CraNE

Co-funded by the European Union

Comprehensive Cancer Care Networks (CCCN´s)

Set of Standard for Radio-oncology

Included are Requirements/Standards:

- Joint Action innovative Partnership Action against Cancer (iPAAC), WP 10 Governance of Integrated and Comprehensive Cancer Care (https://www.ipaac.eu/en/work-packages/wp10/)
- European Cancer Centre Certification Programme
    - Catalogue of Requirements Lung Cancer Centres (cr_lcc-l1_ENG_220831) (https://ecc-cert.org/wp-content/uploads/2023/01/cr_lcc-l1_220831-fin.docx)
    - Catalogue of Requirements Radio-Oncology (cr_radio-K1_ENG_220928) (http://dev.ecc-cert.org/wp-content/uploads/2023/01/cr_radio-K1_ENG_220928_fin.docx)
    - Catalogue of Requirements Pathology (cr_pat-L1_ENG_220928) (http://dev.ecc-cert.org/wp-content/uploads/2023/01/cr_pat-L1_ENG_220928_fin.docx)
- European Cancer Organisation Essential Requirements for Quality Cancer Care (ERQCC): Lung Cancer (2020) (https://www.sciencedirect.com/science/article/abs/pii/S0169500220305912)
- OECI Accreditation and Designation Programme European Quality Standards for Cancer Networks Doc00_OECIUserManual_2_0.pdf (https://www.oeci.eu/accreditation/Attachments/Doc00_OECIUserManual_2_0.pdf)
- European Respiratory Society Guideline on various aspects of quality in lung cancer Care (2022) (https://erj.ersjournals.com/content/early/2022/10/13/13993003.03201-2021)

Developed in the context of CraNE from the working group of Work Package 6, based on the previous work done by the Joint Action iPAAC*

***https://www.ipaac.eu/roadmap/detail/112**

Prologue

This "Set of Standard (SoS) Radio-oncology" sets out the requirements which must be met by the cooperation partner radio-oncology in Comprehensive Cancer Care Networks (CCCNs)
This Set of Standards will be piloted in the scope of the Joint Action "Creation of National Comprehensive Cancer and EU-Networking" (CraNE)" and based on the results of Joint Action "Innovative Partnership Action Against Cancer" both financed by the European Commission.
The Set of Standard Radio-oncology focuses on the tumour entities colorectal, pancreatic and lung cancer
It is to be used together with the SoS for CCCN (https://www.ipaac.eu/res/file/outputs/wp10/cccn-standard.pdf), SoS for Colorectal and Pancreatic Cancer Care (https://www.ipaac.eu/res/file/outputs/wp10/cccn-standard-supporting-document.pdf) and/or SoS for Lung Cancer Care (in development).

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Members of the working group on Implementation of CCCN for lung cancer (Task 6.3) (in alphabetical order) are:

Miguel	Areia	Directorate – General of Health (DGS)
Olga	Balaoura	Athens General Oncology Hospital (Agios Savvas)
Anastasia	Balasopoulou	1st Regional Health Authority of Attica (1st YPE ATTICA)
Harriët	Blaauwgeers	Organisation of European Cancer Institutes (OECI)
Beate	Brenner	Technical University of Dresden (TUD)
Karen	Budewig	Federal Ministry of Health (BMG)
Maja	Čemažar	Institute of Oncology Ljubljana (OI)
M. Rudy	Chouvel	Fédération Hospitalière de France, commission cancer (FHF Cancer)
F.	Costa	Directorate – General of Health (DGS)
Ineta	Derjabo	Riga East University Hospital (REUH)
Anne	Drochon	Institut National du Cancer (INC)
Dorota	Dudek-Godeau	National Institute of Public Health – National Institute of Hygiene (NIZP PZH-PIB)
Markus	Follmann	German Cancer Society (DKG)
Arne	Fosseng	Oslo University Hospital (OUS)
George	Georgiou	Athens General Oncology Hospital (Agios Savvas)
Vasiliki	Gkioka	Athens General Oncology Hospital (Agios Savvas)
Nikolai	Goncharenko	Institut National du Cancer (INC)
Nele	Grapentin	German Cancer Society (DKG)
Ellen	Griesshammer	German Cancer Society (DKG)
Ingrid	Guldvik	Oslo University Hospital (OUS)
Jenny Rui	Henrique	Directorate – General of Health (DGS)
Lidia	Janicka	National Institute of Public Health – National Institute of Hygiene (NIPH-NIH)
Kathy	Jaworski	Institut National du Cancer (INC)
Uroš	Kuhar	Institute of Oncology Ljubljana (OI)

Thomas	Langer	German Cancer Society (DKG)
Claudio	Lombardo	Organisation of European Cancer Institutes (OECI)
Per	Mahle	Oslo University Hospital (OUS)
Magnus		
Delia	Nicoara	The Oncology Institute ”Prof. Dr. Ion Chiricuta”, Cluj-Napoca (ICON)
Simon	Oberst	Organisation of European Cancer Institutes (OECI)
Alain	Ravaud	Fédération Hospitalière de France, commission cancer (FHF Cancer)
Peggy	Richter	Technical University of Dresden (TUD)
Hannes	Schlieter	Technical University of Dresden (TUD)
Sigbjørn	Smeland	Oslo University Hospital (OUS)
Kim	Tiede	German Cancer Aid (DKH)
Sonja	Tomšič	Institute of Oncology Ljubljana (OI)
Xavier	Troussard	Fédération Hospitalière de France, commission cancer (FHF Cancer)
Heidi	van Doorne	Organisation of European Cancer Institutes (OECI)
Simone	Wesselmann	German Cancer Society (DKG); Speaker of WP 6

Valid from 01 January 2023

This Set of Standards (SoS) is binding for all peer reviews from 1 January 2023. All changes to the previously applicable versions of this Set of Standards are marked in yellow.

Tumour-specific requirements are marked as follows:
Colorectal Cancer = violet
Lung Cancer = green
Pancreatic Cancer = red

General Information

Name of the department [1)] _____

Head of department _____

Contact CCCN _____

Address _____

Tel. _____

Email _____

[1)] Definition clinical site: The clinical site is determined by the address. 1 clinical site is 1 cooperation partner of the CCCNe, irrespective of any existing different organisational/legal forms (part of the clinic, medical centres…). In the registration as a cooperation partner only 1 name may be used (

Please indicate for which CCCN the radio-oncology is a cooperation partner:

_____

_____

_____

_____

_____

_____

Scope of radio-oncology

☐ CrC ☐ Panc ☐ LC

Preparation / Updating of the Set of Standard Radio-oncology

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Patient treatment

- ☐ Inpatient: own ward
- ☐ Inpatient: Co-use of ward

Linear accelerator at the clinical site

No.	Designation of equipment accelerator (company)	Year installed
1		
2		
3		
4		
5		
6		

No.	Name planning system	Assignment accelerator (number from above table
1		
2		
3		

Types of therapy at the clinical site

- ☐ Intensity Modulated Radiotherapy (IMRT)
- ☐ Image Guided Radiotherapy (IGRT)
- ☐ Others
- ☐ Brachytherapy
- ☐ Stereotactic radiotherapy

7.1 Interdisciplinarity

Section	Requirements	Explanatory remarks Radio-oncology	
7.1.1	Cooperation agreement When the cooperation partners of a CCCN work under the same funding body or at the same 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: • Description of the treatment processes of relevance for the CCCN 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 CCCN Set of Standards 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 CCCN (e.g. homepage)		
7.1.2	Tumour board • Mandatory participation • Ensuring availability of specialist • Participation and consensus provisions in the case of more than 1 cooperation partner for each specialty (see also provisions "Interdisciplinary cooperation")		
	Online conference If online conferences are used Radio-oncology must be able to present its own documents/images.		
	Therapy plan/tumour board minutes • In principle, the therapy plans and recommendations of the tumour board are the basis for treatment. • The therapy plan/tumour board minutes must be available in the documentation for each patient. • If there are any deviations from the recommended therapy plan, they are to be presented at the tumour board and documented in the patient's medical record.		
7.1.3	Interdisciplinary cooperation • The standard operating procedure for the prompt exchange of information (e.g. on applied cycles/doses, side effects during therapy) between the attending specialties is to be documented (e.g. medical report, short protocoll, CTC notification)		

7.1 Interdisciplinarity

Section	Requirements	Explanatory remarks Radio-oncology	
	In the case of combination therapies toxicities, in particular CTC Grades lll/IV, are to be notified immediately.		

7.2 Accelerators

Section	Requirements	Explanatory remarks Radio-oncology	
	One accelerator with >= 6 MV photons with at least 6-15 MeV electrons		

7.3 Number of radiotherapy treatments

Section	Requirements	Explanatory remarks Radio-oncology	
	Number of complete radiotherapy series for tumour patients (not restricted to the CCCN patients).	Information in the table "Complete radiotherapy series" (at the end of this Section)	
	Tumour-specific characteristics		
lung	Number of radiotherapy treatments per radiotherapy treatment unit Primary treatment: • ≥50 patients with a lung cancer who are given thoracic radiotherapy Total number: • ≥100 patients with a lung cancer who receive a complete radiotherapy series in a curative, palliative or metastatic situation.		

Number of complete radiotherapy series (not restricted to the CCCN's patients)

Clinical site Radio-oncology	CrC	PAN	LC

7.5 Specialists – Radio-oncologists

Section	Requirements	Explanatory remarks Radio-oncology	
	CCCNs	*See also chapter 7 SoS CCCN*	

7.5 Specialists – Radio-oncologists

Section	Requirements	Explanatory remarks Radio-oncology	
	At least two radio-oncologists Specialists are to be designated by name		

Details of the specialists radiotherapy

Name, first name	Title	Specialist qualification	Full-time or part-time as %	Focus tumour-entit

7.6 Medical Physics Expert (MPE)

Section	Requirements	Explanatory remarks Radio-oncology	
	CCCN Medical physicist • At least one medical physicist must be available in the department on workdays • Medical physicists and their backups are to be designated by name A back-up plan must be formulated in writing		

7.7 Medical technical radiology assistants (MTRAs)

Section	Requirements	Explanatory remarks Radio-oncology	
	• 2 MTRAs must be present for each linear accelerator during radiotherapy. • Cover staff rules must be formulated in writing.		
	Name:		

7.8 Radiotherapy processes

Section	Requirements	Explanatory remarks Radio-oncology	
	Radiotherapy processes The instructions in the national radiation protection legislation of the respective country are to be followed.		
	Contingency plan Contingency plan formulated in writing (		
	Combination therapies In the case of combination therapies (e.g. percutaneous radiotherapy/brachytherapy/IORT,		

7.8 Radiotherapy processes

Section	Requirements	Explanatory remarks Radio-oncology	
	simultaneous radio-chemotherapy) the medical and medical-physical responsibility should not change. If a change in this responsibility is essential for organisational reasons, the therapy plan must be agreed and signed by all responsible healthcare professionals prior to the commencement of treatment.		
	•		
	Documentation/Tumour control • The relevant radiation data (single dose, total dose, total treatment time) are to be recorded in line with the Guidelines. Any deviation from the prescribed dose must be justified and documented. • Supportive measures in accordance with the Guidelines are to be described for the individual therapy concepts and documented in detail for each patient.		
	Availability/On-call Presence of one specialist for radiotherapy during working hours, 24-hour on-call service outside working hours, if necessary through cooperation (including weekends and public holidays)		
	• CCCNs must have a written concept for emergency radiotherapy and timely radiotherapy for relief of symptoms in palliative patients. •		

7.9 Radiotherapy planning

Section	Requirements	Explanatory remarks Radio-oncology	
	• Therapy simulator or virtual simulation • CT planning • 3D and IMRT radiotherapy planning system • Access to magnetic resonance imaging (not for LC) • Optional: Integration of PET into therapy planning (not a requirement for LC)		
	• Integration of PET or PET-CT data into the radiotherapy planning system (optional) • MRI for radiotherapy planning (optional,) • 4D computer tomography for radiotherapy planning (optional)		

7.10 Radiotherapy techniques

Section	Requirements	Explanatory remarks Radio-oncology	
	Techniques that must be available: • Image-Guided Radiation therapy (IGRT) • Intensity Modulated Radiotherapy (IMRT, optional: BC)		

7.10 Radiotherapy techniques

Section	Requirements	Explanatory remarks Radio-oncology	
	• 3D-compliant radiotherapy		
	Tumour-specific characteristics		
	Fractionation If indicated, the radiation should be performed hypofractionated.		
colorectal	Patients in whom downsizing is the goal can also be given short-term radiation with a longer interval of up to 12 weeks to surgery (with and without neoadjuvant chemotherapy).		
lung	• Special radiotherapy techniques: extracranial and intracranial stereotactic radiotherapy; consideration of respiratory motion through suitable techniques • Whole brain irradiation alone should be avoided as initial therapy in patients in good general condition and with 1 to 4 stereotaxable brain metastases.		
	• Breath-triggered radiotherapy (optional)		

7.11 Brachytherapy

Section	Requirements	Explanatory remarks Radio-oncology	
	Tumour-specific characteristics		
lung	Brachytherapy should be available. If it is not available external cooperation is possible		

7.12 Systemic tumor therapy by radio-oncology

Section	Requirements	Explanatory remarks Radio-oncology	
	If radiotherapy carries out performs a drug oncological therapy for an entity, the provisions in Section 6.2 of the respective tumour-specific Set of Standard apply in addition.		
	Implementation of systemic tumour therapy using radiation therapy in combination with radiotherapy for solid tumours		
	Case numbers per treatment unit • At least 50 systemic tumour therapies in combination with radiotherapy for solid tumours if not otherwise specified in the tumour-specific requirements. • Calculation method: completed systemic / cytostatic / targeted therapy for each patient (consisting of **several** cycles or applications, combined therapies count as one therapy). For therapies extending over a year, the therapy started in the indicator year counts. 1 therapy per patient = 1 therapy line per disease per patient. • In the event of a shortfall, expertise cannot be proven via cooperation (must be proven by each individual treatment unit).	Case numbers in the table at the end of the chapter	

7.12 Systemic tumor therapy-by radio-oncology

Section	Requirements	Explanatory remarks Radio-oncology	
	The standard operating procedure for sequential/simultaneous radio-chemotherapy is to be described.		
	Treatment documentation for systemic tumour therapy in combination with radiotherapy for solid tumours: • The side effects are to be recorded and evaluated. • Blood count monitoring and laboratory tests must be recorded by the radio-oncologist		
	If the radio-oncologists does not perform the simultaneous chemoradiotherapy him/herself, the responsibilities for the treatment of side effects, interruptions of radiotherapy, dose specification and dose reductions must be clearly defined beforehand. The joint treatment plan must also be signed by a specialist in radiotherapy in every case.		
	Tumour-specific characteristics		
lung	When performing simultaneous thoracic radio-chemotherapy through radiotherapy department: At least 30 lung cancer patients with simultaneous thoracic radio-chemotherapy/year		

Systemic-tumor therapies-carried out by radio-oncology in combination with radiotherapy for solid tumors (not limited to patients of the Centre)

Clinical site Radio-oncology	Colorectal	Pancreatic	Lung

7.13 Palliative radiotherapy

Section	Requirements	Explanatory remarks Radio-oncology	
	• In cases of palliative radiotherapy, the intention of the therapy (local control or solely to alleviate symptoms) must be documented. • Palliative medical measures, as well as the development of symptoms and adverse effects, must be described especially in relation to therapy concepts intended to alleviate symptoms and documented in relation to the individual patient. • Simultaneously administered pharmacotherapy (e.g. pain or tumour-specific therapy) must be documented.		

7.14 Consulting hours/Waiting times

Section	Requirements	Explanatory remarks Radio-oncology	
	Consulting hours • It must be ensured that every patient is presented to a physician before the beginning of a radiation treatment series • At least one additional contact with a physician must be documented at the radiotherapy facility during a radiation treatment series		
	Waiting time • Period between patient's first contact and the initial presentation: < 10 Days • Period between the initial presentation and beginning of treatment, provided there are no medical reasons to the contrary: < 4 weeks • The actual overall treatment time should not exceed the prescribed overall treatment time by more than 10%. Interruptions in radiotherapy for medical reasons or by the patient constitute exceptions • The waiting periods are to be surveyed by random sampling and statistically assessed (recommendation: assessment period 4 weeks per year).		

7.15 Case-related information/Dialogue with patient

Section	Requirements	Explanatory remarks Radio-oncology	
	Adequate information must be provided about diagnosis and therapy planning and a consultation is to be given. This includes *inter alia*: • Structured explanation of indication, action, side effects, treatment schedule • Presentation of alternative treatment concepts • Offer of and aid in obtaining second opinions • Discharge consultation as a standard procedure • Patients must be given written patient information about behaviour during and after radiotherapy. Patient consultations are to be documented for each patient.		
	Tumour-specific characteristics		
LC	Patients must be given written patient information about behaviour during and after radiotherapy, in particular information about programmes on giving up smoking is to be provided.		

7.16 Induction, continuing education/specialty training

Section	Requirements	Explanatory remarks Radio-oncology	
	Continuing education/specialty training • A training plan for medical, nursing and other staff is to be presented listing the planned training sessions for the period of one year. • At least 1 dedicated continuing education/specialty training session for each staff member who carries out quality-relevant activities for the CCCN.		
	Systematic, documented induction of new staff members is to be ensured, which imparts knowledge about the CCCN's respective field of activity. This induction must take place within three months of commencement of employment.		
	Minimum continuing education/specialty training for each staff member and year: at least 0.5 days		

7.17 Quality circles

Section	Requirements	Explanatory remarks Radio-oncology	
	• Quality circles, in which oncological topics are addressed, are to be staged at least 3 times a year. • Scheduling, e.g. in training plan • Minutes of quality circles are to be taken. Participation is to be documented in total and not for each individual CCCN; quality circles can be interdisciplinary, for a specific organ and/or trans-organ in nature (see SoS CCCN 1.1.16).		

7.18 Cross-sectional areas

Section	Requirements	Explanatory remarks Radio-oncology	
	Radio-oncology must take into account the implementation of the requirements from the sections 1.4 Psycho-oncology 1.5 Social work 1.7 Reseach and Clincal Trials 1.8 Nursing care for the patients treated (by using the existing structures of the CCCN or its own organisation).		

7.19 Aftercare

Section	Requirements	Explanatory remarks Radio-oncology	
	The process for the tumour-(radiotherapy-)specific aftercare is to be described This includes: • Appointment/reminder • Type of documentation • Formalised notification of the respective in-house tumour documentation system in the event of recurrences, metastases and death of patients.		

7.20 Tumour documentation

Section	Requirements	Explanatory remarks Radio-oncology	
	Categorization t The documentation must contain clear, evaluable information on whether the patient is a CCCN patient and to which CCCN this patient has been assigned.		
	Follow-up data Follow-up data that have been obtained in radio-oncology are to be notified systematically to the CCCN. The follow-up data of the radio-oncological patients available to the CCCN should be used by radio-oncology to improve quality.		
	Side effects It must be possible to systematically record side effects on the tumour-specific level that have been identified. These records should be evaluated and analysed on an annual basis (e.g. in a quality circle).		

Self-Assessment	• Yes – the chapter has been implemented on a wide scale, and the Deming cycle has been completed twice. • Mostly – the chapter has been implemented in critical places, the Deming cycle completed once. • Partially – the chapter has been only partly implemented, or only recently introduced and not evaluated. • No – the chapter has not been implemented • Not Applicable (rare).	Yes	
		Mostly	
		Partially	
		No	
		Not applicable	