B-QUATRO - Comprehensive Audits of Radiotherapy Practices:

A Tool for Quality Improvement adapted to the Belgian context

Version 2

FOREWORD

As part of a comprehensive approach to quality assurance (QA) in the treatment of cancer by radiation, an independent external audit (peer review) is important to assess adequate quality of practice and delivery of treatment. Quality audits can be of various types and levels, either reviewing specific critical parts of the radiotherapy process (partial audit) or assessing the whole process (comprehensive audit).

Whole process audit methodology has been developed by IAEA through a series of workshops held at IAEA Vienna headquarter in 1999 and 2000 and further, with the input of numerous experts from various parts of the world. It is called "QUATRO, Quality Assurance Team for Radiation Oncology. A tool for quality improvement."

IAEA officers Victor Levin and Bhadrasain Vikram contributed to the development of this document in 2003-2004. The IAEA officer responsible for the original document is Joanna Iżewska of the Division of Human Health.

B-QUATRO is a Belgian adaptation of the IAEA QUATRO[1], covering 2 of the 3 Donabedian criteria through which quality can be measured in an organisation, i.e. *structure* and *process*. The third criteria, *outcome*, is not in the scope of B-QUATRO. Its assessment is done in Belgium by periodic project reports from the KCE and Cancer Registry Foundation that provide hospitals with a feedback on their performances and a national benchmarking.

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[1] *Major contributions to this document by Pierre Scalliet (Belgium), David Thwaites (United Kingdom), Hannu Jaervinen (Finland) and Mary Coffey (Ireland) and suggestions by participants of a workshop "Quality Assurance Team for Radiation Oncology (QUATRO)" held on 9-11 May 2005 : Brunetto, M. (Argentina), Kron, T.(Australia), Smoke, M. (Canada), Cheung, K.(China), Castellanos, M.E. (Colombia), Alfonso, R. (Cuba), Novotny J. (Czech Republic), Nyström H. (Denmark), El-Gantiry, M. (Egypt), Salminen, E. (Finland), Kataria-Sethi, T. (India), Wadhawan, G.S. (India), Yusop, H.M.M. (Malaysia), El- Gueddari, B. (Morocco), Ibn Seddik, A. (Morocco), Olusoji Ojebode, J. (Nigeria), Calaguas, M. (Philippines), Bulski, W. (Poland), Maciejewski, B. (Poland), Engel-Hills, P. (South Africa), Van der Merwe, D., (South Africa), Kunkler, I. (United Kingdom), Stewart-Lord, A. (United Kingdom), Acevedo, T. (Uruguay), Zubizaretta, E. (Uruguay).*

CONTENTS

1. INTRODUCTION

The need for a Belgian adaptation of QUATRO emerged during the first audit campaign (2011-2016), to take into account national specificities and to avoid redundancies in audit parts that have proven to be uniformly qualitative (for example patient identification). Some parts have therefore been simplified. The audits of radiation dose and other relevant medical physics procedures have also been removed from QUATRO since this aspect is covered by the **BeldArt** part of Action 16 of the Cancer Plan. On the other hand aspects of quality and safety management that are not fully developed in QUATRO have been expanded through the integration of the recommendations emitted by a core group of the association of Quality Manager of Radiotherapy of Belgium (QMRT.be) [2].These changes have thus lead in 2017 to the creation of the "B-QUATRO" document which will be used to carry out the future comprehensive clinical audits.

The objective of a comprehensive clinical audit is to review and evaluate the quality of all components of the practice of radiotherapy at the institution, including its professional competence, with a view for quality improvement. A multidisciplinary team comprising a radiation oncologist (RO), a medical physicist expert (MPE), a radiation therapist (RTT) and a quality manager (QM) carries out the audit.

The term audit, as used in this document, is synonymous with an independent external evaluation, assessment or peer-review. This audit is intended to be comprehensive, but cannot be exhaustive as it is only a snapshot of a radiotherapy department at a specific point in time. On the other hand, opportunities for improvement exist in all institutions.

The interpretation of audit results is made against appropriate criteria of good radiotherapy practice (quality standards). As one example of such criteria, the IAEA has given a description of the design and implementation of a radiotherapy programme regarding clinical, medical physics, radiation protection and safety aspects in the report "Setting up a Radiotherapy Department" (International Atomic Energy Agency (IAEA), 2008).

The ultimate purpose of a quality assurance audit is to assess the current situation and to contribute to the continuous quality improvement of the radiotherapy process at the reviewed institution.

A comprehensive audit of a radiotherapy programme reviews and evaluates the quality of all elements involved in radiation therapy, including staff, equipment and procedures, patient protection and safety, and overall performance of the radiotherapy department, as well as its interaction with external service providers. It is centred on the patient trajectory.

Gaps in technology, human resources and procedures would be identified so that the institution would be able to document areas for improvement.

This audit is not designed for:

- Regulatory purposes, i.e. the teams are not convened as an enforcing tool but solely as an impartial source of advice on quality improvement,

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[2] *BATAMURIZA-ALMASI A., BLONDIAU E., CROHAIN J., TONET O., VAANDERING A., and VERCAUTEREN J.* "QMRT's tool: A complementary document to QUATRO" *(http://qmrt.be/downloads/QMRTtool2017.pdf)*

- Investigation of accidents or reportable medical events (misadministration). In the event of an investigation specifically into these aspects, a more focused audit is required,
- Assessments for entry into cooperative clinical research studies as these are conducted by peers within the group involved in the study and are focused on the strict adherence of an institute to a single specified clinical protocol in a selected group of patients.

2. AUDIT STRUCTURE

2.1. Preparation for the audit

The success of an audit depends heavily on thorough preparation of all parties involved.

2.1.1. Institution

The institution's role is to:

- Prepare data and relevant documentation to enable the auditors to complete evaluation according to the format of this document (including completing the B-QUATRO checklist as a form of self-assessment).
- Identify and assure participation of individuals needed for the audit, although the audit team should be free to interview any staff member they deem appropriate,
- Inform the entire department and hospital management of the audit and its timeframe,
- Provide treatment records requested by the audit team, although the audit team should be free to review any records,

2.1.2. Auditors

The auditors are required to:

- Be familiar with the audit procedures, discuss their approach and allocate their responsibilities[3],
- Review the preparatory and background information prepared by the institution and,
- Agree in advance with the counterpart on an appropriate timetable for the audit.
- Request additional information if necessary,
- Provide a comprehensive report on the visit.

2.2. Guiding principles and procedures of the audit

The audit will evaluate the overall performance of the radiotherapy department. In the process, the team should obtain a comprehensive understanding of the total operation of the department. The auditors need to consider the interaction of the radiation oncology department with other hospital departments involved in cancer management, such as gynaecology, surgical specialties and medical oncology, medical imagery and with the hospital administration. The auditors must have free access to all relevant staff members to assess the free and efficient flow of information and cooperation between the different professionals.

[3] Experts should consult the appendices to ensure that terms commonly used are clearly specified in the audited department (e.g., treatment, session, patient).

The auditors must seek evidence for a patient-orientated organization, with a culture of improving through learning and openness to new technologies, and a culture of strong cooperation between staff members. An appropriate quality assurance programme/system should be in place with the objectives of continuous quality improvement.

2.2.1. Entrance briefing

The entrance briefing is required to introduce the auditors to the various staff members and to discuss the methods, objectives, and the details of the audit. The auditors should reassure the department that the patient confidentiality will be respected.

2.2.2. Assessment

Both the infrastructure of the department and the overall radiotherapy programme will be audited.

The auditors will specifically evaluate and analyse the following items:

- The department infrastructure including personnel levels and workload
- Patient related procedures (from patient assessment to follow up)
- Equipment related procedures
- Quality and risk management systems implemented within the department
- Continuous Professional Development (CPD) and training

Aspects of the treatment process, which should have coordinated input from clinicians, medical physicists and RTTs, should be audited by the whole team. Only specialized aspects of the treatment process will be audited by individual team members. A sign-off procedure by the auditing team, assuring the department of individual patient confidentiality may be required.

A series of checklists have been designed to help the auditors organize the audit programme and to ensure coverage of all relevant topics. The following tools are available in order to complete the checklists:

- Staff interviews,
- Complete tour of the facility,
- Review and evaluation of procedures and all relevant documentation, including review of treatment records,
- Practical measurements and other tests of the performance of local systems and procedures, where appropriate and relevant,
- Observation of practical implementation of working procedures.[4]

The reviewed items will be scored as being either existent, in the process of being

[4] Direct observation of patient treatment is part of the review of records. This may require both the patient and doctor's consent.

implemented, non-existent or not applicable[5]. Subsequent to each checklist, the auditors will also provide a global score defining the level at which the department has met the criteria set out in the checklist. This overall score will be based on three levels:

- Compliant (green): the department meets all criteria set out in the checklist and the auditors have no recommendations to issue.
- Partially compliant (orange): the department needs to address a few elements; the auditors emit some minor recommendations that would allow for the department to improve practice.
- Non-compliant (red): the department needs to address a few major elements; the auditors emit some major recommendations that will improve practice.

This evaluation system will allow for the auditors and those audited to obtain spider web charts in order to be able to easily visualize areas of good performance and areas of improvement as illustrated in the figure below (Fig. 1).

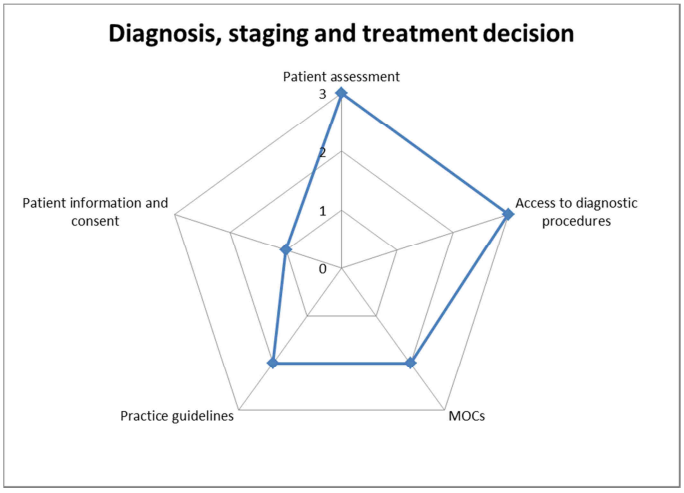

Figure 1 - Spider web chart of global scores attributed to a given department

2.2.3. Exit briefing

It is essential that the auditors present their preliminary feedback to the department. At the completion of the audit, the institution should convene appropriate members from all groups of the therapy team who were interviewed, for an interactive exit briefing. This will include time for questions and should include a detailed and open discussion of all the findings of the experts. Initial recommendations could be made, if obvious.

Immediately after the audit, preliminary recommendations should be presented in written format. The institution should be encouraged to ask questions and give an initial response to the assessment. The steps intended by the institution to respond to the recommendations and improve the activities of the department should also be discussed and recorded.

When measurements have been performed as part of the audit, completed forms and calculations should be left with the institution.

[5] The term "existent" pertains to a process/element that is formally/officially organized within the department.

2.3. Conclusion of the audit team

Auditors are expected to comment on how well the institution has satisfied the criteria as set out in the checklists. They will form and express an opinion regarding the appropriateness of the staffing in relation to the patient throughput. They are also expected to comment on type, quality, and amount of equipment. Evaluation of quality of patient care will be given.

If the department wishes to expand to new areas of expertise, appropriate separate recommendations will be drawn.

The auditors may recommend whether a follow-up visit, or internal audit is required. If the recipients of the audit report fail to implement recommendations and these are considered to be significant because of their potential impact on patient treatment outcomes, the recipients should be informed that they have the responsibility of notifying the regulatory authorities.

With respect to gaps in technology, infrastructure and procedures, the audit team may identify two levels of issues:

- Easily resolved areas for improvement are identified. These may be either minor changes, which are easy to implement, or major areas that require modification in infrastructure, but feasible by the department. These will be included in the detailed recommendations of the audit team.
- Major problems are identified that cannot be resolved by the radiotherapy department without significant changes outside the hospital or without significant resources. The solution to these problems may require government action and, if so, the relevant recommendations need to be included in the audit report.

2.4. The audit report

The audit results are presented in the form of an audit report which consists of two parts, a summary report and a detailed report. The former will summarize the mission and its conclusion, while the latter will include the details of the audit, comments by the auditors, the audit conclusion and recommendations, if any.

A useful audit report must contain conclusions formulated in an unambiguous way, with clear and practical recommendations.

To deliver valid conclusions, the audit group should address a series of key topics and measurements, which will constitute the objective part of the report. These items will be then discussed in the broader perspective of the local radiotherapy organization and culture, in order to produce a comprehensive document describing the audited department. The report should be concise. A suggested structure includes:

- A brief description of audit activities and its mission,
- Description of the facility (General description of the hospital and the department),
- Description of personnel, work organisation, working hours and responsibilities
- Description of demographic patient data and workload
- The inclusion of benchmarking if appropriate,

- Findings and results of the visit (including overall scores, commendations, suggestions and recommendation),
- Conclusions
- Annexes if pertinent.

It is important that the audit report mentions whether the site-visit was welcomed or not. The degrees of cooperation from the institution, department and various members of the radiotherapy team have a significant impact on the credibility of the final report. At all times the audit reports are confidential except for clearly designated recipients and the College staff facilitating the audit.

2.5. Dissemination of report

The detailed audit report will be sent only to staff in responsible positions in the radiotherapy department, e.g. the head of the department, the chief medical physicist, the head RTT, the quality manager and other staff members whose role in the institution is significant to this audit.

3. AUDIT PART I: INFRASTRUCTURE

Infrastructural data will be collected in the "BQUATRO checklist" as seen in the appendix. The auditors will also use as much as possible the data collected through the College QI project.

3.1. Patient demographics

The auditors must familiarize themselves with the definition used to determine a 'new patient' and a 'new cancer' in order to assess patient numbers and statistics. A number of different conventions exist, some of which are addressed in Appendix II. The auditors should collect information on:

- Number of new cases in RT (cancer or patients) per year. *A new patient can have several treatments on the same year. If these multiple treatments are for the same cancer, the new patient counts as one patient. If a patient has 2 or more different cancers, then it counts as several.*
- Number of treatments. *Treatment is defined as corresponding to one billing procedure. Ex: bilateral breast cancer patient is one new case but two new cancer and two treatments.*
- Types of cancer (primary sites and number),
- Ratio of radical (curative) treatment to palliative therapy to palliative treatment,
- Fraction of cancer patients (of the total number in the catchments area) who come for radiotherapy, where the statistical data are available.

3.2. Structure of the radiotherapy department

One of important aspects of the audit is the assessment of staffing levels and their professional competence, organization of work and the adequacy of premises. For those departments possessing one or more satellite sites, the following items need to be addressed:

- Are simulation procedures carried out in the satellite site?
- Is/are the satellite site(s) connected to the main department within the same network environment and using a common data server?
    - Is there a separate TPS in the satellite site?
    - Is there a separate record and verify system?
- Do the personnel working in the satellite site(s) have the same working conditions as those working in the primary site?
- Is there systematic rotation of staff for ROs?
- Is there systematic rotation of staff for the MPEs?
- Is there systematic rotation of staff for the RTTs?

- Are common staff meetings organized on a daily basis (new patients, TP review)?
- Are the used treatment techniques harmonized between the different departments?
- Are the clinical procedures identical between the satellite department(s) and the main department?
- Is there a single quality management system covering all sites?

These elements will underline the level of integration the satellite site has with the main primary department. In case, there is very little integration or very different activities, the auditors might need to foresee a separate BQUATRO checklist for each site.

3.2.1. Personnel

The following questions will help the auditors to gain understanding of the appropriateness of staffing numbers in different professional groups and their professional qualifications. This data includes:

- Number of radiation oncologists (should specify board certified RO + RO in training).
- Number of clinically qualified medical physicists (MPEs) in radiotherapy. This should specify MPE, MPE in training and MPA (dosimetrist). Please also specify if the MPE has additional responsibilities (e.g. diagnostics, radiation protection) and the ratio of MPA to MPE.
- Number of radiation therapists[6] (RTT) (A1 and A2 nurses and/or technologists and specify, including certification in oncology and/or radiotherapy),
- Presence of supportive staff (specialized nurses, social workers, psychologist, etc),
- Staff for maintenance, repair and IT (engineers, technicians…)
- Presence of (a) Quality manager(s)
- Is teaching part of routine activity?
- Is research (basic, clinical) part of routine clinical activity?
- Staff allocated to clinical research.

The staffing levels can be introduced in the *BQUATRO checklist.*

3.2.2. Departmental operation

The questions listed in this section will help the auditors to understand the work organization in the department.

- Contractual working hours (within the department) of the radiation oncologists, medical physicists and RTTs.
- Treatment hours of the department,

[6] In this document, RTT refers to the personnel – primarily composed of nurses and technologists working at imaging for treatment planning (simulation) and responsible for the daily delivery of treatment (at treatment modalities)

- Days per week of operation,
- Are emergency radiation services provided after hours?
- Minimum number of RTTs for each major item of equipment,
- Minimum number of radiation oncologists during treatment hours,
- Minimum number of physicists during treatment hours.

3.2.3. Premises

The physical layout of the department should be made available for auditors in advance, prior to the audit. The following checklist may help the audit team to evaluate the adequacy of the premises in the context of the departmental objectives and operations.

Table 1 - Observations on premises

Item	**Observations**
Location of the radiotherapy department relative to the main hospital	Off-site On-site Integrated into the main building Other:
Size and layout of the department	
Treatment rooms	
Control rooms	
Changing rooms/toilets	
Consultation rooms	
Waiting area	
Dosimetry and physics room	
Storage facilities	
Administrative area	
Mould room	
Other	
Department's proximity to other facilities (including teaching facilities)	
Additional source of medical science	*Library/journals/internet access?*
Associated ward	*Number of beds/number of patient (male/female/paediatric)*
Further comments/observations	

3.2.4. Radiation therapy equipment

A full inventory should be made of all major equipment on site, i.e. teletherapy (status: functioning, partial, redundant), brachytherapy, imaging, mould room, treatment planning. This would include non-functional and decommissioned equipment, which occupy useful space.

Table 2 - Radiation therapy equipment overview

Equipment/system	Type	Commissioning date	Detail and comment on function and location
EBRT equipment			
Equipment 1			
Equipment 2			
Equipment 3			
….			
BT equipment			
Equipment 1			
….			
Imaging equipment			
Equipment 1			
…			
Treatment planning equipment			
TPS 1			
TPS 2			
….			
Other equipment/facilities			
Material	Observations (Detail and comment on function and location)		
Dosimetry equipment			
Radiotherapy management system			
Computerized networked			

imaging	
Patient alignment equipment	
Mould room equipment	
Does the institution have an equipment replacement program	
Does the department have a calendar of preventative maintenance?	
Further comments/observations	

Note: Immobilization devices are evaluated in Checklist. 8

3.3. Workload

3.3.1. Patient throughput on radiotherapy equipment

When assessing the quality of radiotherapy services, patient throughput on radiotherapy equipment is an important aspect to consider. The following information needs to be made available to the auditors:

- Number of new cancer cases[7] or consultations of patients entering the department.

This annual figure can be much larger than the number of treatments with radiotherapy if the department integrates medical oncology and/or haematology.

- Number of new radiation therapy patients treated per annum in the department.
- Number of sessions/fractions given over a one-year period by each teletherapy machine (T),
- Number of applications given annually by each brachytherapy machine (B)[8],
- Annual total of CT scans performed for planning purposes,
- Annual total of simulations performed. If CT sim available, then annual CT number is identical to number of simulation.
- Relative proportion of simple (= Category I and II), intermediate (=Category III) and complex treatments (=Category IV) each machine delivers,
- Average treatment time on each machine.

[7] Refer Appendix II for annotations on quantification of 'cancer cases'

[8] Patient receiving both external beam radiotherapy and brachytherapy are thus recorded twice. Therefore the number of individuals treated in a department is not simply the sum of (T) + (B). Auditors should address this point unambiguously.

Case accrual fluctuates during the year. Maximum daily figures give an indication of what the department can handle when under pressure:

- Maximum number of fractions and fields in any one day on each therapy machine.

The requested information can be collected through the *BQUATRO checklist*

3.3.2. Statistics [9]

The following items should be considered when analysing the adequacy of the existing infrastructure in terms of human resources and equipment in the context of the departmental operations:

- Number of treatments per radiation oncologist annually.
- Number of treatments per physicist (MPE only and MPE + MPA (dosimetrists)) annually,
- Number of treatments per RTT annually,
- Number of treatments per teletherapy machine annually,
- Number of sessions (fractions) per day,
- Average number of fractions per course of treatment,
- Number of treatment sessions or fractions per RTT annually,
- Number of RTTs per equipment item.

[9] Refer to the Appendices I and II for the clarification of terms.

4. AUDIT PART II: PATIENT RELATED PROCEDURES

Patient-related procedures and clinical processes starting from patient assessment to patient follow-up are to be reviewed by the whole audit team except for those sections where the expertise resides exclusively with a particular professional group

4.1. Diagnosis and staging

Investigations leading to tumour diagnosis and staging are necessary to deliver radiotherapy. The auditors will make an assessment of the degree to which the available infrastructure is accessible and used for patient's diagnosis, staging and planning. The intent is to evaluate the presence and use of appropriate tools. The auditors may also consider recommendations on the introduction of cost-effective additional investigations that may be justifiable.

Patient's medical information and investigations should also be easily accessible and complete.

CHECKLIST 1. Patient Assessment

Items to be reviewed by the auditor	YES	In progress	NO	N/A
Does the hospital possess an electronic medical record (EMR) system?	☐	☐	☐	☐
If yes, is the radiotherapy department integrated within this system?	☐	☐	☐	☐
If no, does the radiotherapy department have access to all relevant clinical data/records?	☐	☐	☐	☐
Is there an ease of access to patient imaging data?	☐	☐	☐	☐
Is the pathology report included in all patients' files?	☐	☐	☐	☐
Are patients staged?	☐	☐	☐	☐

Is an international staging system used (TNM[10], AJCC[11], FIGO[12]…)?	☐	☐	☐	☐
Is the pTNM available when indicated?	☐	☐	☐	☐
Is the patient's performance status assessed (WHO[13], Karnofsky or ECOG[14])?	☐	☐	☐	☐
Is systematic geriatric assessment carried out in patients >75 year old?	☐	☐	☐	☐
Comments				

Overall Score	**Compliant**	**Minor recommendations**	**Major recommendations**
Is patient assessment properly carried out by the radiotherapy department?	☐	☐	☐
Commendations/Recommendations			

CHECKLIST 2. Access to diagnostic procedures

Items to be reviewed by the auditor	**YES**	**In progress**	**NO**	**N/A**
Access to Computer Tomography (CT) without any delay?	☐	☐	☐	☐
Access to Nuclear Imaging (scintigraphy) without any delay?	☐	☐	☐	☐
Access to PET/PET-CT procedures without	☐	☐	☐	☐

[10] Tumour, Node, Metastasis

[11] American Joint Committee in Cancer

[12] Féderation Internationale de Gynécologie et d'obstrétique

[13] World Health Organisation

[14] Eastern Cooperative Oncology Group

any delay?				
Access to MRI procedures without any delay?	☐	☐	☐	☐
Are the reports of significant radiological findings in the patient chart?	☐	☐	☐	☐
Comments				

Overall Score	**Compliant**	**Minor recommendations**	**Major recommendations**
Are diagnostic procedures easily accessible without significant delay?	☐	☐	☐
Commendations/Recommendations			

4.2. Indications and decision to treat

Indications and decision to treat are based on clinical assessment and existing guidelines. Any patient in the radiotherapy department must have had a treatment decision taken by a radiation oncologist. This must be carried out in a Multidisciplinary Oncology Consultation (MOC) setting in which all newly diagnosed cancer cases are systematically discussed at a fixed period and in a given hospital. These MOCs should be organized but it is also important these are systematically attended by RO. *It is important that cancer handbook (hospital level handbooks) and departmental practice guidelines (internal to the department) be up to date and accessible.*

The patient must be provided with the necessary information in order to allow him/her to make an informed decision of the treatment(s) he/she would like to pursue for the management of his/her disease. In this mind set, it is important that the radiotherapy department is actively involved in the communication of all relevant information to the patient.

CHECKLIST 3. Multidisciplinary medical approach (MOCs)

Items to be reviewed by the auditor	YES	In progress	NO	N/A
Are decisions to treat based upon meetings of multidisciplinary teams (MOCs)?	☐	☐	☐	☐
Are all frequent cancers covered by MOCs?	☐	☐	☐	☐
Do all patients with a frequent cancer benefit from a MOC?	☐	☐	☐	☐
Do RO systematically attend the MOCs?	☐	☐	☐	☐
Is there coverage for absences of RO as related to MOCs?	☐	☐	☐	☐
Comments				

Overview of MOCs

Frequency of MOCs	In hospital	Outside of hospital		
		Site 1 Name:	Site 2 Name:	Site 3 Name
Breast				
Lung				
Prostate				
Colorectal				
H&N				
CNS				
Other:				

Overall Score	Compliant	Minor recommendations	Major recommendations
Are the majority of decisions to treat based on MOCs?	☐	☐	☐
Commendations/Recommendations			

CHECKLIST 4. Practice guidelines

Items to be reviewed by the auditor	YES	In progress	NO	N/A
Are written cancer handbooks available for the most common clinical management situations?	☐	☐	☐	☐
Are written departmental protocols available for the most common clinical management situations?	☐	☐	☐	☐
Have cancer handbook protocols been ratified by an oncology committee?	☐	☐	☐	☐
Have clinical protocols been ratified by a departmental committee?	☐	☐	☐	☐
Are the treatment protocols regularly reviewed?	☐	☐	☐	☐
Is there protocol review committee that verifies that treatments conform to protocols/GUIDELINES) (at MOC level)?	☐	☐	☐	☐
Are treatments not corresponding to a protocol/guideline medically justified?	☐	☐	☐	☐
Have all research protocols been ratified by an institutional ethics committee?	☐	☐	☐	☐
Comments				

Overall Score	Compliant	Minor recommendations	Major recommendations
Are the guidelines and departmental policies adequate?	☐	☐	☐
Commendations/Recommendations			

CHECKLIST 5. Patient information and consent

Items to be reviewed by the auditor	YES	In progress	NO	N/A
Are benefits and risks of radiation therapy explained to patients?	☐	☐	☐	☐
Do patient receive written support explaining all the risks and benefits of the RT treatment?	☐	☐	☐	☐
Are patients of childbearing potential systematically assessed for pregnancy?	☐	☐	☐	☐
Does the RTT have a systematic role in delivering information to the patient?	☐	☐	☐	☐
If yes, how is it organized?				
Comments				

Overall Score	Compliant	Minor recommendations	Major recommendations
Is information given to the patient in an optimal manner?	☐	☐	☐
Commendations/Recommendations			

4.3. Treatment preparation - instruction for planning

Preparation and planning phases must precede delivery of treatment and be completed in a precise and reproducible way. The checklist will assess the equipment and procedures used for localization, simulation and immobilization, including mould room devices and procedures.

4.3.1. Simulation

CHECKLIST 6. Treatment preparation and image acquisition infrastructure

Items to be reviewed by the auditor	YES	In progress	NO	N/A
Specify major equipment used for localisation:				
Fluoroscopic simulator	☐			
CT in radiology dedicated for planning*	☐			
CT simulator in radiotherapy department	☐			
CT simulator with 4D acquisition	☐			
***IF CT located outside of RT department:** Is there a flat couch table top?	☐	☐	☐	☐
Is there the possibility of indexed fixation?	☐	☐	☐	☐
Are there mobile lasers?	☐	☐	☐	☐
Are these imaging modalities networked with the RT department?	☐	☐	☐	☐
Are there sufficient time slots for RT patients?	☐	☐	☐	☐
If use of MRI in treatment preparation phase:				
Is there a flat couch table top?	☐	☐	☐	☐
Is there the possibility of indexed fixation?	☐	☐	☐	☐
Are there mobile lasers?	☐	☐	☐	☐
Are these imaging modalities networked with the RT department?	☐	☐	☐	☐
Are there sufficient time slots for RT patients?	☐	☐	☐	☐

If use of PET-(CT) in treatment preparation phase: Is there a flat couch table top? Is there the possibility of indexed fixation? Are there mobile lasers? Are these imaging modalities networked with the RT department? Are there sufficient time slots for RT patients?	☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐
Comments				

Overall Score	**Compliant**	**Minor recommendations**	**Major recommendation**
Is there consistency throughout these various imaging modalities?	☐	☐	☐
Commendations/Recommendations			

CHECKLIST 7: Simulation procedures

Items to be reviewed by the auditor	**YES**	**In progress**	**NO**	**N/A**
Is there a procedures manual available for simulation?	☐	☐	☐	☐
Are the roles of the various staff defined in the procedures?	☐	☐	☐	☐
Do the clinical tumour/site-specific protocols contain instructions for immobilization?	☐	☐	☐	☐

Is there an available exposure chart (kV and mAs)?	☐	☐	☐	☐
Are CT protocols adapted to anatomical sites?	☐	☐	☐	☐
Is there a setup marking protocol (reference/isocentre marking)?	☐	☐	☐	☐
How are the marks maintained?				
Is there appropriate patient setup documentation (immobilization system used, marking, photos…)?	☐	☐	☐	☐
Are patients with radiation-sensitive implanted material identified (ex: pacemaker)?	☐	☐	☐	☐
Is IV contrast workup systematically completed prior to simulation (renal function, allergies)?	☐	☐	☐	☐
Does the department have a formal policy on managing IV contrast reactions?	☐	☐	☐	☐
Is patient identity verified before simulation?	☐	☐	☐	☐
Is relevant clinical information provided to the RTTs before simulation?	☐	☐	☐	☐
Is there adequate time for simulation procedures?	☐	☐	☐	☐
Is the delay between the patients' 1st consultation and simulation reasonable?	☐	☐	☐	☐
Comments				

Overall Score	Compliant	Minor recommendations	Major recommendations
Are simulation procedures appropriately adapted to the anatomical sites?	☐	☐	☐
Commendations/ Recommendations			

CHECKLIST 8. Immobilization systems

The table below will allow for the auditors to judge of the implementation, accessibility appropriateness and consistency of the immobilization systems used as a function of the treatment techniques used.

The different evaluation elements can be answered as follows:

- Implementation: have the systems been checked before clinical use, are there procedures describing the use of the immobilization system, has the staff been trained in its use….
- Consistency – is the system used harmoniously for the same indication?
- Appropriateness – is the system used in accordance with the technique used?
- Accessibility – is the system appropriately stored? Is it easily accessible? Is it easily available at each treatment modality?

(*Check if it is the case*)

Normo-fractionated treatments				
2D acquisition (N/A:☐)				
Immobilization system use	Implementation	Consistency	Appropriateness	Accessibility
_____	☐	☐	☐	☐
3D acquisition (N/A:☐)				
Immobilization system use	Implementation	Consistency	Appropriateness	Accessibility
H&N	☐	☐	☐	☐

Brain	☐	☐	☐	☐
Breast	☐	☐	☐	☐
Lung	☐	☐	☐	☐
Pelvis	☐	☐	☐	☐
Other: _____	☐	☐	☐	☐
4D acquisition (N/A:☐)				
Immobilization system use	Implementation	Consistency	Appropriateness	Accessibility
Lung	☐	☐	☐	☐
Liver	☐	☐	☐	☐
Other: _____	☐	☐	☐	☐
Hypo-fractionated treatments				
3D acquisition (N/A:☐)				
Immobilization system use	Implementation	Consistency	Appropriateness	Accessibility
H&N	☐	☐	☐	☐
Brain	☐	☐	☐	☐
Breast	☐	☐	☐	☐
Lung	☐	☐	☐	☐
Pelvis	☐	☐	☐	☐
Other: _____	☐	☐	☐	☐
4D acquisition (N/A:☐)				
Immobilization system use	Implementation	Consistency	Appropriateness	Accessibility
Lung	☐	☐	☐	☐
Liver	☐	☐	☐	☐
Other: _____	☐	☐	☐	☐
Comments				

Overall Score	Compliant	Minor recommendations	Major recommendations
Are the immobilization systems used adapted to the site treated and technique used?	☐	☐	☐
Commendations/ Recommendations			

4.3.2. Contouring

It is of importance that the delineation of target volume and OAR should be in accordance with the latest published guidelines and that these be carried out in an optimal manner.

CHECKLIST 9: Roles in contouring

Who contours the target volumes? Radiation oncologist MPE MPA RTT Other, specify _____	 ☐ ☐ ☐ ☐ ☐
Who contours the OARs? Radiation oncologist Medical physicist RTT Other, specify _____	 ☐ ☐ ☐ ☐
Comments	

CHECKLIST 10. Generation of target volume and OAR delineations

Items to be reviewed by the auditor	YES	In progress	NO	N/A
2D				
Are all contours based on volumetric acquisitions?	☐	☐	☐	☐
If NOT for all: For curative (radical) patients?	☐	☐	☐	☐
For palliative patients?	☐	☐	☐	☐
3D				
Are the following target volumes used (ICRU 50 & 62, 83)?				
Gross Tumour Volume (GTV)	☐	☐	☐	☐
Clinical Target Volume (CTV)	☐	☐	☐	☐
Planning Target Volume (PTV)	☐	☐	☐	☐
Irradiated Target Volume (ITV)	☐	☐	☐	☐
Planning Organ at Risk (PRV)	☐	☐	☐	☐
Other volume: _____	☐	☐	☐	☐
Are the used margins between CTV and PTV clearly defined?	☐	☐	☐	☐
What are these margins based on?				
In house measurements?	☐			
Literature research?	☐			
Both (depending on localization)	☐			
Other: _____	☐			
Is an automatic delineation tool used for OAR? (atlas based segmentation,…)	☐	☐	☐	☐

Are the contours supervised by the RO in charge?	☐	☐	☐	☐
Is there a peer review of generated contours?	☐	☐	☐	☐
Is 4D deformation calculated?	☐	☐	☐	☐
Comments				

Overall Score	**Compliant**	**Minor recommendations**	**Major recommendations**
Is the delineation methodology appropriately adapted to the anatomical sites?	☐	☐	☐
Commendations/ Recommendations			

CHECKLIST 11. Mould room and beam modification devices

Items to be reviewed by the auditor	**Yes**	**In progress**	**NO**	**N/A**
Does the department use customized (individualized) blocks?	☐	☐	☐	☐
Are the blocks appropriately verified?	☐	☐	☐	☐
Comments				

Overall Score	**Compliant**	**Minor recommendations**	**Major recommendations**	**N/A**
Are beam modifications devices appropriately used?	☐	☐	☐	☐
Commendations/ Recommendations				

4.3.3. Treatment prescription

CHECKLIST 12. Treatment prescription

It is important that the patient's treatment's prescription be easily available and clearly defined.

Items to be reviewed by the auditor	YES	In progress	NO	N/A
Is the dose per fraction stipulated?	☐	☐	☐	☐
Is the total dose stipulated?	☐	☐	☐	☐
Is the number of fractions stipulated?	☐	☐	☐	☐
Is the total treatment time for schedules other than once daily 5 times per week stipulated?	☐	☐	☐	☐
Is the prescription signed/approved by the radiation oncologist?	☐	☐	☐	☐
Comments				

Overall Score	Compliant	Minor recommendations	Major recommendations
Is the treatment prescription clearly defined and available?	☐	☐	☐
Commendations/ Recommendations			

4.4. Treatment planning

This section audits the process of teletherapy/radiotherapy planning. The auditors will evaluate:

- The interaction between different members of the staff and whether they work well together as a functional unit.
- Means for ensuring the quality and reproducibility of radiation administration.
- QA procedures.

CHECKLIST 13. Treatment planning

Items to be reviewed by the auditor	YES	In progress	NO	N/A
Are there formal protocols for treatment planning?	☐	☐	☐	☐
Are dose constraints on target volumes and OAR clearly defined in the treatment planning protocols?	☐	☐	☐	☐
Does the RO communicate patient specific planning goals?	☐	☐	☐	☐
Are site and side verified with a secondary source document at the time of planning?	☐	☐	☐	☐
Is the impact of previous radiation treatments on the current treatment plan evaluated?	☐	☐	☐	☐
Is there a policy on maximum and minimum doses to PTV?	☐	☐	☐	☐
Is treatment planning endorsed (signed) by the medical physicist?	☐	☐	☐	☐
Is treatment planning endorsed (signed) by the radiation oncologist?	☐	☐	☐	☐
Is treatment planning endorsed (signed) by treatment modality RTT?	☐	☐	☐	☐
Can the treatment start in the absence of endorsement?	☐	☐	☐	☐
Is there a secondary check of the treatment plans (overall check)?	☐	☐	☐	☐
Are there planning peer review meetings?	☐	☐	☐	☐
If yes, what is their frequency, the extent of the meetings, use of defined parameters (checklist)?				
Comments				

Overall Score	Compliant	Minor recommendations	Major recommendations
Is treatment planning carried out using formal procedures and safety barriers?	☐	☐	☐
Commendations/ Recommendations			

4.5. From planning to delivery and pre-treatment checks

It is important the department carry out all necessary pre-treatment checks before treatment delivery can be carried out.

CHECKLIST 14. Data transfer from planning to delivery

Items to be reviewed by the auditor	YES	In progress	NO	N/A
Is data transfer from planning to delivery realized automatically	☐	☐	☐	☐
Is the data transfer double-checked?	☐	☐	☐	☐
By who?				
Is the pre-treatment physics plan review consistent with the appropriate guidelines?	☐	☐	☐	☐
Do the RTT review treatment chart prior to treatment start?	☐	☐	☐	☐
Do the RTT have adequate time to review treatment chart prior to treatment start?	☐	☐	☐	☐
Comments				

Overall Score	Compliant	Minor recommendations	Major recommendations
Are pretreatment checks carried out in an optimal manner?	☐	☐	☐
Commendations/ Recommendations			

4.6. Treatment delivery

It is crucial that mechanisms be put into place to ensure that the correct patient and that patient's correct anatomical area is treated; otherwise the risk of radiotherapy misadministration increases.

Patient identification will depend on the systems available However, the audit team must ensure that an appropriate system is indeed in place and in use.

Auditors are encouraged to visit the different treatment units and explore the IGRT and treatment delivery procedures directly on site. If the department treats children, auditors need to consider any necessary differences (general anaesthesia, immobilisation, etc.).

CHECKLIST 15. Patient identification on a daily basis.

Items to be reviewed by the auditor	YES	In progress	NO	N/A
Is there a formal policy on patient identification?	☐	☐	☐	☐
At what moment of the treatment process are patients identified?				
At reception	☐	☐	☐	☐
At the treatment modality	☐	☐	☐	☐
Inside the treatment room	☐	☐	☐	☐
Is patient identification realized in an unambiguous manner?	☐	☐	☐	☐

Is patient identification realized in an unambiguous manner for paediatric patients?	☐	☐	☐	☐
Is patient confidentiality adequately ensured?	☐	☐	☐	☐
Comments				

Overall Score	**Compliant**	**Minor recommendations**	**Major recommendations**
Is patient identification properly carried out?	☐	☐	☐
Recommendations			

CHECKLIST 16. Patient set up and set up verification

Items to be reviewed by the auditor	**YES**	**In progress**	**NO**	**N/A**
Is there psychological preparation for the patient?	☐	☐	☐	☐
Is there a formal preparation/information session organized for the patient?	☐	☐	☐	☐
What modalities are used to ensure that the proper setup and immobilization devices are being used?				
Written document	☐	☐	☐	☐
Text in R&V system	☐	☐	☐	☐
Photographs	☐	☐	☐	☐
Digitally (set up recognition system, RFID, bar codes…)	☐	☐	☐	☐
Other	☐	☐	☐	☐

Is there a time out period performed before the first session of a treatment?	☐	☐	☐	☐
Is sufficient time allocated to the <u>first</u> treatment session?	☐	☐	☐	☐
Is sufficient time allocated for all treatment sessions?	☐	☐	☐	☐
Is a RO present: – For all first treatments? – For particular treatment techniques only? – For difficult set-up problems only? – Other?	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐
Comments on RO presence				
Is a MPE present: – For all first treatments? – For particular treatment techniques only? – For difficult set-up problems only? – Other?	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐
Comments on MPE presence				
<u>Patient set-up (positioning and immobilization)</u>				
Does the department have formal/written patient setup procedures?	☐	☐	☐	☐
Are these procedures actually followed/applied?	☐	☐	☐	☐
If required, how are changes in the set-up managed?				

Is patient setup performed with care and precision?	☐	☐	☐	☐
Is there sufficient time allocated to patient setup?	☐	☐	☐	☐
Is patient set up performed in a logical manner?	☐	☐	☐	☐
Is there a formal policy on double checking patient/ treatment setups (=secondary independent check of patient setup by RTT/secondary system)?	☐	☐	☐	☐
Is there a formal protocol to override treatment set-up?	☐	☐	☐	☐
Is IGRT carried out on daily basis? For all sites?	☐ ☐	☐ ☐	☐ ☐	☐ ☐
Is patient set up verified through volumetric IGRT? For all sites?	☐ ☐	☐ ☐	☐ ☐	☐ ☐
Are there IGRT protocols available which define the site of match, the frequency and the IGRT modality/treatment site?	☐	☐	☐	☐
Are there IGRT protocols available which define motion management strategies/treatment site?	☐	☐	☐	☐
Is there a procedure for reviewing patient set up images offline?	☐	☐	☐	☐
Comments				

Roles in IGRT procedures

	All the time	1st day of treatment only	Particular treatment only (SRS, SBRT)	Never
Who performs the co-registration of patient set up imaging? RTT	☐	☐	☐	☐

RO MPE Other: _____	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Comments				

Overall Score	**Compliant**	**Minor recommendations**	**Major recommendations**
Is patient set up and verification during treatment properly carried out?	☐	☐	☐
Commendations/ Recommendations			

Checklist 17: Treatment delivery

Items to be reviewed by the auditor	**YES**	**In progress**	**NO**	**N/A**
Is there a formal policy for handling planned interruptions in treatment?	☐	☐	☐	☐
Is there a formal policy for handling unplanned interruptions in treatment?	☐	☐	☐	☐
Is there a formal policy for handling no-shows?	☐	☐	☐	☐
Are there procedures for plan changes during treatment?	☐	☐	☐	☐

If more than one work shift, is there a formal change-over protocol?	☐	☐	☐	☐
Is the delay between simulation and patients' first treatment reasonable?	☐	☐	☐	☐
Are all patients clinically reviewed during treatment?	☐	☐	☐	☐
If so, how frequently?				
By whom : Radiation oncologist RTT Specialist nurse Other (specify) _____	☐ ☐ ☐ ☐			
Is patient condition and follow up well documented?	☐	☐	☐	☐
Is patient clinical information easily accessible to the RTTs *(including lab results)*?	☐	☐	☐	☐
Are there available patient care procedures?	☐	☐	☐	☐
Is a routine check of treatment chart carried out?	☐	☐	☐	☐
How often?				
By whom?				

Comments				
Is the need for simulation clinically justified?	☐	☐	☐	☐
In-vivo dosimetry:				
Is in-vivo dosimetry carried out? For all treatments?	☐ ☐	☐ ☐	☐ ☐	☐ ☐
Types of in-vivo dosimetry: Point dosimetry Transit dosimetry Other (specify): _____	☐ ☐ ☐			
Frequency of in-vivo dosimetry				
Comments on in-vivo dosimetry				
Hygiene procedures:				
Are there formal procedures on hygiene practice?	☐	☐	☐	☐
Are hygiene procedures properly carried out?	☐	☐	☐	☐
Comments on hygiene practice				

Overall Score	Compliant	Minor recommendations	Major recommendations
Is patient treatment delivery properly carried out in a safe and efficient manner?	☐	☐	☐
Commendations/ Recommendations			

4.7. Treatment summary (documentation)

This section refers to the recording and reporting of a treatment after its delivery. In many countries there is a legal requirement for record keeping. Also, internal audit and clinical research requires access to previous treatment data.

CHECKLIST 18. Documentation of treatment summary report

Items to be reviewed by the auditor	YES	In progress	NO	N/A
Is the completeness of the treatment checked?	☐	☐	☐	☐
By whom?				
Is there a radiotherapy treatment summary?	☐	☐	☐	☐
Is patient treatment information electronically archived?	☐	☐	☐	☐
How long is the file kept?				
In the archive, are the elements necessary for the complete reconstruction of the treatment available?	☐	☐	☐	☐
Are archived treatments easily retrievable?	☐	☐	☐	☐
Is there a record of the treatment in the patient's (hospital) records?	☐	☐	☐	☐
If yes, is there easy access to the documents?	☐	☐	☐	☐
Is a copy of treatment details sent to the referring physician?	☐	☐	☐	☐
Is a copy of treatment details given to the	☐	☐	☐	☐

patient?				
Comments				

Overall Score	**Compliant**	**Minor recommendations**	**Major recommendations**
Is the treatment summary summarized and accessible to all involves parties?	☐	☐	☐
Commendations/ Recommendations			

4.8. Follow-up

Follow-up of patients is the essential source of information to determine the treatment effect (cancer control, side effects, misadministrations). It is an important tool for internal and external audit. Auditors should appreciate the level of consistency of follow-up policy throughout the department.

CHECKLIST 19. Patient follow-up

Items to be reviewed by the auditor	**YES**	**In progress**	**NO**	**N/A**
Is there a systematic feedback to the RT department on tumour control, failure and complications at follow-up recorded?	☐	☐	☐	☐
Comment:				
Is follow-up done by physicians other than radiation oncologists?	☐	☐	☐	☐
Is the follow-up done by nurses or social workers?	☐	☐	☐	☐
If performed outside the radiotherapy department, are the reports on the outcome of patients available to the radiotherapy department?	☐	☐	☐	☐
Is radiation toxicity documented?	☐	☐	☐	☐

Is radiation toxicity graded?	☐	☐	☐	☐
Are the follow-up data analysed in terms of the above?	☐	☐	☐	☐
By whom?				
Is there a policy of systematic review of serious complications?	☐	☐	☐	☐
Comments:				

Overall Score	**Compliant**	**Minor recommendations**	**Major recommendations**
Is patient follow-up formally organized with the department /cancer centre?	☐	☐	☐
Commendations/ Recommendations			

4.9. Review of typical treatments

A representative number of cases for curative, palliative and post-operative treatment and various treatment techniques should be selected by the auditors.

In other words, typical treatments (at least 10-15 files) of common cancer cases are to be requested for a review and analysis by the auditors, e.g.

- Solitary bone metastasis (non-weight bearing bone).
- Multiple brain metastases.
- Radical treatment for a common cancer (cervix, lung, etc.):
    - Breast cancer after conservative surgery
    - Lung cancer
    - Prostate cancer
    - H and N cancer
    - Rectal
    - Other

CHECKLIST 20. Elements to be reviewed during case analysis

% of patient charts in which the pathology report is included (n/10 random charts %)	
% of patients charts in which the staging is properly documented (n/10 charts %)	
% of patients charts in which the performance status is included (n/10 charts %)	
% of carts of patients >75 years old in which the geriatric assessment has been carried out (n/10 charts %)	
Are the tumour/site-specific protocols applied consistently within the department? (*Are the tumours of a particular site and stage treated the same way?)*	
% of charts where the dose per fraction stipulated?	
% of charts where the total dose stipulated?	
% of charts where the number of fractions stipulated	
% of charts in which the RT prescription is evidence-based	
% of charts in which a photograph of the treatment site or field marks are included	
% of charts with complete documentation of setup	
% of charts where patient condition and follow up is well documented	
RTT relevant clinical information, patient specificities and characteristics	
Physics elements (Patient QA documentation, in vivo dosimetry or equivalent, MPE sign off…)	
Comments	

Overall Score	**Compliant**	**Minor recommendations**	**Major recommendations**
Overall, are the patients' charts accurate and comprehensive?	☐	☐	☐
Commendations/ Recommendations			

5. AUDIT PART III: EQUIPMENT RELATED PROCEDURES

5.1. Equipment quality assurance – medical physics aspects –QA checklists

Equipment quality control procedures and their documentation, and records, where appropriate, should be reviewed for all medical physics items. Look for recommendations followed.

The auditors should note who routinely performs the medical physics activities below: a resident medical physicist(s), a contracted medical physicist or duties are delegated to other personnel.

CHECKLIST 21. Imaging equipment (CT, CTsim, MRI, PETCT, other)

Items to be reviewed by the auditor	YES	In progress	NO	N/A
Is a manual of operation available at the equipment?	☐	☐	☐	☐
Are MPE involved in preparation of imaging procedures?	☐	☐	☐	☐
Are the acceptance testing procedures available and signed by the MPE (as applicable)? CT/CTsim: MRI: Other? ……	 ☐ ☐ ☐	 ☐ ☐ ☐	 ☐ ☐ ☐	 ☐ ☐ ☐
Has the personnel received training for the following equipment (as applicable)? CT/CTsim: MRI: Other? ……	 ☐ ☐ ☐	 ☐ ☐ ☐	 ☐ ☐ ☐	 ☐ ☐ ☐
Are the commissioning procedures available for the following equipment (as applicable)? CT/CTsim: MRI: Other? ……	 ☐ ☐ ☐	 ☐ ☐ ☐	 ☐ ☐ ☐	 ☐ ☐ ☐

Is an incident logbook available for the following equipment (as applicable)? CT/CTsim: MRI: Other?	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
CT/CTsim:				
Is there a daily test on the mobile lasers carried out?	☐	☐	☐	☐
Are the QC procedures available and signed by the MPE?	☐	☐	☐	☐
Are QC carried out after upgrade?	☐	☐	☐	☐
Comments on frequencies, action levels, performed by MPE, MPA:				
Which recommendations are followed? (i.e. AAPM, NCS, IAEA,…)				
Comments:				
MRI:				
Are the QC procedures available and signed by the MPE?	☐	☐	☐	☐
Comments on frequencies, action levels, performed by MPE, MPA:				
Which recommendations are followed? (i.e. AAPM, NCS, IAEA,…)				
Comments:				
Other (specify) (ex: PET)				
Are the QC procedures available and signed	☐	☐	☐	☐

by the MPE?				
Comments on frequencies, action levels, performed by MPE, MPA:				
Which recommendations are followed? (i.e. AAPM, NCS, IAEA,…)				

Overall Score	**Compliant**	**Minor recommendations**	**Major recommendations**
Are the QA procedures correctly implemented at the imaging sites?	☐	☐	☐
Commendations/Recommendations			

CHECKLIST 22. Localisation and immobilization

Items to be reviewed by the auditor	**YES**	**In progress**	**NO**	**N/A**
Is a manual of operation available?	☐	☐	☐	☐
Has the personnel received initial training?	☐	☐	☐	☐
Are MPE involved in preparation of procedures related to QA?	☐	☐	☐	☐
Has the equipment been officially accepted and commissioned?	☐	☐	☐	☐
By whom?				
Is there a regular QC program on the immobilization equipment?	☐	☐	☐	☐
Is the equipment well-stored?	☐	☐	☐	☐
Comments				

Overall Score	Compliant	Minor recommendations	Major recommendations
Are the QA procedures correctly implemented for immobilization equipment?	☐	☐	☐
Commendations/Recommendations			

CHECKLIST 23. Treatment equipment

Items to be reviewed by the auditor	YES	In progress	NO	N/A
Is a manual of operation available?	☐	☐	☐	☐
Has the personnel received training?	☐	☐	☐	☐
Has the equipment been officially accepted?	☐	☐	☐	☐
Is a report of the commissioning procedures and results available?	☐	☐	☐	☐
Is the report available and signed-off by a MPE?	☐	☐	☐	☐
Which recommendations are followed? (i.e. AAPM, NCS, IAEA,…)				
Comments:				
QC programs				
Are written procedures for QC available?	☐	☐	☐	☐
Are mechanical tests well implemented and results well documented?	☐	☐	☐	☐
Are dosimetry tests well implemented and results well documented?	☐	☐	☐	☐
Are the test on on-board imaging well-implemented and results documented for: Portal imaging:	☐	☐	☐	☐

Volumetric imaging: Other:	☐ ☐	☐ ☐	☐ ☐	☐ ☐
Which recommendations are followed for QC? (i.e. AAPM, NCS, IAEA)				
Which dosimetric protocol is used for reference dosimetry?				
Comments on frequencies, action levels, performed by MPE, MPA:				
Participation in external audits (other than BELdART, QUATRO)?	☐	☐	☐	☐
If yes which one(s)?				
Comments				

Overall Score	**Compliant**	**Minor recommendations**	**Major recommendations**
Are the QA/QC procedures correctly implemented for treatment equipment?	☐	☐	☐
Commendations/ Recommendations			

CHECKLIST 24. Treatment equipment (special techniques)

Type of special treatments performed

Types of treatment performed	Yes	No	In progress
TBI			
TSET			
SBRT			
SRS			
Other: _____			
Comments			

Items to be reviewed by the auditor	YES	In progress	NO	N/A
Has the personnel received specific training?	☐	☐	☐	☐
Has the equipment been officially accepted for these special techniques?	☐	☐	☐	☐
Is a report of the commissioning procedures and results available?	☐	☐	☐	☐
Is the report available and signed-off by a MPE?	☐	☐	☐	☐
Which recommendations are followed? (i.e. AAPM, NCS, IAEA,…)				
Comments:				
Does the commissioning include small field dosimetry?	☐	☐	☐	☐
QC program:				
Are written procedures for QC available?	☐	☐	☐	☐

Is pre-treatment patient specific QA (dose verification) performed for the following treatment modalities? IMRT QA SBRT QA SRS QA Electron block factors	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐
Are specific mechanical tests well implemented and results well documented?	☐	☐	☐	☐
Are specific dosimetry tests well implemented and results well documented?	☐	☐	☐	☐
Which recommendations are followed? (i.e. AAPM, NCS, IAEA)				
Comments on frequencies, action levels, performed by MPE, MPA.				
Participation in external audits for these treatments (other than BELdART, QUATRO)?	☐	☐	☐	☐
Participation in BELdART 3?	☐	☐	☐	☐
If other, which ones?				
Comments				

Overall Score	**Compliant**	**Minor recommendations**	**Major recommendations**
Are the QA/QC procedures correctly implemented for specific treatments?	☐	☐	☐
Commendations/ Recommendations			

CHECKLIST 25. Treatment planning equipment

Items to be reviewed by the auditor	YES	In progress	NO	N/A
Is a manual of operation available?	☐	☐	☐	☐
Has the personnel received training?	☐	☐	☐	☐
Has the equipment been officially accepted?	☐	☐	☐	☐
Is a report of the commissioning procedures and results available?	☐	☐	☐	☐
Is the report available and signed-off by a MPE?	☐	☐	☐	☐
Which recommendations are followed? (i.e. AAPM, NCS, IAEA,...)				
Comments:				
Dosimetric QC of TPS:				
Do test calculations / sample plans exist?	☐	☐	☐	☐
Are independent double MU calculations performed?	☐	☐	☐	☐
Type of detectors for in-vivo dosimetry? TLD: Diodes: Portal imaging (transit dosimetry): Other:	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Is the centre performing end-to-end testing?	☐	☐	☐	☐
Comments on frequencies, detectors and phantoms used:				
Is there a plan check protocol by a second physicist implemented?	☐	☐	☐	☐

Are there quality checks protocols on dose calculations?	☐	☐	☐	☐
Is there a QC check on data transfer?	☐	☐	☐	☐
Comments:				

Overall Score	**Compliant**	**Minor recommendations**	**Major recommendations**
Are the QA/QC procedures sufficiently developed and correctly implemented for TPS?	☐	☐	☐
Commendations/ Recommendations			

CHECKLIST 26. Dosimetry equipment

Items to be reviewed by the auditor	**YES**	**In progress**	**NO**	**N/A**
Is there a QC program foreseen on dosimetry equipment?	☐	☐	☐	☐
Is the local standard ionisation chamber calibration traceable to a PSDL/SSDL?	☐	☐	☐	☐
What is the calibration frequency?				
Are the field instruments regularly cross calibrated?	☐	☐	☐	☐
Is the dosimetry equipment well stored?	☐	☐	☐	☐
Comments				

Overall Score	Compliant	Minor recommendations	Major recommendations
Are the QA procedures for dosimetry equipment correctly implemented?	☐	☐	☐
Commendations/ Recommendations			

5.2. IT safety

CHECKLIST 27. IT safety

Items to be reviewed by the auditor	YES	In progress	NO	N/A
Has the personnel received specific IT safety training?	☐	☐	☐	☐
Is the radiotherapy network integrated in the HIS network?	☐	☐	☐	☐
Where are the radiotherapy servers located? In the department? In the HIS	 ☐ ☐	 ☐ ☐	 ☐ ☐	 ☐ ☐
Comments				
Are the servers easily accessible?	☐	☐	☐	☐
Is there a specific back-up policy?	☐	☐	☐	☐
How is the data stored? Physically? Virtually?	 ☐ ☐	 ☐ ☐	 ☐ ☐	 ☐ ☐
Is the format DICOM or DICOM compatible?	☐	☐	☐	☐
Is a report of the commissioning procedures and results available?	☐	☐	☐	☐

Is there a QC program on the network?	☐	☐	☐	☐
Is there support for maintenance and repair?	☐	☐	☐	☐
If yes by whom? Company: HIS engineer: Radiotherapy engineer: WEBEX	☐ ☐ ☐ ☐			
Is there a VPN connection?	☐	☐	☐	☐
Is it controlled?	☐	☐	☐	☐
Comments				

Overall Score	**Compliant**	**Minor recommendations**	**Major recommendations**
Has the IT network sufficiently been integrated within the radiotherapy QA procedures?	☐	☐	☐
Commendations/Recommendations			

6. AUDIT PART IV: QUALITY MANAGEMENT SYSTEM

The comprehensive, clinical and "patient-oriented" character of the QUATRO audits confers undeniable advantages to these types of audits. Nevertheless, an internal initiative of the association of the Belgian quality managers (Quality Managers of Radiotherapy of Belgium (QMRT.be), highlighted the need for developing certain parts of the QUATRO audits in order to optimize the evaluation of quality management systems (QMS). These elements are described in a reference document entitled "QMRT tool"[15], which aims at describing guidelines for the implementation and the evaluation of a quality and risk management systems in radiotherapy departments.

The QMRT tool covers the following set of topics:

- Quality Management System(QMS)
- Document Management System
- Quality Manual
- Quality Policy
- Quality Indicators
- Process management
- Organisational charts
- Tasks and responsibilities
- Resource Management
- Communication Management
- Risk Management System
- Management of breakdowns
- Patient satisfaction
- Audits

Each chapter of this reference document is addressed by including the general standards, theoretical framework and practical modalities of its implementation as well as templates. The audit of the QMS structure itself will primarily be carried out by the QM and will be based on the checklists. However, the evaluation of how the quality management system actually translates into practice will be realized at a multidisciplinary level. **This is particularly the case for communication management As such, this topic has been integrated into a separate chapter (chapter 7).**

[15] http://qmrt.be/downloads/QMRTtool2017.pdf

This chapter's aim – based on the recommendation of QMRT's tool – is to evaluate the existing department's quality and risk management systems based on the criteria established by the "*QMRT's tool reference document*"[16].

Note – in italics are items considered to be compulsory element of a QMS

6.1. General quality management system

CHECKLIST 28. QMS

Items to be reviewed by the auditor	YES	In progress	NO	N/A
Is there a QM in the department?		☐	☐	☐
FTE:				
Is the QM included in the department's organizational chart?	☐	☐	☐	☐
Are the responsibilities and missions of the QM defined?	☐	☐	☐	☐
Are the QMS' processes and interactions identified?	☐	☐	☐	☐
Is there an existing document management system[17]*?*	☐	☐	☐	☐
Are the legal requirements and regulations applied?	☐	☐	☐	☐
Is quality management system planning implemented to maintain the integrity of the quality management system (audits, document/procedure review, projects...)?	☐	☐	☐	☐
Are changes within the department (TPS, change in TPS/treatment units...) properly planned and documented?	☐	☐	☐	☐
Are the necessary resources required for QMS implementation, maintenance and continuous improvement available?	☐	☐	☐	☐
Are the corrective and preventive actions monitored and follow-up?	☐	☐	☐	☐

[16] http://qmrt.be/downloads/QMRTtool2017.pdf

[17] Also see CHECKLIST 29

Are analyses of the results periodically performed (audits, customer satisfaction, indicators ...)?	☐	☐	☐	☐
Are specific meeting set up to analyze the results over time and define the actions and objectives of the following period?	☐	☐	☐	☐
Are the results and the actions taken reported in the department?	☐	☐	☐	☐
Are tools applied for the implementation of continuous improvement (Kaizen, 5M, lean ...)?	☐	☐	☐	☐
Does a risk management system exist in the department?	☐	☐	☐	☐
Comments				

Overall Score	**Compliant**	**Minor recommendations**	**Major recommendations**
Is a quality management system implemented within the department?	☐	☐	☐
Recommendations			

6.2. Document management system

It will be important to verify the coherence between existing procedure and what is done at the points of use (are the procedures up to date?)

CHECKLIST 29. Document management system

Items to be reviewed by the auditor	YES	In progress	NO	N/A
Is there and existing document management system (departmental level or hospital level)?	☐	☐	☐	☐
Is this DMS at the departmental level or hospital level?				
Is there an existing procedure concerning	☐	☐	☐	☐

document management?				
Does it ensure that documents are approved prior to its distribution?	☐	☐	☐	☐
Does it describe the renewal/update process for distributed documents?	☐	☐	☐	☐
Are changes and current revision statuses of documents identified?	☐	☐	☐	☐
Are relevant versions of the applicable documents available at points of use?	☐	☐	☐	☐
Are documents legible and readily identifiable?	☐	☐	☐	☐
Are documents of external origin identified and controlled?	☐	☐	☐	☐
Are the different types of documents easily identifiable?	☐	☐	☐	☐
Are there department specific document models?	☐	☐	☐	☐
<u>On the approved documents</u>				
Is it possible to identify the person involved in the verification and/or approval of the document?	☐	☐	☐	☐
Is it possible to identify the reference number, the version and the date of approval?	☐	☐	☐	☐
Are the documents regularly updated/revised?	☐	☐	☐	☐
Is there an existing system to disseminate the documents?	☐	☐	☐	☐
Is there an existing archiving system for outdated documents?	☐	☐	☐	☐
Are outdated documents inaccessible?	☐	☐	☐	☐
Is it possible to track the different versions of a document?	☐	☐	☐	☐
Can the personnel easily access the approved documents and procedures?	☐	☐	☐	☐

Comments	

Overall Score	**Compliant**	**Minor recommendations**	**Major recommendations**
Is a proper document management system implemented within the department?	☐	☐	☐
Recommendations			

6.3. Quality manual

A quality manual is an element that is often desired in a QMS. However its existence is not compulsive.

CHECKLIST 30. Quality manual

Items to be reviewed by the auditor	**YES**	**In progress**	**NO**	**N/A**
Is there a quality manual?	☐	☐	☐	☐
Is the scope of the quality manual properly defined?	☐	☐	☐	☐
Is the quality manual periodically revised?	☐	☐	☐	☐
Is the quality manual readily available and approved?	☐	☐	☐	☐
Is the quality manual properly structured?	☐	☐	☐	☐
Does the quality manuel represent /reflect the actual practices?	☐	☐	☐	☐
Comments				

Overall Score	**Compliant**	**Minor recommendations**	**Major recommendations**	**N/A**
Is there a quality manual in the department?	☐	☐	☐	☐

Recommendations		

6.4. Quality policy

The existence of a quality policy within the department allows for the department to express its vision on quality. It is therefore sets an overall vision for the establishment of a QMS.

CHECKLIST 31. Quality policy

Items to be reviewed by the auditor	YES	In progress	NO	N/A
Is there a quality policy in the department?	☐	☐	☐	☐
Is the quality policy broadcasted to and known by the department?	☐	☐	☐	☐
Does the quality policy include the department's objectives?	☐	☐	☐	☐
Is the quality policy included in the quality manuel?	☐	☐	☐	☐
Is the quality policy approved/validated by the head of department?	☐	☐	☐	☐
Is the quality policy made accessible to the patients? (visible)	☐	☐	☐	☐
Is the quality policy updated?	☐	☐	☐	☐
Comments				

Overall Score	Compliant	Minor recommendations	Major recommendations
Is there an updated and visible quality policy within the department?	☐	☐	☐
Recommendations			

6.5. Quality indicators

The existence of quality indicators is essential for the department to monitor its performance and quality levels.

CHECKLIST 32. Quality indicators

Items to be reviewed by the auditor	YES	In progress	NO	N/A
Does the department participate in the College QI project?	☐	☐	☐	☐
Are there defined QI in the department?	☐	☐	☐	☐
Are the QI evaluated/measured?	☐	☐	☐	☐
Are the defined QI in accordance with the quality policy?	☐	☐	☐	☐
Are the QI SMART?	☐	☐	☐	☐
Are the QI periodically reviewed?	☐	☐	☐	☐
Are improvement actions put into place after QI analysis?	☐	☐	☐	☐
Are the QI results communicated?	☐	☐	☐	☐
Are the QI results conserved?	☐	☐	☐	☐
Comments				

Overall Score	Compliant	Minor recommendations	Major recommendations
Are quality indicators being monitored in the department?	☐	☐	☐
Recommendations			

6.6. Process management

The definition treatment processes are sub processes are a valuable input in a QMS

CHECKLIST 33. Process management

Items to be reviewed by the auditor	YES	In progress	NO	N/A
Are the treatment processes clearly defined?	☐	☐	☐	☐

Are the sub processes logically defined?	☐	☐	☐	☐
Are the processes approved and readily available?	☐	☐	☐	☐
Is the involved personnel clearly identified at each sub process?	☐	☐	☐	☐
Are the processes linked to the department's procedures?	☐	☐	☐	☐
Comments				

Overall Score	**Compliant**	**Minor recommendations**	**Major recommendations**
Have the department's main processes been clearly defined?	☐	☐	☐
Recommendations			

6.7. Organizational chart

The establishment of organizational charts allows for the clear definition and visualization of personnel's position within the hospital's/department hierarchy.

CHECKLIST 34. Department's organizational chart

Items to be reviewed by the auditor	**YES**	**In progress**	**NO**	**N/A**
Is there a defined organisational chart (in the department)?	☐	☐	☐	☐
Does the organizational chart clearly represent the actual status of the department's organisation?	☐	☐	☐	☐
Is the QM included in the department's organizational chart?	☐	☐	☐	☐
Is the connection between the RT QM and the rest of institution clear?	☐	☐	☐	☐
Is the organisational chart clear enough?	☐	☐	☐	☐
Comments				

Overall Score	Compliant	Minor recommendations	Major recommendations
Is there a clear organisational chart at the departmental level?	☐	☐	☐
Recommendations			

6.8. Task and responsibility definition

CHECKLIST 35. Personnel's tasks and responsibilities.

Items to be reviewed by the auditor	YES	In progress	NO	N/A
Are the job descriptions of the radiation oncologists clearly defined?	☐	☐	☐	☐
Are the job descriptions of the medical physicists clearly defined?	☐	☐	☐	☐
Are the job descriptions of the nurses/RTTs clearly defined?	☐	☐	☐	☐
Are the job descriptions of the quality manager clearly defined?	☐	☐	☐	☐
Are the job descriptions of the administrative personnel clearly defined?	☐	☐	☐	☐
Are the job descriptions of the logistics personnel clearly defined (technical support staff, engineers,…)?	☐	☐	☐	☐
Are the job descriptions of the supportive staff clearly defined (nurse specialists, psychologists, social worker, dieticians…)?	☐	☐	☐	☐
Is the job description of the QM clearly defined?	☐	☐	☐	☐
In the RT process				
Are the radiation oncologist's tasks clearly defined?	☐	☐	☐	☐
Are the medical physics' tasks clearly defined?	☐	☐	☐	☐
Are the RTTs' tasks clearly defined?	☐	☐	☐	☐

Are the technical-engineer's tasks clearly defined?	☐	☐	☐	☐
Are the administrative personnel's tasks clearly defined?	☐	☐	☐	☐
Are the logistic personnel's tasks clearly defined?	☐	☐	☐	☐
Are the QM's tasks clearly defined?	☐	☐	☐	☐
Comments				

Overall Score	**Compliant**	**Minor recommendations**	**Major recommendations**
Are the department's professional group's job descriptions and tasks clearly defined?	☐	☐	☐
Recommendations			

6.9. Resource management

Training of personnel should be formalized, and competencies monitored. The auditors are also required to assess if there are professional education and training programs for any of the professional classes of personnel, i.e. radiation oncologists, radiotherapy medical physicists and RTTs.

CHECKLIST 36. Resource management

Items to be reviewed by the auditor	**YES**	**In progress**	**NO**	**N/A**
Human resources				
Is there an existing formalized training plan for new recruits?	☐	☐	☐	☐
Is there an existing formalized training plan for interns?	☐	☐	☐	☐
Is internal training organized?	☐	☐	☐	☐
Is external training organized?	☐	☐	☐	☐
Is there a specific person appointed to coordinate formalized internal training?	☐	☐	☐	☐

Is external training funded by the department/by the hospital?	☐	☐	☐	☐
Are minimal numbers of staff for external training/ meetings defined?	☐	☐	☐	☐
Are the personnel's competencies monitored?	☐	☐	☐	☐
Is this defined in a plan/evaluation system?	☐	☐	☐	☐
Is there an existing CPE program/policy for: ROs? MPEs? RTTs? Others?	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐
If others, which other professional group?				
Equipment resources				
Is a list of equipment established?	☐	☐	☐	☐
Does this list coincide with the needs of the department?	☐	☐	☐	☐
Comments				

Overall Score	**Compliant**	**Minor recommendations**	**Major recommendations**
Are human and equipment resources properly managed?	☐	☐	☐
Recommendations			

6.10. Risk management

An incident in radiotherapy administration refers to any therapeutic treatment delivered to the wrong patient or the wrong volume. This results in a dose or dose fractionation that differs substantially from the values prescribed. Near incidents are those events which could have caused harm to the patient but did not reach the patent as it was intercepted before it affected the patient. Patient safety aspects of radiotherapy should as such be reviewed.

This chapter focuses on all elements that are put into place within the department and/or at the hospital level in order to prevent or to manage incidents and near incidents. This includes, amongst others, reactive risk management as well as proactive risk management and all elements that are put into place within the department and at the hospital level in order to ensure the optimal and safe delivery of radiotherapy treatments.

CHECKLIST37. Deviations in radiotherapy administration

Items to be reviewed by the auditor	YES	In progress	NO	N/A
Is there an existing event reporting and analysis system?	☐	☐	☐	☐
Is it easily accessible?	☐	☐	☐	☐
Is this system integrated within the hospital's system?	☐	☐	☐	☐
Is there a formal procedure on the declaration of events within the department?	☐	☐	☐	☐
Is the PRISMA Methodology used for the analysis of events?	☐	☐	☐	☐
Are the context variables used for the description of root causes?	☐	☐	☐	☐
Does the department participate in the national benchmark database?	☐	☐	☐	☐
Annual number of reported events (proportion of incidents and near incidents):				
Of which incidents?				
Of which near-incidents?				
% PRISMA analysis on total number of events:				
Is there a formal procedure on the management of significant events?	☐	☐	☐	☐
Is there a no-blame/just culture policy?	☐	☐	☐	☐
Is the radiation oncologist in charge of the patient notified of an incident?	☐	☐	☐	☐
Are significant deviation reported to regulatory authorities?	☐	☐	☐	☐

Is there a formal policy regarding informing patients about incidents?	☐	☐	☐	☐
Are there regular meeting held for event analysis and determination of improvement actions?	☐	☐	☐	☐
Is this a multidisciplinary team?	☐	☐	☐	☐
Are improvement actions determined on the basis of event reporting and analysis?	☐	☐	☐	☐
Are these improvement actions listed and accessible?	☐	☐	☐	☐
What is the mechanism for the implementation and monitoring of the improvement actions?				
Is feedback given to the reporter of the event?	☐	☐	☐	☐
Is feedback given to the RT team?	☐	☐	☐	☐
If yes, how? *Newsletter* ☐ *Mailing list* ☐ *Dashboard* ☐ *Meetings* ☐ *Other* ☐ _____				
Are there regular safety training sessions organized?	☐	☐	☐	☐
Is proactive risk analysis carried out?	☐	☐	☐	☐
If yes, in which case?				
Comments				

Overall Score	Compliant	Minor recommendations	Major recommendations
Is there a comprehensive risk management system within the department?	☐	☐	☐
Recommendations			

6.11. Breakdown management

Procedures and systems allowing for the management and monitoring of breakdown is recommended.

CHECKLIST 38. Breakdown management

Items to be reviewed by the auditor	YES	In progress	NO	N/A
Is there an existing breakdown management system (including loss of treatment time, types of fault/errors…)?	☐	☐	☐	☐
Is an analysis of existing data regularly carried out?	☐	☐	☐	☐
Are corrective and preventive actions defined in accordance with breakdown data analysis?	☐	☐	☐	☐
Are specific QI put into place?	☐	☐	☐	☐
Is there a defined procedure for patient workflow management in case of breakdowns?	☐	☐	☐	☐
Are there procedures describing the measures to be taken in case of emergency radiation protection situations?	☐	☐	☐	☐
Are these emergency radiation protection measures known by the personnel?	☐	☐	☐	☐
Comments				

Overall Score	Compliant	Minor recommendations	Major recommendations
Are procedures concerning breakdown management properly implemented?	☐	☐	☐
Recommendations			

6.12. Patient satisfaction

Monitoring of patient satisfaction is considered an asset in improving the department's quality of care – allowing it to meet patients' expectations.

CHECKLIST 39. Patient satisfaction

Items to be reviewed by the auditor	YES	In progress	NO	N/A
Is patient satisfaction considered in the department?	☐	☐	☐	☐
Are statistical analyses of patient satisfaction carried out?	☐	☐	☐	☐
Are these results of the analysis communicated?	☐	☐	☐	☐
Do improvement actions originate from the results of the patient satisfaction surveys?	☐	☐	☐	☐
Comments				

Overall Score	Compliant	Minor recommendations	Major recommendations
Is patient satisfaction monitored in the department?	☐	☐	☐
Recommendations			

6.13. Audits

Audits are useful tool allowing for department to objectively quantify their quality levels.

CHECKLIST40. Audits

Items to be reviewed by the auditor	YES	In progress	NO	N/A
Are internal audits carried out in the department?	☐	☐	☐	☐
Are internal audits planned?	☐	☐	☐	☐
Are there existing internal audit procedures?	☐	☐	☐	☐
Are external audits carried out in the department?	☐	☐	☐	☐
Are external audits planned? *(This also refers to "physics" audits such as BELdART)*	☐	☐	☐	☐
Are there existing external audit procedures?	☐	☐	☐	☐
Is the QM involved in the internal audits?	☐	☐	☐	☐
Is the QM involved in the external audits?	☐	☐	☐	☐
Are the recommendations following the audits stored and managed?	☐	☐	☐	☐
Are the results of the audits conserved?	☐	☐	☐	☐
Do improvement actions originate from the results of the audits?	☐	☐	☐	☐
Comments				

Overall Score	Compliant	Minor recommendations	Major recommendations
Does the department use audits as a quality improvement tool?	☐	☐	☐
Recommendations			

7. AUDIT PART V: COMMUNICATION MANAGEMENT

The relevant documentation illustrating the processes of dissemination of information throughout the radiotherapy program should be prepared by the department and made available to auditors on site.

- Record keeping and documentation (clinical, medical physics).
- Across disciplines, access to hospital and physician records. Computer and fax equipment. Adequacy of telephone communication.
- Horizontally (between staff members with the same function) and vertically (between senior and junior staff members),
- Between different areas of the radiotherapy process,
- Between shifts when applicable.

The auditors should take note of the existing meetings organized within and outside (but implicating) the radiotherapy department.

The following questions should be kept in mind by the auditors: “is communication managed in such as way as to ensure effective communication favoring the establishment of a safety culture?

CHECKLIST 41. Communication management

Items to be reviewed by the auditor	YES	In progress	NO	N/A
Are meetings organized in the department?	☐	☐	☐	☐
Is an agenda proposed for all meeting?	☐	☐	☐	☐
Are minutes generated after meetings?	☐	☐	☐	☐
Are the meetings' agenda and minutes archived?	☐	☐	☐	☐
Are communication tools implemented in the department?	☐	☐	☐	☐
Are improvement actions communicated?	☐	☐	☐	☐
Are department's memos communicated?	☐	☐	☐	☐
Does the department easily communicate with other departments inside the hospital?	☐	☐	☐	☐
Does the department easily communicate with other hospitals?	☐	☐	☐	☐
Does the department easily communicate with outside companies/suppliers?	☐	☐	☐	☐

Does the department's management communicate in an optimal matter with the department's personnel?	☐	☐	☐	☐
Do the different disciplines in the department communicate with each other in an optimal matter?	☐	☐	☐	☐
Are significant incidents communicated to the department?	☐	☐	☐	☐
Are significant incidents communicated to the management of the hospital?	☐	☐	☐	☐
Are significant incidents communicated to authorities?	☐	☐	☐	☐
Is there an existing dashboard/ information delivery system that present a clear overview of quality indicators, safety issues and important elements to be communicated?	☐	☐	☐	☐
Comments				

Overall Score	**Compliant**	**Minor recommendations**	**Major recommendations**
Overall, is communication properly managed?	☐	☐	☐
Recommendations			

8. AUDIT PART VI: RADIATION PROTECTION OF STAFF AND POPULATION (AND OCCUPATIONAL HEALTH FOLLOW-UP)

Measures should be taken by the department to ensure the radiation protection of staff and the population as a whole. Some of these elements are monitored by the Federal Agency of Nuclear Control through the radiation protection officer. The main focus will thus be on reviewing the control reports and to ensures that the necessary corrective actions are put into place

CHECKLIST 42. Radiation protection of staff and population

Items to be reviewed by the auditor	YES	In progress	NO	N/A
Is there a health physics department in the hospital?	☐	☐	☐	☐
Are the MPE involved in the periodic radiation protection (RP) controls carried out in the radiotherapy department?	☐	☐	☐	☐
Comments on radiation protection controls				
Are the recommendations emitted by the RP control stored by the department?	☐	☐	☐	☐
Are the recommendations emitted by the RP control followed up on by the department?	☐	☐	☐	☐
Is training in radiation protection regularly provided to the department staff?	☐	☐	☐	☐
Which staff?				
Can staff easily access personal dose monitoring values (dosimeter values)?	☐	☐	☐	☐
Is there a procedure for handling overexposure of staff?	☐	☐	☐	☐
Is there a radiation safety procedure for visitors of the radiotherapy department?	☐	☐	☐	☐
Are there regular planned visits of the department by the occupational health staff?	☐	☐	☐	☐
Are the recommendations emitted by occupational health staff stored by the department?	☐	☐	☐	☐

Are the recommendations emitted by occupational health staff followed up on by the department?				
Comments				

Overall Score	**Compliant**	**Minor recommendations**	**Major recommendations**
Are staff and population based radiation protection requirements correctly implemented?	☐	☐	☐
Recommendations			

9. AUDIT PART VII: RTT ROLES AND RESPONSIBILITIES

The RTT's scope of practice is rapidly evolving and changing. This extension of practice needs to be realized in a proper framework within the limits of what is defined within the department and taking into account the increasing complexity of treatments

CHECKLIST 43. RTT roles and responsibilities

Items to be reviewed by the auditor	YES	In progress	NO	N/A
Is there an orientation program for newly hired RTTs?	☐	☐	☐	☐
If yes, please comment on the orientation program (length, content, clinical trainer, exams…)				
Do RTTs formally participate in equipment selection?	☐	☐	☐	☐
Do RTTs participate in training by the vendor upon arrival of new equipment/software	☐	☐	☐	☐
Is there sufficient time allotted to RTTs for equipment/software training?	☐	☐	☐	☐
Comments on training of RTTs relative to new equipment/software				
Is radiation protection part of a yearly CPD program?	☐	☐	☐	☐
Are RTTs familiar with radiation protection protocols?	☐	☐	☐	☐
Do RTTs actively carry out quality control procedures on the treatment modalities?	☐	☐	☐	☐
If yes, list them If no, who does them				
Do RTTs actively carry out quality control procedures on the simulation unit?	☐	☐	☐	☐

If yes, list them If no, who does them				
Do RTTs actively participate in the quality management?	☐	☐	☐	☐
Do RTTs actively carry out checks on immobilization and fixation devices?	☐	☐	☐	☐
If yes, list them If no, who does them?				
Is rotation of staff ensured?	☐	☐	☐	☐
If yes, how many times a year?				
Comments				

Overall Score	**Compliant**	**Minor recommendations**	**Major recommendations**
Are RTTs actively involved in department's managerial decisions and quality control procedures?	☐	☐	☐
Recommendations			

ADDITIONAL RELATED DOCUMENTS

- Template of audit report (main headings)
- Excel document with BQUATRO audit checklist
- *QMRT reference manual (http://qmrt.be/downloads/QMRTtool2017.pdf)*

APPENDIX I - GLOSSARY

AFCN/FANC	Agence Fédérale de Contrôle Nucléaire/ Federaal Agentschap voor Nucleaire Contrôle
BELdart	BELgian Dosimetry Audits in RadioTherapy
EBRT	External Beam Radiotherapy
QA	Quality Assurance
KCE	Federaal Kenniscentrum / Centre Fédéral d'expertise
IAEA	International Atomic Energy Agency
MPA	Medical Physics Assistant
MPE	Medical Physics Experts
NCS	Nederlandse Commissie voor Stralingsdosimetrie
PSDL	Primary Standard Dosimetry Laboratory
RO	Radiation Oncologist
RT	Radiotherapy
RTT	Radiation TherapisT
PRISMA	Prevention and Recovery Information System for Monitoring and Analysis
QUATRO	Quality Assurance Team for Radiation Oncology
SMART	Specific, Measurable, Attainable, Realistic, Time limited
SSDL	Secondary Standard Dosimetry Laboratory

APPENDIX II - REMARKS ON CONSISTENCY OF TERMINOLOGY USED IN RADIOTHERAPY

In order to avoid misconceptions and misunderstandings in the use of terminology at various radiotherapy departments worldwide, auditors are encouraged to make themselves familiar with the explanations below. These were devised for the purpose of consistency. However, this does not constitute the intent to set definitions on these various terms.

Patient

Patient is an individual with one or more cancers.

Cancer case

Cancer case is a new cancer registered, possibly several different cancers in a single individual (synchronous or metachronous).

Treatment or course of treatment:

Treatment is a course of radiotherapy made of a number of sessions, treating a given cancer. Whether it is in one or several different target volumes (T and N) is considered as one treatment. An additional irradiation at distance from the primary (e.g. prophylactic cranial irradiation in SCLC[18]) could be considered a different course of treatment, since the additional workload linked to it might amount to a new treatment (different simulation, different set-up at the treatment machine, different dose calculation).

The auditors should note in their report what is comprised in a treatment at the audited department and give some examples.

Treatment plan

Treatment plan is at least a 2D distribution of doses.

Treatment session/fraction

Treatment session is synonymous with a fraction. One irradiation session comprises one or more fields on one or more target volumes concerning the same patient. Sessions are sometimes understood as a time slot at a treatment machine (10 minutes for example). A complex treatment might use more than one time slot (e.g. treatment of a child with medulloblastoma); therefore it can be registered as one or as several sessions depending on the departmental definition. Auditors need to clarify what is understood as a treatment session in an audited department, and the report of the audit must be unambiguous in that matter.

Treatment field

Treatment field is a single radiation beam. Each beam orientation may include more than one field size. Auditors need to determine what definition is used.

Shift

Shift is normal working hours for a given professional class. A department might be open for longer daily hours and therefore use successive shifts for the personnel.

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[18] SCLC : Small Cell Lung Cancer

Workload

Workload of a radiotherapy department is determined by the number of treatments.

RTT

RTT refers to the personnel – primarily composed of nurses and technologists working at imaging for treatment planning (simulation) and responsible for the daily delivery of treatment (at treatment modalities)

Some remarks on the enumeration of patients and cancer cases

While the concept of a 'patient' is uncontroversial, the number of 'cancer cases' is recorded and reported differently not only in developing countries but also between industrialised countries and from institution to institution. The auditors must establish the basis from which these statistics are derived.

Catchments area

Are the cancer cases an attempt at a National or Regional Cancer Registry derived from the entire country or region?

Are they derived from all the hospitals affiliated to the major hospital being audited or only those patients presenting to the audited institution?

Source of information

Do the cases include both clinical and pathological diagnoses or only the latter?

Management

Do these cases include patients who may have been simply sent home for terminal care; or those managed by surgery or chemotherapy besides those seen in a combined assessment clinic? Or are the cases only those who have received radiotherapy?

Skin cancer: Inclusions/exclusions

Do these cases include all cases of skin cancer or are only malignant melanomas included (in conformity with IARC guidelines for National Cancer Registries? Are all cases of Kaposi Sarcoma (AIDS and HIV negative) included?

Counting

It is usual to count a patient with synchronous or metachronous cancer at a second primary site as a second case. In some institutions, the development of metastases subsequent to the primary management is recorded as a further case.

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