**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. D. Ukena

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| * ADT - Association of German Tumour Centres * AIO - Working Group for Internal Oncology * AOP - Working Group for Oncological Pathology * AOT - Working Group for Oncological Thoracic Surgery * 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 * BVDST - German Professional Association of Radiation Therapists * BNHO - Association of Practice-based Haematologists and Oncologists in Germany * BDP - Federal Association of Pneumologists in Germany * CAO - Surgical Working Group for Oncology * CAO-V - Surgical Working Group for Oncology - Visceral Surgery * DGHO - German Association of Haematology and Oncology * DGP - German Society for Palliative Medicine * DGP - German Society for Pathology * DGP - German Respiratory Society * DEGRO - German Society for Radiation Oncology * DRG - German X-Ray Society * DGT - German Society of Thoracic Surgery * DVSG - German Association of Social Work in Health Care * KOK - Conference on Oncological and Paediatric Oncological Care * NOA - Neuro-oncology Working Group * POA - Pneumological-Oncological Working Group   **Entry into force on 18 July 2018**  This Catalogue of Requirements (CR) is binding for all audits conducted from 1 January 2019. The changes made to the version valid in the audit year 2018 are highlighted in "turquoise" in this Catalogue of Requirements.  Consideration was given to:  Interdisciplinary S3 Guidelines of the German Society for Pneumology and the German Cancer Society "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 2019 (DIMDI) and the OPS classification OPS 2019 (DIMDI) |

**Details of the Lung Cancer Centre**

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| Lung Cancer Centre (LC) |  |
| Head 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 (clinic/place) - Pneumology |  |  |  |  |  |
| only for cooperating LCs |  |  |  |  |  |

**QM system certification**

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| QM system certification |  | yes |  | no |

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

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

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| Certification body for QM |  |

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**Network/Main cooperation partners**

The Centre's cooperation partners are registered in a master data sheet with the certification agency 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 the head, contact data) must be corrected in the master data sheet prior to the annual surveillance audit. The master data 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 |  |

**Table of Contents**

1. General details of the Lung Cancer Centre
   1. Structure of the network
   2. Interdisciplinary cooperation
   3. Cooperation referrers and aftercare
   4. Psycho-oncology
   5. Social work and rehabilitation
   6. Patient involvement
   7. Study management
   8. Nursing care
   9. General service areas (pharmacy, nutritional counselling, speech therapy...)
2. Organ-specific diagnostics
   1. Consulting hours
   2. Diagnostics
3. Radiology
4. Nuclear medicine
5. Surgical oncology
   1. Cross-organ surgical therapy
   2. Organ-specific surgical therapy
6. Medicinal oncology / Systemic therapy
   1. Medical oncology
   2. Organ-specific systemic therapy
7. Radio-oncology
8. Pathology
9. Palliative care and hospice work
10. Tumour documentation / Outcome quality

Annex:

Data sheet / Matrix outcome quality  
(Excel template)

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

| **1.1**  **Structure of the network** | | | |
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| 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 |  |  |
|  | 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 models  Cooperation 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. * Possible exception: * If 1 clinic head has represented 2 departments since at least 1 January 2011, one of the two departments must independently meet the surgical case numbers, the 2nd department at least 50% (>= 38 anatomical lung resections)   Multi-location Lung Cancer Centre  With maximum three pneumology departments, a clinic for thoracic surgery can form a multi-location LC when at least 100 primary cases/year are proven for each pneumology department (definition in accordance with CR 1.2.1). |  |  |
|  | Independent Lung Cancer Centre – Cooperation thoracic surgery  A 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. |  |  |
|  | Precondition for multi-location cooperation models:   * Joint tumour conference * The Technical and Medical requirements and performance indicators must be separately met and proven for each location. * Prior structural assessment by OnkoZert is necessary |  |  |
|  | 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. |  |  |
| 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   The following points are to be dealt with 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 | 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. |  |  |
| 1.1.5 | 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. |  |  |
| 1.1.6 | Contact partners of the Lung Cancer Centre  The 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. |  |  |
| 1.1.7 | The funding body/bodies of the Lung Cancer Centre make sufficient funds / resources available in order to meet the staffing, spatial and material requirements |  |  |
| 1.1.8 | 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 |  |  |
| 1.1.9 | The LC should have a certified QM system (ISO 9001, KTQ, PCC, JC etc.) which is continuously developed. |  |  |

| **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 case of the Centre:   * All patients with newly diagnosed or not yet pretreated/treated 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 * Two primary cases with metachronous treatment of bronchial carcinomas * Synchronous tumour in another tumour entity can be counted as a primary case for each tumour entity   Colour legend: change vis-à-vis the version dated 27.09.2017 | Details in the Data Sheet:  Basic data / Indicator 1 (Excel template) |  |
|  | 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 (Def. surgical spectrum CR 5.2.2 | Details in the Data Sheet:  Basic data / Indicator 1 9a and 9b (Excel template) |  |
| 1.2.3  a) | Cycle  The 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. |  |  |
| b) | Participants tumour conference  The main treatment partners (Section 1.1.1.) regularly attend the 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 ~~engaged in palliative activities~~ (neurology, neurosurgery, surgery, pain therapy, orthopaedics, etc.) are to be included in the tumour conference.  Colour legend: change vis-à-vis the version 27.09.2017 |  |  |
| c) | Preparation tumour conference The 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 material Any 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) | Minutes  The 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 conference  All 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. |  |  |
| 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   Colour legend: change vis-à-vis the version 27.09.2017 | 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 therapy If, 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 planning  On 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. |  |  |
| 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. |  |  |
| 1.2.11 | Requirement Systemic therapy   * Cisplatin-based chemotherapy * Combined radio-chemotherapy | Indicator 19 (Excel template)  Indicator 20 (Excel template) |  |

| **1.3** **Cooperation referrers and aftercare** | | | |
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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 | Contacts  The Centre's contacts are to be given to the referrers in line with their function (e.g. telephone number, email). |  |  |
| 1.3.3 | Medical reports  Medical 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 system  A 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 survey  Every 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 education  The 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 or * Physicians   with psychotherapeutic specialty training  and psycho-oncological continuing education (see below) (Proof required)  Staff cover arrangements are to be documented in writing.  The representatives of other psychosocial professional groups (like qualified pedagogues, social workers, etc.) can be approved on presentation of the above-mentioned psycho-oncological qualifications. In this case the qualification is to be presented in a curriculum (initial, further/specialty training, psycho-oncological experience) that undergoes individual examination.  The assumption of psycho-oncological tasks by the social services, self-help groups or pastoral care is not sufficient.  Recognised training courses  "Specialty training in psychosocial oncology" recognised by the Working Group for Psycho-Oncology (PSO) or dapo or other adequate continuing education with a volume of > 100 teaching units |  |  |
| 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 (instrument e.g. see S3 Guidelines Psycho-Oncology, and the result is to be documented.  Scope of treatment  Patients who have received psycho-oncological support are to be documented. The frequency and duration of the sessions is to be recorded. |  |  |
|  | Number of patients who received psycho-oncological support (duration of session > 25 minutes) | Indicator 4 (Excel template) |  |
| 1.4.3 | Psycho-oncology resources  at least 0.5 full-time staff members are available to the Centre (names are to be given), recommendation: 0.5 full-time staff members per 200 primary cases |  |  |
| 1.4.4 | Premises A suitable room is to be provided for psycho-oncological patient consultations. |  |  |
| 1.4.5 | Organisation plan  If 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 – tasks  The 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. |  |  |

| **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  Resources:  For patient counselling in the Centre at least 1 full-time staff member is available for 400 counselling sessions for patients of the Centre (primary cases, secondary metastasis, recurrence)  Staff cover arrangements for holidays and sickness must be documented.  Premises:  A suitable room is to be provided for social counselling work.  Organisation plan:  If the social service provides its services for several specialty units or sites, 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 vis-à-vis the version 27.09.2017 |  |  |
| 1.5.2 | Social work – Offer and access  Each 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 and be open to the patient for the entire duration of treatment. This also includes information about rehabilitation options.  Counselling social services:  Cancer patients who have received support from the social services are to be documented. |  |  |
|  | Number of patients who received counselling from the social services. | Indicator 5 (Excel template) |  |
| 1.5.3 | Tasks of psychosocial counselling   * Identification of social, economic and mental health emergencies * Elaboration of perspectives and solutions of relevance for daily life bearing in mind personal and social factors, the patient's wishes and available resources * Advice on the options of rehabilitation and participation, initiation 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 when selecting services * Advice on outpatient and inpatient treatment options * Referral to support offerings, specialised services, care services and self-help groups * Support for professional and social reintegration * Cooperation with service funding agencies and service providers, counselling centres * Intervention in emergencies * Help with transfer to/placing in palliative care facilities and hospice care (outpatient / inpatient) |  |  |
| 1.5.4 | Further tasks:   * Multi-professional cooperation particularly with physicians, nursing staff, psychologists, physiotherapists, pastoral services *inter alia* * Participation in ward conference, social visits and tumour conferences * Participation in supervision * Public relations * Participation in the setting up and further development of oncological networks   Documentation and evaluation   * The activity of the social services is to be documented in full compliance with data protection (outpatient/inpatient case numbers, focus of counselling, family members, etc., for example with specific dedicated software) * The exchange of information with other professional groups is to be ensured. * The quota of counselled patients is to be recorded. * Evaluation is recommended every 2 years. |  |  |
| 1.5.5 | Continuing education  1 continuing education course for each staff member (every year at least 2 days or 15 hours) Contents: basic oncological knowledge, social law, psychosocial counselling expertise, knowledge of the relevant care structures |  |  |

| **1.6** **Patient involvement** | | | |
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| 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 consultation  Each 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 conference  Patient 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 patients  The 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 groups |  |  |
| 1.6.7 | Complaint management  An official procedure for complaint management is in place. The patients are given feedback. Complaints are taken into account in the improvement process. |  |  |
| 1.6.8 | Self-help groups  The 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 groups  Written 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** | | | |
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| Section | Requirements | Explanatory remarks of the Lung Cancer Centre |  |
| 1.7.1 | Access to studies The patient must have access to studies. The studies conducted at the Lung Cancer Centre must be listed and published, for instance on the Centre's homepage. |  |  |
| 1.7.2 | Study manager  The name of the physician in charge of the study is to be given. |  |  |
| 1.7.3 | Study assistant /study nurse  A study nurse /study assistant should be available for initial certification (mandatory after 3 years).  He/she can work in a parallel manner for several "units conducting studies".  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 description The 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 | Details in the Data Sheet: Indicator 6  (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 Centre'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.   Colour legend: change vis-à-vis the version 27.09.2017 |  |  |

**List of Studies**1)

|  |  |  |  |
| --- | --- | --- | --- |
| Responsible cooperation partner 2) | | Study name | Number of  centre’s patients  recruited in 20173) |
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|  | |  |  |
|  | |  |  |
|  | Numerator: Indicator no. 14 „study quota “ | |  |

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 ~~be active~~ 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.V.* - DKG) * or Advanced Practice Nurse (master title) plus 2 years’ practical oncological occupational experience (full-time equivalent)   Colour legend: change vis-à-vis the version 27.09.2017 |  |  |
| 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)   Colour legend: change vis-à-vis the version 27.09.2017 |  |  |
| 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.  Colour legend: change vis-à-vis the version 27.09.2017 |  |  |
| 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. |  |  |

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

| **2.1**  **Consulting hours** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks of the Lung Cancer Centre |  |
| 2.1.1 | Lung consulting hour  On 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. |  |  |
| 2.1.3 | How long are the waiting times for an appointment  Requirement: < 2 weeks  Emergency 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 final diagnosis (communication of histological result to patient): < 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 patient  Adequate 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. 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)   Colour legend: change vis-à-vis the version 27.09.2017 | 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 (1620.1x9 |  |  |
|  | * 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 in  endoscopic/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 | Diagnosis  The 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. * 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. |  |  |
| 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   Conduct PET-CT  When a PET-CT is to be carried out, it is to be carried out pretherapeutically ~~must be carried out preoperatively~~ prior to curative therapy (and not post-operatively).  Colour legend: change vis-à-vis the version 27.09.2017 |  |  |
|  | Conduct of PET-CT  If 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-CTs  A specialist for radiology must be on hand when conducting PET-CTs. |  |  |
| 4.5 | Diagnosis  The 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 members  Systematic, documented induction of new staff members is to be ensured, which imparts knowledge about the Oncology Centre's respective field of activity.  This induction must take place within three months of commencement of employment. |  |  |
| 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** **Cross-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 theatres  At 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 diagnosed with cancer.  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   Colour legend: change vis-à-vis the version 27.09.2017 | Details in the Data Sheet: Indicators 9a and 9b  (Excel template) |  |
|  | * The share of pneumectomies may amount to at most 25% of the resections mentioned. | Details in the Data Sheet: Indicator 10  (Excel template) |  |
|  | * Bronchio/angioplasty surgeries must account for a share of 10%. | Details in the Data Sheet: Indicator 11 (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:   * 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) |  |
|  | * Revision surgery in < 10% of cases | Details in the Data Sheet: Indicator 14 (Excel template) |  |
|  | * R-0 resections in stages l and ll > 95% | Details in the Data Sheet: Indicator 15  (Excel template) |  |
|  | * R-0 resections in stage lll > 85 % | Details in the Data Sheet: Indicator 16 (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 education  A 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 medicine  Number 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~~ | ~~For post-operative ventilated primary cases the average post-operative length of stay (in d) and the average post-operative ventilation duration (in h) on the intensive care ward are to be indicated (minimum, maximum, median).~~ |  |  |
| 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** | | | |
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|  | 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 or  b) Specialist for pneumology or internal medicine and pneumology or  c) 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 * ~~At least~~ 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.   Colour legend: change vis-à-vis the version 27.09.2017 |  |  |
| 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 * ~~Simultaneous~~ 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.  Colour legend: change vis-à-vis the version 27.09.2017 |  |  |
| 6.2.4 | Qualification of the respective treatment unit (clinical department or practice-based physicians)  a) 150 systemic therapies (chemotherapy series, therapies with targeted therapeutics, immunotherapies) a year with lung carcinoma patients or  b) 50 systemic therapies a year for primary cases of the Centre  or 200 chemotherapy series in total (various tumour entities) |  |  |
|  | 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 diseases  Standards 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 treatment  Available 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.   Colour legend: change vis-à-vis the version 27.09.2017 |  |  |
| 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. |  |  |
| neu | 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.  Colour legend: change vis-à-vis the version 27.09.2017 |  |  |
| 6.2.11 | Information / dialogue with the patient  Adequate 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.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.onkozert.de](http://www.onkozert.de/). |  |  |

| **9.** **Palliative care** | | | |
| --- | --- | --- | --- |
| 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) * For these patients symptoms and strains are to be repeatedly recorded using validated tools (e.g. MIDOS, iPOS). * Access to palliative care ~~can~~ 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.   Colour legend: change vis-à-vis the version 27.09.2017 |  |  |
| 9.2 | Supportive therapy and symptom alleviation in the palliative situation   * The options of supportive/palliative inpatient therapy are to be described (process description / algorithm). * A pain therapist must be available. The pain therapy process (algorithm) is to be described and proven using documented cases for the assessment period. Pain therapy expertise:   50 / year in patients with a lung carcinoma  100 / year in total |  |  |
| * Access to nutritional counselling is to be described and proven using documented cases for the assessment period. * Access to psycho-oncological, psychosocial and pastoral care is to be described.   If provided by cooperation partners, a cooperation agreement is to be entered into for the above requirements. |
| 9.3 | 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** | | | | | |
| --- | --- | --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks of the Lung Cancer Centre | | |  |
| 10.1 | Requirements tumour documentation  Tumour 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 data  The full data are to be presented for the respective last calendar year. |  | | |  |
| 10.3 | Requirements to be met by tumour documentation  A 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 ~~input~~ transfer to the competent cancer registry is done in a timely manner ~~after completion of primary therapy (radiotherapy/chemotherapy).~~ Any existing federal state laws for notification deadlines are to be complied with.  Colour legend: change vis-à-vis the version 27.09.2017 |  | | |  |
| 10.4 | Cooperation with cancer~~/tumour~~ 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 ~~requirements for~~ presentation of the Data Sheet and outcome quality a~~nd tumour documentation~~ should be ~~covered~~ ensured through the cancer~~-/tumour~~ 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 ~~clinica~~l 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.   Colour legend: change vis-à-vis the version 27.09.2017 |  | | |  |
| 10.5 | Documentation officer  At least 1 documentation officer is to be appointed who bears responsibility for the tumour documentation.  Name/Function:  The documentation officer has the following tasks:   * ~~Verification of~~ 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 ~~interdisciplinary documentation~~ * 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 resources  The 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 ~~regional clinical~~ 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 quality  Kaplan-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. * ~~The published data of the quality report in line with Section 137, fifth book of the Social Code (SGB V) are, when requested, to be checked for comparability and proof provided of a corresponding evaluation.~~ * If benchmarking is offered, the results of benchmarking/~~annual report~~ are to be taken into account in the analysis. * ~~The analysis of each completed age cohort is to be recorded in a short protocol with details of any concrete action taken (examination of selected casuistics e.g. with local recurrences~~ *~~inter alia~~* ~~with regard to treatment in conformity with the guidelines.)~~ * 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-up  Details are to be given of how aftercare data are collected and what the current follow-up status is (see outcome matrix)  Functioning ~~clinical~~ 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 malignancy  deaths  lives currently at the address  Termination 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/)