

Directive on the evaluation of primary cases/number of cases (directive on primary cases)

Completion/changes to the 02.11.2015 version are marked in red.

A number of primary cases smaller than the imposed target value is a critical situation regarding the admission of initial certification, the maintenance of the certificate and the extension of the certificate. This directive contains the evaluation bases applicable for the specialized experts and the Certificate Awarding Committee and for (critical) situations of primary cases on different organs.

Initial certification

The conditions for audit admission and release of certificate:

- Fulfillment of primary cases from the last calendar year and last 12 months.

Surveillance audit

In case of a positive audit result (=the auditor recommends maintaining the certificate, or as the case may be, solving the deviations) the maintenance of the certificate is possible even if the number of primary cases is not accomplished (a declaration regarding the situation of primary cases is required).

Addition (27.08.2012)

At the Gynaecology Cancer Centres the decrease in the number of cases from the imposed limit is limited to max. 10%.

Recertification audit

Condition for the **legal** certificate extension:

In the average of the last 3 calendar years, the target value of oncological cases must be reached (see the chart on next page). Thus, the proof of accomplishing the number of cases in “the last calendar year and last 12 months” is not enough.

The limited extension of the certificate (12 months) when:

- Accomplishing the number of cases in the last calendar year, but not the average of the last 3 years.
- The number of cases is reached in the average of the last 3 calendar years. However, in the last calendar year calendaristic the decrease from the imposed limit of the cases is greater than 20%.

For another extension of the certificate’s validity, the number of cases must be accomplished for the last calendar year at the next audit.

When decreasing below the target value:

Suspension of the certificate for min. 12 months, starting from the “Expiry date of the certificate’s validity”.

The condition for reactivating the certificate is the achievement of a new **audit**, as well as a positive evaluation given by the Certificate Awarding Committee.

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General dispositions

Analysis of the last 12 months	<ul style="list-style-type: none"> • Data no longer than one year • Date of evaluation = date of audit (resp. date of evaluation by Committee)
Presentation of the primary cases situation	When decreasing under the imposed limit of primary cases, respectively in the limit situation of primary cases, there is a general requirement to present the primary cases detailed on months, in the forms provided by OnkoZert.

The imposed number of cases per calendar year

The assessments refer to the following number of cases in the catalogue of requirements.

Organ	Chapter in catalogue	Name/requirement for number of cases
Breast	BZ 5.2.1	≥ 100 primary cases
Colorectal	VZ 1.2.0	Operative expertise of the Centre <ul style="list-style-type: none"> • ≥ 30 colon cancers • ≥ 20 rectal cancers
Gynaecological	1.2.1	≥ 75 cases (= total number of cases), din care ≥ 50 cazuri primare
Skin	HZ 1.1.3	Cases of malignant epithelial tumors: ≥ 100 patients Cases of invasive malignant melanoma: ≥ 40 patients
Head and Neck	KHT 1.2.1	≥ 75 primary cases
Pediatric	KIO 1.2.1	≥ 30 patients (cases per centre) at the age from 0 to 17 years
Liver	VZ 1.2.0	≥ 30 patients with primary diagnosis of a HCC (hepatocellular carcinoma)
Lung	1.2.1	≥ 200 patients with primary diagnosis of Lung Cancer
Lung	1.2.2	≥ 75 pulmonary anatomical resections in patients diagnosed with ICD code
Gastric	VZ 1.2.0	≥ 30 patients with primary diagnosis
Neuro-oncology	NOZ 1.2.1	≥ 100 primary cases
Neuro-oncology	NOZ 5.2.3	≥ 60 primary operative cases
Pancreatic	VZ 1.2.0	≥ 25 patients with primary diagnosis
Prostate	PZ 1.2.1	≥ 100 primary cases per year
Prostate	PZ 5.2.1	≥ 25 prostatectomies (is not related to primary cases)

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Primary evaluation of colorectal cancers (result of the Visceral Certification Committee of 17.03.2016)

For Colorectal Cancer Centres in case of recertification audits the following special regulation is available:

In the case of primary cases of 18-19 rectal cancer surgeries and/or 27-29 colon cancer surgeries, and if the result of the audit is normal, the certificate may be extended.

Cancer Centre

- The valid certificates of Organ Centres and Modules will be recognized in the analysis of the Cancer Centres.
- If the extension of a certificate is not possible in an Organ Centre, respectively a Module, the existing certificate for the Cancer Centre can be still be kept, even if some structural requirements for the Cancer Centre are not met temporarily (for example the number of the Organ Cancer Centre/ Module, validity domain quota, ...). The extension of the certificate for the Cancer Centre would not, however, be possible.
- The suspension of the certificate for the Cancer Centre must be on minimum 12 months, starting from the "Expiry date of the certificate's validity".

**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.*