**Catalogue of Requirements Pathology**

This "Catalogue of Requirements (CR) Pathology" sets out the requirements which must be met by the cooperation partner pathology in Oncology Centres and/or Organ Cancer Centres certified by the German Cancer Society (*Deutsche Krebsgesellschaft* - DKG). The Catalogue of Requirements Pathology is, therefore, an annex to the Catalogue of Requirements Oncology Centres and organ-specific Catalogues of Requirements. This means the presentation in the organ-specific Catalogues of Requirements will, therefore, be replaced from the audit year 2017.

|  |  |
| --- | --- |
| Name of the Institute 1) 2) |  |
| Head of the Institute |  |
| Contact certification |  |
| Address |  |
| Tel. |  |
| Email |  |

|  |  |
| --- | --- |
| 1) | Definition clinical site: The clinical site is determined by the address. 1 clinical site is 1 cooperation partner of the Centre, irrespective of any existing different organisational/legal forms (private practice, part of the clinic, medical care centres…). In the registration as a cooperation partner only 1 name may be used (artificial name is possible from a combination of the legal forms). |
| 2) | Details of any additional existing frozen section laboratories are to be given on the next page. |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | OC |  | BC |  | GC |  | CC |  | LCC |  | GCC |  | PAN |  | ESO |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | HC |  | SC |  | HNT |  | PED |  | LC |  | NOC |  | PC |  | SAR |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | KID |  | BLA |  | TCC |  | ACC |  |  |  |  |  |  |  |  |

|  |  |  |
| --- | --- | --- |
| **Preparation / Updating of the Catalogue of Requirements Pathology** |  |  |
| **List of Abbreviations**   * **Oncology Centre** = OC; **Visceral Oncology Centre** = VC; **Uro-oncology Centre** = UC * **Organ Cancer Centres:** BC = Breast Cancer Centre, CC = Colorectal Cancer Centre, GC = Gynaecological Cancer Centre,HC= Centre for Haematological Neoplasia, SC = Skin Cancer Centre, LC = Lung Cancer Centre, PCC= Prostate Cancer Centre * **Modules:** ACC = Anal Cancer Centre, HNT = Head and Neck Tumour Centre, LCC = Liver Cancer Centre, GCC = Gastric Cancer Centre, NOC = Neuro-oncology Centre, PAN = Pancreatic Cancer Centre, PED = Paediatric Cancer Centre, ESO = Esophageal Cancer Centre, SAR = Soft Tissue Sarcoma Centre; KID = Kidney Cancer Centre; BLA = Bladder Cancer Centre, TCC = Testicular Cancer Centre | | |

**Entry into force on 28 September 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 years 2022 are highlighted in "green" in this Catalogue of Requirements.

**Multi-site Pathology Institute (network structure)**

The Catalogue of Requirements refers to 1 clinical site. Pathologies, which encompass (eventually “serve”) multiple clinical sites (= network), must process the Catalogue of Requirements for each clinical site. Only frozen section facilities do not constitute a clinical site within the meaning of certification.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Clinical site of a network |  |  | yes |  |  | no | If "no", then the following information is not relevant. |

|  |  |
| --- | --- |
| Name of the network |  |

|  |  |
| --- | --- |
| Comments on the network (optional) |  |

|  |  |  |
| --- | --- | --- |
| No. | Name of the clinical sites in the network which participate in the certification system 3) 4) | Address (street name, postal code and city) |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |
| 4 |  |  |
| 5 |  |  |

|  |  |
| --- | --- |
| 3) | if there is a main clinical site, it should be mentioned first. |
| 4) | Meeting all certification-relevant requirements; no frozen section laboratories |

**Structural data on the clinical site**

**A. Organisational structure (multiple responses possible)** 5)

|  |  |  |
| --- | --- | --- |
|  |  | Clinic department |
|  |  |  |
|  |  | (sub-area) medical care centre |
|  |  |  |
|  |  | Independent institute |

|  |  |
| --- | --- |
| 5) | Mixed forms 🡪 Multiple responses possible; indicate lead organisation structure with an "X" and other structural forms with an "n" |

**B. Funding body structure / Legal form (multiple responses possible)**

|  |  |  |
| --- | --- | --- |
|  |  | Public hospital funding body |
|  |  |  |
|  |  | Church hospital funding body / not-for-profit |
|  |  |  |
|  |  | Private hospital funding body |
|  |  |  |
|  |  | Owner-managed by doctors |

**Structural data on the clinical site**

**C. QM documentation of the clinical site** (if available)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| QM standard |  | ISO 9001 |  | KTQ / proCum Cert |  | Joint Commission |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| DAKKS accreditation(in line withDIN EN ISO 17020) |  | yes |  | no |

|  |  |  |  |
| --- | --- | --- | --- |
| Initial accreditation |  | Certificate valid up to |  |

**D. Scope of the Catalogue of Requirements / Participation tumour board**

| **Clinical site / hospital** | **Organs (C/M)** 6) 7) | **Timepoint / Cycle Tumour board** | **Attendance Tumour bord in %** |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

|  |  |
| --- | --- |
| 6) | If several pathology institutes are named as cooperation partners for a certified Organ Cancer Centre/Module (C/M), participation in at least one in every four tumour board is sufficient. |
| 7) | "List of abbreviations" of organs on page 1 of the Catalogue of Requirements |

**E. Frozen section laboratories**

|  |  |  |
| --- | --- | --- |
| No. | Frozen section laboratories 8) | Address (street, postal code and city) |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |
| 4 |  |  |

|  |  |
| --- | --- |
| 8) | related to the one clinical site of the Pathology Institute to which this Catalogue of Requirements refers; hence, any other frozen section laboratories do not have to be mentioned here |

**F. Molecular pathology**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Molecular pathology on site |  | yes |  | no |

If molecular pathology is performed in cooperation, the cooperation partners for molecular pathology are to be listed below (multiple entries possible).

|  |  |  |
| --- | --- | --- |
| No. | Molecular pathology | Address (house number, street, postal code and place) |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |
| 4 |  |  |

| **8.1** **Interdisciplinarity** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Pathology |  |
|  | Cooperation agreement  When the cooperation partners of a Centre work under a funding body or at a clinical site, no written agreements are needed (nonetheless the implementation of the following points must be ensured).  The following points are to be dealt with:  (see also "Template Cooperation Agreement")   * Description of the treatment processes of relevance for the Centre bearing in mind the interfaces * Obligation to implement indicated guidelines * Description of cooperation on tumour documentation * Declaration of willingness to cooperate on internal/external audits * Undertaking to comply with the relevant DKG criteria and the annual submission of the relevant data * Upholding of medical confidentiality * Participation in continuing education/specialty training schemes and public relations work * Declaration of consent to be publicly identified as part of the Oncology Centre (e.g. homepage) |  |  |
|  | Tumour board   * Binding participation Pathology * Ensuring availability specialist level * Participation and consensus provisions in the case of more than 1 cooperation partner per specialty (see also provisions "Interdisciplinary cooperation") |  |  |
| SC | Participation Pathology/Dermatohistology optional |  |  |
|  | Demonstration visual material Patient-related images (e.g. pathology, radiology) must be available at the conference and suitable technical equipment must be provided for the presentation of this visual material. A computer-aided presentation is sufficient. |  |  |
|  | **Organ-specific characteristics** |  |  |
| BC | Discussion of special cases  Special cases are discussed in the quality rounds and/or the interdisciplinary tumour boards. |  |  |

| **8.2** **Case numbers per Pathology Institute** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Pathology |  |
|  | Case numbers Pathology Institute  At least 10,000 histologies/year (case numbers, documentation via journal no.) |  |  |
|  | **Organ-specific characteristics** |  |  |
| GC | * Every year at least 100 histologies of cases of genital malignancies (i.e. invasive neoplasias of female genitals and BOT) (requirement in section OP) |  |  |
| CC | * Ever year at least 50 histologies of colon/rectum biopsies * Ever year at least 50 histologies of colon/rectum specimens |  |  |
| ACC | At least 10 histologies of anal biopsies or resections of anal cancer per year. |  |  |
| LCC | Every year at least 10 LCC histologies |  |  |
| GCC | Every year. at least 30 histologies of gastric carcinomas/ AEG |  |  |
| PAN | Every year at least 12 pancreatic surgery histologies |  |  |
| ESO | Every year at least 30 neoplastic esophageal histologies (incl. HDG, HGIEN) |  |  |
| SC | Dermatohistological/pathological experience   * Ever year at least 250 histologies of malignant skin tumours (not only primary cases) * Experience in the examination of lymph nodes (all tumour entities): every year at least 100 histologies of lymph nodes   (The examination of lymph nodes after a lymphadenectomy (LAD) must be carried out by a pathology specialist.  If necessary, this can also be done within the framework of a second diagnosis by a specialist in dermatology with additional qualification in dermatohistology.  Sentinel for skin tumours: assessment by a dermatology speialist with the additional designation “dermatohistology” or pathology specialist) |  |  |
| MB | At least 50 malignant urinary bladder tumours a year |  |  |
| MN | At least 30 malignant kidney tumours a year |  |  |
| NOC | Case numbers Institute/Department of Neuropathology  Every year at least 1,000 histological, including cytological and immunohistochemical tests (case numbers, documentation via journal no.) |  |  |
| SAR | Yearly at least 100 sarcoma histologies in line with the range of care (according to diagnostic list in the Data Sheet). Documented double diagnosis is recognised. |  |  |
|  | Changes compared to version of 14.12.2021 |  |  |

| **8.3** **Specialists - Number / Qualifications** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Pathology |  |
|  | **Oncology Centres**   * At least 3 pathology specialists (board pathologists) when the Oncology Centre is handled by only 1 pathology institute * Otherwise, the following applies: At least 2 pathology specialists for each institute involved |  |  |
|  | Head   * Pathology specialist (Board pathologist)   Requirements (desirable)  Authorisation for specialty training in the field of pathology. |  |  |
|  | **Organ Cancer Centres/Modules**   * At least 2 qualified pathology specialists |  |  |
|  | **Organ-specific characteristics Module:** |  |  |
| BC | Qualifications specialist   * Histological assessment of mammary tissue samples * Assessment of tissue from other parts of the body * Cytology specimens from the serous cavities, aspiration cytology specimens * Qualified cover staff provision is ensured. * Experience with preparation of the sentinel lymph node in line with current valid Guidelines * Experience with preparation of tissue samples from the breast and axillary lymph nodes in line with the S3 Guideline on Early Detection, Diagnosis, Treatment and Aftercare of the mammary carcinoma. * Knowledge of the quality indicators laid down in the Guidelines |  |  |
| SC | Specialists   * At least 1 dermatology specialist with the additional qualification "dermatohistology" and 1 pathology specialist   or   * 2 pathology specialists |  |  |
| HNT | Specialists   * At least 1 pathology specialist out of the total number of pathologists at the Oncology Centre * Provision of cover staff with the same qualification is to be documented in writing. |  |  |
| PED | Specialists   * A pathology specialist, who is the contact person for paediatric oncology, is available to the Centre on workdays (Mon-Fri). * All paediatric oncology cases are to be assessed by a permanent contact person with paediatric expertise. * Provision of cover staff with the same qualification must be documented in writing.   The name of the department is to be given. |  |  |
| NOC | Specialists   * At least 2 neuropathologists are available to the Centre (possibly in cooperation). |  |  |
| SAR | Specialists   * At least 1 pathology specialist from the total number of pathologists in the Oncology Centre.   Provision of cover staff with the same qualification must be documented in writing. |  |  |
|  |  |  |  |

**Specialists pathology institute**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name, first name** | **Title** | **Specialist (S)** | **Full-time or part-time as %** | **Additional qualification /  Organ focus** 9) |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

9) The requirement of medical and technical competence for the corresponding tumour entity is described below.

| **8.4** **Specialists - Competence** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Pathology |  |
| BC | Experience specialist   * Every year at least 100 routine histologies of mammary cases * Every year more than 3,000 histological tests (documented via journal numbers) |  |  |
| GC | 20 histologies of cases with genital malignancy i.e. invasive neoplasms of the female genitalia, BOT and STIC/year for each named specialist (including PE) |  |  |
| HNT | The specialist must assess at least 60 malignant head and neck tumours a year. Diagnoses in the scope of second opinions are also recognised as proof of competence (30 cases preoperatively, 30 cases postoperatively). |  |  |
| LC | Each named specialist must assess 100 malignant lung tumours a year. |  |  |
|  | **If additionally certified as a mesothelioma unit:**  One of the pathology specialists designated for the LC must provide evidence of at least 10 histological diagnostic confirmations of mesothelioma per year.  If the minimum requirement is not met, all diagnoses must be made in cooperation with the external reference pathologist. |  |  |
| PC | The specialist must assess 100 prostate cases a year. |  |  |

| **8.5** **MTAs** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Pathology |  |
|  | A sufficient number of qualified MTAs / technical assistants must be available. |  |  |

| **8.6** **Procedures that must be available** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Pathology |  |
|  | Procedure to be followed  - Immunohistochemical analysis  - In-situ hybridisations (not for PC)  - Molecular pathology (not for PC)  These special services may only be commissioned to pathology institutes, which must be named upon presentation of a cooperation agreement. The institutes should have a recognized QM system or a valid accreditation or prove successful participation in interlaboratory comparisons. |  |  |
|  | **Organ-specific characteristics** |  |  |
| SC | Procedures that must be available   * Immunohistochemical tests * Molecular pathology   The outsourcing of ~~T~~these special services may only be performed at Pathology Institutes which are to be named with the submission of a cooperation agreement. The institutes should have a recognised QM system or valid accreditation or document successful participation in interlaboratory experiments. |  |  |
| LC | Evidence of quality-assured NGS diagnostics.  Diagnostics must be carried out via:   * nNGM centre or * Accredited molecular pathology (DIN EN ISO17020) with proof of successful participation in national and/or international EQA schemes on diagnostically mandatory tests for lung cancer (EGFR, BRAF, ALK, ROS1, RET, NTRK). Proof of valid EQA certificates. |  |  |
|  | Changes compared to version of 14.12.2021 |  |  |

| **8.7** **Autopsies** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Pathology |  |
|  | Within the Centre the unlimited carrying out of autopsies must be possible and encouraged in the case of SC/PC. An autopsy room must be documented (possibly in cooperation). |  |  |

| **8.8)** **Frozen sections** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Pathology |  |
|  | * The technical and organisational preconditions for frozen sections must be in place for each surgical clinical site. * The readiness for operation of the cryostat must be ensured (does not apply to SC). * Telepathological frozen sections are not admissible. |  |  |
|  | Parameter frozen sections  Time needed (in minutes) and time point measured from arrival in pathology to communication of the result (guidance value maximum 30 minutes)  Evaluation of time needed: Min / max / range value |  |  |
|  | **Organ-specific characteristics** |  |  |
| NOC | Assessment frozen sections / specimens   * All frozen sections / sections are to be diagnosed by neuropathologists (as a rule on site, possibly via cooperation; cooperations > 45 km are to be justified). * In exceptional cases the cutting of the frozen section may be undertaken by pathologists on site. In these cases, the tele-medical microscopic assessment of the frozen sections must be done by the neuropathology specialist. |  |  |

| **8.9** **Time to histological result** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Pathology |  |
| BC | Time to reception of the pathology report (biopsy)  Requirement: within 2 working days  Time to reception pathology including immunohistochemistry  Requirement: maximum 5 working days |  |  |
| VC  CC  ACC | Time to reception of pathology reports   * Biopsates / polyps maximum 3 working days * OP specimens maximum 5 working days |  |  |
| LC | Time to the first pathology report (pirmary diagnostic) – requirement ≤ 3 working days. |  |  |
| HNT | Time to result routine histology  Requirement: ≤ 5 workingdays  (Exceptions are to be justified.) |  |  |
| SAR | Time to first pathology report  Requirement: ≤ 5 working days  (Reasons are to be given for any exceptions) |  |  |
|  | Changes compared to version of 14.12.2021 | |  |

| **8.10** **Storage times** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Pathology |  |
|  | * Archiving paraffin blocks ≥ 10 years * Storage fresh material ≥ 4 weeks after reception * Cryopreservation should be possible. |  |  |
| LC | Preservation of tumour-free lung tissue, e.g. for dust analysis, with corresponding clinical indications. |  |  |
|  | Changes compared to version of 14.12.2021, shift from chapter 8.11 | | |

| **8.11** **Pathology reports** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Pathology |  |
|  | Pathology reports must contain, for macroscopic and microscopic assessment, 100% of the information stipulated in the Guidelines (In particular: histological type according to the current WHO classification, grade, TNM stage (GZ or FIGO), R classification). |  |  |
|  | **Organ-specific characteristics** |  |  |
| BC | Mandatory information pathology report   * Peritumoural ~~L~~lymph vessel and vein invasion * Oestrogen and progesterone receptor status * HER-2 status (procedure for questionable positive HER-2 status (2+) is to be regulated (e.g. via FISH-/CISH analysis) * Multifocality / Multicentricity * Ki 67 proliferation index of invasive carcinomas (optional) |  |  |
| GC | Mandatory details pathology report  After trachelectomy or radical hysterectomy (cervical carcinoma) and in the case of vulva specimens (vulva carcinoma):   * Detection/no lymph or vein invasion (L and V status) * Detection/no perineural invasion (Pn status), * Invasion depth and spread in mm for pT1a1 and for cervical carcinoma pT1a2 * Three-dimension tumour size in cm (from pT1b1)   in addition after/in the case of:   1. Radical hysterectomy (cervical carcinoma):   In the case of conised patients (TNM) staging with due consideration of conisation report   1. Vulva specimens for vulva carcinoma:   Metric details of minimum distance carcinoma/VIN to the vulvar resection margin and to the soft-tissue resection margin  In the case of resection of the vulvo-vaginal or vulvo-anal transition and, where applicable, of the urethra metric details of the corresponding resection margins |  |  |
|  | Mandatory information pathology report - Endometrium  **Fractionated Abrasion**  When detecting tumor tissue in the cervical fraction of a fractional abrasion, a definite statement should be made regarding the evidence or absence of endocervical stroma infiltration.  **Hysterectomy specimen**  • Histological type according to WHO  • In the case of mixed carcinomas, the percentage with respect to the total tumor  • Grading  • Evidence / absence of lymphatic or blood vessel intrusions (L and V status)  • Evidence / absence of perineural infiltration rates (Pn status)  • Staging (pTNM)  • Metric specification of the invasion depth in relation to the myometrium thickness in mm  • Three-dimensional tumor size in cm  • In the case of vaginal infiltration, metric specification of the minimum distance to the vaginal resection edge  • R-classification (UICC) |  |  |
| CC | Mandatory information pathology report   * Localisation * Pathologist must always give details of the resection margins and the minimum distance to resection margin (Quality Indicator Guidelines); (Deviations are to be justified). * Lymph vessel vein/perineural invasion * TME quality (Quality Indicator Guidelines) / CRM quality * Tumour regression grade in neoadjuvant therapy cases (optional) |  |  |
| ACC | Mandatory pathology report  after local excision:   * R-status all sides (also to depth) * HPV/p16 status * Graduation (squamous cell carcinoma, Paget's disease, adenocarcinoma, GIST, lymphoma, sarcoma, NET, etc.)   after extirpation additionally:   * Lymph node status * Evidence/absence of lymphatic or blood vessel invasion (L- and V-status) * Detection/absence of perineural sheath infiltrates (Pn status) * Tumour regression grade after combined radiochemotherapy   Changes compared to version of 14.12.2021 |  |  |
| LCC | Mandatory information pathology report   * Status of the surrounding liver |  |  |
| GCC | Mandatory information pathology report   * Tumour localisation * Laurén classification * Local depth of infiltration if not contained in the TNM * Vein invasion, lymph vessel and perineural invasion |  |  |
| PAN | Mandatory information pathology report   * Status of the resection area with regard to the remaining part of the pancreas and the circumferential resection margins (marked in Indian ink) * R0 narrow/wide * Lymph vessel invasion * Vein invasion * Perineural invasion |  |  |
| ESO | Mandatory details pathology report:  General:   * Type of neoplastic lesion (LGD, LGIEN, HGD, HGIEN, carcinoma)   Specific:  Biopsy:   * In the case of lesions in the distal oesophagus: Barrett’s mucosa containing goblet cells?   Excised material after endoscopic resection:   * Size of lesion in 3 dimensions (does not apply to EMR, in this case vertical dimension) * Maximum depth of infiltration (T and µm) * Vein invasion, lymph vessel invasion * Low vs high risk resection margins or * In the case of *in toto* resection: circular and basal resection margin   Surgically resected tissues:   * Size of lesion in 3 dimensions * Localisation of the tumour centre with regard to oesophagogastric transition and details of the intersection of the oesophagogastric transition * Oral, aboral and circumferential resection margins * Vein invasion, lymph vessel invasion   After neoadjuvant therapy: details of regression score |  |  |
| SC | Tests reports  Test reports must contain, for the macroscopic ande microscopic assessments, 100% of the information required in the Guidelines (in particular: histological type according to the current WHO classification, grade, TNM stage, R classification). |  |  |
| SC | Additional information melanoma:   * Tumour density according to Breslow, ulceration,Optional: mitosis rate for tumour density < 1 mm according to the AJCC classification 2017. * Histopathological specificities like possible association with a melanocytic nevus, a regression zone, morphological specificities (e.g. desmoplastic melanoma parts) and vessel infiltration |  |  |
| HNT | Mandatory information pathology report   * Tumour localisation (clinician is responsible for clinical information); * Macroscopic tumour size; * Depth of invasion (for tumours of the base of the mouth, cheeks and the oral tongue); * Lymph vessel, venous and perineural invasion; * Local infiltrated structures; * Lymph nodes: Per localisation / level number of lymph nodes prepared and affected by tumour (the clinician is responsible for adequate labelling); diameter of the largest metastasis; presence / absence of extracapsular spread * Safety margin to the resection margins * Classification pT: information required from the Clinic: The clinician is responsible for providing details of the affected areas and sub-areas, infiltrated anatomic structures, vocal cord fixation, mobility/fixation of the vocal lips; |  |  |
| LC | Mandatory information pathology report   * Determination regression grading or complete pathological regression in the case of patients with neoadjuvant treatment. * Description of tumour localisation * ~~Asservation of tumour-free lung tissue, e.g. for dust analysis in the case of corresponding clinical details~~   A template for preparing guideline-compliant, complete pathology reports for biopsies or resection specimens of lung cancer can be downloaded at:  <https://www.krebsgesellschaft.de/zertdokumente.html>  Changes compared to version of 14.12.2021, shift from chapter 8.10 |  |  |
| PC | Macroscopic processing prostatectomy specimens:   * Measurements (mm) in 3 dimensions * Marking in Indian ink (ventral and dorsal in different colours to determine minimum border) * Vesical and apical resection surfaces are to be marked with Indian ink, too. Both areas should be excised in 3-5 mm slices in a right angle to the urethra. * The slices should then be laminated parasagittally and fully embedded. * The resection margins of both sperm ducts and both seminal vesicles should be embedded separately for each side. * Transversal lamination (3-5 mm) and full embedding |  |  |
| PC | Test report punch biopsy   * The result of preoperative histology is to be available within 5 working days. * Positions must be tagged in line with the clinical details. * Processing whilst maintaining the position tagging. * Number and localisation of carcinoma-positive tissue samples. * Semi-quantitative estimation of the percentage of the total carcinoma area/total punch cylinder area. * Gleason grade: Details of all primary and secondary grades and the least differentiated grade as a %. Details of the total Gleason scores in line with the modifications approved by ISUP in 2015 . Separate details for each punch site affected by the tumour Differentiation according to Gleason grades1 and 2 has still to be undertaken. * Lymph vessel (L) and venous (V) invasion (L0 or L1, V0 or V1). * Perineural infiltration (Pn0 or Pn1) * If assessable, capsule infiltration, extracapsular growth and seminal vesicle infiltration should be indicated. |  |  |
| PC | Test report of the prostatectomy specimens   * The result of postoperative histology is to be available within 7 working days. * Carcinoma localisation and semi-quantitative estimated tumour spread (% of the affected parenchyma). * pT2-4 category and parameters similar to the punch biopsy (8.11) * Subdivision of the category pT3a according to Epstein *et al.* {Epstein, 1996 860 /id} into focal capsule penetration and extensive capsule penetration |  |  |
| BLA | Diagnostic report TUR-B   * Histology results within 5 working days * Full embedding of the material * Details in the diagnostic report:   + Tumour stage, tumour grade according to WHO 1973 und 2016   + Presence or absence of a carcinoma *in situ* carcinoma, lympth and blood vessel invasion (L, V)   + Presence of detrusor muscle   Diagnostic report cystectomy   * Histology results within 7 working days * Macroscopic processing:   Resection margins urethra and ureter bilateral, complete embedding of all visible tumours and urothelial changes   * Exemplary examination of various regions of the urothelium * Staining and examination of the depth of the resection margins * Details in diagnostic report:   + Tumour stage, TNM classification, tumour grade according to WHO 1973 and 2016   + Lymph, blood vessel and   perineural invasion (L,V,Pn)   * + Resection margins   Presence of a carcinoma *in situ* |  |  |
| TCC | Report of the testicular sample   * localization (right/left) * Testicular size * max. tumour size (in 3 dimensions) * Macroscopic features of epididymis, spermatic cord and tunica vaginalis * Tumour infiltration of the resection margin (yes/no) * histopatholog. type with specification of individual components and percentage determination according to WHO 2016 * peritumoural venous and/or lymphatic invasion * Invasion of the tunica albuginea (yes/no) * Invasion of the tunica vaginalis (yes/no) * Invasion of the rete testis (yes/no) * Invasion of the soft tissue of the hilar, epididymis, or spermatic cord (yes/no) * Germ cell neoplasia in situ in non-tumorous parenchyma * pT category according to the TNM classification of 2017 |  |  |
| SAR  a) | Pathology report  Pathology reports for soft-tissue tumours with the exception of GIST must contain the additional following details (deviations are to be justified):   * Tumour localisation (clinical details are the responsibility of the clinician); * Macroscopic tumour size; * Histological tumour type according to WHO classification; * Histological tumour grade according to FNCLCC (if applicable); * Depth localisation; * Locallly infiltrated structures; * Classification pT: details of affected regions and sub-regions, infiltrated anatomical structures are the responsibility of the clinician (TNM classification can also be determined in an interdisciplinary manner, e.g. post-operative tumour board); * R status and safety margins in mm;   in the case of condition after neoadjuvant therapy: details of the degree of tumour necrosis/tumour regression |  |  |
| SAR  b) | Pathology reports for GIST must contain the additional following details (deviations are to be justified):   * Number of mitos~~i~~es (in a 5 mm² area) * Tumour localisation (clinical details are the responsibility of the clinician); * Macroscopic tumour size; * R status; * Details of absence/presence of a tumour rupture outward;   in the case of condition after neoadjuvant therapy: details of the degree of tumour necrosis/tumour regression. |  |  |
|  | Changes compared to version of 14.12.2021 |  |  |

| **8.12 Lymph nodes (LN)** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Pathology |  |
|  | * All lymph nodes in the surgical specimen are to be examined macroscopically and microscopically. * Deviations from the minimum numbers in the Guidelines are to be discussed on an interdisciplinary level. * The lymph nodes must be examined in line with the Guidelines. * The localisation of the lymph node (at least regional versus distance from the tumour) is to be indicated. |  |  |
|  | **Organ-specific characteristics** |  |  |
| CC | At least 12 lymph nodes in the surgical specimen are to be examined. (Quality Indicator Guidelines) | Details in Data Sheet Colorectal (Excel template) |  |
| GCC | According to D2-LAD at least 25 regional lymph nodes in the surgical specimen are to be examined. |  |  |
| PAN | At least 12 regional lymph nodes in the surgical specimen are to be examined. | Details in Data Sheet Pancreas (Excel template) |  |
| ESO | After two-field LAD at least 20 regional lymph nodes are to be examined in the surgical specimen. |  |  |
| GC | Endometrial carcinoma  • Indication of the number of affected lymph nodes in relation to the number of removed lymph nodes in association with the location of the removal (pelvic, paraaortal),  • Indication of the extent of the largest lymph node metastasis in mm / cm,  • Indication of the absence / evidence of a capsular breakthrough of the lymph node metastasis,  • Indication of evidence of isolated tumour cells in the lymph nodes as well as evidence of lymphatic vessel intrusions in the perinodal adipose tissue and / or the lymph node capsule. |  |  |
| SC | The following information should be contained in the histopathological report of the sentinel lymph node:  • Evidence of nevus or melanoma cells  • In the case of melanoma cells, prognostically important parameters (eg according to GL: largest diameter of the largest tumour cell accumulation, maximum depth of penetration of melanoma cells into the lymph node parenchyma, invasion of melanoma cells into the lymph node capsule or capsule breakthrough, Localisation of melanoma cells in perinodal lymphatic vessels)  • Largest diameter of the micrometastasis |  |  |
|  | For each region a minimum of 6 lymph nodes are to be examined. |  |  |
| LC | * The localisation of the LN (IASLC Classification) is to be indicated. * Guidance value: At least 6 lymph nodes are to be examined in the surgical specimen. |  |  |
| PCC | * Details of any capsule penetration and extracapsular extension |  |  |
| BLA | Diagnostic report lymphadenectomy  The diagnostic report must contain at least the following details:   * Localisation * Number of detected/affected lymph nodes * Extracapsular growth (y/n)   maximum size of metastases (mm, one-dimensional) |  |  |
| BLA | After a bilateral pelvic lymphadenectomy a minimum of 10 lymph nodes in the surgical specimen are to be examined. |  |  |
|  |  |  |  |

| **8.13** **Distance to resection margin /safety margin** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Pathology |  |
|  | Pathologist must always give details of the resection margins (deviations are to be justified). |  |  |
|  | **Organ-specific characteristics** |  |  |
| SC | Details are always to be provided by the dermatohistologist/pathologist of the resection margins (Deviations are to be justified). |  |  |
| PCC | For R0 status details of the minimum margin distance in mm for R1 status details of resection margin involvement of the carcinoma (post, postero-lateral, anterior, apical, proximal-vesical, distal-urethral), spread of involvement (mm) and absence/presence of the prostate capsule in this area.  Deviations have to be explained (justified). |  |  |

| **8.14** **External quality assurance** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Pathology |  |
|  | Regular successful participation in external quality assurance measures (example benchmarking, external quality circles) particularly in interlaboratory experiments (example QUIP) every 2 years. |  |  |
|  | Consultative second opinion  Facilitation of consultative second opinion when asked by clinic or patient or when definitive assessment is not possible. |  |  |
|  | **Organ-specific characteristics** |  |  |
| BC | Regular successful participation in external quality assurance measures in particular interlaboratory experiments annually |  |  |
| GC  ) | The procedure for an external second diagnosis is to be outlined, particularly for rare tumours (e.g. trophoblast tumours, BOT, sarcomas. |  |  |
| VC  CC | The procedure for an external second diagnosis is to be outlined.  Another example external quality assurance  - KRAS testing if conducted in VC |  |  |
| ~~HC~~ | ~~In particular, successful participation in interlaboratory comparisons on flow cytometry and cytomorphology should be demonstrated.~~ |  |  |
| SC | Regular successful participation in external quality assurance measures (examples QUIP, benchmarking, external quality circles) annually, e.g. section seminars |  |  |
| LC | * For EGFR testing it should be documented whether this is an Exon 21, Exon 19 mutation or an uncommon mutation. |  |  |
| PC | Another example external quality assurance  - Gleason school |  |  |

| **8.15** **Quality circles** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Pathology |  |
|  | * Quality circles, in which oncological aspects are addressed, are to be conducted at least 3 times per year. * Scheduling, e.g. in training plan * Minutes of quality circles are to be taken.   Participation is to be proven in total and not for each individual organ; quality circles can be interdisciplinary, for a specific organ and/or trans-organ in nature (central quality circles of the Oncology Centre are, for instance, recognised pursuant to CR OC Section 1.2.14). |  |  |
|  | Shift compared to version of 14.12.2021 in the Catalog of Requirements form for centres for haematological neoplasms | |  |

| **8.16** **Continuing education/specialty training** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Pathology |  |
|  | * A training plan for medical and non-medical staff listing the training sessions planned for the period of one year is to be submitted (in the case of SC only for medical staff). * At least 1 dedicated continuing education/specialty training session for each staff member who carries out quality-relevant activities for the Centre. |  |  |
|  | **Organ-specific characteristics** |  |  |
| BC | Continuing education/specialty training should be provided by a professional specialised company. |  |  |
| VC  CC | Continuing education/specialty training should be provided by a professional specialised company for a specific organ. |  |  |
| LC | For medical staff regular continuing education/specialty training in lung pathology (this includes *inter alia* IAP seminars and scientific congresses). Continuing education/specialty training should be provided by a professional specialised company for a specific organ. |  |  |
| PC | Medical staff regularly attend (at least once a year) continuing education/specialty training on prostate pathology (this includes *inter alia* IAP seminars and scientific programmes). |  |  |

| **8.17** **Other organ-specific requirements** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks Pathology |  |
| BC | Familial mammary carcinoma  When both of the following points present together, the pathologist should examine the possibility of a hereditary background:   * Invasive carcinoma (NOS) with medullary characteristics * G3 morphology * Oestrogen, progesterone and HER-2 status negative (triple negative) |  |  |
| BC | Evaluation HER-2 status  Annual evaluation of the IHC score sub-divided into 0, 1+, 2+ and 3+. |  |  |
| GC | In the case of suspected HNPCC/Lynch syndrome in patients with an endometrial carcinoma (= positive check list)  Use of the algorithm: [<http://www.krebsgesellschaft.de/deutsche-krebsgesellschaft-wtrl/deutsche-krebsgesellschaft/zertifizierung/erhebungsboegen/organkrebszentren.html>](http://www.krebsgesellschaft.de/deutsche-krebsgesellschaft-wtrl/deutsche-krebsgesellschaft/zertifizierung/erhebungsboegen/organkrebszentren.html)  Precondition for:   * immunohistochemical examination of MMR proteins: documentation of successful participation in the IHC interlaboratory experiment for colorectal carcinoma (also applies to delegated services) * MSI analysis: documentation of successful participation in the MSI interlaboratory experiment for colorectal carcinoma (also applies to delegated services) |  |  |
| CC | Microsatellite instability  If no examination is done directly at the pathologist's then a cooperation agreement is to be entered into. |  |  |
| CC | Diagnostics  MSI testing should be carried out  - according to the LL algorithm in the case of a positive patient questionnaire with suspected hereditary CRC (LL CRC: "Algorithm: Genetic Diagnostics and Screening")  - in patients between the 50th and 60th year of life with MSI-suspicious histology  - in mKRK optional for determining the therapy strategy  - before adjuvant chemotherapy in stad. II if indicated |  |  |
| HC | Reference pathology   * Proof of cooperation with a reference pathology (the name is to be given) for lymphoma or proof that this role can be fulfilled by the center. * The process for obtaining a reference pathological assessment must be described and demonstrated using individual examples. |  |  |
| PED | Telephone call (**immediate advance notice**) within one working day to notify abnormal results requiring intervention (cf. CR Paediatric Oncology 2.2.3). Transfer by fax alone is not sufficient. The standard operating procedure is to be outlined. |  |  |
| PED | **Reference pathology** must be ensured: mailing within maximum 5 working days after receipt (exception: e.g. decalcification). |  |  |
| PED | The dispatch of the specimens for **molecular diagnosis** must be done at the latest in parallel to the dispatch of the reference diagnostic/histopathological evaluation (description of the procedure).  The need for a later human genetics diagnosis must be taken into account when preparing the samples for molecular diagnosis if the sampling volume permits (e.g. asservation of fresh tissue). |  |  |
| PED | The Centre has an obligation to participate in the **reference diagnostics** and to dispatch the test material in line with the study protocols (see CR Paediatric Oncology 1.7.3). |  |  |
| PED | Neuropathology   * Clinical sites which perform neurosurgery within the framework of the Paediatric Oncology Centres must give the name of one neuropathology specialist. * The name of 1cover staff member with the same qualification must be given. * The specialist must be available on working days*, inter alia*, for frozen section diagnosis. * Reasons are to be given for any cooperations at distances over 45 km. * All frozen sections/specimens are to be diagnosed by neuropathologists  - as a rule neuropathology on site  - in exceptional cases: frozen section cutting may be done by pathologist, assessment of frozen section by neuropathologist. |  |  |
| NOC | Histological classification   * According to the criteria of the current WHO classification of tumours of the central nervous system * The histological, cytological, histochemical and immunohistochemical methods required under the WHO criteria must be established. |  |  |
| NOC | Stereotactic brain biopsies  Possibility of processing and gaining experience in the microscopic assessment of stereotactic brain biopsies must be available. |  |  |
| NOC | Cytopathological assessment  Possibility of processing and gaining experience in the microscopic assessment of liquor-cytological specimens must be available. |  |  |
| NOC | Molecular diagnostics  Possibility to determine relevant neuro-oncological markers according to the WHO classification 2016 (e.g. MGMT promoter methylation, 1p/ 19q deletion, mutations in the IDH1 gene) (possibly in cooperation) and to gain experience in the assessment of molecular pathological findings must be available. |  |  |
| NOC | Asservation of tissue samples  In addition to the asservation of the paraffin blocks and sliced specimens, the possibility of asservation of shock-frozen tissue samples at temperatures of at least -80oC must be available. |  |  |
| NOC | Participation in clinical trials and translational research projects   * Provision/dispatch of tissue samples for reference histological evaluation as part of clinical trials * Asservation, provision and possibly dispatch of tissue samples for translational research projects as part of clinical trials. |  |  |
| SAR | Molecular diagnostics  The possibility to determine relevant molecular markers is to be available (where necessary in cooperation). In this case both diagnostically relevant molecular markers (e.g. tumour-specific transclinical site) and predictive biomarkers are to be used. Experience in the assessment of molecular-pathological results must be available.   * Successful participation in 3 interlaboratory experiments per 3 years, of which at least 1 sarcoma-specific interlaboratory experiments (e.g. GIST, CD117) (proof). * For GIST the following applies:   For patients who are about to undergo drug therapy, a mutation analysis (KIT- or PDGFRA-Gen, where appropriate other genes, too) is mandatory. |  |  |
| SAR | Reference pathology  The procedure for seeking a reference pathology assessment is to be described and documented by means of individual examples. |  |  |

**Appendix 1 - Interlaboratory comparisons**

An overview of current interlaboratory comparisons is available at <https://www.quip.eu/de_DE/zerpa/trials>.