists, physiotherapists, pastoral services *inter alia*
* Participation in multi-professional case reviews Supervision
* Public relations and networking
* Interdisciplinary cooperation, especially with doctors, nurses, physiotherapists, psychooncologists, pastoral care, etc.

**In the case of additional certification as a mesothelioma unit:**When treating patients with malignant mesothelioma, cooperation with the staff of the accident insurance institutions responsible for rehabilitation must also be ensured.Documentation and evaluation* The activity of the social services is to be documented (e.g. CareDS, KIS) and evaluated
 |  |  |
| 1.5.5 | Continuing educationEvery year at least 1 specific continuing education course per staff member (min.1 day per year) |  |  |

| **1.6** **Patient involvement** |
| --- |
| Section | Requirements | Explanatory remarks of the Lung Cancer Centre |  |
| 1.6.1 | Patient surveys:* At least every 3 years all Centre patients are given the opportunity over a period of at least 3 months to take part in a patient survey.
* The response rate should be documented.
 |  |  |
| 1.6.2 | Evaluation patient survey* Responsibility for the evaluation is to be specified.
* The evaluation must encompass the patients of the Lung Cancer Centre.
* A protocolled evaluation is to be made and presented during the audit.
* Actions are to be laid down on the basis of the evaluation.
 |  |  |
| 1.6.3 | Patient information (general)* The Lung Cancer Centre should present itself and its treatment options (e.g. in a brochure, patient folder, on the 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 option of seeking a second opinion is in place.
* The patient is always informed of the diagnosis by the attending physician.
* The patient's autonomy is respected and independent actions are supported.
* "Informed consent" is ensured.
 |  |  |
| 1.6.4 | Discharge consultationEach patient is given a discharge consultation (short documentation / check list) in which the following topics at least are addressed and the corresponding information provided:* Therapy planning
* Individual aftercare plan (where appropriate handing over of an aftercare pass)
* Option of psycho-oncological care
* Option of social worker counselling
 |  |  |
| 1.6.5 | Results tumour conferencePatient is to be informed of the recommendations of the tumour conference.Patient information (case-related):On request, the patient is given a copy of the final medical report. It contains the histology, surgical report and information on the planned therapy (tumour conference minutes). |  |  |
| 1.6.6 | Event for patientsThe Centre is to stage an information event for patients and/or interested persons at least once a year. If possible, in cooperation with self-help groupsIf patient events are (co-)financed by industry, this fact, including potential conflicts of interest of the lecturers, must be disclosed. The centre must exclude any direct influence on patients by industry representatives.Colour legend: Changes vis-à-vis version from 09.07.2020 |  |  |
| 1.6.7 | Complaint managementAn official procedure for complaint management is in place. The patients are given feedback. Complaints are taken into account in the improvement process. |  |  |
| 1.6.8 | Self-help groupsThe self-help groups, with which the Lung 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. |  |  |
| 1.6.9 | Agreement with self-help groupsWritten agreements with the self-help groups are to be entered into which cover the following points:* Access to 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 LC)
* Options to display information brochures of self-help groups
* Regular provision of rooms at the LC for patient consultations
* Quality circles with the participation of representatives of psycho-oncology, self-help groups, social services, pastoral care, nursing care and medicine
* Personal discussions between the self-help groups and the Lung 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
 |  |  |

| **1.7** **Study management** |
| --- |
| Section | Requirements | Explanatory remarks of the Lung Cancer Centre |  |
| 1.7.1  | Access to studiesThe patient must have access to studies. The studies conducted at the Lung Cancer Centre must be listed and published, for instance on the Cen’re's homepage. |  |  |
| 1.7.2 | Study managerThe name of the physician in charge of the study is to be given. |  |  |
| 1.7.3 | Study assistant /study nurseA study nurse /study assistant should be available for initial certification (mandatory after 3 years).He/she can work in a parallel manner for sever“l "units conducting stud”es".The range of tasks is to be laid down in writing (via position/function descriptions with the scale of the time needed) and can encompass, *inter alia*, the following contents:* Conduct of studies together with the physician in charge of the studies
* Patient care during the study and in aftercare
* Organisation, coordination of diagnosis, laboratory, sample dispatch and test medication
* Collection and documentation of all data of relevance for the studies
* Preparation of and support for audits and authority inspections

The activity of the study assistant can be combined with other activities like tumour documentation. |  |  |
| 1.7.4 | Process descriptionThe processes are to be described for the taking on/initiation of new studies and the conduct of studies (information, conduct and aftercare). |  |  |
| 1.7.5 | Proportion study patients* Initial certification:

At the time of initial certification >= 1 patients must have been included in the studies.* after 1 year: at least 5% of the primary case number

**In case of additional certification as a mesothelioma unit:**At least 1 mesothelioma unit must have been included in a mesothelioma-specific study (from initial certification per calendar year). If possible, every mesothelioma patient should be able to receive treatment via a study protocol. Regardless of the study quota, as many patients as possible should participate in a biobank study. | Details in the Data Sheet: Indicator 7 LungIndicator 7 Mesothelioma(Excel template) |  |
|  | All patients with lung cancer included in studies can be taken into account when calculating the study rate (share study patients based on the Cen’re's primary case number).Only the inclusion of patients in studies for which a valid ethical vote is available counts as study participation.Inclusion in studies whose sole objective is to collect material (biobanking) does not count.General preconditions for the definition of the study quota:* Patients can be counted once per study, time: date of patient consent.
* Patients in the palliative and adjuvant situation can be counted, no limitations regarding stage of disease.
* Patients who are taking part in several studies can be counted several times.
 |  |  |

**List of Studi–s - lungs**1)

|  |  |  |
| --- | --- | --- |
| Responsiblecooperation partner 2) | Study name | Number of centre’s patients recruited in 20213) |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  | Numerator: Indicator no.6 “study quota “ |  |

**List of Studies - Mesothelioma** 1)

|  |  |  |
| --- | --- | --- |
| Responsiblecooperation partner 2) | Study name | Number of centre’s patients recruited in 20213) |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  | Numerator: Indicator no.7 “study quota “ |  |

1) The list of studies must be completed. It is not possible to simply refer to the Catalogue of Requirements for oncology centres.

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

3) Only patients that are “Centre patients” and were recruited in 2017 can be counted as “study patients”

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

| **1.8** **Nursing care** |
| --- |
| Section | Requirements | Explanatory remarks of the Lung Cancer Centre |  |
| 1.8.1 | Specialist oncology nurses* At least one full-time specialist oncology nurse must work on day duty in the Centre.
* The names of specialist oncology nurses are to be given.
* In areas in which patients are treated, the activity of a specialist oncology nurse is to be documented.
* The performance of tasks/staff cover arrangements are to be laid down in writing and documented.

The precondition for recognition as a specialist oncology nurse is: * Continuing education specialist oncology nurse in line with the respective federal state regulations
* or the Model Federal State Ordinance of the German Hospital Federation (*Deutsche Krankenhausgesellschaft e.–.* - DKG)
* or Advanced Practice Nurse (master title) plus 2 years’ practical oncological occupational experience (full-time equivalent)
 |  |  |
| 1.8.2 | Patient-related tasks:* Specialist assessment of symptoms, side-effects and strains
* Individual determination of interventions on the basis of nursing standards
* Conduct and evaluation of nursing and therapeutic measures
* Identification of individual patient-based need for counselling.
* The need for specialist counselling is to be defined already in the nursing concept of the Lung Cancer Centre
* Ongoing provision of information to and counselling of patients (and their family members) throughout the entire course of the disease and conduct, coordination and documentation of structured counselling sessions and instructions to patients and their family members. In line with the concept these activities may also be carried out by other long-serving specialist nurses with specialist oncological expertise.
* Need-based participation in the tumour board
* Initiation of and participation in multi-professional case discussions/nursing visits. The objective is to find solutions in complex nursing situations. Criteria for the selection of patients are to be laid down. At least 12 case discussions/nursing visits are to be documented for each year and Centre

Superordinate activities:* A nursing concept it to be developed and implemented in which the organ-specific aspects of oncological nursing care are taken into account in the Lung Cancer Centre.
* Drawing up of specialist in-house standards based (if possible) on evidence-based guidelines (e.g. S3-LL Supportive)
* Offer of consultation with/supervision by colleagues
* Networking between oncology nurses in a joint quality circle and participation in a quality circle in the Lung Cancer Centre.
* Interdisciplinary exchange with all professional groups involved in treatment
* Responsibility for implementing the requirements for the specialist nurse who administers chemotherapy (see Section 6.2.2)
 |  |  |
| 1.8.3 | Induction The induction of new staff members must be undertaken on the basis of a specialist oncological induction catalogue/plan with the participation of the specialist oncology nurse. |  |  |
| 1.8.4 | Continuing education* A continuing education 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 course for each staff member (at least 1 day a year) who carries out quality-relevant activities for the Centre.
 |  |  |

| **1.9**  **General service areas** |
| --- |
| Section | Requirements | Explanatory remarks of the Lung Cancer Centre |  |
| 1.9.1 | The Centre must offer the following conservative treatment methods:* speech therapy
* breathing therapy
* physiotherapy
* nutritional counselling

Responsibilities must be clearly defined for all procedures. Descriptions of the procedures must be available. |  |  |
| 1.9.2 | Smoking cessation programmes* All patients who smoke should be offered a professional smoking cessation programme with documented motivational sessions.
* at least 1 person from the medical and 1 person from the non-medical area should have a certified qualification in smoking cessation (e.g. through a curriculum of the German Medical Association [BÄK], German Respiratory Society [DGP], Federal Association of Pneumologists in Germany [BdP]).

The names of the persons are to be given.* Stocks of medication for smoking cessation (nicotine replacement therapy, varenicline) must be kept in the hospital.
* Cooperation with an outpatient, multi-modal smoking cessation programme should be in place.
 |  |  |
| 1.9.3 | Supportive therapy and symptom relief* The possibilities for supportive / palliative inpatient therapy are to be described (process description / algorithm).
* A pain therapist must be available. The process for pain therapy (algorithm) shall be described and demonstrated on documented cases for the period under consideration.

Expertise for pain therapy:* 50 / per year for patients with lung cancer; 100 / per year in total
* ~~Access to nutritional advice shall be described and demonstrated on documented cases for the period under consideration.~~
* Nutritional counselling must be an integral part of the LC, an SOP should be available.
* The need for nutritional counselling must be actively determined and carried out in relation to the patient´s need.
* The metabolic risk ("Nutritional Risk") should be determined at the latest during hospitalization by means of Nutritional Risk Screening (NRS), e.g. according to Kondrup 2003.
* Access to psycho-oncological and psychosocial care and pastoral care shall be described.
* In the case of implementation via cooperation partners, a cooperation agreement must be agreed for the above-mentioned requirements.

Colour legend: Changes vis-à-vis version from 09.07.2020 |  |  |

**2.** **Organ-specific diagnostics**

| **2.1**  **Consulting hours** |
| --- |
| Section | Requirements | Explanatory remarks of the Lung Cancer Centre |  |
| 2.1.1 | Lung consulting hourOn what basis is a special consulting hour held? (Medical care centre, participating physician, personal authorisation, institute authorisation, polyclinic authorisation) |  |  |
| 2.1.2 | The lung consulting hour must be held at least once a week and cover the following topics:* Lung cancer detection
* Therapy planning
* Aftercare
* Counselling in the case of benign respiratory disorders
* Offers for smoking cessation programmes
* Recording of smoker status (the following breakdown is recommended: year of commencement, year of discontinuation, packs and pack years and breakdown into current smoker, ex heavy smoker, light smoker and never a smoker)

If appropriate, the topics can be covered in special, separate consulting hours.**With additional certification as a mesothelioma unit:**The mesothelioma consultation must be offered at least weekly and cover the following topics:* Diagnostics/ mesothelioma detection
* therapy planning
* treatment
* counselling
* Aftercare

During the mesothelioma consultation, the patient must be made aware of the significance of mesothelioma as an occupational disease and informed that he or she may be contacted by the responsible accident insurance institution. The immediate reporting of a mesothelioma disease or a corresponding suspected case to the accident insurance institution must be ensured. The process must be presented in the audit. |  |  |
| 2.1.3 | How long are the waiting times for an appointmentRequirement: < 2 weeksEmergency consultation possible daily.The waiting times are to be recorded on a random basis and statistically evaluated (recommendation: evaluation period 4 weeks a year). |  |  |
| 2.1.4 | In the case of (special) lung consulting hours, the following services are to be provided:* Lung function laboratory
* Ergospirometry
* X-ray (conventional)
* Computer tomography/MRI
* Laboratory (haematology, clinical chemistry, ...)
* Sonography (pleura, upper abdominal ultrasound, echocardiography)
* Possibility for outpatient bronchoscopy
* Nuclear medicine tests
 |  |  |
| 2.1.5 | Time to first pathology report (primary diagnosis)Requirement: ≤ 3 working days |  |  |
| 2.1.6 | Diagnosis communication dignity* Communication of a diagnosis, particularly in the case of malignant findings, must be done personally by and in direct contact with a physician.
* Time to diagnosis communication: < 1 week
 |  |  |
| 2.1.7 | Repeated presentation of patient is to be organised in the event of therapeutic side effects. |  |  |
| 2.1.8 | Information / dialogue with the patientAdequate information must be provided about diagnosis and therapy planning and a dialogue is to be entered into. This includes *inter alia*:* Presentation of alternative treatment concepts
* Offer of and aid in obtaining second opinions
* Discharge consultation as a standard procedure

A general description is to be given of the way in which information is provided and the dialogue organised in a protected room. This is to be documented for each patient in medical reports and minutes/records. |  |  |

| **2.2**  **Diagnosis** |
| --- |
| Section | Requirements | Explanatory remarks of the Lung Cancer Centre |  |
| 2.2.1 | The Centre must offer the following functional diagnostic procedures:* Lung function with whole body plethysmography, measurement of diffusion capacity, measurement of muscle function and exercise test (6-minute walk test)
* Blood gas test at rest and during exertion
* Spiroergometry
* Echocardiography
* Quantifiable lung ventilation-perfusion scintigraphy

Descriptions of the procedures used must be available. |  |  |
| 2.2.2 | The Centre must offer the following procedures for endoscopy and interventional bronchoscopy:* Rigid and flexible bronchoscopy(video chip technology)
* Pneumothorax therapy
* Thorascopy
* Lung biopsy and lung puncture
* Pleural puncture
* Lymph node biopsy and puncture -transbronchial and transtracheal
* Radioscopy
* Endobronchial/endoluminal ultrasound with needle puncture with ultrasound control
* CT-controlled biopsy and puncture
* Thermal recanalisation procedures(ND:Yag laser or Argon plasma beamer or electric cautery
* Stent implantation in the trachea and bronchial tubes
* Electronic imaging documentation and archiving for diagnostic endoscopic procedures

Responsibilities must be clearly defined for all procedures. Descriptions of the procedures must be available.A list must be kept of all necessary equipment. |  |  |
| 2.2.3 | Expertise for endoscopic / interventional procedures: |  |  |
|  | * Flexible bronchoscopy: >=500 bronchoscopies/ year in the Centre
 | Details in the Data Sheet: Indicator 7(Excel template) |  |
|  | * Surgical bronchoscopic interventions in the event of tumour occlusion or stenosis (also in the case of non-oncological patients): ≥ 10/year (thermal methods and stenting)
 | Details in the Data Sheet: Indicator 8(Excel template) |  |
|  | The number per year must be given for the following procedures (no minimum number specified): |  |  |
|  | * Rigid bronchoscopy (1620.1~~x~~)

colour legend: Changes vis-à-vis version from 09.07.2020 |  |  |
|  | * Transbronchial lung biopsies (1430.2)
 |  |  |
|  | * EBUS tests
 |  |  |
|  | * CT-controlled lung biopsies
 |  |  |
|  | The responsibilities for the functional procedures used must be clearly defined. |  |  |
| 2.2.4 | Physicians working for the LC inendoscopic/interventional diagnostics* The specialist standard (with qualified staff cover arrangements) is to be ensured for each of the procedures used.
* The names of the physicians are to be given.
* 2 years’ experience in the conduct and interpretation/analysis of the results of the functional procedures used
* Description of the special expertise in the conduct of the procedures and interpretation/analysis of the results
 |  |  |
| 2.2.5 | Assistance staff (nurses or MTAs)* At least 2 qualified staff members for each procedure
* The names of the staff members are to be given.
 |  |  |
| 2.2.6 | Timeline for the provision of the necessary information to the co-attending physicians(If possible immediately, always < 24 h after test) |  |  |
| 2.2.7 | The option of inpatient admission must be available. |  |  |
| 2.2.8 | Continuing education* A continuing education plan is to be presented for the medical and other staff (RTAs) involved in the endoscopic / interventional procedures, which outlines the qualification measures planned for the period of one year.
* At least 1 dedicated continuing education course for each staff member (at least 1 day a year) who carries out quality-relevant activities for the Centre.
 |  |  |

| **3.** **Radiology** |
| --- |
| Section | Requirements | Explanatory remarks of the Lung Cancer Centre |  |
| 3.1 | Specialists* At least 1 specialist for radiology
* Cover arrangements for staff with the same qualification is to be documented in writing.
* The names of the specialist and cover staff are to be given.
 |  |  |
| 3.2 | Radiology RTAs:At least 2 qualified RTAs must be available and their names given. |  |  |
| 3.3 | Procedures available in radiology: * Spiral-CT
* MRI
* X-ray
* Interventional radiology (cava stent, embolisation, abscess drainage...)

Responsibilities must be clearly defined for all procedures. A list of equipment must be kept.If the Centre does not offer these procedures itself, the corresponding cooperation agreements must be in place. |  |  |
| 3.4 | Description of radiology procedures (SOPs)The imaging techniques are to be described and checked once a year to ensure they are up to date. |  |  |
| 3.5 | DiagnosisThe written report of the radiologists must be available to the co-attending doctors at the latest 24 h after the test.  |  |  |
| 3.6 | The option of inpatient admission must be available. |  |  |
| 3.7 | Continuing education* A continuing education plan is to be presented for the medical and other staff (RTAs) involved in the imaging procedures, which outlines the continuing education courses planned for the period of one year.
* At least 1 dedicated continuing education course for each staff member (at least 1 day a year) who carries out quality-relevant activities for the Centre.
 |  |  |

| **4.** **Nuclear medicine**  |
| --- |
| Section | Requirements | Explanatory remarks of the Lung Cancer Centre |  |
| 4.1 | Nuclear medicine specialists* At least 1 specialist for nuclear medicine is available. Radiologists with additional training in nuclear medicine diagnostics (“Zusatzweiterbildung nuklearmedizinische Diagnostik für Radiologen”) are also recognized as specialists.
* Cover arrangements for staff with the same qualification is to be documented in writing.
* The names of the specialist and cover staff are to be given.

colour legend: Changes vis-à-vis version from 09.07.2020 |  |  |
| 4.2 | MTAs of nuclear medicine:At least 2 qualified MTAs must be available and their names given. |  |  |
| 4.3 | Procedures available in nuclear medicine:* Bone scintigraphy
* Lung scintigraphy
* ~~PET and PET-CT~~
* FDG-PET/CT

Conduct PET-CTWhen a PET-CT is to be carried out, it is to be carried out pre-therapeutically prior to curative therapy (and not post-operatively).If OMD is suspected in the primary diagnosis: PET-CT pre-therapeuticcolour legend: Changes vis-à-vis version from 09.07.2020 |  |  |
|  | Conduct of PET-CTIf a PET-CT procedure is to be conducted, it must be done prior to surgery (and not after). |
| 4.4 | Process descriptions (SOPs)The imaging techniques in nuclear medicine are to be described and checked once a year to ensure they are up to date.Special features PET-CTsA specialist for radiology must be on hand when conducting PET-CTs. |  |  |
| 4.5 | DiagnosisThe written report of the nuclear medicine specialist must be available to the co-attending doctors at the latest 24 h after the test. |  |  |
| 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* A continuing education plan for medical and other staff is to be presented listing the planned continuing education courses for the period of one year.
* At least 1 dedicated continuing education course for each staff member (at least 1 day a year) who carries out quality-relevant activities for the Centre.
 |  |  |

**5.** **Surgical oncology**

| **5.1** **Multi-organ surgical therapy**  |
| --- |
| Section | Requirements | Explanatory remarks of the Lung Cancer Centre |  |
|  | The Catalogues of Requirements of the Organ Cancer Centres and Oncology Centres have a uniform table of contents. For the Lung Cancer Centres this section does not specify any Technical and Medical Requirements. |  |  |

| 5.2 Organ-specific surgical therapy |
| --- |
| Section | Requirements | Explanatory remarks of the Lung Cancer Centre |  |
| 5.2.1 | Operating theatresAt least 1 operating theatre must be regularly available for the whole day, 7 days a week for lung surgery. |  |  |
| 5.2.2 | For each department at least 75 anatomical lung resections/year (OPS (German procedure classification): 5-323 to 5-328) are to be conducted for patients with diagnosis ICD-10: C34.0-9, C78With a share of ≤75 C34 diagnoses in the total number of anatomical resections, it must be demonstrated on a case-by-case basis that the characteristics of anatomical lung resections ("Definition Anatomical Lung Resection") are fulfilled for all surgeries performed on non-C34 patients.Definition of surgical therapy:- Anatomical resections (anatomical segment resection, lobectomy, pneumectomy, bronchio- and angioplasty).- Atypical resections (wedge resections) cannot be counted among the primary surgical cases or among the operated patients with diagnosis ICD-10: C34.0-9, C78.0.- The range of operations must be documented using the 6-digit OPS codes (OPS: 5-323 to 5-328).Definition anatomical lung resection:* Separate surgical treatment of vessels (arteries and veins) and bronchus independently of parenchyma section with documentation in the surgical report.
* Parenchymal incision along the anatomical segment
* Separate pathological examination of the resection margins: artery/ies, vein(s), bronchus, parenchyma

VATS/RATS anatomical resection in addition:* Surgical intervention video-assisted (minimal-invasive)
* Ancillary incision max. 7cm long
* No rib spreading

**With additional certification as a mesothelioma unit:**Definition surgical resection pleural mesothelioma:* Extrapleural pleuropnectomy (EPP) (OPS 5-328.6)
* Pleurectomy/ decortication (P/D) (OPS 5-344.0 and 5-344.2)

colour legend: Changes vis-à-vis version from 09.07.2020 | Details in the Data Sheet: Indicators 11a and 11bIndicator 2 - Mesothelioma(Excel template) |  |
| 5.2.3 | Thoracic surgeons for the Lung Cancer Centre:At least two full-time or a corresponding number of part-time thoracic surgery specialists working for the Lung Cancer Centre in line with the staffing schedule. The names of the specialists are to be given. |  |  |
| 5.2.4 | Curricula are used to describe the qualifications of the thoracic surgeons named in Section 5.2.3.The following parameters must be fulfilled:* Holding of a specialist title with the focus on thoracic surgery
* Proof of the following operations:

 at least 100 independently conducted lung resections with systematic lymphadenectomy after training as a specialist, including at least 15 pneumonectomies, 10 bronchio/angioplastic resections, 10 extended resections* At least 1 lung-specific specialty training course per surgeon and year
 |  |  |
| 5.2.5 | Outcome quality lung cancer:* 30-day lethality after resection < 5%
 | Details in the Data Sheet: Indicator 12(Excel template) |  |
|  | * Bronchial stump/anastomosis insufficiency< 5%
 | Details in the Data Sheet: Indicator 13(Excel template) |  |
|  | * R-0 resections in stages l and ll > 95%
 | Details in the Data Sheet: Indicator 14(Excel template) |  |
|  | * R-0 resections in stage lll > 85 %
 | Details in the Data Sheet: Indicator 15(Excel template) |  |
|  | If a number is exceeded, submission of an individual case analysis with a corresponding action plan |  |  |
| 5.2.6 | The following quality-determining processes are to be described with details of the responsibilities:* (Pre-)inpatient admission
* Therapy planning (timing pre-operative)
* Peri-operative management
* Surgery management (surgical procedures, reprocessing material, documentation)
* Post-operative pain management
* Ward management
* Discharge management

Sufficient resources must be available to conduct the processes.Average values for the waiting time between conclusion of diagnosis / registration for surgery by the practice-based physician / decision in the tumour conference and inpatient admission for surgery and post-operative time in hospital is to be recorded. |  |  |
| 5.2.7 | Continuing educationA continuing education plan for medical, nursing and other staff is to be presented listing the planned continuing education courses for the period of one year. |  |  |
| 5.2.8 | Qualifications Staff – nursing staff* at least 1 quality circle with the participation of one experienced thoracic surgery nurse
* Every year at least 1 continuing education course with a link to activity for the Lung Cancer Centre in cooperation with the medical area
 |  |  |
| 5.2.9 | Intensive medicineNumber of intensive care beds for the Lung Cancer Centre is to be given (intensive medicine and intermediate care)If the intensive medicine unit is not under the management of the Lung Cancer Centre, a cooperation agreement is to be entered into. |  |  |
| 5.2.10 | A description is to be given of the ward and the beds (monitoring). |  |  |
| 5.2.11 | The frequency of nosocomial infections is to be recorded and evaluated in accordance with the guidelines of the Robert Koch Institute (RKI) / guidelines of the Infection Protection Act (*Infektionsschutzgesetz* - IfSG).The recording does not have to be limited to the patients of the LC. Participation in a National Reference Centre KISS module lobectomy is recommended. |  |  |
| 5.2.12 | The following quality-determining processes are to be described with details of the responsibilities:* Post-operative care of lung patients
* Weaning
* Transfer to normal ward

Sufficient resources must be available to conduct the processes. |  |  |

| **6.**  **Medicinal Oncology / Systemic therapy****6.1** **Medical oncology** |
| --- |
|  | The Catalogues of Requirements of the Organ Cancer Centres and Oncology Centres have a uniform table of contents. For the Lung Cancer Centres this section does not specify any Technical and Medical Requirements. |  |  |

| **6.2**  **Organ-specific systemic therapy** |
| --- |
| Section | Requirements | Explanatory remarks of the Lung Cancer Centre |  |
| 6.2.1 | Conduct of medicinal oncological therapy (chemotherapy, anti-coagulant therapy, TKI therapy):a) Specialist for internal medicine and haematology and oncology orb) Specialist for pneumology or internal medicine and pneumology orc) Specialist for radiotherapy |  |  |
|  | The names of at least two representatives from the circle of internal specialists a) and b) are to be given for the conduct of sole systemic therapy. Specialists from group c) with corresponding qualifications can conduct medicinal oncological therapy within the framework of radio-chemotherapeutic therapy concepts.Exceptions apply to the intra-operative administration of cisplatin or other forms of local chemotherapy. They can be undertaken by the specialists for thoracic surgery in cooperation with internal medicine specialist colleagues (pneumologists, oncologists) after joint definition of the indication. |  |  |
|  | The above-mentioned specialists must prove the active conduct of medicinal tumour therapy.  |  |  |
|  | After acquisition of the specialist title, a 2-year ongoing activity in the field of oncological systemic therapy with evidence of the conduct and treatment of complications and side effects must be proven. For sole systemic therapy (for specialists a) and b)), the indication must have been made, within a 2-year period, for a total of 100 chemotherapy series consisting of on average 4-6 chemotherapy cycles, including at least 50 chemotherapy series with thoracic-oncological clinical pictures, and the information and the management of patients as well as their control and monitoring must have been undertaken and documented. |  |  |
|  | For specialists from group c) 80 patients with simultaneous radio-chemotherapy must be proven in 2 years, including at least 1/3 with thoracic-oncological clinical pictures.At the time of certification/recertification the period of proof of the above-mentioned expertise may not date back more than four years. |  |  |
| 6.2.2 | Specialist nurse / specialist medical assistant* Inpatient, day patient or clinic outpatient settings in which medicinal oncological therapies are carried out by non-medical staff must be under the specialist direction of a specialist oncology nurse. Cooperating practices are not affected by this rule.
* The preconditions for the specialist nurse / specialist medical assistant who is responsible for administering chemotherapy:
* at least 1 year's professional experience in oncology
* 50 chemotherapy administrations (for initial certification an estimate is possible, in the ensuing years proof must be provided.)
* Proof 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
* Documentary proof is to be provided of care counselling and/or education of patients.
 |  |  |
| 6.2.3 | The Centre must offer the following procedures:* Chemotherapy (neoadjuvant, adjuvant, palliative), including supportive therapy
* Systemic therapies with targeted therapeutics (monoclonal antibodies, angiogenesis inhibitors, what are known as "small molecules") also in combination with systemic chemotherapy
* Combined radio-chemotherapy, (sequential and simultaneous) including supportive therapy

Responsibilities must be clearly defined for all procedures. Descriptions of the procedures must be available.A list must be kept of all necessary equipment. |  |  |
| 6.2.4 | Qualification of the respective treatment unit (clinical department or practice-based physicians)a) 150 drug therapies for tumours (cytostatic therapies and/or targeted therapeutics and/or AB/immune therapies, no hormone therapies) a year with lung carcinoma patients orb) 50 drug therapies for tumours (cytostatic therapies and/or targeted therapeutics and/or AB/immune therapies, no hormone therapies) a year for primary cases of the Centreor200 drug therapies for tumours (cytostatic therapies and/or targeted therapeutics and/or AB/immune therapies, no hormone therapies) in total(various tumour entities)* Counting method: completed systemic/cytostatic/ targeted therapy per patient (consisting of **several** cycles or applications, combination therapies count as 1 therapy). In the case of multi-year therapies, the therapy started in the year of the collection of data counts. 1 therapy per patient = 1 therapy line per disease per patient
* If the value falls below this level, expertise cannot be proven through cooperation (to be demonstrated individually by each treatment unit).
 |  |  |
|  | For simultaneous radio-chemotherapy by radio-oncologists the following applies:At least 30 lung cancer patients with simultaneous thoracic radio-chemotherapy/year. |  |  |
| 6.2.5 | Process descriptions* The procedure for medicinal oncological therapy is to be described for all phases (start, conduct and conclusion of therapy).
* Supportive measures in line with the guidelines are to be described for the individual therapeutic concepts (e.g. antiemesis, procedure in cases of anaemia, mucosal and dermal toxicity, administration of growth factors, bisphosphonates, nutrition, handling port systems) and documented for each patient.
 |  |  |
| 6.2.6 | Standards comorbidities and secondary diseasesStandards are to be drawn up for the treatment of comorbidities and secondary diseases, in particular for the treatment of extravasations, infections and thromboembolic complications. |  |  |
| 6.2.7 | Emergency treatmentAvailable emergency equipment and written action plan for emergencies |  |  |
| 6.2.8 | Chemotherapy must be possible in an outpatient centre, day clinic or in an inpatient facility. |  |  |
| 6.2.9 | Cytostatic preparation* The preparation of the cytostatic solutions by the pharmacy must be possible within 48h (where necessary in cooperation)
* Preparation is done with due consideration of all statutory provisions.
* It must be possible to speak to the unit responsible for preparation during the period in which the therapy is administered.
* Procedural description is available for preparation.
 |  |  |
| 6.2.10 | Medicinal therapy in the metastasised situation* The procedures for the care (diagnosis/therapy) of patients with local recurrence/metastasis are to be described (presentation of the patient pathways).
* A regular toxicity assessment of therapy must be undertaken using selected and documented measurement parameters (symptoms, indicator metastasis, or the like).
* An evaluation of the therapeutic effect must be documented for each patient every 3 months.
 |  |  |
|  | In the case of stage IV NSCLC patients a PD-L1 expression assay is to be carried out prior to commencement of medicinal systemic therapy. |  |  |
| 6.2.11 | Information / dialogue with the patientAdequate information must be provided about diagnosis and therapy planning and this must be explained to the patient during a medical consultation. This includes *inter alia*:* Presentation of alternative treatment concepts
* Offer of and aid in obtaining second opinions
* Discharge consultation as a standard procedure

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. |  |  |
| 6.2.12 | Continuing education* A continuing education plan for medical and nursing staff is to be presented listing the planned continuing education courses for the period of one year.
* At least 1 dedicated continuing education course for each staff member (at least 1 day a year) who carries out quality-relevant activities for the Centre.
* The continuing education programmes indicated by pneumological, thoracic surgery, radiotherapy and internal-oncological working groups for Lung Cancer Centres should be part of the continuing education (currently being prepared)
 |  |  |

| **7** **Radio-oncology** |
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| Section | Requirements | Explanatory remarks of the 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 per 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 Radio-Oncology" on [www.ecc-cert.org](http://www.ecc-cert.org) and [www.onkozert.de](http://www.onkozert.de/). |  |  |

**8** **Pathology**

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| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks of the 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 per 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 Pathology" on [www.ecc-cert.org](http://www.ecc-cert.org) and [www.onkozert.de](http://www.onkozert.de/). |  |  |
| 8.4 | **In the case of additional certification as a mesothelioma unit:**One of the pathology specialists appointed for the LZ must provide evidence of at least 10 histological diagnoses of mesothelioma per year. If the minimum requirement is not met, all diagnoses must be made in cooperation with the external reference pathologist. |  |  |

| **9.** **Palliative care** |
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| Section | Requirements | Explanatory remarks of the Lung Cancer Centre |  |
| 9.1 | Palliative care* Proof is to be provided of cooperation agreements with specialised inpatient and outpatient palliative care teams, palliative medicine consultation services, inpatient hospices and palliative wards. 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 Guideline Palliative Medicine (Figure 3, p. 174) with the names of all involved persons.
* A physician with additional specialty training must be available for consultations and tumour conferences.
* The group of patients with incurable cancer is to be defined. They are to be informed in a timely manner about palliative medical support services (SOPs). (S3 Palliative Medicine Guidelines)
* To identify the need for treatment, it is necessary to carry out a screening to record symptoms and stress (see S3 guideline Palliative Care) (MIDOS or IPOS).
* Access to palliative care is to be offered to patients with an incurable cancer disease in parallel to tumour-specific therapy. The procedure in the Centre is to be described in a standard operating procedure (SOP).
* The number of primary cases with an incurable cancer disease is to be documented.
* Palliative counselling and care should be offered within the first 2 months of diagnosis of an incurable cancer disease.
 |  |  |
| 9.2 | The Centre must offer the following palliative therapies:* Pleurodesis procedure (conservative by means of drainage and invasive procedures involving thoracoscopy)
* Palliative pain therapy
* Long-term oxygen therapy

Responsibilities must be clearly defined for all procedures. Descriptions of the procedures must be available.A list must be kept of all necessary equipment. |  |  |

| **10.** **Tumour documentation / Outcome quality** |
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| Section | Requirements | Explanatory remarks of the Lung Cancer Centre |  |
| 10.1 | Requirements tumour documentationTumour 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 a 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 must be used in line with the uniform basic oncological data set and modules of the Working Group of German Tumour Centres (*Arbeitsgemeinschaft Deutscher Tumorzentren* - ADT) and the Association of Population-based Cancer Registries in Germany (*Gesellschaft der epidemiologischen Krebsregister in Deutschland e.V.* - GEKID).The Centre must ensure that the data transfer to the competent cancer registry is done in a timely manner. Any existing federal state laws for notification deadlines are to be complied with. |  |  |
| 10.4 | Cooperation with cancer registries* Cooperation with the competent 65c-cancer registry is to be documented in a cooperation agreement ([www.tumorzentren.de](http://www.tumorzentren.de)).
* The full data are to be made available to the cancer register in an ongoing manner.
* The presentation of the Data Sheet and outcome quality should be ensured through 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 register is unable to meet the requirements imposed, the Centre is to use additional or alternative solutions. The Centre is responsible in the case of a non-functioning external solution.
 |  |  |
| 10.5 | Documentation officerAt least 1 documentation officer is to be appointed who bears responsibility 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
* Ensuring and monitoring the timely, complete and correct recording of patient data
* Qualification and support for the staff involved in data collection
* Regular analysis of the assessments particularly over the course of time
 |  |  |
| 10.6 | Provision of resourcesThe required staff capacity should be made available (guidance value: 0.5 full-time position for 200 primary cases, 0.1 full-time position for 200 aftercare cases) for documentation and data recording tasks (e.g. through a cancer register). |  |  |
| 10.7 | The following selection options must be possible at least for the tumour documentation system:* Years
* TNM classification or comparable classification
* Forms of therapy (surgical therapy, radiotherapy, hormone therapy, immunotherapy, chemotherapy)
* Date of the recurrence/metastasis
* deaths
* Follow-up status (latest update)
 |  |  |
| 10.8 | Tumour-specific indicators of outcome qualityKaplan-Meier curves:* Overall survival (OAS) for all patients in

sub-groups according to pT categories, c+p stages* Local recurrence-free survival for all surgical patients and sub-groups
* Post-progression survival (PPS)

A table with patient numbers and survival data is a component of each Kaplan-Meier curve. Organ-specific detailed requirements are compiled in the annex to the matrix outcome quality |  |  |
| 10.9 | Data evaluation* The evaluations for the indicators of outcome quality (see point above) must be possible for recertification.
* The data in the tumour documentation system are to be evaluated at least once a year.
* If benchmarking is offered, the results of benchmarking are to be taken into account in the analysis.
* The results must be discussed in an interdisciplinary manner. If there are any regional or national networks, they are to be participated in.
 |  |  |
| 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)Functioning cancer registers constitute the follow-up status.Where this option is not available, work will be undertaken on a regional solution together with the Centres, ADT, DKG and the respective government agencies.The follow-up status includes:any progressions (local recurrences, where appropriate regional lymph node recurrences, distant metastases, at least for the first progression)secondary malignancydeathslives currently at the addressTermination of follow-up (e.g. moves away from catchment area, federal region) |  |  |
| 10.11 | Requirements to be met by follow-up of the patients recorded in the tumour documentation system |  | From 1 January 2015 |  |  |
| Minimum requirement for successful recertification |  | ≥ 80 % |  |  |
| Recertification or maintenance of certification only possible subject to conditions (e.g. reduced validity term, concept for increasing the return rate...). |  | Up to 79% |  |  |

**Data Sheet / Matrix outcome quality**

An EXCEL template is available to Centres to record the indicators and data on outcome quality. This EXCEL template 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 EXCEL template made available by OnkoZert. The EXCEL template may not be changed.

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