

Basic information regarding certification

This document contains the basic information and experiences regarding the certification of the Organ Cancer Centres, which must be taken into consideration especially before structuring a certified Centre. **Information marked in yellow is of great importance.**

Making a request

The request can be sent at a very early date. Thus, the advantage is that the Centres registered with a request will be informed about the news that appeared regarding the certification system (e.g. in case of changes in the Catalogue of Requirements).

If the cooperation partners that must be included in the request are not yet definitively established, then the naming of the partners can also be made later (the following terms will be made in the cooperation partners list: “Naming will be made later”). The request forms can be found on our website.

Defining the Centre and location

The Centre presents the interdisciplinary and the overall network, consisting of the following main groups:

- Location (Leading/management unit of the Centre; contains the operative unit including the stationary care services)
- Internal cooperation partners (residing in the location)
- External cooperation partners (that are not based in the location)

Master data sheet

Firstly, the structure of a Centre will be communicated to OnkoZert in the request form. The data contained in this request will be registered at Onko Zert and transferred to a so-called master data sheet. **Issuing a certificate for a cooperation partner is possible only if it is also included in the official master data sheet.**

Location

There will be a control at the location of each Centre for the interdisciplinary network of the Centre, consisting of internal and external cooperation partners. **The surgical care is an elementary component of a location.** This means that a „surgical unit” always represents a location, and without a surgical unit the name of „location” is not possible.

On the main certificate only locations can be mentioned by the name. For the cooperation partners it is possible to receive a separate certificate.

Basic information regarding certification

The maturity degree for certification obtaining – degree of implementation of the requirements

At the time of the initial certification, the Centres must prove the implementation of the certification requirements in an established and functional form. The statements of intent or the presentation of solutions in the future are in principle not sufficient. In general the following principle is valid: at the time of the initial audit, the Centre has to prove the fulfillment of the certification requirements retrospectively for a period of 3 months at the time of the initial audit. In the initial certification audits, this 3-month period is also the main observation period, from which the patient documentation and discussion protocols are considered.

The cooperation partners

- Distance cooperation partners

The distance between the cooperation partners' premises and the location of the clinic must be of max. 45 km resp. the travel time must be of max. 45 min. (calculation via <https://maps.google.com/> – the fastest route).

- More cooperation partners on one specialty

There is the possibility to name more cooperation partners on one specialty (e.g. 2 radiologists). This, however, must be rather an exception and be argued on individual case. Anyway, a registered cooperation partner will need to provide the proof that the requirements relevant to it have been met.

- Structure evaluation

If the structure of a Centre shows complex cooperative structures, then the admission of the certification procedure may require an evaluation of the structure (subject to a mandatory fee). Criteria for determining the degree of complexity is the number of cooperation partners (especially with regard to a specialty and the distance to the location of the Centre). The number of cooperation partners will be analyzed in correlation with the primary cases of the Centre.

- Further take-over of new cooperation partners

The structure of a Centre is dynamic, reflecting the adoption of current developments and changes. That is why the structure of a certified Centre must be able to be modified. Expanding the Centre with more cooperation partners is possible, on request, in the annual audits.

- Recommendation for initial certification

The more cooperation partners there are, the more complex a Centre is. According to experiences, a large number of cooperation partners lead to difficulties for the initial certification. Therefore, in the first phase, a "simplified" option is recommended when structuring a Centre.

- Other observations

In the "Defining the cooperation partners" document there are detailed explanations regarding the admission of cooperation partners in a Centre within the certification process.

Basic information regarding certification

Frequent questions

Are only the registered cooperation partners allowed to treat the patients of the Centre?

- Accomplishment in proportion of 100% of all therapeutic steps through the Centre's cooperation partners is neither achievable nor required by the certification system. Each patient has the freedom to choose his treatment partners. However, a large amount of the therapy should also be done through the Centre's network.

Can a cooperation partner collaborate with more Centres?

- A cooperation partner can collaborate with several Centres/clinics, no matter if they are certified or not.
Example: A radiotherapy unit regularly collaborates with 5 clinics distributed in the region, having their own referral structures.

Who cannot be a cooperation partner?

- If a cooperation partner, within the patients' care in the Centres, is not adequately active, the naming as cooperation partner is not possible. Determining the appropriate measure depends, among others, on the regional importance of the cooperation partner.
Example: A Gastroenterology Unit wishes to be a cooperation partner of a Colorectal Cancer Centre. However, the diagnosed patients will hardly ever be operated in that Colorectal Cancer Centre.

Who must be a cooperation partner?

- If a particular unit will perform central therapeutic steps in a large proportion, then it must be admitted to the Centre in accordance with the certification requirements.
Example: The Radiotherapy Unit performs radiotherapy at over 80% of patients of the Breast Cancer Centre.

Cooperative Centres

A cooperative Centre consists of several clinics (locations) where surgical care of the primary cases occurs. The establishment of the cooperative Centres is underestimated by participants in terms of effort and requirements. In principle, location cooperations should be an exception, especially if the participating clinics have different administrative institutions.

If there is any planning for a cooperative Centre, it is strongly recommended to contact OnkoZert as soon as possible in order to discuss the possibilities and the difficulties of the proposed cooperation.

Basic information regarding certification

Experiences

There are many critical experiences regarding the certification of cooperative Centres. The authorization requirements as well as the approval procedures for multiple locations for a Centre have been significantly tightened to prevent negative certification decisions.

Despite these critical statements, there are several cooperative Centres that have evolved positively and that fully meet the expectations of a certified Centre.

Partnerships instead of cooperations

It is generally considered that a collaboration between the Centres (e.g. common Cancer Committee) is possible, without establishing a cooperation.

Simultaneous initial certification of multiple locations

- **Simultaneous initial certification of multiple locations should be avoided.** In case of cooperative Centres, usually, an already certified Centre (with a positive result) will be extended by another location.

Simultaneous initial certification is possible only in the case of particularly positive structural conditions (among others, the existence of identical administrative institutions). In this case, OnkoZert will perform a pre-audit in advance. In order to continue the certification process, the result of the pre-audit must be positive.

- In case of time-delayed certification, the date of expansion with the second location can be freely chosen, depending on the results obtained at the certification (location 1). The results of the certification will be assessed in particular according to the capability of expansion/cooperation.

Structure evaluation

Each cooperation will require a written evaluation of the structure, which decides upon the authorization of the cooperation (subject to mandatory fees). For the evaluation of the structure there are special request templates, available from OnkoZert. The structure evaluation is a complex and time-consuming process in which the structural and other central certification requirements are intensively analyzed.

Depending on the complexity of the structure, OnkoZert includes also the Certificate Awarding Committee in the evaluation of the structure. The data processing time is, usually, of 1-2 months.

Requirements for cooperative Centres

Each location will have to prove that all the certification requirements are met. The requirements for defining the primary cases are also included here (the number of cases cannot be

Basic information regarding certification

supplemented). Please contact Onkozert regarding special regulations if planning a cooperative Centre.

Number of cooperative locations

Cooperations with more than 2 locations are an absolute exception. In this context, one will take into consideration in particular the observations from the “Simultaneous initial certification of multiple locations” chapter.

Videoconferences

Basically conducting the tumour board by videoconferencing is, in principle, possible. Within the certification audits the videoconferences systems has to be proved online. The basis will be the following:

- Presentation of the patients will be done through images. For the participant that makes the presentation (radiologist, surgeon, ...) a practical technical solution will be found. The presentation of images and, where appropriate, other documents, must be centrally viewable on the screen by all participants (it is not enough to distribute images previously). Active demonstration must be possible, for example cursor movement and visible text viewing online, for example in the tumour board protocol or in the tumor documentation system.
- The sound quality must have at least fixed-line quality. Each participant must be able to hear all participants and be able to talk to all participants. Participants do not have to see each other through the webcam (recommendation, not obligatory).
- In order to operate the system, more people must be qualified (independent functionality will be ensured by certain people).
- In case the tumour board is not technologically feasible (system failure), there must be a documented failure concept. A telephone conference is not enough.
- The periodical personal presence of minimum 2 times a year in the designated cooperation partners circle will be ensured (valid exclusively for the cooperation partners of the specialties for which the permanent presence at the tumour board is mandatory). This personal presence can take place, for example, through the participation in the conventional tumour board, Quality Circles or other events (Morbidity and Mortality Conferences, specializations, ...).

Generally, the admission of cooperative partners in the tumour board has proven to be a positive experience. Organizing the tumour board between two cooperative locations with their own interdisciplinary structures is considered to be critical.

Basic information regarding certification

Assigning names to the Centres

By the chosen name, an outside person has to be able to recognize the validity domain of the certified Centre. The name should not leave the impression that other units could also be certified. Also through the name, the Centre should not be confused with an already certified unit.

The names of the certified Centres must meet certain requirements. These are set out in the document “Directive on assigning names to the Centres”.

Analysis of the certificate draft

The name of the Centre must be specified in the certificate, mandatorily. That is why, normally, the certificate structure will be agreed together with OnkoZert in the preparatory phase.

Primary cases

For the admission of the certification, the proof of minimum number of primary cases on each organ must be proven.

The accuracy of the number of primary cases is checked during the on-site audit on the basis of the patients’ documentation.

At the date of the certification audit, a smaller number of primary cases automatically means the failure of the audit.

On the certification date, the data must not be older than 3 months. Complete quarters must be analyzed.

Limit situations for primary cases

We are talking about a limit situation of primary cases if:

- The minimum required number has not been exceeded by more than 10%
- The minimum required number has not been reached, not even once, in the last 3 years.

Recommendation for limit situations of primary cases

- Performing a 100% check of primary cases
- Upon request, OnkoZert can carry out a documented check of primary cases in advance (subject to mandatory fees).

**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.*