

Recommendation for the preparation of a quality handbook for radiation oncology

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SRO Swiss Society
for Radiation Oncology

SGSMP
SSRPM
SSRFM 

Schweizerische Gesellschaft für Strahlenbiologie und Medizinische Physik
Société Suisse de Radiobiologie et de Physique Médicale
Società Svizzera di Radiobiologia e di Fisica Medica



SVMTRA/ASTRM

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Preamble

In April 2017, the Federal Office of Public Health (FOPH) released the new radiation protection ordinance together with the associated technical ordinances, which formally went active by January 1st, 2018. The Swiss Society of Radiobiology and Medical Physics (SSRMP) launched a working group (RPO2MPP) dealing with the implementation of the radiation protection ordinance (RPO) into medical physics practice (MPP). Based on a workshop in August 2017, several topics were jointly elaborated and prioritized. One of the topics is the requirement to provide a recommendation for the radiation therapy community dealing with the preparation of a quality handbook. The creation of the quality handbook is related to the scope of clinical audits, which have been newly established as a peer review procedure on a national level.

The RPO2MPP working group (chaired by Peter Manser) created an expert sub-group of medical physicists (co-chaired by Thomas Götzfried and Hans Neuenschwander) and discussed the topic intensely with the members of RPO2MPP working group. Members of the Swiss Society for Radiation Oncology (SRO), and the Swiss Society of Radiation Therapists (SVMTRA), were also involved in the creation of this document. The translation into English was done by Nicoletta Lomax.

The boards of the three societies SSRMP, SRO and SVMTRA approved this recommendation in Summer 2018 and thank all the contributors for their important work and their efforts.

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1. Introduction

This document is intended to be used as a guideline for radiotherapy centres in the preparation of a quality handbook (QHB), as required by Article 43 of the Radiation Protection Ordinance (RPO) of 26 April 2017. During a clinical audit according to RPO Article 41, the audited institution must be able to present the QHB. This recommendation should primarily ensure that when creating the QHB, none of the required content is overlooked. It is, therefore, structured in such a way that the individual chapters refer directly to the content mentioned in Article 43. Additional aspects that are specific for radiation oncology are also addressed.

The QHB may be in physical or electronic format. Existing quality management (QM) documents may be referenced. For example, a QHB structure with the items mentioned according to this recommendation could be included in a separate chapter of one's own QM system, pointing to corresponding QM documents.

The QHB as required according to RPO Article 43 does not cover all aspects of a clinical audit as mentioned in RPO Article 41. In particular, an important focus of clinical audits is put on the implementation of proper patient- and staff-related procedures in an institution making use of ionizing radiation. These procedures should be defined and documented as part of the QM-system. The checklist in the appendices of this recommendation is intended to give an idea of the scope and help in the preparation of a clinical audit in radiation oncology.

2. Duties and responsibilities

Recommendations:

- documentation showing the organisation of the radiotherapy centre (organigram);
- documentation of duties, responsibilities and competencies regarding the operation of the facility;
- documentation of duties, responsibilities and competences regarding radiation protection.

Notes:

It is good practice to have job descriptions available for all members of the team, including assignment of duties, responsibilities and competences of the individual employees, in particular if special tasks are allocated. An organigram can be used to help illustrate the structure and responsibilities. A template for a possible organigram of a radiotherapy centre can be found in the appendix.

As a minimum, the following functions should be named and briefly described:

- licence holder;

- radiation protection experts/advisors (for the use of ionizing radiation on patients, for radiation protection of employees and members of the public);
- Clinical Head of Department;
- Head of Medical Physics;
- Head Radiographer (Head RTT);
- person responsible for the QM system (including QHB);
- special tasks of individual employees (e.g. personal dosimetry, training managers for RTTs etc.).

In addition, the deputy for each function should be designated.

3. Equipment used for examination and treatment

Recommendations:

- list of all devices requiring licences;
- documentation of all equipment used in the preparation/planning and implementation of radiotherapy;
- inventory of radioactive sources and relevant documentation.

Notes:

The documentation should include the following items:

- type of device;
- date of installation, acceptance protocol;
- FOPH licence (number, date of issue, expiry date);
- radiation protection plans and calculations;
- service contracts
- instruction manuals;
- regulations regarding training, operation and maintenance necessary for the device.
- most of the above mentioned documents are typically found in the radiation device handbook ("Anlagebuch", "dossier technique"), which can be referenced.

For the sake of completeness and clarity, it is also useful to show the location of the radiation devices, controlled and supervised areas ("Kontroll- und Überwachungsbereiche", "secteurs contrôlés et surveillés") and radioactive sources on a plan of the department.

4. Staff training

Recommendations:

- documentation for the induction of new employees;
- documentation of the education and training status of all employees;
- documentation of the individual radiation protection training of all employees;

- check procedures to ensure that the requirements of the training regulations in radiation protection are met for each employee.

Notes:

Due to the variety of equipment and processes in different radiotherapy centres, careful attention must be paid to the induction of new employees. This should therefore be structured and documented.

Regular internal and external continuing education and training in areas of radiotherapy and radiation protection should be made available.

With regard to radiation protection, the Ordinance on Trainings and Permitted Activities in Radiation Protection regulates the objectives, the requirements and the scope of the training for all staffing groups concerned. The training in radiation protection should therefore be recorded and documented for all relevant employees (doctors, physicists, radiographers, medical practice assistants etc.).

It is advisable to document the status of training, continuing and further education for each employee in a comprehensive manner. The content, the extent and the provider of training and continuing/further education should be documented.

4.1 Physician (Radiation oncologist)

According to Article 40 MedBG/LPMéd, continuing medical education is mandatory for practicing doctors. For radiation oncologists this is regulated by the continuous medical education programme of the Swiss Society for Radiation Oncology (SRO) (last successful access on 17.04.2018: <https://www.sro-ssro.ch/continuous-medical-education/general-information/>).

The practical training in radiation protection takes place in the context of the postgraduate training as a specialist in radiation oncology at a recognised postgraduate training centre. The extent of continuing education in radiation protection is regulated in the Ordinance on Trainings and Permitted Activities in Radiation Protection (8 teaching units in 5 years).

The radiation oncologist is personally responsible for attending the required training and must be able to show documented evidence of the training at all times.

4.2 Medical Physicist

In order to maintain the professional recognition, the obligatory continuing professional development must be fulfilled in accordance with the guidelines of the SSRMP (last

successful access on 17.04.2018: <http://ssrmp.ch/certification-for-medical-physicists/rules/>).

Appropriate training in radiation protection is a part of the SSRMP certification process in medical physics. The extent of continuing education in radiation protection is regulated in the Ordinance on Trainings and Permitted Activities in Radiation Protection (8 teaching units in 5 years, the continuing education being subject to recognition). The medical physicist is personally responsible for attending the required training and must be able to show documented evidence of the training at all times.

4.3 Radiographers (RTTs)

The continuing professional development of radiographers (RTTs) is regulated by the radiotherapy centres and may be internal and / or external (e.g. SVMTRA/ASTRM training events).

The practical training in radiation protection takes place whilst qualifying as an RTT. The extent of continuing education in radiation protection for RTTs is regulated in the Ordinance on Trainings and Permitted Activities in Radiation Protection (8 units in 5 years).

The level of qualification, the induction of new staff members and the continuing education of staff members should be documented and the documentation should be continually updated.

4.4 Other staff

For other persons (medical practice assistants, nursing staff, technicians etc.), the person responsible for radiation protection must individually determine the extent to which these persons are obliged to undergo training and continuing education in radiation protection. This must be documented accordingly.

5. Justification of the individual application (Indication)

Recommendations:

In this chapter of the QHB, the radiotherapy centre should define:

- the minimum amount of documentation required to make the indication for radiotherapy;
- according to which general guidelines the indication is made;
- specific standard protocols to be used for specific indications, if available;
- with which tumour boards radiation oncology is directly involved;
- with which tumour boards there is a co-operation;

- the requirements of the documentation for making the indication for radiotherapy for each individual patient. As a minimum, this should include the principles on which the indication is based (e.g. guidelines) and, if available, the recommendation made by the tumour board.

In addition, the process of regular review of the standard practices, for example in the context of self-audit, should be documented.

Notes:

When making the indication for radiotherapy treatment, the radiation oncologist should, in general, follow national and international guidelines. The following organisations provide quite comprehensive guidelines:

- DEGRO: <https://www.degro.org/ueber-uns/veroeffentlichungen/leitlinien/>;
- ASTRO: <https://www.astro.org/Clinical-Practice-Statements.aspx>;
- NCCN: https://www.nccn.org/professionals/physician_gls/f_guidelines.asp.

If no guideline exists, the basis for the indication should be documented (evidence from the literature, general or local consensus, personal experience etc.).

Today the majority of all tumour diseases are discussed in tumour boards. The radiation oncologist is required to include recommendations of the tumour board in his considerations and inform the patient of alternative treatment options, if they exist.

In order for important new findings on the efficacy or side-effects of treatment methods to be incorporated into clinical practice, the justification for indications should be regularly reviewed by the radiation oncologist and adapted as necessary.

6. Patient identification and information

Recommendations:

- documentation of measures taken to ensure the correct identification of a patient;
- definition of the scope of documentation for a particular patient and his therapy;
- definition of the procedure when informing the patient of his medical situation and treatment options, as well as the scope of the information given;
- presentation of the circumstances under which treatment is refused (taking into account the medical justification and the patient's wishes).

Notes:

The radiotherapy centre must ensure that all necessary patient data required in making the indication and in the implementation and follow-up of the radiotherapy treatment are collected and updated and also remain available after completion of the treatment.

The data belonging to a patient must be unambiguously marked. A mistake in the patient identity during the treatment, in the aftercare, or within the legally required duration of the data storage, must be excluded.

The patient is usually informed about the indication for radiation therapy and the planned treatment procedure during a consultation with the radiation oncologist. The consultation should be documented, with documentation including as a minimum:

- the explanation of the chances of cure and risks involved in the intended radiotherapy, as well as the prognosis with and without the treatment;
- information about alternative treatments, if any, and their risks;
- the consent of the patient to the prescribed radiation treatment (a patient signature is not required by law);
- the reasoning behind why radiotherapy may be out of the question (from a medical and / or patient perspective).

For a patient to legally consent to treatment, the patient must be sufficiently well informed. In case of dispute, the physician or the hospital must be able to prove that correct and sufficient information was provided. A written documentation outlining the patient consultation/information is, therefore, essential. The nature and extent of information and explanation given to the patient are regulated by the cantonal health laws (see, for example, Article 39 of the Health Law (GesG), Bern). Furthermore, reference may be made to the code of conduct of the Swiss Medical Association (FMH).

It is more straightforward for the patient to be led through a written patient information sheet which can later be reread. For this reason, and also to provide proof in case of a later dispute, it is worth considering the use of a written patient information sheet, to be signed by the patient.

7. Medical treatment instruction (Radiotherapy prescription)

Recommendations:

- definition of the documentation required for the radiotherapy treatment instruction;
- documentation as to which standard protocols are used (dose prescription, tolerance doses etc.);
- definition of the procedure and the documentation requirements in case of deviations from the standard protocols;
- definition of the procedure for the quality assurance of the treatment instruction.

Notes:

The radiotherapy centre must ensure that a radiotherapy treatment instruction is prepared for the individual patient for the intended therapy. This must be defined and documented

by a radiation oncologist before the first irradiation. The documentation may be kept electronically and should contain the following information (see Appendix 5 of the Accelerator Ordinance):

- date of issue of the radiotherapy prescription and identification of the responsible physician;
- information regarding the identity of the patient;
- medical history;
- special issues such as pacemaker, defibrillator, previous radiotherapy treatment dose etc.;
- brief description of the disease;
- goal and treatment intent of radiation treatment;
- standard protocols according to guidelines, e.g. NCCN guidelines (including single fraction dose, total dose and fractionation);
- description of target volumes and regions at risk;
- tolerance doses for risk structures according to guidelines, e.g. QUANTEC;
- selected treatment plan;
- description of planned combined therapies, for example hyperthermia and chemotherapy.

Subsequent changes must be justified and documented.

8. Patient specific irradiation instruction

Recommendations:

- definition of the requirements for the documentation of the irradiation instruction;
- definition of the criteria for the acceptance of a treatment plan taking into account the individual treatment instruction;
- definition of the procedure for the quality assurance of the individual irradiation instruction.

Notes:

The radiotherapy centre must ensure that a patient-specific irradiation instruction is prepared on the basis of individual treatment planning in order to implement the prescribed medical treatment instruction. The patient specific irradiation instruction contains all the information needed to carry out the irradiation, in particular those for patient positioning and set-up and those pertaining to the accelerator (or irradiation unit) settings. The patient-specific irradiation instructions can be kept electronically and should contain the following information (see Appendix 5 of the BeV/OrAc):

- date and identification of persons responsible for planning the treatment (doctor, medical physicist, dosimetrist);
- information regarding the identity of the patient;

- treatment planning documents (medical imaging, target volumes, organs at risk, previous irradiation dose etc.);
- treatment plan with dose distribution;
- information on measures taken to verify the treatment (imaging, in vivo dosimetry, laboratory tests etc.);
- information about the patient positioning and fixation and about special procedures (e.g. respiratory control, surface monitoring, transponder tracking etc.)
- particulars of the radiation delivery (in particular number of fields, number of fractions per day and total number of fractions, intervals between fractions);
- physical radiation parameters (in particular irradiation technique, type of radiation, radiation energy, individual and total doses to the target volumes and organs at risk, monitor units / treatment time);
- geometric parameters of the irradiation device and the treatment couch (in particular field size, angles, positional parameters, focus-skin distance), as well as instructions for positioning and fixation of the patient;
- field-specific accessories (wedge filters, shielding blocks, compensators, multi-leaf collimators etc.).

If changes are made to the treatment plan, the patient specific treatment instructions must be updated accordingly.

9. Documentation of the treatment

Recommendations:

- definition of the minimum requirements for the documentation of the radiotherapy treatment in the patient chart;
- definition of the minimum requirements for the documentation of the treatment in reports sent to referring physicians and other physicians involved in the patient treatment.

Notes:

All parameters of the treatment, which are necessary in order to reconstruct the delivery of the radiotherapy treatment and the applied dose, must be documented and accessible at all times. The radiotherapy centre must take suitable measures to ensure that a dose reconstruction of the treatment is possible. Information on minimum information for the documentation of irradiation can be found, for example, in the BeV/OrAc (Appendix 5), the RöV/OrX (Article 20) and the MeQV/OSRM (Article 5). The documentation may be stored electronically. Persons who carry out the irradiation must be able to access and print this data at any time.

Essential information and documents are:

- identification of the physician responsible for the radiotherapy treatment;

- medical treatment instruction (see chapter 7 of this document);
- patient-specific irradiation instructions (see chapter 8 of this document);
- proof of irradiation according to Appendix 5 BEV/OrAc.

Documentation should also include instructions on the method of informing the referring physicians and other physicians involved with the patient treatment about the radiotherapy treatment delivered.

Information required in a treatment report (to referring and other physicians):

- patient administrative data;
- list of diagnoses / symptoms and progression of the disease;
- physician to receive the results;
- treating doctor, including any supervisor, contact details for enquiries;
- date and duration of radiotherapy;
- description of the radiotherapy delivered (volume, dose, fractionation, mention of any special procedures, e.g. stereotactic, respiratory control etc.);
- description of the outcome, including any side effects or complications and the therapeutic measures taken to deal with such complications;
- potential side effects which may be expected, with instructions for dealing with them.

10. Treatment evaluation (Follow-up / aftercare)

Recommendations:

- documentation of the follow-up program;
- description of the type and extent of the evaluation of clinical outcome (collection and analysis of the data).

Notes:

At the end of the treatment there should be a final consultation between the doctor and patient and a final report should be sent to the referring physician. Following this a follow-up / aftercare programme should be in place. Aftercare should include a detailed recording and documentation of all outcomes of the radiotherapy treatment. The type of aftercare is usually disease dependent.

The process of follow-up or aftercare must be documented, for example:

- contact person or doctor responsible for the treatment;
- type and frequency of follow-up checks:
 - Follow-up consultations when, for which patients?
 - internal follow-up checks, enquiries with referring physician, external reports;
- planning and structure of follow-up;

- documentation and recording of the outcomes of the disease / treatment, for example:
 - quality of life;
 - support (psycho-oncology, self-help group, cancer counselling);

11. Data management

Recommendations:

Documentation of processes for:

- data control and transfer (including image documentation) to referring doctors or others upon justified requests;
- data protection;
- data backup;
- archiving of data.

Notes:

Personal medical data is subject to general data protection and medical confidentiality requirements. The records may be stored in electronic format, as long as the requirements of the relevant data protection laws are met (Federal Law on Data Protection (DSG/LPD), cantonal data protection laws). The data required for the reconstruction of radiotherapy treatments must be accessible at any time during the obligatory period for storage (radiotherapy: 20 years) and must be accessible in an unmodified state. Damage caused by natural hazards must also be ensured against, for example by redundant storage of data.

12. Quality assurance (QA)

Recommendations:

- documentation of equipment acceptance and commissioning (to be used as a reference for the QA program);
- documentation of the QA programs of all devices and technical equipment (for both the manufacturer and the operator/user);
- documentation and archiving of quality assurance results;
- documentation of the processes and measures for dealing with equipment malfunctions and procedures in place in case the tolerance limits are exceeded (recording, communication, tracking etc.);
- documentation of staff responsible for QA and rules regarding delegation and training of QA work.

Notes:

The radiotherapy centre must take measures to maintain the safety and functionality of all equipment required for the preparation and delivery of radiotherapy treatment. Servicing (inspection, maintenance and repair) and quality control measures must be documented.

Test methods, frequencies, tolerances and intervention thresholds are based on guidelines and recommendations published by the FOPH and the SSRMP, backed up where necessary by current scientific and technical literature.

13. Self Evaluation / Continuous Improvement Process (CIP)

Recommendations:

- methods for self-audit of processes and measures for furthering quality must be defined and documented;
- process of implementing measures resulting from the self-audit must be documented;
- means of dealing with incidents, irregularities and deviations from intended procedure must be documented.

Notes:

The QM system and its procedures should be reviewed at least annually in order to obtain objective criteria for assessing the effectiveness of all aspects of the checks to be carried out ("internal audit").

Different methods can be used:

- regular evaluation of the procedures by the various professional groups involved;
- identification and review of the nature and extent of errors that have occurred (which must be documented in accordance with Article 50 RPO), as well as measures taken as a consequence in order to make good the error, follow up on it and ensure a similar error is avoided in the future.
- Critical Incident Reporting System (CIRS);
- system for the anonymous capture of all varieties of errors and incidents.
- therapy outcome;
- patient satisfaction, for example with regard to waiting time, atmosphere, adequate information;
- feedback from referring physicians.

Considerations as a result of external audits:

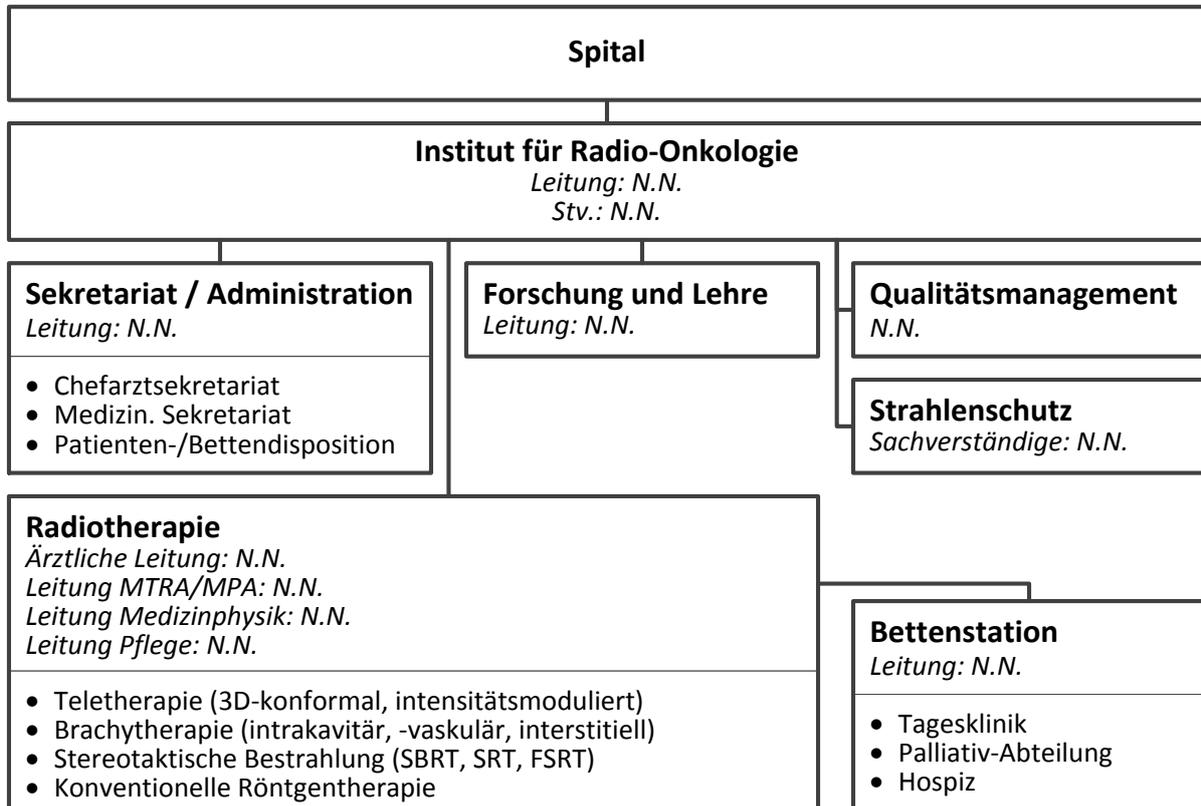
- results of FOPH audits;
- results of clinical audits;
- results of other external audits, e.g. as part of certifications;
- results of SSRMP dosimetry intercomparison.

14. Appendix

14.1 Checklist for clinical audits

➤ External document: CA_AuditContent.pdf

14.2 Example organigram of a radiotherapy centre



14.3 List of abbreviations

| | |
|---------|--|
| ASTRM | Association Suisse des techniciens en radiologie médicale |
| ASTRO | American Society for Radiation Oncology |
| BeV | Beschleunigerverordnung |
| CIP | Continuous improvement process |
| CIRS | Critical incident reporting system |
| DEGRO | Deutsche Gesellschaft für Radioonkologie |
| DSG | Bundesgesetz über den Datenschutz |
| FMH | Foederatio Medicorum Helveticorum (Swiss Medical Association) |
| FOPH | Federal Office of Public Health |
| GesG | Gesundheitsgesetz Kt. Bern |
| LPD | Loi fédérale sur la protection des données |
| LPMéd | Loi sur les professions médicales |
| MedBG | Medizinalberufegesetz |
| MeQV | Verordnung über den Umgang mit geschlossenen radioaktiven Quellen in der Medizin |
| NCCN | National Comprehensive Cancer Network |
| OrAc | Ordonnance sur les accélérateurs |
| ORaP | Ordonnance sur la radioprotection |
| OrX | Ordonnance sur les rayons X |
| OSRM | Ordonnance sur l'utilisation de sources radioactives scellées en médecine |
| QA | Quality assurance |
| QHB | Quality handbook |
| QM | Quality management |
| QUANTEC | Quantitative Analysis of Normal Tissue Effects in the Clinic |
| RöV | Röntgenverordnung |
| RPO | Radiological Protection Ordinance |
| RTT | Radiation Therapist ("MTRA") |
| SRO | Swiss Society for Radiation Oncology |
| SSRMP | Swiss Society of Radiobiology and Medical Physics |
| StSV | Strahlenschutzverordnung |
| SVMTRA | Schweizerische Vereinigung der Fachleute für med. tech. Radiologie |