ONKOZERT
Unabhängiges Zertifizierungsinstitut
der Deutschen Krebsgesellschaft
Gartenstraße 24, D-89231 Neu-Ulm
Tel. +49 (0)7 31 / 70 51 16 - 0
www.onkozert.de, info@onkozert.de

General provisions Certification

These "General Provisions" regulate the implementation of certification procedures by OnkoZert. OnkoZert carries out the certification procedures on behalf of the professional societies identified on the certificates (e.g. German Cancer Society e.V., German Society for Senology e.V., ...), which design the certification system, define the professional requirements and in whose name the certificate is issued. The tasks of OnkoZert include in particular the administrative control of the certification procedures as well as the processing and presentation of certification results. The experts appointed by the German Cancer Society and the members of the Certification Committee are independent in their professional assessment.

The certification system includes, among others, oncological centres, organ cancer centres, practices as well as other oncological institutions such as cooperation partners of different disciplines (e.g. pathologies, dysplasia units/consultations, ...), which are hereinafter referred to as organisations. For the different certification systems as well as for special questions, there may be further provisions and requirements which are published at www.onkozert.de and whose significance is regulated in individual cases.

These "General Provisions" are binding for both OnkoZert and the organisations in the certification process.

Auditors

The certification procedures are carried out by so-called auditors. The nomination and commissioning of an auditor for a certification procedure is carried out by OnkoZert. The certified organisation can reject the appointed auditor once without giving reasons. If an auditor drops out immediately before or during the audit, OnkoZert will appoint another auditor, or the audit date will be postponed.

Evaluation Catalogue of Requirement

In the run-up to the initial certification, the centre processes the Catalogue of Requirements. The aim of this Catalogue of Requirements is to uncover fundamental deviations from the certification requirements and thus minimise the risk for a successful certification procedure. The auditor makes a recommendation regarding the continuation of the certification procedure based on the completed Catalogue of Requirements. This recommendation is not binding with regard to a successful certification, i.e. despite a positive recommendation, the result of the certification can be negative. Deadlines must be observed for processing the Catalogue of Requirements (see section Deadlines).

Certificate awarding/renewal

At the end of initial certification audits and re-audits (recertifications), the auditor commissioned to carry out the certification procedure makes a recommendation regarding the awarding/renewal of the certificate and documents this in the audit report. Based on the audit documentation prepared by the auditor, the "Certificate Awarding Committee" checks whether the prerequisites for certificate award/renewal are met and, in the case of a positive result, awards the certificate or extends it. The Certificate Awarding Committee may impose conditions for the award/renewal of the certificate. The prerequisites for awarding/renewing a certificate are:

- Correction of all deviations identified in the audit (assessment of the correction of open deviations by the auditor).
- Fulfilment of all conditions imposed by the Certification Committee

The requirements for issuing a certificate and for renewing a certificate (recertification) are basically identical. The validity period of certificates is max. 3 ½ years for initial certifications. The period of validity can be reduced individually by the Certificate Award Committee, e.g. if the long-term fulfilment of the technical and medical requirements is not clearly ensured. In the case of recertification, the certificates are usually extended by a further 3 years (based on the validity period of the certificate). Here, too, the Certificate Awarding Committee may determine correspondingly reduced periods of validity.

Use of the certificate

The certificate may be used for advertising purposes and for external presentation. The scope of the certificate is indicated on the certificate and on the so-called master data sheet or OncoMap. Treatment partners who are neither named on the certificate nor in the master data sheet or OncoMap may not present themselves externally as part of the certified centre. Misuse of the certificate may lead to suspension or withdrawal of the certificate. As soon as a certificate loses its validity (e.g. expiry of the certificate, suspension/withdrawal of the certificate), the certified organisation including its cooperation partners may no longer use the certificates issued or other references to the certified status in any form. This includes, among other things, the internet presence, presentations in brochures and other references to the certification from the certified organisation and its cooperation partners.

Correction of deviations

If deviations are defined by the auditor within the scope of an initial certification, surveillance or re-audit, these deviations must be rectified within a specified period of time (see section Deadlines). Evidence of the elimination of a deviation is usually provided by the evaluation of submitted documents or by a re-examination audit. The type of proof is determined by the auditor.

Unabhängiges Zertifizierungsinstitut
der Deutschen Krebsgesellschaft
Gartenstraße 24, D-89231 Neu-Ulm
Tel. +49 (0)7 31 / 70 51 16 - 0
www.onkozert.de, info@onkozert.de

General provisions Certification

Maintaining the certificate

The maintenance of the certificate requires that the monitoring defined for the maintenance (e.g. annual surveillance audit, REDZYK procedure, ...) as well as the re-audit (usually every 3 years) are carried out successfully. The performance of these surveillance audits and recertification (=re-audits) are bound to deadlines (see section Deadlines). If the certified organisation does not enable the performance of the planned surveillance or repeat audits to be carried out in the required scope/period, or if the deviations identified in these audits are not rectified by the centre within the deadline, OnkoZert may initiate the procedure of certificate suspension or withdrawal.

Deadlines

The following deadlines generally apply to certification procedures. If deadlines are violated, OnkoZert is entitled to terminate the certification process (e.g. initial certification) or to initiate a certificate suspension or withdrawal procedure. Further regulations on the deadlines, which take into account the special features of the different certification systems (e.g. oncology centres, organ cancer centres, practices, ...), are specified in the current form at www.onkozert.de. In the event of an expected non-compliance with deadlines, an extension of the deadline can be applied for in individual cases (subject to a fee), which is usually decided by the Certificate Awarding Committee (application to OnkoZert; if possible, a few weeks before the deadline expires).

Request/ application	The submission of the written request for certification and the written application to initiate the certification procedure shall be made as early as possible with regard to the planned certification date. The notes "Entitlement to certification" are to be observed here. The deadlines for setting up certification are defined for each certification system at www.onkozert.de.
Submission documents	An assessment of documents requires that documents are available in a complete and correct form for the assessment. The set-up deadlines are defined in relation to the certification system at www.onkozert.de.
Assessment Catalogue of Requirements Initial certification	The centre receives a written assessment of the submitted Catalogue of Requirements. The on-site audit must take place within 6 months after this assessment has been made. If this six-month period is exceeded, the centre has to update the survey form and go through the "Assessment of Catalogue of Requirements" phase again.
Remedy deviations	The evaluation of the rectification of a deviation is usually carried out by the auditor. The time limit for the correction of the deviation is recorded in the deviation report and is max. 3 months from the date of the audit. The organisation has to provide the necessary evidence for the assessment in good time or to make the date for a re-examination audit possible. The documents to rectify the deviation shall be submitted in such a way that the assessment by the auditor can be carried out within the deadline. Incomplete and not positively assessable evidence can also lead to the certification procedure being terminated or the certificate suspension/withdrawal being initiated.
Initial certification	The initial certification audit must take place within 6 months after receipt of the written assessment of the Catalogue of Requirements. If the audit date cannot be met, see notes under "Assessment of Catalogue of Requirements initial certification".
Termination surveillance-/ re-audit	Surveillance and re-audits must be carried out at the earliest 3 months before and at the latest 3 months after the "cut-off date" (usually the last audit day of the initial certification). If a re-examination audit is required for the initial certification, the deadline also refers to the last day of the initial certification (not the day of the re-examination audit).
Parallel QM system certification	QM system certification is partly subject to independent deadlines. OnkoZert does not consider these deadlines. This is to be coordinated independently by the certified organisation with the QM certification board commissioned by it (only relevant in the case of simultaneous auditing).

Definition date of initial certification

The date of initial certification is the last audit day on site within the framework of the initial certification of the organisation (e.g. breast cancer centre was audited from 16-17 July => date of initial certification 17 July; this means that, starting from 17 July, dates and deadlines are defined that relate to the date of initial certification). The validity period of the certificate is calculated accordingly on the reference date.

Obligations of the certified organisation

The certified organisation commits to create the necessary conditions for the performance of the individual certification activities. This includes in particular the provision of and access to all data and information necessary for the verification of the technical and medical requirements. The certified organisation shall appoint a contact person for handling the certification procedure. The certified organisation is also responsible for ensuring that the necessary contact persons as well as representatives of the certified organisation are available for questioning during on-site audits. In the run-up to surveillance and re-audits, the audit documents defined for the respective certification system must be submitted in due time. The deadlines are communicated to the centre as part of the preparation for the audit.
The certified organisation must inform OnkoZert in writing of any significant changes (e.g. change of provider, change of head/centre coordinator). Furthermore, OnkoZert must be informed in writing if the fulfilment of central certification requirements can no longer be ensured by the certified organisation or could lead to the withdrawal or suspension of the certificate.
The necessary requirements must be ensured in particular for internal/external treatment partners who are registered with OnkoZert as cooperation partners of the certified organisation. The certified organisation commits to monitor compliance with the technical and medical requirements relevant to the cooperation partner and to initiate appropriate measures to rectify any deviations that exist. If the certified organisation no longer has a valid certificate, any certificates issued by the cooperation partners automatically lose their validity. The certified organisation must ensure that its cooperation partners implement the requirements set out in the section "Use of the certificate".

ONKOZERT
Unabhängiges Zertifizierungsinstitut
der Deutschen Krebsgesellschaft
Gartenstraße 24, D-89231 Neu-Ulm
Tel. +49 (0)7 31 / 70 51 16 - 0
www.onkozert.de, info@onkozert.de

General provisions Certification

Entitlement to the certification

Organisations aiming initial certification or reinstatement of the certificate do not have a binding right to participate in the certification process. Participation in the certification process or the realisation of certain audit dates may not be possible for the following reasons, for example:

- Availability of qualified/independent auditors not given in the desired period of time
- There was no clear positive assessment of certification requirements that could jeopardise the overall success of certification (e.g. borderline case numbers, ongoing/planned restructuring, change in management functions)
- Conformity with the current certification criteria is not given and an alternative assessment basis (e.g. change of Catalogue of Requirements or new/changed implementation regulations/interpretation guidelines), which may be under discussion, is not available in an approved form for the existing situation
- Jeopardising an independent assessment due to expectations expressed by the interested/certified organisations which might contradict the certification requirements.
- Other reasons that may jeopardise the proper implementation of the certification process.

Commitment to dates and deadlines

(Desired) dates for on-site audits stated by the organisation are only a basis for planning. Even if the stated date is not contradicted, it is still not confirmed (agreement on the audit date requires, among other things, the naming of the complete audit team and, if necessary, coordination with the parallel QM certification).

Dates already agreed for audits and other assessments may be cancelled or postponed in justified situations. The organisation cannot claim any damages due to the cancellation or postponement. The reasons for a cancellation/postponement of already agreed audit dates are partly mentioned under "Entitlement to certification". Further reasons are to be seen in the availability of the certification personnel, e.g. absence due to illness, disruptions during the journey (strike/weather-related, ...), withdrawal of leave of absence of the auditor by his employer (patient care in the clinic endangered, ...) as well as other reasons which generally justify an employee-related presence of the auditor in the own hospital.

Certificate suspension

The certificate can be suspended if the fulfilment of the certification requirements is not ensured or if there are considerable doubts about the future fulfilment of the certification requirements. In contrast to the "withdrawal of the certificate", in the case of the "suspension of the certificate" there is justified confidence that the fulfilment of the certification requirements can be ensured again within a defined period of time. The suspension of the certificate can be initiated by the Certificate Award Committee or at the request of the certified centre. Reasons for suspension are e.g.:

- Prerequisites for the future fulfilment of central professional requirements are (partly) not given.
- Possibilities for a timely and proper implementation of surveillance/re-audits are not given.
- Deviations are not corrected in time or proof of this is not provided in time.
- Proof of QM certification can no longer be provided (if requirement is obligatory).
- Fees for the certification procedure are not paid.
- Violations of the provisions set out in this document.

The conditions as well as the deadlines under which the reinstatement of the certificate takes place (e.g. successful re-audit) shall be communicated to the centre in writing. If the certification procedure is suspended, the centre is no longer entitled to use certificates or references to certification for internal and external purposes. The centre will be removed from the list of certified centres (OncoMap) unless otherwise decided by the Certification Awarding Committee. Further details can be found in the document "Application for Suspension of Certificate", which also describes the requirements for reinstatement of a certificate (www.onkozert.de).

Certificate withdrawal

A certified organisation can have its certificate withdrawn within the validity period stated on the certificate. In the case of "withdrawal of the certificate", there is insufficient confidence compared to the "suspension of the certificate" or the preconditions are considered insufficient that the fulfilment of the certification requirements can be ensured again within a defined period of time. The possible reasons for a certificate withdrawal are identical to those for the "suspension of certification" (see section "Certificate suspension").

Appeal certificate suspension/withdrawal

The Certificate Awarding Committee decides on a certificate suspension/withdrawal. Before the decision is made, the Centre has the opportunity to comment on the critical points. The Centre shall be notified in writing of the decision taken by the Certificate Awarding Committee.

In accordance with the paragraph "Appeal/Settlement of Disputes", the Centre may appeal against the decision "Suspension of Certification" and "Withdrawal of Certificate". In case of withdrawal/suspension of the certificate, the centre is no longer entitled to use certificates or references to the certification for internal and external purposes (e.g. presentation on the internet). The centre will be removed from the list of certified centres (OncoMap).

Unabhängiges Zertifizierungsinstitut
der Deutschen Krebsgesellschaft
Gartenstraße 24, D-89231 Neu-Ulm
Tel. +49 (0)7 31 / 70 51 16 - 0
www.onkozert.de, info@onkozert.de

General provisions Certification

Termination of certification procedure

The certification procedure can be terminated at the request of the centre. OnkoZert must be informed of this in writing at least 3 months before the planned surveillance/re-audit. If OnkoZert or auditors have already incurred expenses for the planned audit, these will be invoiced to the centre.

Upon termination of the certification procedure, the centre is no longer entitled to use certificates or references to certification for internal and external purposes. The centre will be removed from the list of certified centres (OncoMap).

Appeal/settlement of disputes

If the organisation does not agree with an assessment/decision, then the organisation can appeal against this assessment/decision. The objection must be submitted in writing to OnkoZert within 20 calendar days after the respective audit or after the date of dispatch of the written assessment (e.g. audit report, minutes of certificate issue, ...). The evaluation of this objection as well as the determination of a decision is usually carried out by the Certificate Awarding Committee. The evaluation responsibility can be defined by the German Cancer Society in individual cases or also taken over independently.
If the organisation does not accept the decision made within the framework of the appeal, the chairpersons of the respective Certification Committee can be involved. The chairpersons of the Certification Committee can make a decision or decide to consider the situation in a group of experts or within the Certification Committee. The decision of the Certification Committee is final and binding. There is no provision for direct contact with the chairpersons of the Certification Committee or the Certification Awarding Committee.

Handling of complaints

If complaints are addressed to OnkoZert regarding misuse of certificates or other serious violations of the applicable technical and medical requirements, OnkoZert is obliged to process these complaints. As a rule, only written complaints whose origin is known will be processed. The certified organisation concerned is informed in writing about the complaint received. Furthermore, the certified organisation is requested to submit a written statement, which must be received by OnkoZert within 10 working days. According to the situation found, OnkoZert is entitled to initiate an unscheduled inspection.
Complaints from patients/relatives in which the care in a certified organisation is criticised are forwarded to the office of the German Cancer Society. The office of the German Cancer Society handles this complaint independently and, if necessary, issues instructions to OnkoZert on how to take this situation into account in the certification process.

Proof of QM certification

Since the 2017 audit year, proof of a certified QM system (unless otherwise specified by the system) is no longer a prerequisite for DKG certification. The recommendation for the continuation and implementation of a certified QM system still exists.

Changes to the DKG certification system

The legislative responsibility for the certification system does not lie with OnkoZert, but with the German Cancer Society. In addition to the requirements for the certified organisations, these specifications may also affect the certification process. The certification system is subject to constant further development, which may result in changes. Changes may be necessary, for example, due to new findings or legal requirements. These changes may imply new or additional requirements for the certification and thus for the certified organisation, which OnkoZert and the certified organisation are obliged to implement during a defined transition period. In addition to the technical and medical requirements for the certified organisation (Catalogue of Requirements, guidelines, ...), the changes may also affect the certification process or organisation (e.g. audit duration, fees, ...).

Consent to publication / information on data usage

OnkoZert and the professional societies (e.g. DKG, DGS, ...) indicated on the respective certificate are entitled to publish the certified centres. This authorisation includes, among other things, the publication of the data stated on the certificate and the master data sheet and other information provided by the certified organisations that is of general interest (e.g. study offer). The information and data obtained in the course of certification or the information provided by the certified organisations (e.g. Catalogue of Requirements, data sheet, ...), including personal data, will be processed and used (e.g. recorded/stored/processed/evaluated) by OnkoZert and the scientific societies shown on the respective certificates for the purposes of the certification procedure as well as for the purposes of scientific research and used for corresponding publications and presentations of the research results. Personal data is anonymised as soon as this is possible according to the purpose of the research. Until then, the characteristics with which individual data on personal or factual circumstances can be assigned to a specific or identifiable person are stored separately and only merged with the individual data if the research purpose requires this. Personal data shall only be published if the person concerned has consented or if this is indispensable for the presentation of research results on events in contemporary history.

Unabhängiges Zertifizierungsinstitut
der Deutschen Krebsgesellschaft
Gartenstraße 24, D-89231 Neu-Ulm
Tel. +49 (0)7 31 / 70 51 16 - 0
www.onkozert.de, info@onkozert.de

General provisions Certification

Confidentiality

OnkoZert is obliged to maintain the confidentiality of the information and data received during the certification procedure. The exchange of data and information between OnkoZert, the QM certification societies commissioned by the centre and the scientific societies identified on the certificates (e.g. DKG, DGS, ...) is not subject to this confidentiality.

Liability of OnkoZert

Claims for damages due to breach of duty by OnkoZert, its legal representatives or vicarious agents (e.g. auditors) are excluded, unless OnkoZert, its legal representatives or vicarious agents commit the breach of duty intentionally or with gross negligence. OnkoZert shall not be liable for commissioned auditors who provide services within the framework of the certification procedure. If a centre's certificate is not granted, suspended, or withdrawn, OnkoZert shall not be liable for any financial or other damage incurred. The same applies in the event of unjustified non-granting, suspension, or withdrawal of the certificate.