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General certification terms

These “General Terms” settle the achievement of the OnkoZert certification procedures. OnkoZert leads the certification procedures at the request of the scientific societies mentioned in the certificates (for example the German Cancer Society, the German Society for Senology), which form the certification system and define which are the technical requirements and in whose name the certificate is issued. The OnkoZert tasks include especially the administrative management of the certification procedures, as well as the preparation and presentation of the certification results. The specialized auditors appointed by the German Cancer Society, as well as the members of the Certificate Awarding Committee are independent in their professional assessment.

The certification system includes the Oncology Centres, Organ Cancer Centres, Medical offices as well as other oncology institutes as for example: cooperation partners of various specialties (e.g.: pathologies, dysplasia units/ consultations), hereinafter referred to as organisations. For the different certification systems, as well as for special issues, there may be other terms and requirements, that are published on www.onkozert.de and whose significance is regulated individually.

These “General Terms” are mandatory both for OnkoZert and for the organizations that are in the certification process.

Specialized auditors

The OnkoZert certifications are accomplished by specialized auditors. The naming and the assignment of a specialized auditor is done by OnkoZert. The certified organization has the right to reject the assigned auditor, without any reason.

If an auditor cannot participate to an audit for non-imputable reasons, OnkoZert will appoint another auditor and respectively the audit carrying out term may be delayed.

Evaluation of the Catalogue of Requirements

Before the initial certification, the Organ Cancer Centre will fill out a Catalogue of Requirements. The purpose of the catalogue is to detect the elementary deviations from the certification requirements, and thus to minimize the risk for the accomplishment of the certification procedure. Based on the catalogue, the auditor will give a recommendation on the continuation of the certification procedure. This recommendation does not necessarily lead to a successful certification, so despite a positive recommendation, the result of the certification may be negative. When filling out the catalogue, the established deadlines will be taken into consideration (see the chapter: Deadlines).

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General certification terms

Awarding/extending the certificate

At the end of the initial certification/re-certification audit, the auditor assigned to conduct the certification procedure, will make a recommendation regarding the awarding/extending of the certificate and will document it in the audit report. Based on the audit documentation made by the auditor, the Certificate Awarding Committee will check if the certificate awarding/extending conditions are met, and in case of a positive result they will award or extend the certificate. The Certificate Awarding Committee may impose requirements for awarding/extending the certificate.

The conditions for certificate awarding/extending are:

- Solving all the deviations found during the audit (nonconformities) (auditor's evaluation of the pending deviations)
- Fulfillment of all the conditions formulated by the Certificate Awarding Committee.

The conditions for awarding and extending the certificate (re-certification) are basically identical.

The validity term of the OnkoZert certificates is max. 3 1/2 years in case of initial certification. The validity can be reduced individually by the Certificate Awarding Committee, for example if long-term compliance with the technical requirements is not clearly ensured. In case of re-certification, the certificates will be normally extended for another 3 years (based on the period of validity of the certificate). Here as well, the Certificate Awarding Committee can establish validity terms reduced accordingly.

Using the certificate

The certificate can be used for promotional purposes and for public presentations. The scope of the certificate is stated on the certificate and on the master data sheet created by OnkoZert. The treatment partners that are not mentioned neither on the certificate nor on the master data sheet, are not allowed to introduce themselves as part of the certified Centre. The abusive use of the certificate may lead to its cancellation and respectively to its immediate withdrawal. As soon as a certificate looses its validity (e.g. certificate expiration, suspension/withdrawal), the certified organization, including the cooperation partners, are no longer allowed to use the issued certificates or other indications of the certified status in any form.

These terms refer among others to internet appearances, brochure illustrations and other publications regarding certification of the certified organization and their cooperation partners..

Solving of deviations

If during initial audits, surveillance audits, or re-audits the auditors will define deviations, then these deviations must be rectified within the established timeframe (see chapter Deadlines). The proof of the correction of a deviation is usually made through the assessment of the submitted documents or through a re-audit. The auditors will determine the way the evidence is provided.

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Maintaining the certificate

The maintenance of the certificate requires the successful completion both of the surveillance audits defined in order to maintain the certificate (at the Organ Cancer Centres for example: annual surveillance audit REDZYK procedure (reduced cycle), ...) and of the re-audit (usually after each cycle of 3 years).

The performance of these surveillances and recertifications (=re-audits) are subject to deadlines (see chapter Deadlines). If the certified organization fails to perform the required surveillance/re-audits within the necessary required deadlines, or if the deviations identified in these audits are not solved by the Organ Cancer Centre on time, then OnkoZert may initiate the procedure for suspension or withdrawal of the certificate.

Deadlines

The following general deadlines are available for the certification procedure. If these deadlines are exceeded, OnkoZert is entitled to initiate the procedure of suspension or withdrawal of the certificate. Further regulations regarding the deadlines which consider the particularities of the different certification systems (Organ Cancer Centres, medical offices, ...), are available on www.onkozert.de. In case of the probability of a non-compliance with the deadlines, an extension of the deadline may be requested in individual cases. The Certificate Awarding Committee usually decides in this case (the application is submitted to OnkoZert, if possible, a few months before the deadlines expire).

Submitting the application	-Submitting the written application for certification and the written request should be made as soon as possible with regard to the planned certification date. The observations in the „Application for Certification" are to be taken into consideration.
Submitting the documents	-Evaluation of the documents assumes that the documents are available in complete and correct form. The deadlines are defined on www.onkozert.de
Evaluation of the requirements catalogue	-The Organ Cancer Center will receive a written evaluation of the submitted Catalogue of Requirements. Within 6 months after evaluation, the on-site audit should be conducted. If these six months are exceeded, then the Catalogue of Requirements must be updated by the Organ Center and the phase of the "Evaluation of the Catalogue of Requirements" will be done again.
Solving of deviations	-Evaluation of a deviation solving will be usually carried out by an auditor. The deadline for resolving the deviation is established in the deviation protocol and is of max. 3 months from the date of the audit. The certified organization must provide the evidence required with the necessary evidence in time, respectively must offer the possibility of a re-audit. Incomplete and not positively assessable evidence can also lead to the procedure of the certificate suspension or withdrawal.
Initial certification	-Within 9 months from the date the document "Decision regarding the outcome of the Evaluation of the Catalogue of Requirements" is made, the on-site certification audit must take place (initial certification).

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	-The Organ Cancer Centre must provide the proof of the deviation solving or the conduction of re-audits within 3 months from the date of the initial certification.
Setting deadlines for the surveillance/ recertification audit	-Not earlier than 3 months before and at the latest 3 months after the initial certification date (the last day of the initial certification audit=day zero), in case of initial certification a re-audit is necessary. Then the deadline also refers to day zero when the deviations were formulated.
Parallel certification of the quality management system	-Certification of the quality management system is partly subject to separate deadlines. OnkoZert will not consider these deadlines. These deadlines must be established by the certified organizations, independently, together with the quality management system certification body (relevant only for simultaneous auditing).

Defining the date of initial certification (day zero)

The date of initial certification is the last day of the on-site audit during the initial certification of the organization (for example BZ was audited on 16-17.07.14 –> the date of initial certification is 17.07.14. This means that starting from 17.07, the deadlines referring to the date of initial certification will be established). The date of certificate validity will be also considered accordingly.

Obligations of the certified organization

The certified organization is required to meet the conditions for conducting individual certification activities. They consist, especially, in making available and granting access to all the necessary data and information in order to review the requirements. For the accomplishment of the certification procedure, a contact person has to be named by the certified organization. The certified organization is also responsible for ensuring that the required contact persons and the representatives of the certified organization are available for the questionnaires on-site. Prior to the surveillance/ recertification audit, the Organ Cancer Centre will submit an updated Catalogue of Requirements. The deadlines will be communicated to the Organ Cancer Centre during the preparation for the audit.

The Certified Organization will inform OnkoZert in writing about significant changes (e.g. changing the administrative institution, changing the director/ coordinator of the Organ Cancer Center). OnkoZert will also be informed in writing if the certified organization can no longer ensure the fulfillment of the central certification requirements, respectively if this situation can lead to the withdrawal or cancellation of the certificate.

The necessary conditions will be ensured especially at the internal/external medical partners named for OnkoZert as being cooperation partners of the certified organization. The certified organization is obliged to monitor the compliance with the technical requirements relevant for the cooperation partners. If deviations are detected, the certified organization is obliged to implement the appropriate measures in order to solve them. If the certified organization no longer has a valid certificate, then automatically any certificates of the cooperation partners will lose their validity. The certified organization will ensure that

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its cooperation partners will implement the requirements mentioned in the "Using the certificate" chapter.

Entitlement to certification

The organizations seeking an initial certification or a renewal of the certificate, do not have a binding right to participate in the certification process. Participation in the certification process respectively the impossibility to attend at certain audit dates, may not be possible due to the following reasons:

- Qualified/ independent specialized auditors are not available for the desired period
- There is no clear positive evaluation of the certification requirements, which can endanger the overall outcome of the certification (e.g. outstanding amounts due, current/ planned restructuring, changes in management positions)
- Conformity with the current certification criteria is not met. There is no available alternative evaluation base agreed for the existing situation (e.g. changing the requirements catalogue or new/amended dispositions/directives).
- Endanger of an independent evaluation due to the expectations expressed by the interested/ certified organizations, that might be in contradiction with the certification requirements.
- Other reasons that could endanger the proper conduct of the certification process.
- Etc…

Obligation of deadlines

The stated (desired) dates by the certified organizations for the on-site audits are only a basis for planning. Even if the established deadline is not disputed, it is not considered to be confirmed (the approval of the deadline for the ongoing of the audit requires the nominal assignment of the full audit team and, where appropriate, the coordination with parallel certification of the quality management system).

Already agreed dates for auditing as well as for other evaluations may be omitted or postponed in justified situations. The certified organization can not assert claims for compensations due to the cancellation or delay of these deadlines. The reasons for a cancellation/postponement of already established deadlines or their delay are partly mentioned under the "Entitlement to Certification". Further causes may be the availability of the certifying staff, for example the absence because of medical problems, problems at arrival (strikes, bad weather, ...), withdrawal of the right to excercise the auditing profession (as a second profession) by the auditor's main employer (because of endangering the patients' care in the clinic due to his temporary absence, ...) as well as other reasons related to the absence of the employees.

Certificate suspension

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The suspension of the certificate may happen if the compliance with the certification requirements is not met respectively or if there are significant doubts regarding the fulfillment of the certification requirements in the future. Compared to the „Certificate withdrawal", the „Certificate suspension" has a legitimate expectation that the certification requirements can be met within a defined timeframe. The suspension of the certificate can be ordered by the Certificate Awarding Committee or can take place at the request of the certified centre.

The reasons for suspension are as for example:

- No conditions or partially no conditions for accomplishment of the requirements in the future
- No possibility to carry out surveillance/ re-audits within the foreseen deadlines and in the appropriate conditions
- The deviations are not solved on time respectively or the evidence is not submitted on time
- The fees for the certification procedure were not paid
- Failure to comply with the provisions established in this document

The conditions and deadlines for the certificate renewal (e.g. re-audit with positive result) will be communicated in writing to the Centre. In the event of a suspension of the certification process, the Centre is no longer entitled to use the certificates or certification references for internal and external purposes. The Centre will be removed from the certified centres list, unless otherwise decided by the Certificate Awarding Committee. More details can be found in the chapter "General conditions for certificate suspension". The conditions for certificate renewal are also described here.

Certificate withdrawal

The certificate may be withdrawn from a certified organization within the period of validity specified on the certificate. In case of "Certificate withdrawal", towards the case of suspension, there is no sufficient confidence respectively the conditions are considered to be insufficient to meet the certification requirements within a defined timeframe. The possible reasons for the withdrawal of a certificate are identical with those for "Certificate suspension" (see chapter "Certificate suspension").

Opposition to the certificate suspension/withdrawal

The Certificate Awarding Committee has the power to decide upon the suspension/withdrawal of the certificate. Prior to issuing this decision, the Centre has the possibility to provide a point of view regarding critical topics. The decision taken by the Certificate Awarding Committee will be communicated to the Centre in writing.

According to the "Appeals/Settlement of disputes" paragraph, the Centre can appeal the decision of „Certificate suspension" and „Certificate withdrawal". In case the certificate is suspensed/withdrawn, the Centre is no longer entitled to use the certificate or certification references for internal and external purposes (e.g. internet presentation). The Centre will be removed from the certified centres list.

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Ending the certification procedure

The certification procedure can be ended at the request of the Centre. This must be notified in writing to OnkoZert at least 3 months before the expiry date mentioned on the certificate, for every year. (e.g. expiry date on the certificate: 20.11.2018 => the notification deadlines are 20.08.2016, 20.08.2017 and 20.08.2018).

When the certification procedure has ended, the Centre is no longer entitled to use the certificates or certification references for internal and external purposes. The Centre will be removed from the certified centres list.

Appeals/Settlement of disputes

If the certified organization does not agree with the communicated evaluation/decision, then the certified organization may lodge an appeal against that evaluation/decision. The appeal will be submitted in writing at OnkoZert within 20 calendar days after the audit, respectively after the date of the submission of a written evaluation (e.g. audit report). The evaluation of this appeal as well as the establishment of a decision usually takes place in the Certificate Awarding Committee. The evaluation competence can be defined by the German Cancer Society in individual cases, or can also be taken over completely by it.

If the certified organization does not accept the decision established within the appeal, then the president of the Certification Committee may be included in the analysis. The president of the Certification Committee makes a decision or decides to analyze the situation within a circle of experts or within the Certification Committee. No direct contact with the president of the Certification Committee is provided without the co-opting of the Certificate Awarding Committee. The Certification Committee’s decision is final and binding.

Dealing with complaints

If OnkoZert receives complaints about abusive use of certificates or other serious non-compliance with the available technical requirements, then OnkoZert is obligated to process these complaints. In general, only written complaints of known origin will be processed. The affected certified organization will be informed in writing about the complaint received. Furthermore, the certified organization is requested to provide a written statement, which must be submitted to OnkoZert within 10 working days. According to the identified situation, OnkoZert has the right to start an unplanned checking.

Complaints from patients/memberships regarding care happening in a certified organization, will be retransmitted to the headquarters of the German Cancer Society. The German Cancer Society will process the complaint and will formulate instructions to OnkoZert about how the situation will be analyzed in the certification process.

Proof of Quality Management System Certification

General certification terms

DKG-certified centres should implement a certified QM system, but there is no obligation to certify a QM system. Different types of QM systems at the locations are disadvantageous (e.g., 2 KTQ sites and one ISO 9001 site). If the cooperating centre consists of more than 2 locations, it is advisable to have a cross-location QM system in which the cooperation between the locations is regulated and controlled.

Changes to the certification system

The legislative competence for the certification system lies not with OnkoZert, but within the German Cancer Society. These terms, in addition to the requirements for certified organizations, may refer to the course of certification. The certification system undergoes a continuous process of development, which may result in changes. Changes may become necessary, for example as a result of new information or legal requirements. These changes may mean new or additional certification requirements, and implicitly for the certified organization. OnkoZert and the certified organization are obliged to implement these changes within a defined transition period. In addition to the technical requirements for the certified organization (Catalogue of Requirements, directives, ...), the changes may also affect the process or organization of the certification (e.g. audit duration, fees).

Agreement on publication;/-references regarding data use

OnkoZert and the specialized companies mentioned on the certificate (e.g. DKG, DGS) are entitled to publish the list of the certified Organ Cancer Centers. This right includes, among others, the publication of the data indicated on the certificate and the master data sheet, as well as other information of general interest made available by the certified organizations (e.g. clinical study offer). The information and data acquired during the certification and the data submitted by the certified organizations (e.g. the Catalogue of Requirements, the indicators/quality of results), including personal data, will be processed and used by OnkoZert and the specialized societies mentioned on the certificates, for the purpose of the certification procedure as well as for scientific research purposes (e.g. recorded/kept/disposed/evaluated). These will be used for appropriate publications and presentations of research results. Personal data will be anonymous, as far as possible for the purpose of research. Until then, the features attributable to certain individuals will be archived separately, with individual data about personal and objective situations. These will be correlated with the individual data only to the extent that the purpose of research will impose this. Personal data will be published only if the person concerned has given his or her consent or if it is necessary for presenting the results of research regarding contemporary events.

Confidentiality

OnkoZert is obliged to confidentially keep the information and data obtained during the certification procedure. The exchange of data and information between OnkoZert and the certification bodies for the quality management systems mandated by the Organ Cancer Cetre, as well as the specialized companies mentioned in the certificates (e.g. DKG, DGS) are not subject to this confidentiality clause.

OnkoZert's liability

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The compensation claims arising from the non-compliance with OnkoZert's obligations, legal representatives or auxiliary agencies (e.g. specialized experts) are excluded, except the situations when OnkoZert, the legal representatives or the auxiliary agencies will intentionally or by gross negligence break these obligations. OnkoZert is not responsible for the mandated qualified auditors who provide services within the certification procedure.

If an Organ Cancer Centre will not receive the certificate, if it will be suspended or withdrawn, OnkoZert will not be liable for any financial damage arisen or for other damages. The same thing is valid also in case the certificate is not given, is suspended or withdrawn improperly.

**In the event of conflict or inconsistency between the terms of the German version of this document and the English translation, the German version shall prevail.*

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