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Acronyms

RT:	Radiotherapy
QMS:	Quality Management System
QM:	Quality Manager
RO:	Radiation Oncologist
MPE:	Medical physicist expert
MPA:	Medical Physicist Assistant
RTT:	Radiation Therapist
QA:	Quality Assurance
QC:	Quality Control
FTE:	Full Time equivalent
AEE:	Adverse error-event

Introduction

Since 1969, the International Atomic Energy Agency (IAEA) has been internationally and actively involved in the development and the installation of dosimetric audits in radiotherapy. In order to meet the needs of various countries, the IAEA decided to develop more clinically focused audits. As a result, an advisory group composed of radiation oncologists (RO), medical physicists (MP) and Radiation Therapists (RTT) also known as QUATRO (Quality Assurance Team for Radiation Oncology) was created in 2005 (1). In 2007, the group published “Comprehensive Audits of Radiotherapy Practices: a tool for quality improvement” (2). This document describes, in a complete way, the guidelines necessary for the conduct of comprehensive audits which address equipment, infrastructure and clinical practices of the radiotherapy department, the whole approach being patient-focussed. The interpretation of the results of the audit is in function of the criteria of “good practices” appropriate to radiotherapy quality standards. In Belgium, action 16 of the cancer plan (2009) allowed the employment of persons in charge of quality in all Belgian radiotherapy departments in order to establish quality management systems in each one of these departments (3). In the same way, the College of Radiotherapy initiated the training of QUATRO auditors and since 2010, 5 radiotherapy departments a year are audited based on the QUATRO methodology. As of 2015, all radiotherapy departments have been audited.

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). This document, also known the QMRT tool, aims at describing guidelines for the implementation and the evaluation of a quality and risk management systems in radiotherapy departments. It is partly based on the ISO 9001 standard while adapting it to the Belgian radiotherapy departments and this in a comparable manner as the ASN n°5 guide (4).

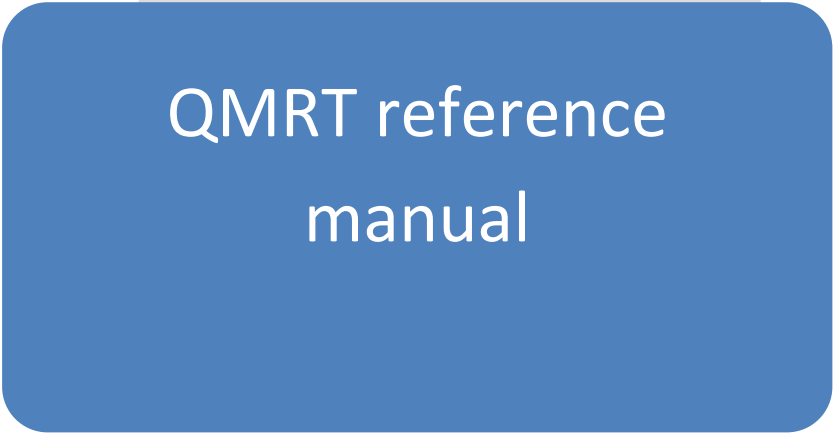
The QMRT tool covers the following set of topics:

- Chapter 1: Quality Management System(QMS)
- Chapter 2: Document Management System
- Chapter 3: Quality Manual
- Chapter 4: Quality Policy
- Chapter 5: Quality Indicators
- Chapter 6: Process management
- Chapter 7: Organisational charts
- Chapter 8: Tasks and responsibilities
- Chapter 9: Resource Management
- Chapter 10: Communication Management

- Chapter 11: Risk Management System
- Chapter 12: Management of breakdowns
- Chapter 13: Patient satisfaction
- Chapter 14: Audits

Each chapter is addressed by including the general standards, theoretical framework and practical modalities of its implementation as well as templates. These templates are documents that can be used as a framework or source of inspiration when these need to be generated with a department. Moreover, each chapter contains a checklist of items needing to be reviewed/evaluated by the auditors.

The approach of constituting this document is in fact complementary to the QUATRO document of the IAEA and this in order to widen the field of the audits conducted in Belgian Radiotherapy departments.



QMRT reference
manual

Chapter 1: Quality Management System

1 General definitions

At this stage, it is important to define the main terminologies that will be used throughout this document as these are at the forefront of a quality management system. These definitions are mainly based on the ISO 9000 (V 2004) standards.

Term	Definition
Quality management system (QMS)	Organisational structure defining the responsibilities of each stakeholder, procedures, processes and resources necessary to implement effective policies. The search for efficiency is the scope of a QMS which aims for continuous improvement within an organisation by the achievement of objectives based on the Plan-Do-Check-Act (PDCA) methodology (5) (6).
Continuous improvement	Ongoing activity which aims at improving the [organisation's] ability to meet its requirements (virtuous circle of quality) (5) (6) (7).
Goals	Results [that need to be] to achieved (5) (6).
Indicators	Measurable results (5) (6).
Process	Set of activities using resources, and managed in order to enable the transformation of inputs into outputs (6).
Adverse error-event	An event that results in unintended harm either minor or serious to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient. All treatment related side effects are excluded (8).
Quality Assurance	"Part of coordinated activities to guide and control a health establishment quality status focused on providing confidence regarding the needs or expectations expressed, implied or usually imposed for quality» (4).
Quality Assurance in radiotherapy	"All procedures that ensure consistency of the medical prescription, and safe fulfilment of that prescription, as regards the dose to the target volume, together with minimal dose to normal tissue, minimal exposure of personnel and adequate patient monitoring aimed at determining the end result of the treatment" (9).
Quality Control	"Regulatory process, through which the actual quality

	<p>performance is measured, compared with existing standards, and the actions necessary to keep or regain conformance with the standards. Quality control is one part of overall quality assurance. It is concerned with operational techniques and activities used:</p> <ul style="list-style-type: none"> ●To check that quality requirements are met; ●To adjust and correct performance if the requirements are found not to have been met” (9).
Audit	A methodical, independent and documented process, to verify conformance to standards and to evaluate them objectively to determine the extent to which the audit criteria are fulfilled (10).
Corrective actions	Action to eliminate the cause of nonconformities or adverse events in order to prevent its recurrence (10).
Preventive actions	Actions [put into place] to eliminate a perceived weakness in the system or the cause of a potential nonconformity or other undesirable potential situations in order to prevent [its] occurrence (8) (10).
Management review	Scheduled meetings that take place within an organisation to review its quality management system (10).

2 Theoretical framework

Ideally the Quality Management System (QMS) is under the responsibility of the head of the radiotherapy department (often a radiation oncologist). QMS monitoring and updating is assigned by the head of department to the Quality Manager (QM) in radiotherapy.

The Quality Manager ensures the daily management of the quality system and ensures it is updated following decisions taken, either by the institution or by the radiotherapy department -and this with the support and involvement of the entire RT team.

2.1 Basis of a quality management system

A QMS relies on 8 principles, which are as follows (5):

1 - **Customer focus:** "Identification of current and future needs to ensure that customer requirements are determined and met, aiming at the enhancement of customer satisfaction and exceeding customer expectations."

2 - **Leadership:** "Management involvement that establishes the quality policy and objectives of the organisation. They should create and maintain the internal environment in which people can become fully involved in achieving the organisation's objectives, through the provision of resources, access to training and recognition"

3 - **Staff involvement:** "use of staff skills to meet the needs of the organisation. People at all levels are the essence of an organisation and their full involvement enables their abilities to be used for the organisation's benefit"

4 - **Process approach:** "Desired results are achieved more efficiently when activities and related resources are managed as a process"

5 - **System approach to management:** "identifying, understanding and managing interrelated processes as a system contributes to the effectiveness and efficiency of the company's achievement of goals"

6 - **Continuous improvement:** "involvement of the entire staff in the achievement of continuous improvement goals of a quality management system. This includes questioning the processes and systems in order to meet the strategic objectives of the organisation."

7 - **Factual approach to decision making:** "analysis of evidence by valid methods for decision making and direction of choice." Effective decisions are based on the analysis of data and information"

8 - **Mutually beneficial supplier relationships:** "An organisation and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value"

2.2 The Deming wheel

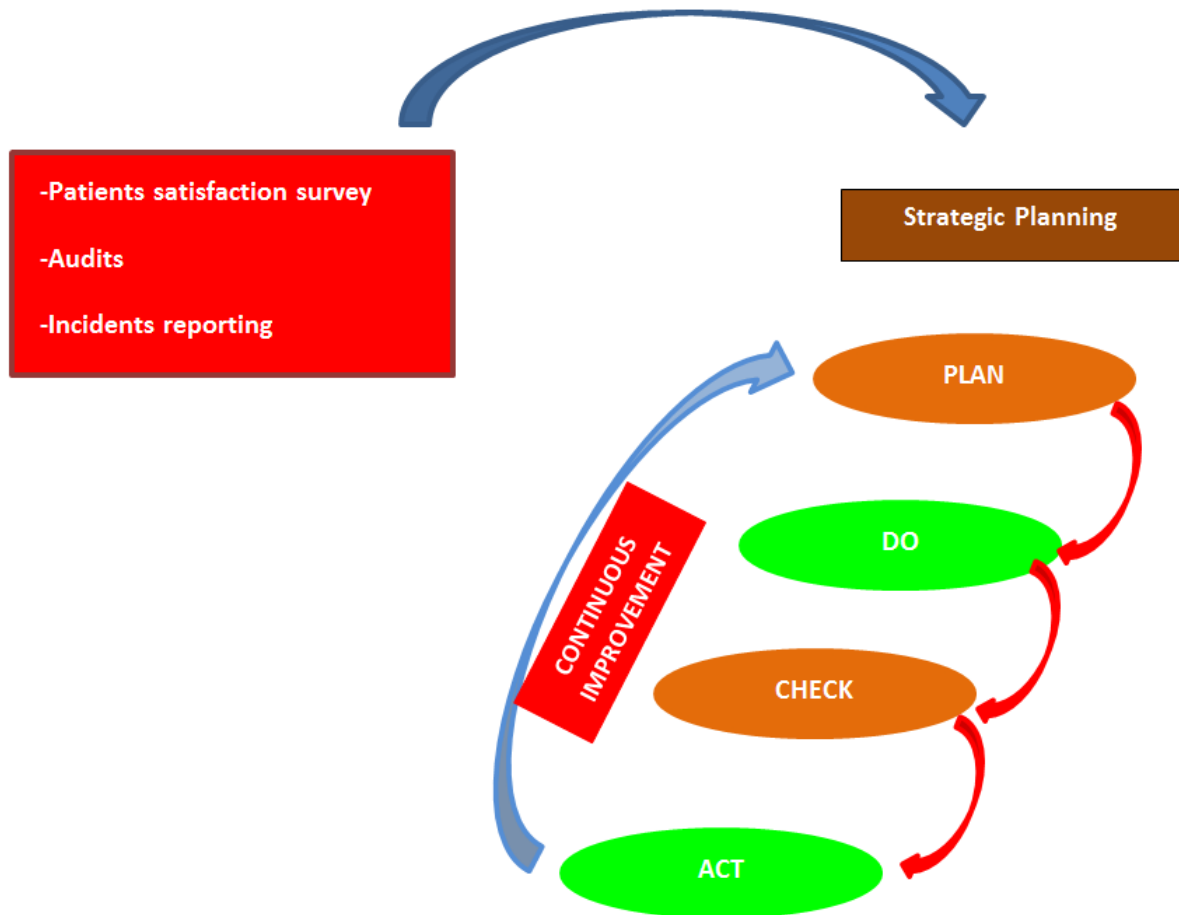


Figure 1- Deming wheel

The QMS is a system for planning, measuring, checking and improving all processes of a radiotherapy department (Fig. 1). This can be facilitated through the PDCA cycle (Plan-Do-Check-Act) – a four step management method which allows for continuous improvement (11) (12). The PDCA cycle was made popular by Dr W. Edwards Deming - considered to be the father of modern quality control - but, he often referred to it as the "Shewhart cycle". Later in Deming's career, he modified the term PDCA to "Plan, Do, Study, Act" (PDSA) because he felt that "check" accentuated evaluation/inspection over analysis (13). Nevertheless, throughout this document, the term PDCA will be used

The four steps of the PDCA cycle are as follows (14) (11) (12):

1. **Plan:** Strategic Planning (prepare, plan what has to be done)

This step includes the establishment of the action plan and processes and the formulation of objectives to meet the demands of patients as well as the legal and regulatory requirements. Different elements need to be foreseen, such as the:

- **Quality policy:** which highlights the department's quality objectives (see Chapter 4: Quality Policy)
- **Quality objectives:** are described by management and need to be clear and precise (see Chapter 4: Quality Policy)
- **Quality Indicators:** need to be defined in order to assess the operation the system (see Chapter 5: Quality Indicators)
- **Internal Audits:** need to be planned for the department's self-assessment against reference documents, regulations, etc. (see Chapter 14: Audits)
- **Necessary resources:** Resources are planned in line with the defined objectives (Chapter 9: Resource Management)

2. **Do:** Deployment (develop, achieve, implement)

This step's aim is to put into place the different actions points in order to achieve established goals and processes. These actions can be launched at different levels of the QMS:

- **Production processes:** implementation of activities related to patient workflow in the radiotherapy department
- **Monitoring and evaluation processes:** implementation of processes aiming at monitoring and evaluating the results of activities
- **QA and QC processes:** Implementation of actions points aiming at increasing the performance of existing QA programs and QC activities.

3. **Check:** monitor and verify

This steps objective is to evaluate the actions points that have been put into place in step 2.

This can be realised using various methodologies such as:

- Planning and carrying out internal audits of processes: implementation of planned audits, which can highlight the need for corrective and/or preventive actions.
- Monitoring of adverse error-event occurrence following the implementation of the actions points: management of identified adverse events, root cause analysis and definition of corrective and preventive actions.

4. **Act** (adjust)

This step consists of adjusting the action points in order to optimise results.

This includes:

- Management review: review of feedback, indicators, audits and analysis of data to identify future goals
- Analysis of strengths and weaknesses of the current system
- Overview of corrective and preventive actions and their management
- Identifying opportunities for improvement though analysis of current data

3 Practical modalities

3.1 Quality monitoring

The quality manager should ideally track a set of tools and indicators to ensure the management and continuous improvement of the quality management system.

3.1.1 Incident management (see Chapter 11: Risk Management System)

The adverse error-events are collected and analysed by the radiotherapy Quality Manager (QM) (with the eventual help of other staff experts). This analysis of the events will allow for feedback and the implementation of corrective and preventive actions. The statistical analysis of this data will also give the department a view on the evolution and/or trends in the events being reported.

3.1.2 Management and monitoring of internal/external audits (Chapter 14: Audits)

The objective, impartial and independent nature of audits allows for the evaluation of the organisation's status and operational methods according to quality criteria. The exit briefing and resulting report should be at a minimum be known by the QM and ideally by the entire staff.

3.1.3 Monitoring of corrective and preventive actions

The corrective and preventive actions that are put into place need to be recorded and monitored by the QM. The QM will also manage the status of the actions and will send the necessary reminders to the responsible staff members. The on-going progress of the actions points will also be presented, by the QM, during management and/or quality meetings.

3.1.4 Monitoring of quality indicators (Chapter 5: Quality Indicators)

Quality indicators are essential tools for monitoring the performance status of a process. These need to be defined in a multidisciplinary fashion and evaluated on a regular basis.

3.2 Management review (Annual Quality Committee)

At the beginning of the year, the QM and the head of the radiotherapy department should lead a meeting to present results of the previous year and to set new goals and plans for the coming year.

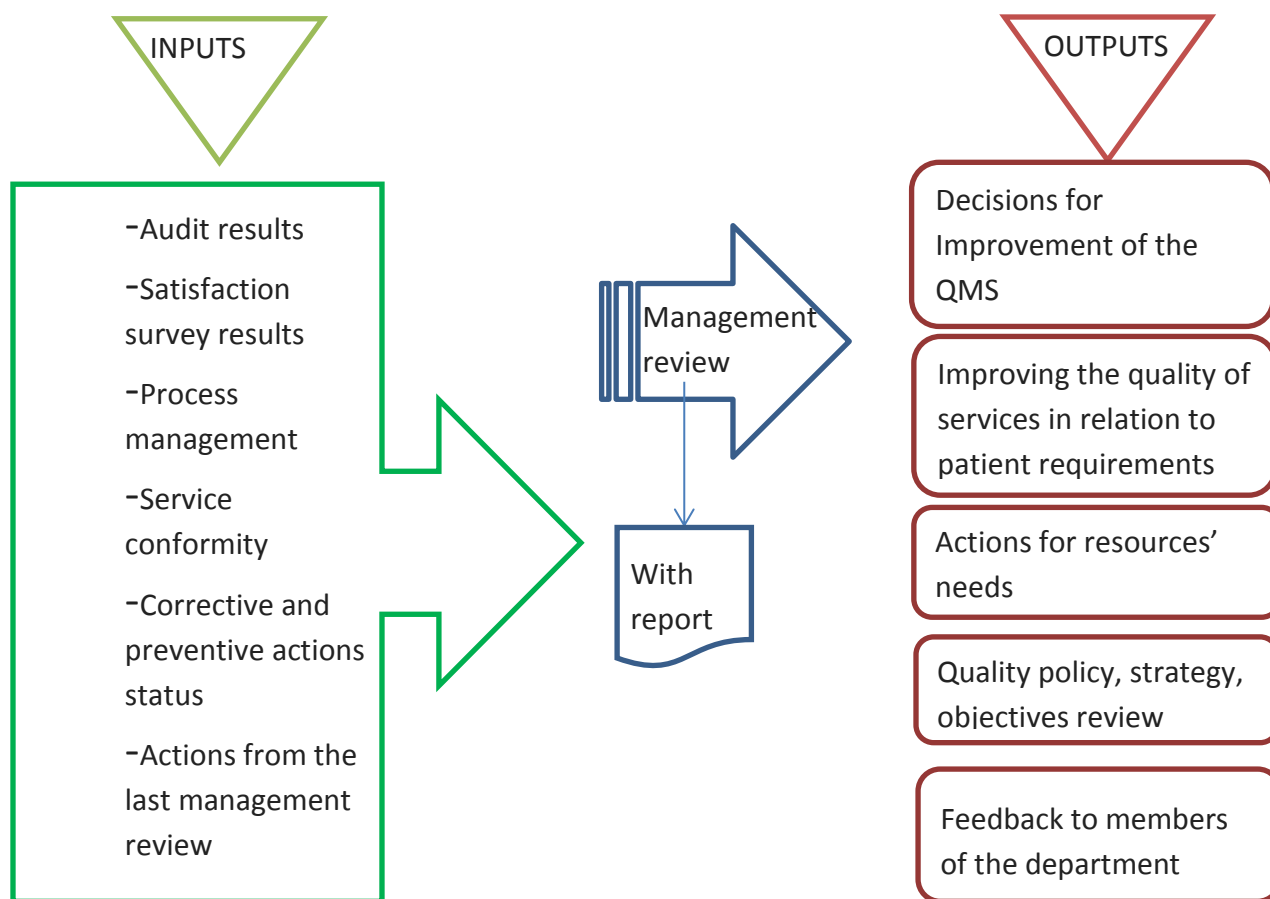


Figure 2- Management review process

The management review (Quality Committee) meeting allows for the representative (QM or someone else depending on each centre's organization) of the RT department to convey information to management concerning the radiotherapy quality system. It gives the department the opportunity to take a step back from the system and to objectively analyse its performance. The representative of the department must also take that opportunity to trigger improvement actions or to request for adequate resources to achieve the quality objectives.

The requirements for a management review meeting are as follows (10):

- The need for early preparation: be in possession of the right information;
- Develop a systematic approach: define a clear agenda;
- Perform a review with all heads of staff of the RT department;
- Monitor on going status and react: trigger progress actions;
- Set up a participative meeting and include the majority of staff in order to avoid misinformation.
- Ensure that proper feedback is given to staff

The steps involved in organizing a management review meeting are as follows (10):

3.2.1 Preparation

During the preparation phase, it is necessary to:

- Set the date, time, place, participants and agenda of the meeting;
- Collect key data; analyse and organize data so as to present, in summary form, quality results.

Examples of key information:

- Results of *patient satisfaction surveys*
- *The operation of a process (synthesised process reviews);*
- *The results of internal and external audits;*
- *The progress of action plans;*
- *The status of corrective and preventive actions;*
- *Type and status of patient claims;*
- *Changes that could affect the QMS;*
- *Recommendations for improvements,*
- *The action plans from previous reviews.*

3.2.2 Conducting a management review

3.2.2.1 Question the present and future organisation of the company:

- Have there been any changes since the last management review that may influence /affect the QMS?
- Will changes soon take place in the institution's organisation? Could they affect the QMS?
- What actions should be taken?

3.2.2.2 Analyse the current situation

Analyse the situation of the on-going action plans:

- Are the objectives consistent with the quality policy?
- What is the status of the action plans?
- What is the status of the actions plans agreed upon at the previous review meeting?
- What points need to be emphasized?

Review the resources necessary for maintaining the QMS:

- Are the resources for maintaining the QMS sufficient?(number of auditors, IT system, document management system, ...)

Suitability of organisation of the QMS:

- What are the strong points and difficulties?
- Are resources globally available?
- What action points should be undertaken?

Patient related information:

- What are the new expectations of the patient?

- What information is available regarding benchmark data?
- What are the strengths and weaknesses of the department?
- Are patients satisfied?
- What are the main complaints?
- What actions should be undertaken?

Results of the analysis of processes, activities, quality of internal audits, the status of corrective and preventive actions:

- What are the highlights?
- The strong points?
- The weaker points?
- What actions should be undertaken?

3.2.2.3 Give recommendations

- What actions should be undertaken to make our system more efficient?

3.2.2.4 Concluding remarks

- Is the management system effective?
- Is the system in continuous improvement?
- Are resources adequate?
- Is the quality policy still relevant?
- What are the actions to be undertaken regarding the:
 - o The processes?
 - o The partners?
 - o The staff? The staff's skills and responsibilities?
 - o The methods used?
 - o The organisation of the QMS?
 - o The environment?

3.2.3 Establishing an action plan following the management review meeting (Action plan)

The action plan following a management review meeting can be laid out by covering these different aspects:

- **Reasons for the action plan:** set the context and purpose of the plan;
- **Content of the action plan:** name and describe the content of the action plan;
- **Person responsible for the action plan :** designate the staff members and stakeholders responsible for the action;
- **Manner in which the action plan will be implemented:** state the human or material resources needed;

- **Time frame and deadlines of the action plan:** define the start and end date of the action plan;
- **Scope of action of the action points:** state the implicated staff group and the extent of the action points;
- **Evaluation of the action plan:** define how the action plan will be evaluated and the criteria for success.

3.3 Tools used for quality improvement

The Quality Manager can use several tools to improve the QMS; a few examples are presented below (15).

3.3.1 Process optimisation

Process optimisation is a discipline in which processes are improved by adjusting a specified set of parameters.

This optimisation can be realised through:

- Benchmarking
- A diagnostic analysis of the department's process performance (monitoring of indicators)

3.3.2 Brainstorming

Brainstorming is a working session to produce, as a group, a maximum number of ideas within a minimum time on a given theme. This technique often used as a problem solving tool by:

- Identifying the problem;
- Looking for the causes of the problem;
- Proposing solutions to the problem.

3.3.3 Diagram of causes/effects (Ishikawa diagram)

This causal diagram is often realised in a group setting and aims at classifying the identified causes of an effect within families and subfamilies of categories. It aims at identifying potential elements that could cause an overall effect. The diagram thus takes the form of a fishbone (Fig.5) (15).

Once the causes are identified, the following steps are followed:

- Define the families of causes around the "5M":
 - Man power: skills, absenteeism, training, motivation
 - Machine: machinery, equipment, capacity, technology
 - Material: includes raw material, documents, computer data
 - Method: process, working rules, procedures, protocols, ways of doing ...
 - Medium: environment, infrastructure, space, noise, lighting, temperature ...

- Assign each cause of the problem to one of the families:

If the causes are many within a family, identify sub-families or sub-causes: e.g., in the family “training”, one can add the subfamily “initial training”, “professional training”...

- Search for finer causes; go further into the details for each of the main causes.
- Create a cause and effect diagram structuring.
- Search for corrective or improvement actions to be implemented in accordance with the identified causes

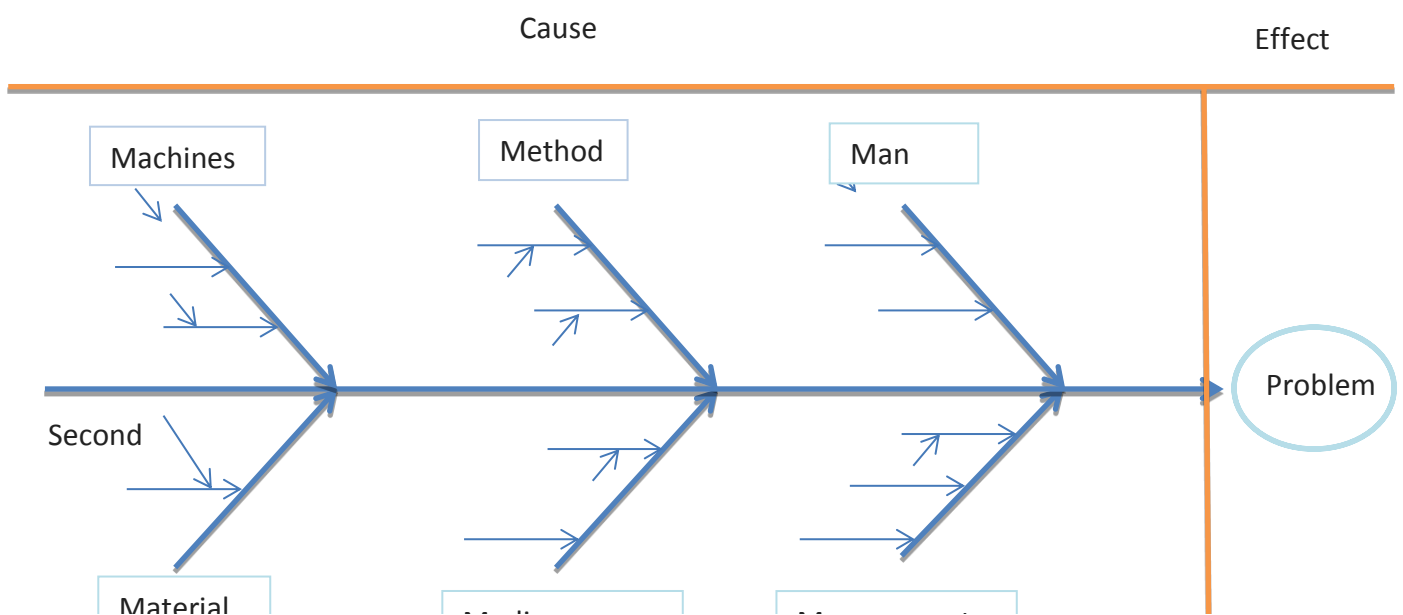


Figure 3- ISHIKAWA diagram

3.3.4 WWWWHW methodology (What, Who, Where, When, How, Why)

The goal of this tool is to have a clear and complete understanding of the underlying items within a problem, a question, a solution or a situation.

In this methodology, the following questions must be asked:

- **WHAT** is this about; what action, which operation...?
- **WHO** is concerned, who are the participants, who is the person in charge? With what level of training?
- **WHERE** does the action take place? Concept of location (s), distances, steps,...
- **WHEN** does the action take place? At what moment?(schedule, duration, frequency ...)
- **HOW** is it done? (Materials, equipment, necessary means, method, procedure...)
- **WHY** is this action carried out/necessary? (Procedure, necessity...)
- And for each question it is necessary to include **HOW MUCH?** (Investment, cost....)

3.3.5 Clinical Pathways

Clinical pathways describe, for a given pathology, all elements of the management process of patient care based upon the patient care pathway. This method is to plan, streamline and standardize the multidisciplinary and / or multi professional management of patients with a comparable health problem (15).

The various interventions of professionals involved in patient care are defined, optimised and sequenced and the essential steps of patient care are detailed.

To develop a clinical pathway, it is necessary to:

- Define the group of patients included in the clinical pathway;
- Identify all stages of the care pathway;
- Analyse recommendations of professional practices for each of these steps;
- Precisely describe all actions necessary to achieve this care.

Clinical pathways help in establishing guidelines and recommendations, improving coordination and communication and are a favourable tool in risk management. They also simplify treatments while minimising the variability of practices.

4 Templates

4.1 Action plan

Example of specific action plan form that can be used to properly define an action plan. (See next page)

D
A
T
A
R
E
Q
U
I
R
E
D

LOGO	Quality codification	Level
	Action request	Revision :
		Date :

<input type="checkbox"/> Corrective action	<input type="checkbox"/> Préventive action	<input type="checkbox"/> Opportunity for improvement
<input type="checkbox"/> Management review	<input type="checkbox"/> Intern audit n° :	<input type="checkbox"/> External audit
<input type="checkbox"/> CREX	<input type="checkbox"/> Suggestion	<input type="checkbox"/> Satisfaction survey
N° :		Page to
Name of the department/ the activity / the place:		
Applicant :	Concerned :	Date : / /
<p style="color: blue; margin-top: 0;">Description of the situation</p>		
Signature of applicant:	Date : ... / ... /	Signature of concerned person : Date : / /

Root causes analysis if there are non-conformity: Ishikawa diagram attached :	<input type="checkbox"/> YES	<input type="checkbox"/> NOT
Signature of the process responsible:	Signature of the quality manager:	

Description of the corrective or preventive action to put in place:			
Detailing the action plan:			
The responsible for monitoring:			Due date: / ... /
Visa of applicant:	Date: ... / ... /	Visa of concerned person:	Date: ... / ... /

Checking the effectiveness of corrective or preventive actions:	<input type="checkbox"/> OK	<input type="checkbox"/> NOT
Comments:		
Visa applicant or quality manager:	Date: / /	

Chapter 2: Document Management System

1 General definitions

1.1 Document management

A document management system is a set of various types of documents that are structured and organized.

The aim of a document management system is to effectively and systematically organize all documents of sources of information that an organization needs for its activity. A document management system is governed by a set of rules and procedures describing the manner in which documents are composed, reviewed, approved, monitored and disseminated (16) (5) (17).

1.2 Electronic Document Management (EDM)

In the last few years, paper-based document management systems have been replaced by software / paper-less systems that have allowed for the digital management of documents. The EDM is designed to organize and manage information and documents within a department or institution set workflow. It allows users to digitally create, index, classify, manage, store and access documents in an efficient manner.

2 Theoretical framework

2.1 Documentation requirements

The documents that are required will depend on the referential/certification framework chosen by the hospital, e.g. Accreditation-certification (ISO,...). The hospital will comply with these requirements; the document management system will be implemented so as to provide all necessary documents.

2.2 The aim of a Document Management System (DMS)

The primary goal of a DMS is to meet the hospital's requirements and flowchart of document management.

The objectives of a DMS are as follows:

- Document centralization and secure accessibility
- Written formalization of valid and up-to-date rules and professional practices
- Harmonization of practices
- Safeguarding of knowledge
- Prevention of risks and dysfunctions
- Traceability of the results, communications and decisions

2.3 Document types (5) (18)

2.3.1 Quality manual

More information of the quality manual can be found in the chapter "Quality manual". *However, it is important to note that it is no longer required with the 2015 version of ISO 9001 (19).*

2.3.2 Procedures

A procedure includes the entire process specific to an activity. It is the document that describes and formalizes who should perform a specific task required to implement the process. It is a document that allows for the standardization of professional practices.

Procedure = Who should do what?
--

The procedure allows to:

- 1 - visualize the process quickly;
- 2 - have an analytical approach to the process;
- 3 - specify the sequence of steps;
- 4 - quickly identify the steps that are at risk;
- 5 - identify the categories of staff.

Example of a procedure: clinical pathway of breast cancer patients

Note: There are usually two types of procedures:

- Quality organisational procedures that describe the entire quality system;
- Functional procedures that describe the activity of the department.

2.3.3 Operational documents (protocols, instructions, modus operandi,...)

Operational documents = How to do it/how is it done?

These documents include various types of documents such as instructions, protocols and technical sheets. They all describe how to perform an activity and they are interconnected by the process described in the procedure.

2.3.4 Data recording and forms

According to ISO 9000, a recording is a "document presenting the results or evidence of completion of an activity. (5)".

Examples: Medical Record, adverse error-event reporting form, equipment quality control form.

3 Practical modalities

Each department defines its document management system; this will depend on the available resources (for example: available EDM system) and institutional rules. A document management procedure needs to be established and stipulates the processes involved in management the DMS. It also needs to describe the different document types and their "life cycle".

3.1 Document management rules

The overall objective of the establishment of DMS rules is to ensure that the correct information is available at the right time and at the right place in the department (18).

To achieve this, it is necessary that the hospital or department defines - for each specific type of document- the measures that need to be put into place in order to ensure that the DMS achieves this goal in an optimal manner.

The document management rules need to cover such areas as the identification and referencing of the document. Ideally, all activities and operating rules of the DMS must be described. These practices must be standardized and known by all the staff members.

Examples of rules:

- A document which is not recorded in the system is not valid
- The archived documents cannot be used and should be unavailable.

3.2 A document life cycle

It is necessary to define the flowchart of the document cycle (16) (17):

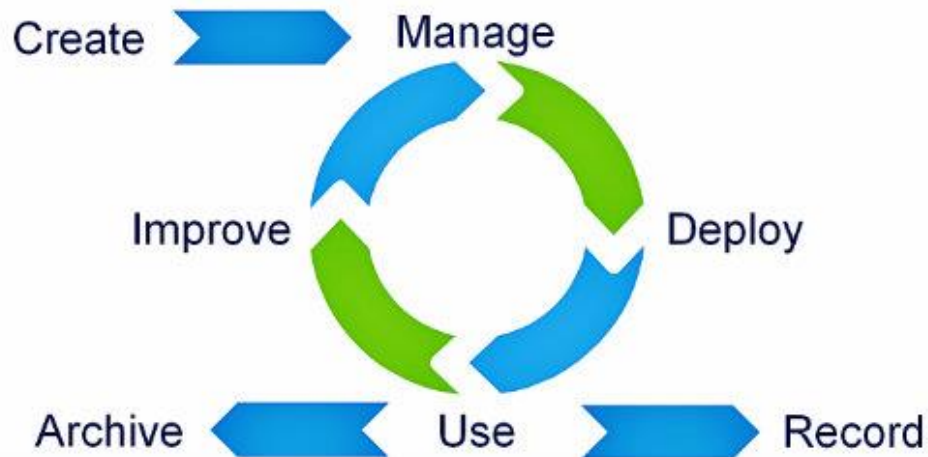


Figure 4- Document Management cycle

3.2.1 Identifying the need for a document

Some factors that may give rise to the creation of a document are:

- Changes induced by regulatory monitoring, scientific papers and/or normative requirements;
- Introduction of new processes/sub-processes/techniques;
- The need to standardize practices of an existing given process;
- The need to clarify practices between different staff members;
- New/adaptation of activities due to the implementation of improvement actions.

3.2.2 Drafting of the document

Before editing a document, it's very important to ask the following questions:

- Who decides that the drafting or revision of the document is necessary?
- Who will write the document? Who will help?
- Who will review / revise the document?
- Is this document needed/useful?
- What are the references used?
- Is this document related to another document?
- Who is the document addressed to?
- When must it be available?
- What media is used?

- What is the layout that must be applied?

3.2.2.1 Design and layout of a document:

It is important to note that the design and layout varies considerably across institutions with the arrival of EDMS. The following information may be presented on documents even though some information is no longer necessary with an EDMS:

- The title,
- The document reference number/identifier,
- The date,
- The revision index,
- The page numbering,
- The scope (for whom, for what)
- The text
- The information pertaining to the individuals involved in its drafting/reviewing/approval

It can also include:

- The abbreviations used
- The signatures (writing, reviewing, approval)
- The changes introduced since the last version

Example of a header of a document:

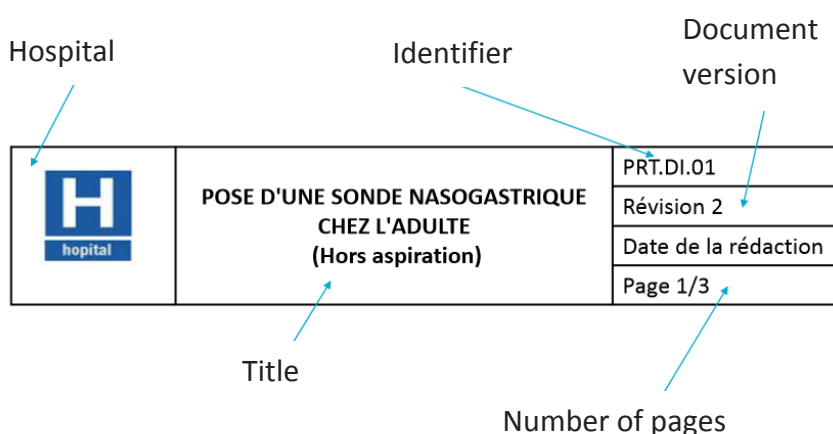


Figure 5 - Exemple of a document header

3.2.2.2 Templates used to draw a flowchart

Flow charts are tools that can be used to visualize and structure activities (Fig.4)

They are a graphical representation of tasks or activities needing to be completed/realized and this allows to:

- Define the scope of the document (IN-OUT);
- Define the actors involved in the process;
- Represent the sequence of activities (implementation and decision);
- Identify control points and monitoring;
- Identify the feedback loop(s) and decision points;
- Show the link between activities.

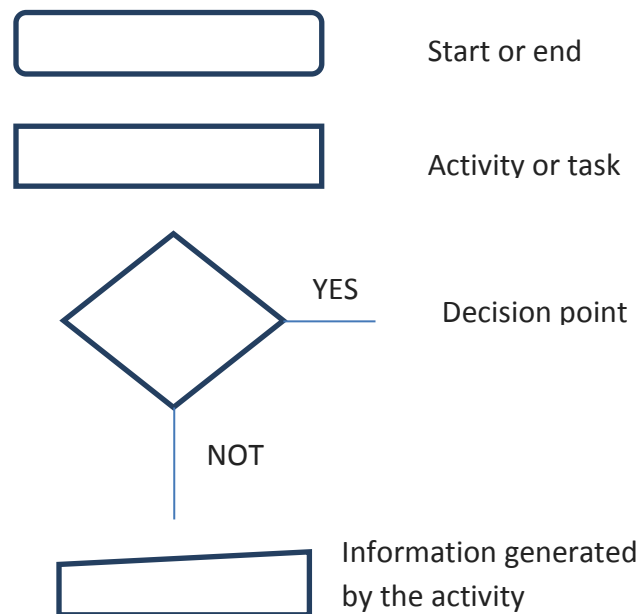


Figure 6- Diagrams typically used in a flowchart

3.2.3 Reviewing and /or approval of the document

The revision/approval of the document assesses the quality of the document, its compliance with the document management rules and its consistency with the existing documentation. This is mainly carried out by an expert in the activity or a staff member responsible for this activity. This expert and/or staff member will be verifying the content of the document. In parallel, the quality manager will have the role of verifying the format of the document (compliance with DMS rules).

3.2.4 Validation and / or approval of the document

The validation or approval is usually performed by the head of the department who allows the dissemination of the document but sometimes approval by higher management is necessary.

3.2.5 Document dissemination

The dissemination of the document consists in making the document accessible to all concerned staff members or workstations.

This consists in:

- Identifying the recipients (ie: those directly or indirectly targeted by the document) (function entity, site, ...);
- Sending or distributing the documents to the recipients;
- Providing information or training on the document's content;
- Ensuring accessibility to the document.

Note: Proof of the dissemination of the document can be saved (acknowledgment, signature ...).

!! Proof of receipt is not proof of reading!!!

3.2.6 Revising the document

The document should be regularly reviewed (ex: every three years). The document can be changed according to the evolution of the activity or a particular request (lack of precision, pictures ...). The change request must be made to the person responsible of the activity and/or the QM according to the document management procedure. This request can be made by completing a form.

3.2.7 Document archiving

Once documents are no longer valid, it is necessary to deactivate and archive them as soon as possible. Archived documents should no longer be available and used in the department. However, they should be archived in such a way as to maintain their integrity throughout time in order to avoid loss of information. The manner and period of time in which the documents are preserved need to be specified in the DMS procedure.

Once the archiving time period is over, the manner in which the documents are destroyed also needs to be defined. Depending on the confidentiality of the document, destruction may be outsourced to a specialized body that will provide a certificate of destruction.

Note: It is important to ensure the safety, protection and retrieval possibilities of the materials used in the DMS (paper, computer data,...).

3.3 Electronic documents management (EDM)

Currently, different types of software are available to facilitate the implementation of a DMS in the institutions. Depending on the software that is chosen, various features can be found such as:

- Structural organization and classification of documents;
- Possibility of defining access levels: access to all documents for all staff members in the hospital or department or limited access according to the status of the staff member;
- Existence of a search tool allowing the user to carry out a document search according to keywords;
- Management of interdependencies between documents;
- Possibility of electronic reviewing, validation and approval of a document;
- Scope identifier;
- Electronic dissemination of documents;
- Automatic archiving system...

Electronic document management software facilitates document management but it is necessary to:

- Properly train the staff in using this tool.
- Implement the necessary means to be able to compensate for the loss or alteration of computer data and to safeguard the system against losses-(periodic back-up, back-up servers, protection of the physical area).
- Ensure that the electronic DMS is compatible with other applications in use.

4 Templates

4.1 Procedure template (English)

Example of a typical template of a procedure. The types of items/subchapters included in a procedure will vary from department to department. However, once a template is approved, the same must be used for all procedures.

Note: The information in **green is not necessary with an EDMS.*

Title				Identification of the document
Written by	Checked by	Validated by	Approved by	Review version
Date and visa	Date and visa	Date and visa	Date and visa	
Date of implementation:				

Revision date(s)	Reviewer	Checked by	Validated by

I. The aim of the procedure:
Subject of the procedure

II. Scope of application:
Define the operational scope of the proceedings

III. Terminology and abbreviations:
Explain abbreviations of concepts

IV. Tasks and responsibilities:
We need to identify systematically:

1. The tasks that must be performed
2. The relevant staff, the skill level to perform a task

V. Documents:
It is all documents associated with the procedure. There are 2 classes of document:

1. External documents:
 - Legislative references
 - Scientific recommendations about subject of the processes.
 - Guidelines

2. Internal documents:
Make a list of internal documents:

- Procedure
- Procedure
- ...

VI. List of annexes:
Must be numbered, make a list, must be annexed

- A1
- A2
- A...

VII. Process description:
Please, describe the process. Present the processes as a logogram, color the risk activities.

Activities (how?)	Actor (who?)	What?

--	--	--

VIII. Evaluation of process performance:

Make a list of evaluation approaches or track performances.

-AMDEC

-Incident reporting and analysis

-...


-...

IX. System improvement:

Explain

4.2 Procedure template (NI -GZA)

Template that can be used for a procedure (courtesy of GasthuisZusters Antwerpen (GZA)(nl)

QMRT's tool: A proposal for a complementary document to QUATRO	
Dienstgebonden document enkel geldig in : Campus : [Campus GZA]	Datum van toepassing : [Datum Van Toepassing] Vervaldatum : [Vervaldatum] Documentverantwoordelijke : [Documentverantwoordelijke]
	 Operaties Zorg Oncologisch Centrum [Topic]
	Versie: {_UIVersionString}

0. Kort overzicht van de wijzigingen ten opzichte van de vorige versie

Typ hier je tekst

Geef voor de gebruiker van deze procedure een korte opsomming van wat er in deze versie verschillend is ten opzichte van de vorige versie.

Wanneer het gaat om kleine aanpassingen, markeer de gewijzigde tekst in het **geel** en ~~doorstreep~~ te verwijderen tekst.

Wanneer er grote aanpassingen gebeuren, geef dan enkel weer welke punten van deze procedure werden gewijzigd (vb. punt 4 werkwijze) zonder de tekst te markeren of door te strepen.

1. Doel

Typ hier je tekst

Doel van de procedure : beschrijf waarover de procedure gaat (**WAT**) en het doel (**WAAROM**).

2. Toepassingsgebied en verantwoordelijkheden

Typ hier je tekst

- omschrijving van de situaties/voorwaarden waarbij de procedure moet toegepast worden (= indicaties)(**WANNEER**)

- omschrijving van de situaties/voorwaarden waarbij de procedure niet mag toegepast worden

(= contra-indicaties)(wanneer niet)

- omschrijving van wie er bij de procedure betrokken is en de kennis, kunde en competenties die nodig zijn om de procedure uit te voeren en wie welke verantwoordelijkheid draagt (**WIE**)
- omschrijf waar de procedure van toepassing is (**WAAR**) (vb. op de consultatie van campus X)

3. Definities en synoniemen

Typ hier je tekst

- geef een verklaring van gebruikte terminologie en afkortingen
- voeg trefwoorden en synoniemen toe van het onderwerp of de aanverwante onderwerpen van deze procedure zodat ze gemakkelijker terug te vinden is

4. Werkwijze

Typ hier je tekst

4.1 Subtitel (optioneel)

Typ hier je tekst of verwijder deze subtitel indien niet van toepassing.

4.2 Subtitel (optioneel)

Typ hier je tekst of verwijder deze subtitel indien niet van toepassing.

Omschrijving van de effectieve werkwijze, procedure (**HOE**).

- geef aan welke activiteiten moeten worden uitgevoerd, in welke volgorde en door wie, voeg zo mogelijk een flowchart of stappenplan toe
- geef aan welke benodigdheden/materialen er nodig zijn
- geef aan hoe en waar er moet gerapporteerd worden
- geef aan welke informatie aan de patiënt moet worden meegedeeld (vb. patiëntenfolders)
- geef aan hoe vaak de procedure mag uitgevoerd worden binnen een bepaalde tijd (frequentie)
- geef aan hoe de kosten/materialen moeten verrekend worden (eventueel artikelnummer)
- geef aandachtspunten rond veiligheid en afvalverwerking
- geef aan welke de mogelijke complicaties zijn

5. Evaluatiecriteria en borging

Typ hier je tekst

- geef aan op basis van welke criteria deze procedure zal worden opgevolgd
- geef aan wie deze criteria zal opvolgen
- geef aan door wie de opgevolgde criteria en de naleving van de procedure zullen worden geëvalueerd en hoe de procedure zal worden bijgestuurd

6. Bijhorende documenten

Typ hier je tekst

Geef een opsomming van de documenten (procedures, bijlagen, formulieren, folders, handleiding, SLA, technische gegevens, ...) die verband houden met deze procedure, werk zo mogelijk met een koppeling naar het document

Opgelet : maak uitsluitend koppelingen naar goedgekeurde documenten in het procedureboek, maak nooit koppelingen naar documenten in de ontwerpruimte of naar bestanden op lokale directories.

7. Bronvermelding, evidentie en wetgeving

Typ hier je tekst

Vermelding van de oorsprong van informatie en afbeeldingen (literatuur, beeldmateriaal, internet, cd...) gebruikt in de procedure. Gebruik daarbij volgende format:

NAAM VOORNAAM AUTEUR. Titel boek, plaats van uitgave, naam van de uitgeverij, jaar van uitgave, pagina('s).

Geef zo mogelijk aan uit welke aanwijzingen of studies blijkt dat de procedure wetenschappelijk onderbouwd is (evidence-based).

Vermelding van de wetgeving waarover de procedure handelt of verband mee houdt.

Vermelding van het JCI-hoofdstuk waaraan de procedure gelinkt is.

8. Disclaimer

Dit document is eigendom van GZA vzw en mag niet zonder toestemming van de directie, clustermanager of medisch diensthoofd verspreid worden buiten GZA. Dit geprint document is enkel geldig indien de inhoud overeenstemt met de definitieve geldige elektronische versie wat impliceert dat dit vóór ieder gebruik moet gecontroleerd worden wanneer het document niet in een 'gecontroleerde kافت' wordt bewaard.

Goedkeuring
Goedgekeurd door :
[Goedgekeurd Door 1]
[Goedgekeurd Door 2]
[Goedgekeurd Door 3]
[Goedgekeurd Door 4]
[Goedgekeurd Door 5]
Ref. nr.: -

Chapter 3: Quality Manual

1 General definitions

The quality manual (handbook) is a document depicting the operation of a Quality Management system (QMS). Its purpose is to describe the overall functioning of a department. It gives an outline of the activities carried out to maintain the QMS (6) (7).

It describes the various sections of the department's quality policy, quality objectives and it gives a description of the processes and their interactions and the means available within the institution to meet these objectives (20).

2 Theoretical framework

The quality manual must describe its field and its perimeter (scope) of application. **Its appropriate format** and its **structure** are to be decided by the organisation and will depend on the size, the culture and the complexity of the concerned organisation (6).

2.1 Format

The format of the quality handbook is to be decided by the RT department, in coherence with the size of the department, its history and its method of functioning.

2.2 Content

The content of the document can be modified according to the needs of the RT department. The quality handbook must contain the signatures of the representative of the issuing department and the management of the institution.

2.3 The key questions that need to be asked

The questions that need to be asked when creating the quality manual are as follows (non-exhaustive):

- Who is/are the person(s)/individual(s) in charge of writing the manual?
- Who is/are the person(s) who validate(s), approve(s) the manual?
- Who has access to the manual?
- Who will be responsible for the broadcasting of and access to the document? In what format will it be presented (paper, web-based, e-document)?
- How will the documents be protected? What system will need to be set up to ensure its protection? What means will be put into place to ensure that the latest version is available?

- How often should the manual be revised?

3 Practical modalities

The following steps are useful in order to properly generate the quality manual:

- Define the structure of the quality manual ;
- Outline the points/chapters that will be addressed (see [template](#) example);
- Interact with the RT quality task group in order to get their feedback;
- Select the format that the quality manual will have ;
- Ensure that the quality manual is integrated with the document management system.

4 Templates

Various templates of quality manuals can be found. Here below are some examples.

4.1 ESTRO template

This template can be visualized in chapter 5 of the ESTRO booklet 4 (7)

<http://www.estro.org/binaries/content/assets/estro/school/publications/booklet-4---practical-guidelines-for-the-implementation-of-a-quality-system-in-radiotherapy.pdf>

4.2 ISO 9001 template

ISO 9001 Quality manual (French) from the Ardennes Quality Assurance (France) (21)
http://zeurg.pagesperso-orange.fr/qualite_iso_9001/manuel_qualite.htm

4.3 WHO quality manual template

http://www.who.int/ihr/training/laboratory_quality/quality_manual/en/

Chapter 4: Quality Policy

1 General definitions

The quality policy is a document that must be produced with the agreement and signature of the management.

It sets the short and long-term objectives of the department while also stating concrete and feasible guidelines. The general characteristics of a quality policy are that (22):

- It is consistent with the general values of the institution;
- It contains the commitment and leadership position of the department in the quality approach and willingness to comply patient satisfaction;
- It describes the “quality” vision of the department, the actions that need to be put into place to achieve this vision and the implication of this quality approach within the general policy of the institution.

According to the ASN (Agence de Sûreté Nucléaire), the quality policy must describe the tendencies and intentions of the health institution towards quality improvement as stated by a person or individuals who will orient and control the establishment to achieve this (4). Meanwhile, the ISO 9001 standard specifies that the quality policy of an organization, service or department must (6):

- Be adapted to the finality of the organization;
- Include a commitment to comply with the requirements and to continually improve the effectiveness of the QMS;
- Provide a framework for establishing and reviewing quality objectives;
- Be communicated and understood within the organization;
- Be periodically reviewed and adapted.

2 Theoretical framework

2.1 Form

The quality policy should have the following characteristics (23) (24):

- Be relatively short: ideally 1-2 pages;
- Contain short and simple sentences;
- Include about ten commitments (objectives);
- Ideally be signed by the team leaders and QM;
- Be regularly reviewed.

The quality policy can be:

- Displayed in the department – keeping in mind that it is essential that it is well-known by all and easily accessible;
- Internally and externally broadcasted according to the wish of the department.

2.2 Content

The quality policy should contain (23):

- A title;
- If possible the scope and exclusions;
- The commitment of the management in the process of continuous improvement;
- The target objectives;
- The means that will be used to achieve the objectives;
- The signatures of the managers according to the organization of the institution;
- The date;
- A reference number as stipulated by the document management system used in the department (see Chapter 2: Document Management System).

3 Practical modalities

The establishment of a quality policy must be realized in several steps. It is important to define (23):

- **To whom** the quality policy is addressed;
- **Who** is responsible for editing, reviewing and validating the document;
- **What** objectives need to be attained in order to optimize patient satisfaction.

Some recommendations

The quality policy:

- Is one of the first documents that can be written in a quality management approach: the drafting of the processes, procedures and evaluation of all activities in the department can help to define the indicators and objectives;
- Can be an integral part of the quality of the radiotherapy department;
- Should define attainable goals;
- Can be used as a communication tool between management and the department (vertical communication) concerning quality management

!! Attention should be paid to the terms that are used in order to ensure that commitments can be achieved.

Necessary steps to establish the quality policy:

- **Define** the nature and the purpose of the department and its vision in term of quality
- **Identify the main recipients of the quality policy**: general, medical, nursing department, heads of staff in the radiotherapy department (medical staff, physician, RTT/nurses), administrative staff (secretaries ...), the quality manager and/or patients. The recipients can thus be department staff but also staff from other departments of the institution (example: doctors who send patients to RT department).
- **Gather information** (23) :
 - Select and prioritize information;
 - Define the shape or form of the document (introduction, management commitment, ...);
 - Meet with management(top managers);
 - Understand the commitments and their reasons within the QMS;
 - Define the quality objectives and the resources that need to be implemented in order to achieve them;
 - Consider patient satisfaction;
 - Ensure continuous improvement;
 - Refer to repositories used in the department or in the institution.

- **Edit the policy:** the quality policy is ideally made by the head of department; he/she may be assisted by members of the quality task group.
- **Verify the content:** the content of the quality policy should be verified by the heads of staff (radiation oncologist, physicist, RTT).
- **Broadcast:** when the quality policy is signed and approved, it is broadcasted by the usual means of communication. It is important to ensure that it is understood and known by the whole staff.

4 Templates

The following model can serve as an example for drafting the quality policy. By completing the table it is possible to structure ideas and write an explanatory text afterwards (25).
Examples of quality policies can also be found on various websites (26).

LOGO	<u>TITLE</u>	
The value of the department : <ul style="list-style-type: none"> • Staff training • The creativity of the department • The respect for patients • The use of up-to-date techniques 		
Value of the service	Axis of the quality policy	Measurable quality objectives
Have a trained and specialized staff	implement continuous internal and external training	Participate in x training or x hours / year
Have a proactive department	Treat quickly	Start treatment x days after consultation
Respect	Meet the patient's expectations	Have an overall satisfaction > x%
Technique	Offer advanced techniques	Increase the number of stereo treatments
...

EXAMPLE OF QUALITY POLICY:

Our radiotherapy department participates in a quality management system, continuous improvement and patient satisfaction. It relies on the general values of the institution and more specifically applies to our practices:

- **The Staff is trained** and specialized, allowing the standardized quality of management of all patients. It is required to follow x hours of training per year to keep knowledge up to date.
- **The department is proactive**, allowing starting a radiotherapy treatment x maximum time after the diagnosis (or after MOC), after the first consultation, the first simulation ...).
- **The Patient compliance**, expectations, needs, it is central to our quality process ... this is evaluated through the establishment of a satisfaction questionnaire after which satisfaction may not be less x%.
- **The Technique:** the Radiotherapy Department is a department where advanced technologies are implemented in routine such as VMAT, stereotactic ... to ensure optimal and modern management of all our patients.

Chapter 5: Quality Indicators

1 General definitions

An **indicator** is “Quantified Information that provides a scale on which a performance can be measured, in accordance with an assessment criterion.” (27).

Examples:

General example: The speed of a dashboard in a car provides a scale for measuring velocity and makes it possible to be evaluated compared to a reference (authorised car speed limit).

Radiotherapy example: Time elapsed between decision to treat and first day of treatment

An indicator of quality and safety of care is “a tool that gauges a health status, practice or the occurrence of an event, and allows for the measuring quality of care and its variations in time and space in a valid and reliable manner” (28).

Several types of indicators (few examples are listed here below) (28):

- Outcome indicator

This indicator refers to the quality of the product or the service offered. It measures the activity and the quality of the various phases of the care process. It also measures the quality of the final results, which actually reflects the health status of the patient.

This type of indicator gives rise to a value at some point in time and reflects reality. It is then measured over time. It can also be called indicator of monitoring.

Example of outcome indicator: the disease free survival rate at 5 years

- Process indicator

This indicator provides information on the compliance to and/or the quality of the existing process. It provides information on the applied professional practices during patient care and management, as well as the methods of operation and coordination of relevant activities.

Example of process indicator: elapsed time between simulation and treatment

- Structural indicator

This indicator reflects the human, equipment and financial resources, necessary for patient care and management.

Example of structural indicator: the number of machine/year

- Satisfaction indicator

This indicator measures the satisfaction level of patients, visitors or other professional bodies concerning the department and/or treatment. It is therefore a representative of “perceived quality”. These indicators are more difficult to define and set up, as they are based on qualitative data. They are however necessary in the context of a qualitative approach.

Satisfaction indicators may also be assessed internally by measuring as to the level of employee satisfaction in relation to working conditions, salary, and atmosphere within the team or other factors.

Example of satisfaction indicator: the satisfaction rate of patients and staff

2 Theoretical framework

2.1 Format

Quality indicators can be presented in several different configurations. The format used will be selected by the RT department.

Ideally, an indicator should be set within a framework whereby the indicator is clearly defined and can be collected and used for analysis and storage of data.

The framework of an indicator ideally includes the following aspects (also refer to [Templates](#)) (28) (29) (30) (31):

2.1.1 Definition of the quality indicator

This is equivalent to establishing what needs to be measured. [**“To know what you want to measure”**]

Example: satisfaction level of the staff

2.1.2 Objective of the quality indicator

This is equivalent to defining the objective/goal that the indicator needs to reach. [**“To know what you want to reach”**]

Example: we aim for a satisfaction level of 99% for all staff

2.1.3 Person/group in charge:

This parameter defines the person who will be responsible for measuring the indicator. [**“To know who will measure”**]

This person or group is responsible for developing, monitoring and collecting data and results of the indicator.

Example: the quality manager

2.1.4 Unit of measurement

It is necessary to define the scale or unit of measurement that will be used for collecting the data. **“To know what unit is used to measure the indicator”**

Example: for the satisfaction level of staff, the unit of measure will be %.

2.1.5 Periodicity of measurement

This item defines the frequency at which the indicator measurements will be carried out. **“To know when we will measure”**

Example: 1X/year, one month before management review

2.1.6 Method of data collection

It is also necessary to define where and in what manner the needed data will be collected. **“To know where to find the data and how to collect them”**

Example: results of the analysis of the staff satisfaction survey

2.1.7 Method of calculation

It is also necessary to define how and with which methods the data will be analysed; **“To know how you will process the data”**

Example: average of the overall satisfaction rate (in %)

2.1.8 Method of data storage

The methodology with which the data will be stored also needs to be defined. **“To know how and where the data will be stored”**

Example: the surveys are kept in the folder X, room Y, cupboard Z

2.1.9 Criteria of inclusion/exclusion

The inclusion and exclusion criterion which defines if data is included or rejected also needs to be established. **“To know what is included and excluded from the analysis”**

Example: recently employed staff (less than 6 months) will be excluded from the survey

2.1.10 Sample size

The sample size included in the analysis also needs to be stipulated as well as how to deal with missing data e.g. low response rate of a patient satisfaction survey. [**“To know what the analysis will include”**]

Example: all satisfaction surveys completed by the staff employed within at least the last 6 months

2.2 Content

The quality indicators should ideally be SMART (29) (31) (32). In other words, they should be:

- **Specific:**

The indicator should reflect one dimension at a time and should be directly related/linked to what needs to be measured (the objective). The indicator should be clear enough as to ensure the proper understanding and adherence to its measurement.

The following questions can be useful in order to ensure that the indicator is specific enough:

- “Could the objective be subdivided into several objectives?” (if yes, then the indicator needs to be more specific)
- “Does one measurement criterion allow me to validate the achievement of the objective?”
- “Is the objective defined in manner that all stakeholders can understand?”

- **Measurable:**

Measurements of the indicator should give rise to quantitative data. The results of the indicator should be easy to interpret and allow for the implementation of improvement actions. The threshold value of the indicator must be specified and linked to the measurement made.

- **Acceptable:**

The framework of the indicator should be defined by a multidisciplinary group in order to allow for the implication and the active involvement of staff/personnel in quality management.

- **Realistic:**

The indicator should be adapted to the department’s contextual factors such as, the financial, material and human resources available within the service.

- **Time-limited:**

The indicator should be measured within a pre-defined timeframe and the objective of an indicator must be achieved before a specified date.

“For example: We need to increase the satisfaction rate by 3% as soon as possible is less specific than saying: “We must increase the satisfaction rate by 3% by 01.01.2016.”

It is worthy to note, that the perfect indicator is sometimes difficult to define. It is necessary to combine a number of indicators in order for them to be more representative. The chosen indicators should be deployed so as to obtain valid information and to facilitate the decision making process (29).

3 Practical modalities

3.1 Steps in building a quality indicator

Quality indicators are chosen and instigated as a function of the department’s objectives. They are rarely defined when initializing a quality approach. They are gradually chosen and implemented and regularly reviewed. Ideally, once an objective of an indicator is achieved and stable, the list of monitored indicators should be reviewed, so as to implement new ones or to better cover the existing ones. Each quality indicator should then be validated by a quality task group, which is, ideally composed of a representative from each discipline. Once validated by the quality task group, the indicator should follow the usual approval cycle as the one implemented by the document management procedure of the department (e.g.: checking, approval and dissemination) (29) (31) (33).

Once the objectives and associated indicators are defined, a dashboard can be set up to have an overall view of the performance of the level of radiotherapy department. This tool allows the department to share, adjust and monitor their performance.

4 Templates

4.1 “Identity card of a quality indicator”

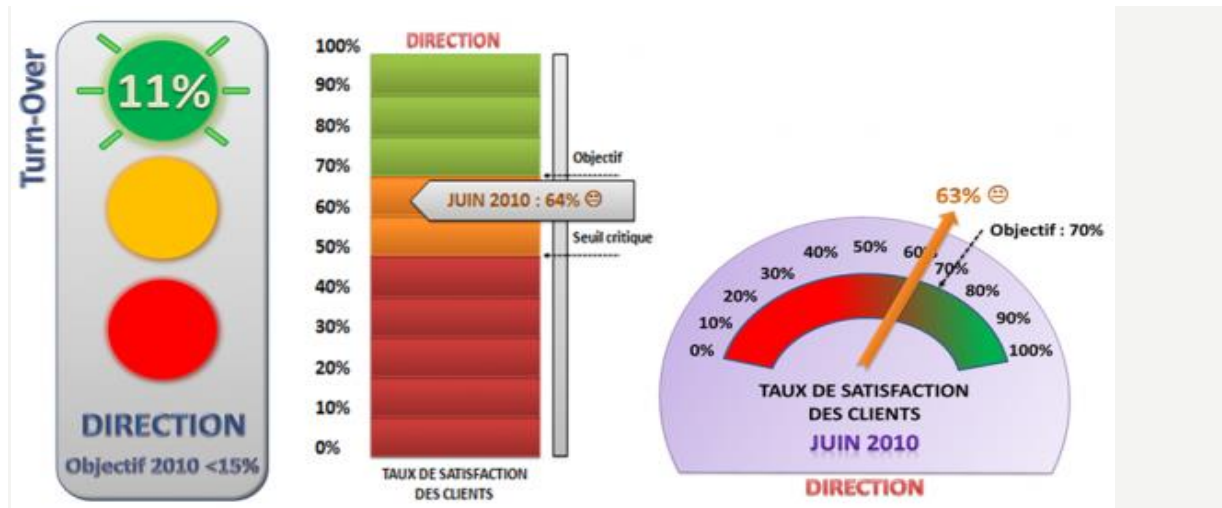
Example of a quality indicator described within its descriptive framework (courtesy of Cliniques de l'Europe, Brussels)

Definition	Compliance rate of the mother tongue of patients
Objective, importance of the topic	The objective is a human approach, adapted to each individual. We want to achieve a compliance rate of the mother tongue at 80%
Type of indicator	Indicator of result/performance
Responsible person	Quality manager
Unit of Measure	Percentage (%)
Periodicity of measurements	Once a year, 1 month before the management review.
Method of data collection	Analysis of the results of the satisfaction survey
Method of calculation	Overall in the surveys, in how many cases, was the patient's language respected: N° of patients for whom the mother tongue is respected / Total patients who responded to the survey and entered the selection criteria.
Method of data retention	Electronic data is stored in the computer system of the institution. Data will be retained for 1 year and destroyed after management review
Criteria of possible inclusion and exclusion	Will be excluded from analysis, patients who have not answered this question in the survey or those whose mother tongue is not precisely defined.
Sample	All surveys completed and recorded within the year prior to management review (minimum 100)

4.2 Dashboard

Example of various dashboards configurations that can be used to quickly visualize the results of quality indicators measurements.

<http://www.qualiblog.fr/objectifs-indicateurs-et-tableaux-de-bord>



Chapter 6: Process management

1 General definitions

Process:

- Set of linked and interactive activities using resources and enabling the transformation of inputs into outputs (6).
- A set of complex tasks and activities to be performed with a common objective intended to meet the needs of a customer (34).

Mapping of the processes (cartography)

- Document presenting in a schematic way the correlation existing between the different standardized processes (20).

Service provider system

- System whose function is to transform an input into output by following the standardized processes and using resources (35).

2 Theoretical framework

2.1 Processes:

In any process, elements of entry (input), exit (output) and associated resources are present (Fig. 1) (35).

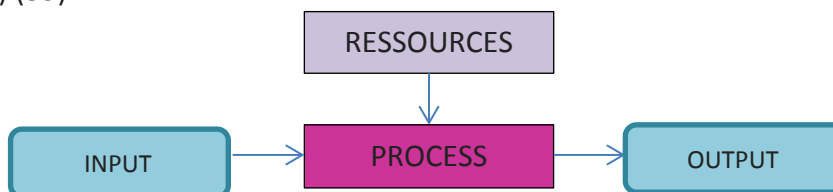


Figure 7- Process layout

- “Input”: in the RT process the input is the patient requiring a treatment of radiotherapy with needs.
- “Output”: Products or services, the result of process. In RT process the output will be a patient having received the treatment with radiotherapy).

- “Resources”: Necessary elements for the good functioning of the process (processing machine, planning,...).
- “Process”: series of actions bringing result.

2.2 Types of processes

The processes can be of various types depending on their purpose (35):

- **Strategic processes** (management) concerns targets defined by the hospital and department **leadership** (framework) based on external or internal expectations;
- **Operational process** which concern an activity and which are directly linked to the patient(ex: completion of the treatment)
- **Support process** which concern activities/functions that support the operational and strategic operations

The various types of process can be linked and assembled in a “macroprocess” representing the whole of the activity of a department. Some examples can be found here below (Fig. 8 and Fig. 9)

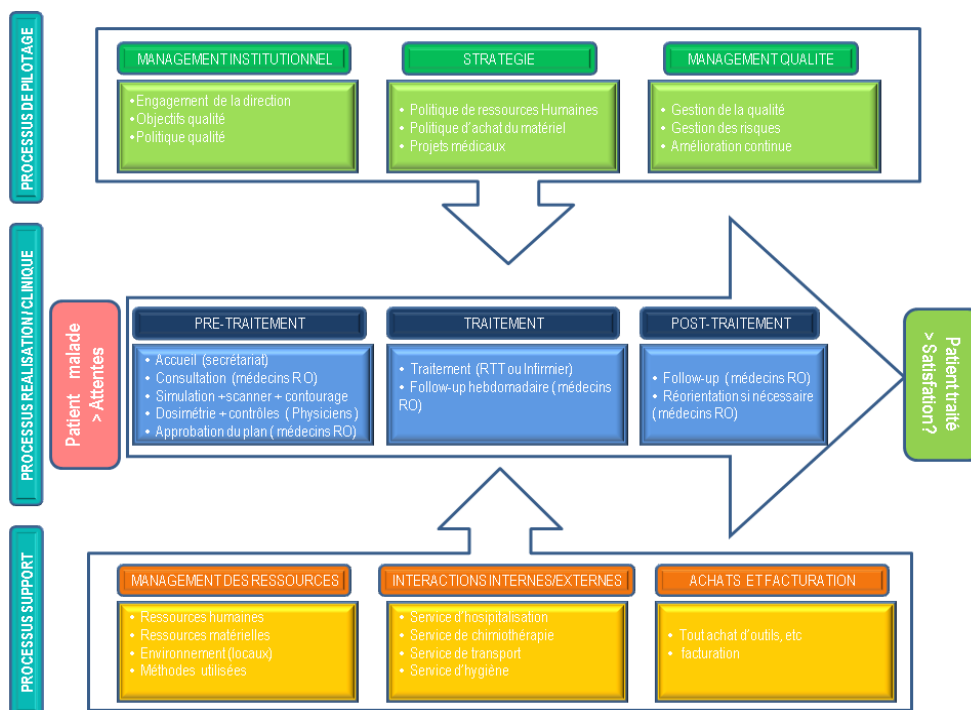


Figure 8 - Example of a macroprocess: (CH EpiCURA - Baudour)

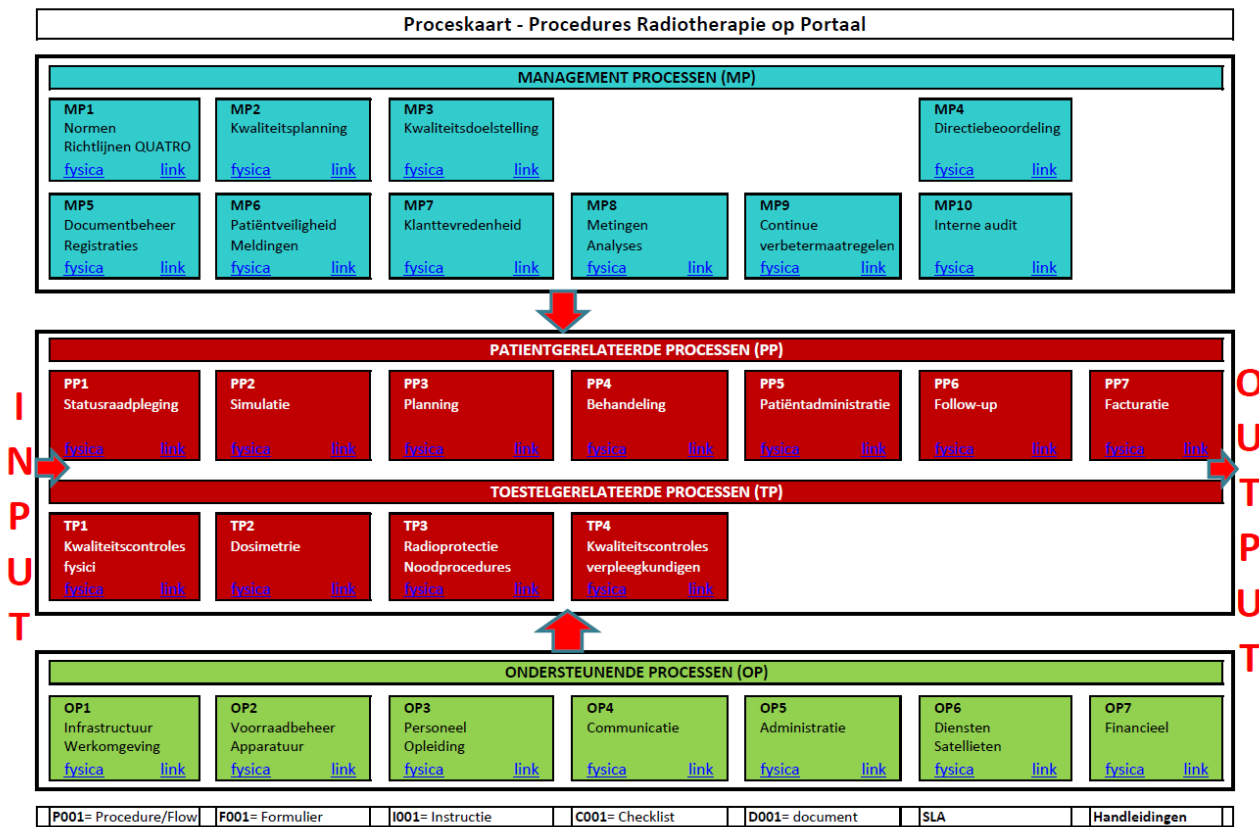


Figure 9 - Example of a Macroprocess (GZA Sint-Augustinus, Wilrijk)

2.3 The constitution of processes

The structure of the process shall be discussed in a working group within the department of radiotherapy. Initially, it is preferable to base the process on the real activity rather than on the desired activity (5). A multidisciplinary working group is necessary in order to clarify the activities and the interactions of the various participants. Special attention shall be paid to the activities with added value for the patient.

2.4 A few Tips (36)

- Correctly define the processes (Input, output) and the required resources;
- Include all the participants involved;
- Describe how the process really works;
- Clearly identify the interfaces/areas of dysfunction;
- Limit the time spent on the description of activities, do not get too bogged down with details
- Adapt the description level to the analysis and the identification of the modes of failure

- Adapt the description level to the analysis and the identification of the modes of failure.

The use of Healthcare Failure Mode and Effect Analysis (HFMEA) TM is recommended to identify and categorize potential risks. And it is advised to implement reliable control or to change process steps with a high risk-level

3 Practical modalities

The steps involved in the constitution of a process are hereby described.

3.1 Description and mapping of the process

- Define the process by describing the activities and their sequence
- Define the participants and their roles within each activity
- Determine the resources used during the implementation of the activities

3.2 Process analysis

When the process is mapped, it can be analysed with the aim of identifying:

- Safety risks e.g. missing double checks
- Inefficiency e.g. down time or time lags
- Ineffectiveness e.g. staff member to not read email reminders to perform certain tasks and to allow the implementation of improvement actions. Certain elements can be used to allow for this analysis, such as the timing of the different stages of the process, the fluidity of the process (down times or lag times), the effectiveness and the efficiency.

3.3 Process improvement

The improvement of a process is a project that needs to be managed according to an action plan, which will define the stages of its implementation, the deadlines and the designated staff responsible for the different stages.

Activity reports can provide data for the measurement of indicators, which have been defined during the improvement process.

3.4 Process improvement evaluation

As mentioned, it is important to evaluate a process after its improvement. This evaluation can be based on various sources of data sources such as the pre-set indicators, the assessment of activity and the number of claims, dysfunctions and nonconformities.

During this process improvement evaluation, it will be better to use the PDCA method, to notify what is Plan (P), who it is done (DO) in practice, how it is evaluated (Check) and what is done to improve the system (Act)

4 Templates

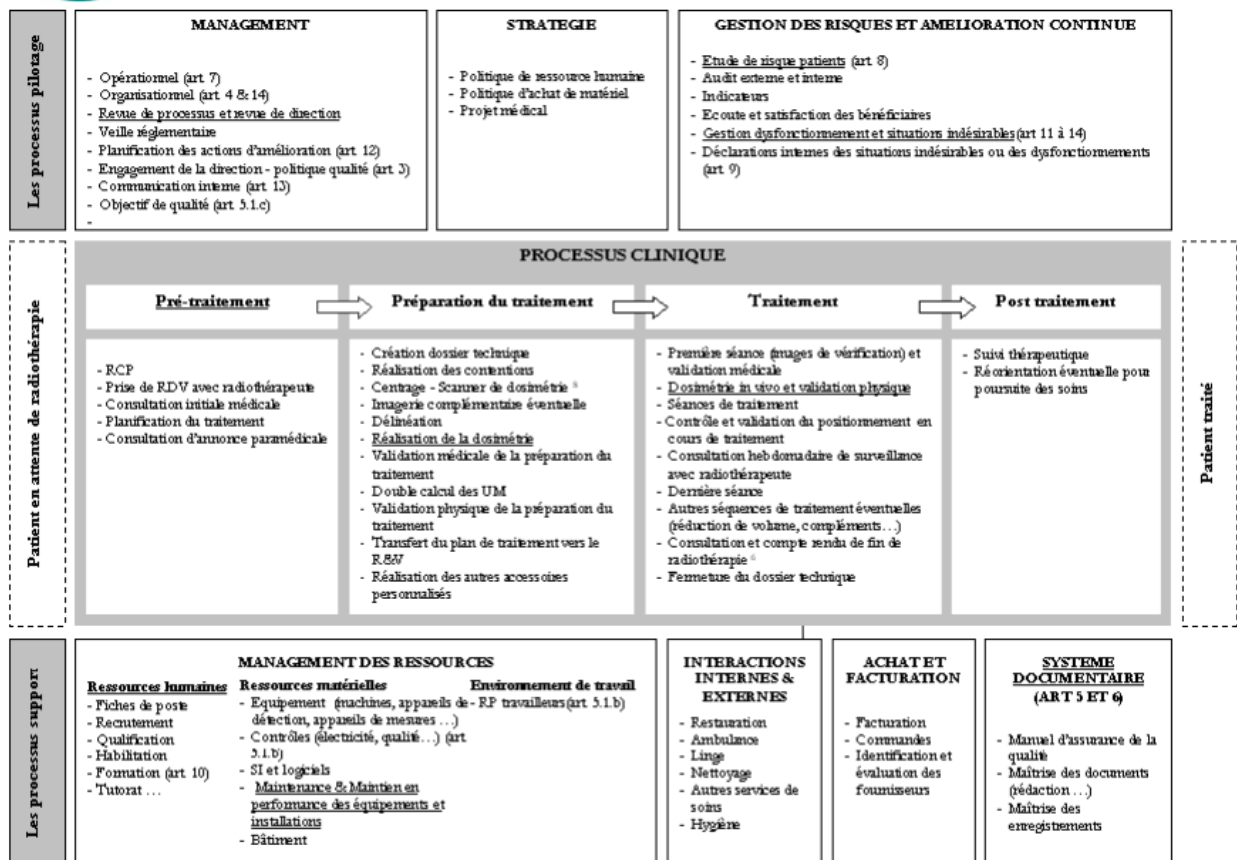
4.1 Macro process

Process mapping of the radiotherapy process as proposed by the ASN (4)



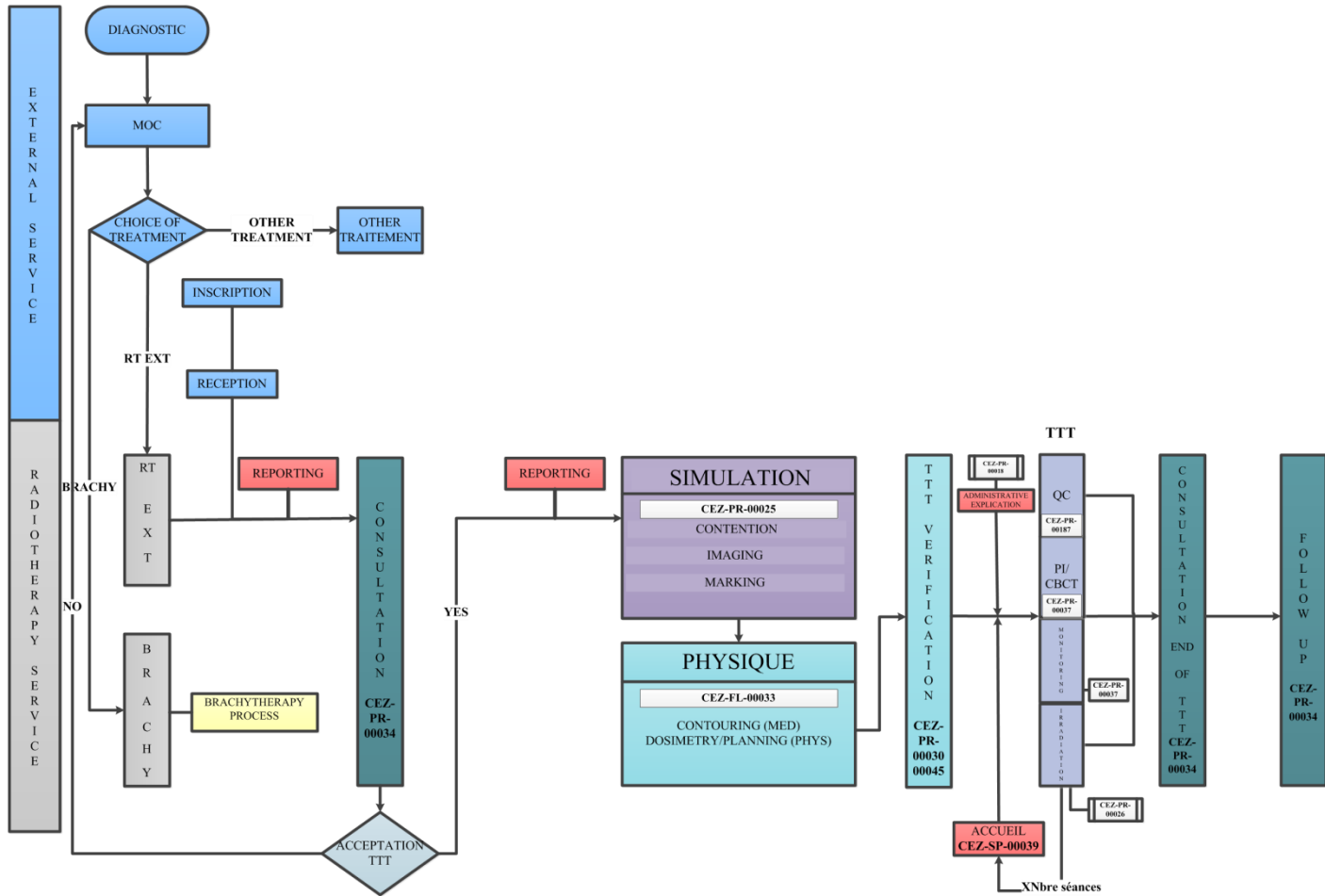
B - Proposition de cartographie des processus

B.2 - Cartographie



4.2 External radiotherapy process

Figure depicting the process mapping of an external radiotherapy process (courtesy of Clinique de l'Europe, Brussels)



Chapter 7: Organisational charts

1 General definitions

An organisational chart is an easily readable schematic representation of the organisation of a hospital or a department. Such a chart makes it possible to quickly identify the responsibilities and the hierarchical and functional links between the various participants (4) (6) (37).

An organisational chart makes it possible to visualize the relationships between the various contributors to e.g. the quality management system (38) (4).

The goals of organisational charts are to:

- Graphically represent the position of the various departments of the hospital and their interactions;
- Distinguish the hierarchical links (direct or indirect authority on individuals) from the functional links (guarantor of the systemic operation of the organisation).

1.1 Organizational chart of the radiotherapy department

As mentioned in the introduction, the establishment of a quality management system in radiotherapy departments was facilitated through the Federal Public Service's Action 16 Cancer plan which allowed for the funding of a QM. However, establishing a QMS in a department requires a collective effort of all its staff members. It is thus necessary to define the hierarchical and functional links at the departmental level and how they are connected to organisational structures. In other words, it is important to have a clearly defined organizational chart of the department and to integrate it within the organisational chart of the hospital (16) (6) (7). Creating structures which permit effective and efficient formal or informal interaction between various team members is recommended.

Depending on the size of the organisation, the QM can be supported by a number of staff members. For example, a "RT quality task group or quality committee" with radiation oncologists, medical physicists, radiation therapists or a member of another professional group. The establishment of a quality-oriented approach does not solely concern the QM or the quality task group: it is a multidisciplinary approach and should be every team member's responsibility. However, it is recommended that the QM be in an independent position from the radiotherapy team.

The ultimate responsibility for performance of the radiotherapy quality management system and monitoring of all quality management elements should be, in accordance with legal regulations and hospital policies, clearly defined within the department e.g. in the quality handbook or job descriptions. The organizational chart should reflect tasks and responsibilities of the various team members as defined in job description.

1.2 Organisational chart of the hospital or institution

The organisational chart should visualize how other hospital departments and functions are linked to the radiotherapy department. Ideally, the radiotherapy QMS should be an integral part of the hospital QMS. For example, a hierarchical or functional link may exist between the hospital quality management department and the radiotherapy quality manager. However, integration is sometimes not or only partially achievable. In this case, a brief description or explanation of the existing structures and processes is recommended in addition to the organisational charts (see Templates).

2 Theoretical framework

2.1 Format

An organizational chart must be clear, quickly comprehensible and ideally summarised on only one page. Various shapes and forms are possible depending on the context and software features (Visio, Word,...). The organisational chart should allow a basic understanding of the various functions and how they are connected. Adding a copy to the quality manual is recommended.

2.2 Content

The content and layout of the organisational chart may be defined by the organisation. It can, for example, include the name, function and photograph of each team member. Helpful questions when creating an organizational chart may be:

- What is the purpose of the organizational chart?
- What is the scope of activity that needs to be included in the chart? Even external partners, for example departments of other hospitals where radiation therapist regularly see patients, may be added to reflect the full scope of activity.
- How does the hospital or the RT department function?
- What are the hierarchical and the functional links between team members and/or departments?
- How should the organizational chart be created e.g. tools used, available software?
- What format should the chart have?

3 Practical modalities

In order to establish an organisational chart, it is important to ensure that:

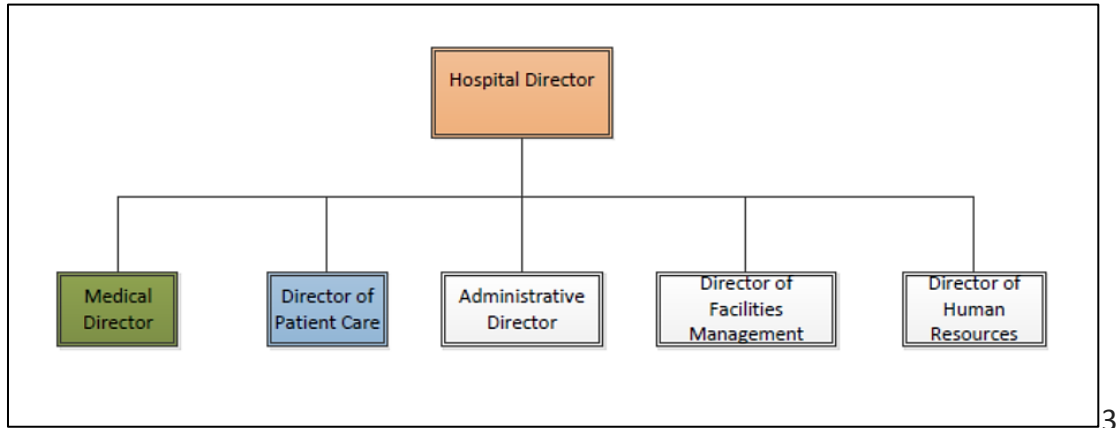
- each person is aware of the actual organisation of the institution or various (quality) departments and their interactions;
- the responsibilities and authorities of each person appearing in the organizational chart are identified and described e.g. in job descriptions;
- it refers to the most recent list of staff, temporary or fixed term staff - external departments or institutions may be included if needed;
- the chart is established on a nominative basis; one should avoid mentioning certain people by their position whereas others are mentioned by their names;
- photographs are only added with permission of the team member; a picture allows for new employees to easily and quickly identify the names and the functions of their colleagues.

4 Templates

4.1 Example of an organisational chart at the hospital level

Hypothetical example of a typical organisational chart that depicts the higher management level of a hospital.

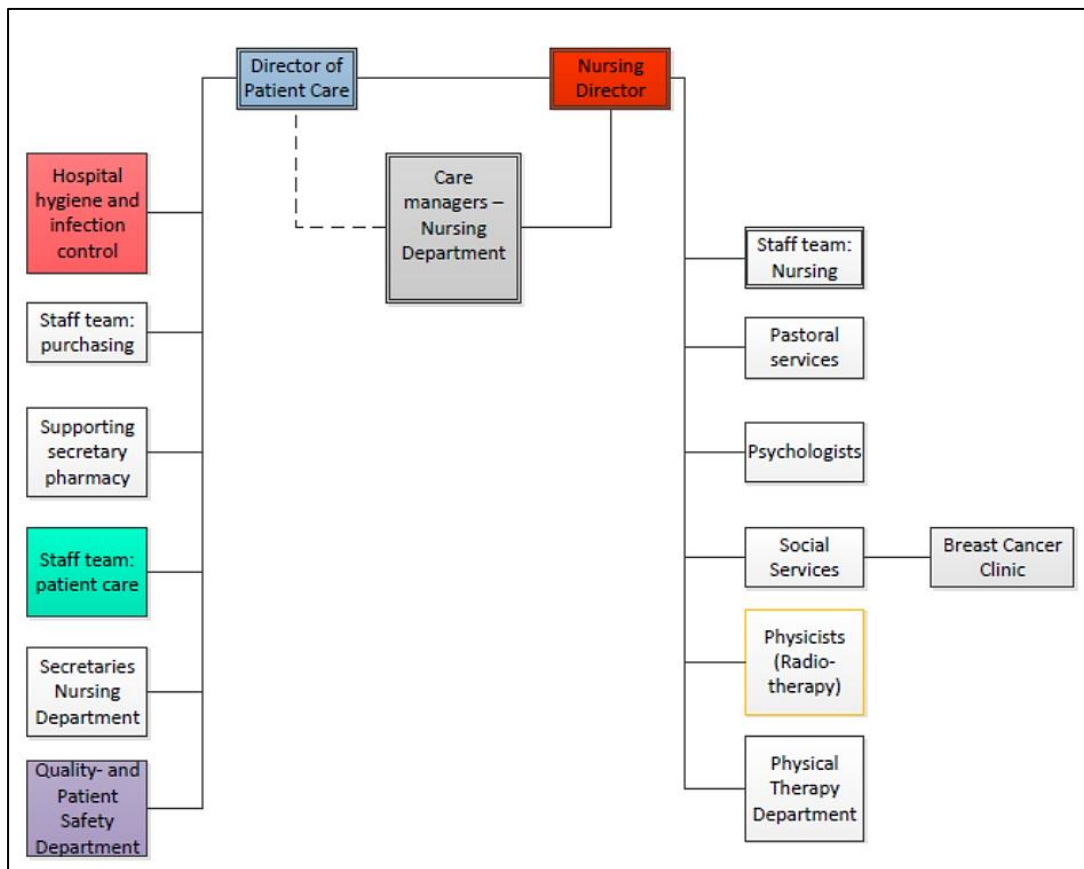
Management of Hospital XY



4.2 Examples of an organisational chart at a departmental level

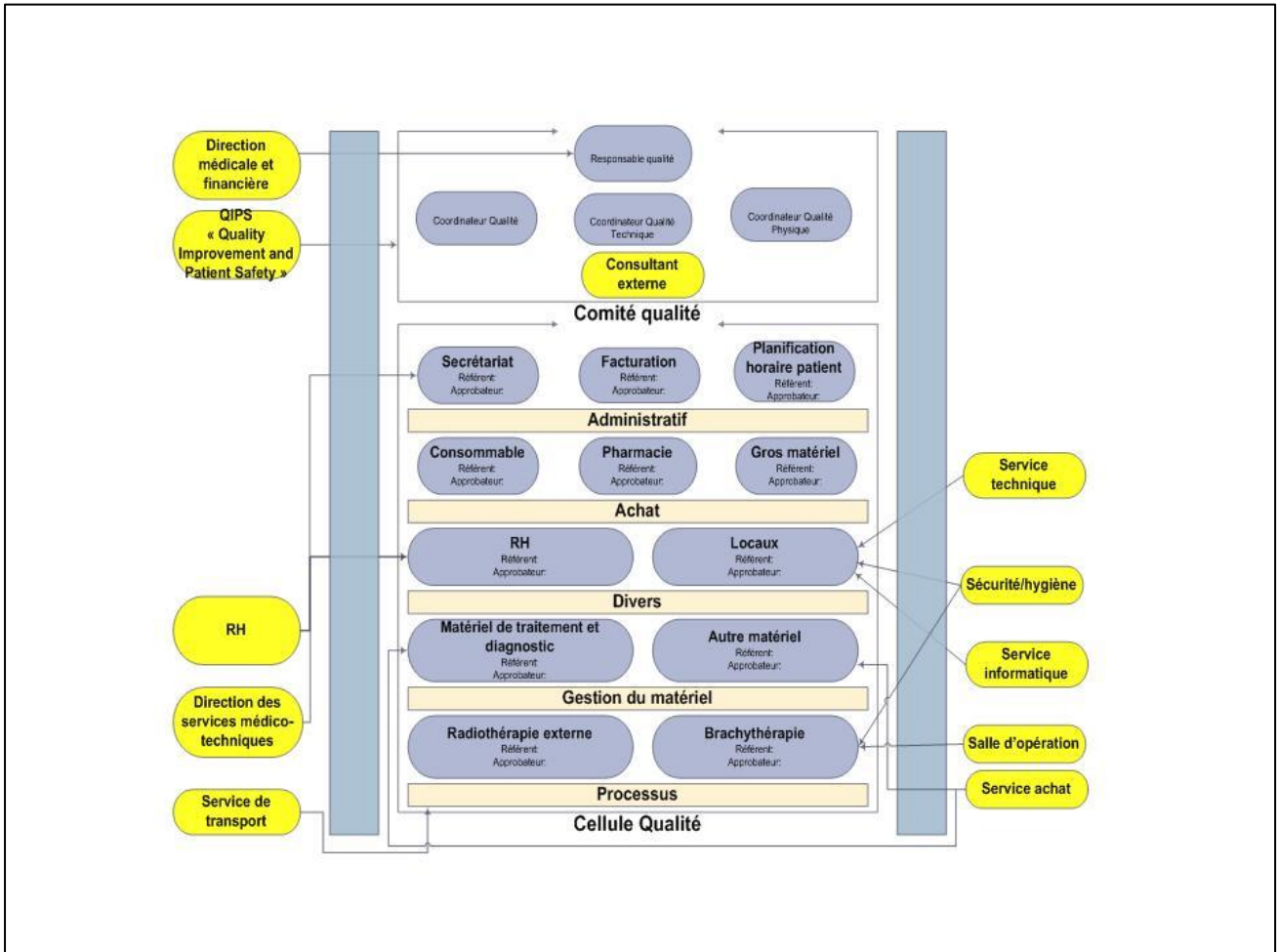
Organizational chart at the nursing department and patient care level with a visualisation of the different staff member found under the director of patient care's and nursing director's management. The functional links are depicted by dashed lines while the hierarchical links are depicted by full lines.

Patient Care and Nursing Department of Hospital XY



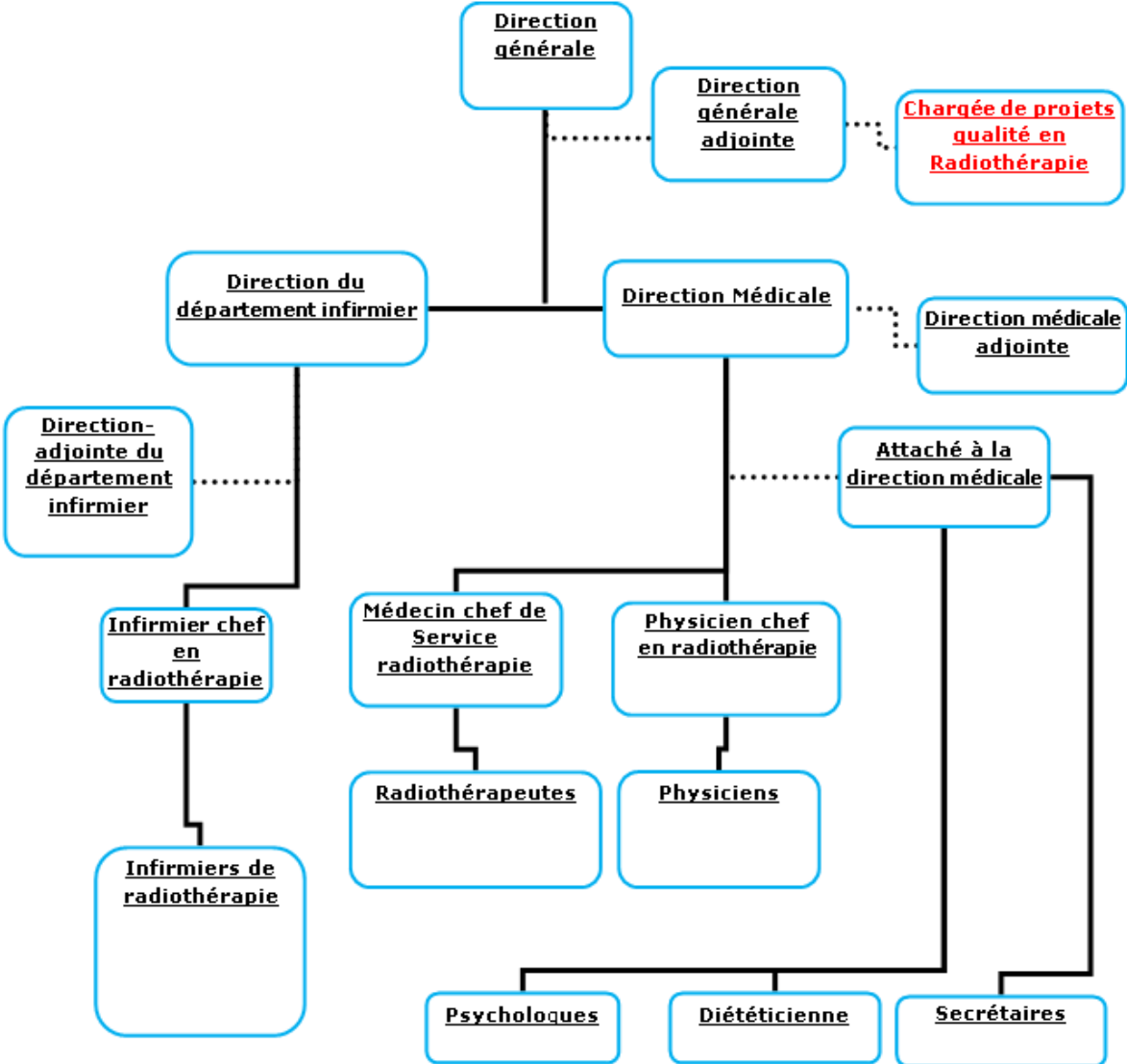
4.3 Examples of an organisational chart at a departmental level (2)

Organizational chart at a departmental level depicting the quality cell/department and this from the higher management level down to the departmental level.



4.4 Examples of organisational chart at the radiotherapy level

Example of an organizational chart comprising the higher management level and the radiotherapy department (courtesy of EpiCURA, Mons)



Chapter 8: Tasks and responsibilities

1 General definitions

1.1 Responsibility

Responsibility is « the state or fact of being responsible, answerable, or accountable for something within one's power, control, or management. » (39)

1.2 Task

A task is “a definite piece of work assigned to, falling to, or expected of a person; duty. » (39)

1.3 Definition of the job description:

A job description stipulates – in a written form - what is expected of an employee. It helps in preventing work overload (or underload), and conflicts in tasks and responsibilities. Its aim is not to describe the activities in detail but to indicate the main characteristics and essential elements that determine the occupation. It generally includes the job's purpose, duties, responsibilities, scope, and working conditions along with the job's title, and the name or designation of the person to whom the employee reports (40).

2 Theoretical and legislative framework

*It is important to mention that this chapter **does not try** to define what the roles and responsibilities of each RT task group is and should be. Its function to give a brief overview of the different professional bodies found within a RT department and to underline the importance of clearly defining roles, job descriptions and responsibilities within a quality management system*

2.1 Job description

It is important that each person employed in the institution has a clear, precise and mostly evolutionary job description. The aim is to be able to position oneself in the department and the institution, to know the work that needs to be carried out but also to be able to evolve in the profession. The department must have the flexibility to adapt each job description according to its size, needs, techniques in place, etc. Job description should not be applied too strictly and must be regularly updated.

Prior to taking up their duties, each employee must be familiar with his/her job description and know his/her job and role in the department.

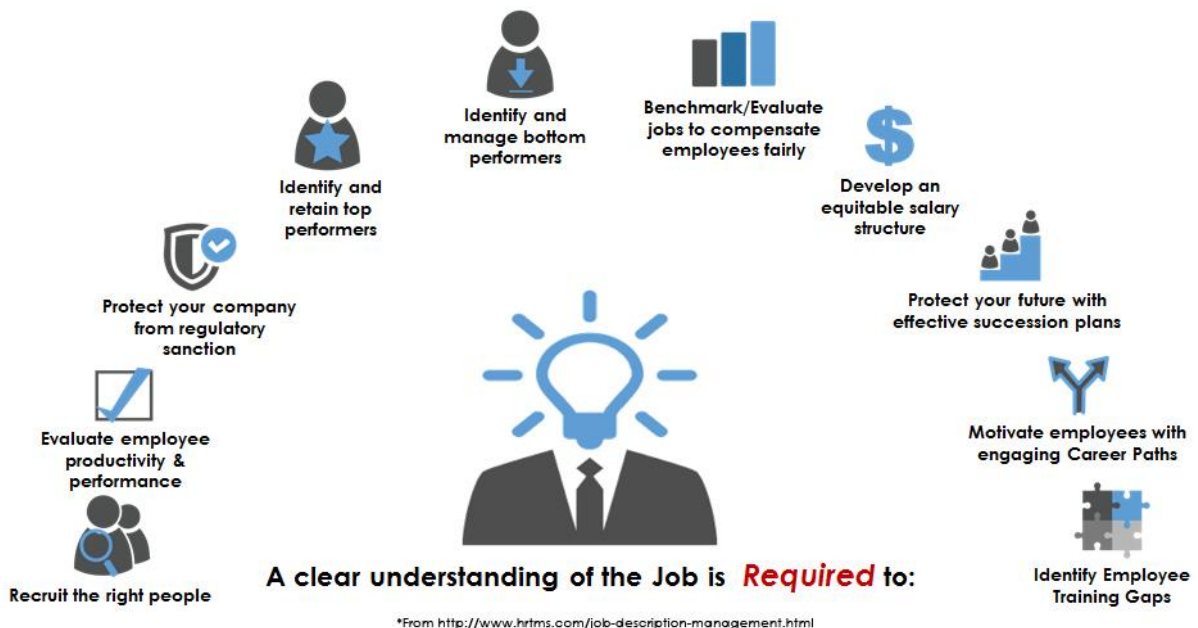
Job descriptions can help identify potential additional skills needed.

This will allow the /management to evaluate and identify (41):

- the level of its staff to carry out its tasks
- the gaps between what is done and what is required:
- the skills that are needed
- the need for training, and plan the training needed to meet the need.

The benefits of clear job description are as follows:

- it will serve as a basis for recruitment and job interviews - it allows for the (future) employee to obtain a clear idea of his / her activities and the expectations of management
- It can be used in staff assessments and adapt their training by assessing the difference between current and required skills.
- It will clarify the Tasks undertaken by the employees
- It represents a communication tool



2.2 Professional bodies found within a RT department

This subchapter aims at helping professionals arising from outside the RT department in gaining a better understanding of the different professional bodies/groups found within a RT department.

2.2.1 Radiation oncologist (RO)

The radiation oncologist (RO) is in possession of a legal degree of doctor in medicine and the specialized title as a physician specialist in radiation oncology. All senior doctors must be accredited by the Federal Agency for Nuclear Control (FANC) (42).

The RO's main responsibilities are in:

- Defining the indication for irradiating and this within the complete care plan;
- Prescribing the full dose by tumour volume;
- Defining acceptable dose limits for organs at risk located close to the tumour;
- Determining the treatment technique to be used,
- Validating the treatment plan in collaboration with the MPEs.
- Monitoring patient during and after treatment:
 - He/she consults with the patient on a regular basis and monitors the effectiveness of treatment and the patient's tolerance to radiation,
 - After completion of the treatment, the patient need to be regularly monitored by the RO or a member of multidisciplinary oncology team and/or the patient attending physician (who needs to be informed about patient's radiation modalities

The radiation oncologist is also actively involved in QMS. He/she defines, along with colleagues, the guidelines that are applicable for each type of treatment and pathology. He/she participates in the working groups to formalize the processes and associated procedures for each type of treatment. He/she complies with validated procedures, reports adverse error- events and must be involved in the analysis of events and proposes corrective and preventive actions.

2.2.1.1 Head of the department (RO)

According to Article 18, 2° of the coordinated law on hospitals and other care institutions of July 10th, 2008, a head physician needs to be appointed for each department of the medical department. It should be understood by "department" (43):

A –accredited hospital services in a specific index,

B -medico-technical services,

C –heavy medical-technical services,

D- services designated as such in the medical procedure.

The minimum tasks for the head of department encompass the organization and coordination of medical activity in the department.

In addition to his/her clinical activities, the head RO of the radiotherapy department task's also include r (44):

- Operation and management of the department : management of medical staff and other professionals, in collaboration with the managers of the other teams;
- Organization and coordination of the activities of the department;
- Promotion of quality of care, monitoring and the application of good professional practices;
- Promotion of collaboration between the different teams,
- Communication with other stakeholders (internally and externally to the department)
- Development of technologies, equipment and innovative techniques.

The head RO is also responsible for the QMS. He/she provides the necessary financial and human resources and may appoint a quality manager responsible for the operation of the QMS in the department. He/she ensures that the legal, regulatory and patient requirements are met. He is responsible, supported by the QM, in the implementation and communication of:

- A quality policy
- Strategic quality objectives;
- Management or quality committee reviews.

The head of department complies with the validated procedures. He/she reports incident/accidents to the Federal Agency for Nuclear Control (FANC) as defined by the FANC directive concerning the procedures and reporting criteria of significant events in the field of radiation protection in radiotherapy (42).

2.2.2 The Medical Physicist Expert (MPE)

The MPE is a professional specialized in the area of physics that is associated with medical practice. The medical physicist must be recognized by the Agency (FANC) in accordance with article 51.7.3 and 51.7.4 (45). He/she is specialized in one or more of the following fields: radiation therapy, in vivo nuclear medicine and/or radiology.

The tasks that are under the responsibility of the medical physics radiation expert include (42) (45) (46):

- Realization of acceptance tests / Commissioning of devices prior to clinical use

- Periodic verification of equipment (QC) to verify for compliance of the devices to acceptance criteria(= compliance testing)
- Intervention (QC) following a breakdown or malfunction,
- Involvement in the drafting of “specification books” for the purchase of new equipment;
- Assist the RO in the use of equipment, devices and accessories;
- Calibration of instruments and measuring devices for dosimetry and activity measurements,
- In collaboration with the RO, optimization of the dose to patients;
- Implementation of quality assurance programs defining QC needing to be carried out;
- Implication in issues related to radiation protection during medical exposure;
- Notification of adverse error events.

In a radiotherapy department, ideally, the MP team should be supervised and managed by a head medical physicist. The medical physicist performs tasks related to quality assurance and defined quality controls to ensure the compliance of the delivered treatment plans and operation of radiotherapy equipment. He may work with the QM to formalize the quality assurance process, breakdown management and preventive maintenance. He/she complies with validated procedures, reports adverse error events, and can be involved in the analysis of events and proposes corrective and preventive actions.

2.2.3 The Medical Physicist Assistant (MPAS)/dosimetrist (10)

In most Belgian radiotherapy centres, physicists are assisted by dosimetrists who perform treatment planning and quality controls including the task of in-vivo dosimetry. Their activities are performed under the supervision of medical physicists. Currently, the work function of dosimetrists is not recognized in Belgium because of the lack of legislation. Discussions are underway within the Radiotherapy College and the FANC to clarify the situation.

The dosimetrist is actively involved in QMS, which include tasks related to quality assurance, quality control and management of equipment. He/she complies with validated procedures, reports adverse error events, and can be involved in the analysis of events and proposes corrective and preventive actions.

2.2.4 The « Radiation Therapist » (RTT)

Under current Belgian law (Art.53 of the Royal Decree of July 20, 2001RGPRI), radiation oncologists doctors are the only ones able to handle radioactive sources and radiation therapy equipment for therapy. They may delegate, under their responsibility, supervision and instructions, the handling of radiation therapy equipment to “radiotherapy auxiliaries” who possess radioprotection certificate (42).

Presently, in Belgium, a majority of ‘radiotherapy auxiliaries’ working at the treatment/simulation units in radiotherapy departments are nurses as stipulated in the Royal Decree of April 5, 1991, which sets the standards that a radiotherapy service must meet to be accredited as medico-technical service (Article 44 of the Law on hospitals, coordinated August 7, 1987) (43) (47) (48). However a study carried out by the VVRO (Vereniging voor Verpleegkundigen Radiotherapie en Oncologie) and the College of Radiotherapy -who studies the profile and training of Belgian "radiotherapy auxiliaries" - , as well as the QUATRO audits demonstrate that other professional profiles are currently now part of this team - such as medical imaging technologists, physiotherapists, midwives and technologists from European radiotherapy departments. Since the profile of radiotherapy auxiliaries varies and to be in accordance with the ESTRO RTT recommendations, in this document, the European term “RTT” (Radiation Therapist) will be used to define the radiotherapy auxiliaries found at the simulation and treatment units in a radiotherapy department (49).

As mentioned previously, the profile of RTTs working in Belgian radiotherapy department varies but is mainly made up of the nursing profession as stipulated by the law; the nursing profession being accessible to professionals having either a bachelor or certificate in nursing (6) (12) (4) (14) (15) (44) (42) (50). However, in the past few years, medical imagery technologists (as well as trained RTTs from other European countries) have integrated the RT teams. This paragraph will thus focus on the two mentioned professional groups keeping in mind that the list of acts of the medical technologists is currently in the process of being changed and will include radiotherapy specific acts – as it is the case for the nursing profession. Furthermore, the educational content to work in radiotherapy are currently undergoing important changes and will most likely have an influence the prerequisites needed for RTT staff to be able to work in radiotherapy departments.

During radiation therapy, the RTT is an intermediary between patients and radiation oncologists. While ensuring good clinical and psychological patient monitoring, RTTs are primarily the professional group responsible for optimal patient treatment preparation (through simulation) and administration of the RT treatment as prescribed by the radiation oncologist. As mentioned by the ICRP (International Commission on Radiological Protection) and the ESTRO RTT Core Curriculum , “Radiation therapy technologists have the

responsibility for the set-up and delivery of treatment, are involved in the simulation of the treatment, and have, therefore, an essential function in noticing any abnormal reaction of the patient or malfunction of the machine and to report them” (49) (51).

In a radiotherapy department, ideally, the RTT team should be supervised and managed by a head RTT.

As mentioned in the previous paragraph, RTTs have the direct responsibility for the administration of radiotherapy to patients. They are therefore very often the last security barrier, which will make the difference between the detection of a near incident and the occurrence of an adverse error-event. They thus play an important role in the reporting of adverse error event and near incidents and play an important role in the prevention of incidents.

As well as the other professional groups, the RTT also has the duty of complying with validated procedures and has the responsibility of ensuring that those procedures are up to date.

2.2.5 Quality Manager

In this document, the term quality manager (QM) will be used for the professional who manages the quality and risk management systems in the radiotherapy department. Other terms can also be used such as quality coordinator or “qualiticien”. The QM function in Belgian radiotherapy departments was created to respond to action 16 of the 2008-2012 cancer plan. This plan provides funding for the gradual introduction of quality management systems in all radiotherapy departments (52).

2.2.5.1 Roles and responsibilities

The QM mainly has the role and responsibility of managing/coordinating the QMS including risk management system. The QM can undertake various tasks and roles however this will depend on the department and hospital’s structure. However it is recommended that the radiotherapy QM ought to be in an independent position within the department organizational chart but in the presence of leadership support ([for examples of organizational charts](#)).

i. Role in the department

- Advises the head of department and RT team with regard to the quality and safety of services and care provided to patients based on general standards (ISO 9001, NIAZ/Qmentum, ...) and standards specific to the RT (QUATRO, IAEA guidelines, ...):
- Supports the head of department and RT team with the implementation and maintenance of a QMS for continuous improvement

- Proposes a departmental risk management system (proactive, prospective and retrospective) in accordance with the institutional risk management system. This includes:
 - With the support of the head of department and RT team, implementing and maintaining an adverse error event voluntary incident reporting and management system in accordance with institution guidelines and the PRISMA-RT network.
 - Identifying and analysing near incidents and adverse error events and proposing corrective or preventive actions
- Proposes and monitors quality indicators specific to the RT process:
 - Supports the head of department and RT team with the implementation of tools for the analysis and monitoring of indicators in order to develop a preventive and proactive approach to quality and safety management;
 - Proposes improvement and corrective actions
 - Develops, analyses and monitors patient and staff satisfaction
- Develops and monitors a document management system in accordance with the institutional document management system.
- Collaborates with various professional groups (RO, MP, RTT, secretaries, ...) of the department and support the department head(s) with the optimization of the radiotherapy process
- Supports the department head(s) with the preparation of audit, accreditation and certification processes in the department;
- Proposes necessary actions to allow for the department's compliance with external and internal quality and safety standards;
- Provides training in the field of quality (information, awareness) in collaboration with the department head(s) and the institution.

ii. Role in hospital

- Provides an intermediary role between the radiotherapy department and the institution by a functional relationship with the institution's patient safety and quality department

- Participates in the institution's accreditation process;
- Participates in internal audits of the institution at different departments

iii. Role outside the institution (other activities)

- Collaborates with the Federal Agency for Nuclear Control(FANC) and responds to requests,
- Collaborates with the Federal Public Service of Public Health (FPS PH)
- Work with the College of Radiotherapy, ESTRO and KCE: participation in various studies and surveys,
- Work with service providers and equipment companies,
- Collaborates and coordinate with other hospitals:
- Works with QM networks (QMRT.be, Mouvement Wallon pour la Qualité, PAQS (Plateforme pour l'Amélioration Continue de la Qualité des soins et de la Sécurité des patients), ...)
- Participate in scientific events related to quality: ESTRO, BHPA, FPS PH, MWQ, federal and regional roundtables.

2.2.6 Other professional groups

Other professional bodies can also be found within a RT department. These include engineers, technicians, dieticians, psychologists, nurses aids etc.... It is important that the department clearly defines their roles with the RT structures while also defining their responsibilities and this specifically the professional is solely hired to profess within the RT department (ex: engineers and technicians involves in the primary intention following equipment breakdown).

3 Practical modalities

To clarify responsibilities and attribution of tasks in the radiotherapy process, it is important:

- To take into account the different legislative texts (amendments royal decrees, ministerial circulars, directives and regulations) that describe the responsibilities and activities of the different professional groups;
- To map out the activities and processes in order to identify the interactions between the activities;
- To define every step of the process, the actors involved and their interaction with other staff members,
- To establish the roles and tasks that each staff member (actor) has to perform in a well-defined step and to include this in formalized Job description;
- To produce a matrix of skills, responsibilities and competencies.

Practical steps to follow when establishing a job description

A profile of duties will be established at the time of a new position opening in order to expose to future candidates to the exact profile sought and the conditions of engagement.

It is also possible that a job description must be written when the function is already in place in the institution (for example, to program evaluations).

Ideally, the drafting and implementation of the job descriptions are carried out in collaboration with the Human Resources Department, the head of department concerned and the implicated employees if it already exists.

The first step is to gather the pre-existing information concerning the job (procedures, legislative measures,).

To do this, several techniques can be used:

- Brainstorming meetings between the various actors (human resources, head of the department, employees ...).
- Service/department visits
- Interviews with the staff of the concerned department.

The second step is to make a draft of the job description itself. Ideally, this should contain the following information:

- The title of the function

- The department to which the function is attached
- Working hours
- The duration of the contract
- Main and secondary tasks
- Its position in the organizational chart
- Its hierarchical and functional links
- The texts of laws
- The educational and experience level required
- The main responsibilities

Subsequently, the first draft can be reviewed by an employee with the same function or other implicated members in the department. The draft will then be adapted before it's validated.

It will then be disseminated within the department and to the implicated personnel.

4 Templates

4.1 Job description

Job descriptions are often formalized at an institutional level and should therefore coincide within the institution's framework. However, some templates can be found on various websites.

A typical template can be found here below (53).

<u>Job description template</u>	
Position title:	_____
Date prepared:	_____
Position level:	_____
Job purpose/mandate	
<i>Description of the general purpose of the role within the organization and/or department</i>	
Specific duties and responsibilities	
<i>Listing of the key responsibilities and duties of the job</i>	
Knowledge and skills	
a. <i>Required educational level and skills</i>	
b. <i>Required specific skills</i>	
<i>(Examples: problem solving, communication, leadership, innovations...)</i>	
Working conditions	
<i>(Salary)</i>	

4.2 Competencies matrix (see Chapter 9: Resource Management)

Chapter 9: Resource Management

1 General definitions

A resource is a source or supply from which benefit is produced. These can be materials, services, staff, energy or other assets that can produce any benefit in a process. They can result in proper functioning of a system and increasing wealth or well being. Several types of resources exist in a radiotherapy department (4) (5):

- Human resources
- Material resources
- Financial resources
- Organisational resources

In this chapter, we will mainly discuss the first 2 types of resources – in other words, the human and material resources

1.1 Human resources

Human resources include all employees of all statuses (manual worker, employee, manager,...) belonging to the organisation (4) (41).

Human resource management: is the set of practices implemented to manage, mobilise and develop human resources involved in the activity of an organisation.

Training: is the learning process that allows an individual to acquire knowledge and expertise, meaning the skills and experience necessary for the exercise of a trade or professional activity.

Continuous education (Continuous Professional Development): is the area of training for employees who have entered the workforce after completing their studies (education). This type of training allows professionally "active" individuals to be trained on a continuous basis so as to improve their skills and to be able to adapt to new technologies, practices and methods applied in businesses/hospitals. It also gives staff the opportunity to make a career change or progression.

Qualification: is assigning a level to a professional skill.

The concept of **competence** is related to the ability to mobilise and combine a number of resources to perform an activity in a certain situation.

1.2 Material resources and infrastructure

Equipment is a set of objects, machinery or instruments used for the proper functioning of a service.

The radiotherapy department is dotted with numerous equipment – a number of whom are dedicated to simulation and patient treatment. But equipment also includes - amongst others- computer hardware and software systems allowing for treatment planning calculations and visualisation, nursing and medical record keeping, as well as equipment necessary for machine and treatment QC (4) (5).

It is also important to mention the need for equipment necessary for patient care such as those necessary for radiation-induced secondary effects management.

Infrastructure is set of amenities (premises,...) and equipment (machinery, computer,...) necessary for a community to engage in an activity.

Ideally, the RT department should have a clear description of its infrastructure.

Maintenance / Support is a set of operations necessary to maintain or restore a piece of equipment and/or device to a given state or to its specific operational capabilities. These should also be implemented in a RT department so as to guarantee optimal functioning and workflow.

2 Theoretical framework

2.1 Human resources

Once a staff member is recruited, he/she must be trained by the department. The level of training will depend on the initial training level of the new staff member and the technical and organisational specificities of the department. The heads of staff will ensure proper training by developing tools to monitor and evaluate the progress of the new staff. A reference person may also be designated to transmit his expertise, knowledge and experience through training the new staff member.

The records concerning training of the new staff can be presented in various forms. It can, for example, be presented in a table format defining the objectives, the deadlines and the responsible staff overseeing the training. This type of format allows for the continuous monitoring of the learning objectives, as well as providing a framework for defining the logical steps that need to be followed.

Example of an objective: to be able to install a patient in the treatment position before position verification imaging or isocentric shifts.

When a new staff member arrives in a radiotherapy department, he must have the required training in radiation protection. Regular training is organised by colleges and universities. The check will be conducted by the competent authorities.

"Active" staff in the radiotherapy services should also receive continuous training to maintain their level of skill. Institutions often offer in-house training. This training is either given by a specialized employee from the institution or by a guest lecturer/speaker. Externally organised courses are also accessible to staff in health care institutions – this specifically for more specialised fields or specific hardware.

It is also important to take into account students who are undergoing their practicums in the radiotherapy department. Students often need to fulfil a minimum number of practical training hours in order to obtain their degree or professional qualification. Their scopes of practice or learning objectives are often stipulated in training logbooks. The duration of their internship will depend on the educational program. For example, medical physicist trainees need to successfully complete one year of practical training prior to be officially recognized as MP.

2.2 Material resources

The list of the minimal equipment that a radiotherapy department must have in order to be approved as a “heavy medical and technical department” is stipulated in the Royal Decree of April 5, 1991 (54).

Machine and equipment maintenance are regularly performed and require the presence of technicians. These will occupy the machine for a period ranging from a few hours to several days.

The equipment/machine failures that cannot be resolved by physicists or service maintenance technicians must be managed by the corresponding firm. A maintenance contract is signed between the institution and the firm in order to ensure rapid interventions (so they have limited impact on the patients). The breakdowns should be recorded in a logbook to assist stakeholders in their repairs and to perform statistics on the total time lost due to breakdowns, etc ... (see Chapter 12: Management of breakdowns)

3 Practical modalities

3.1 Human resources

The RT department can have a list of all staff and skills.

The department must ensure that the staff has all the required skills necessary to perform their activities. This is ensured by recruiting staff based on their qualifications and acquired skills (experience). The training plan of the staff members should ideally be based on these experiences and will ensure that they are regularly updated.

Training can be either internal (knowledge, skills, life skills,... - acquired by the employees) or external (work tools, work team, network ... - used by the worker). Thus, a training plan

needs to help staff to remain continuously aware of the practices (4).

To manage staff training, it can be useful to follow these steps:

- a. Identify what skills need to be acquired;
- b. Review staff responses concerning "training" ;
- c. Discuss the training needs ;
- d. Organise the training in terms of priorities, objectives and actions;
- e. Map out the training plan
- f. Evaluate the training plan

An example can be visualized in [Templates](#).

3.2 Management of material resources

In a general sense, it may be important to make a list of materials, equipment, machinery, tools (computer, dosimetry ...) available in the organisation. Ideally, all equipment must be identified and referenced and this specifically to ensure its connection with the maintenance plan.

Other points that need to be taken into account:

- A maintenance plan (and contracts) should be available and in possession of the staff in charge of the machines. There should be an annual overview, prepared together with the manufacturer firm, which defines the frequency of maintenance and to eventually schedule acceptance tests. The maintenance plan defines all the interventions that need to be made (technical cleaning, checking, inspection), on the equipment and this to maintain the reference state. This helps to have a global view of all the actions to be taken to ensure the smooth operation of machinery (see Chapter 12: Management of breakdowns).

It can also be managed on hospital level by the biotechnical department for example.

- The equipment logbook must be kept up to date (see chapter "Breakdown management").
- It is useful to define the people in charge of each modality in the department and to establish links with the support services (IT, procurement ...).

4 Templates

4.1 Training program

Below is a template of an external training program and a table in which the different training programs can be enumerated.

Training program 2015
COMPANY: N°ONSS: EQUAL SUBCOMMITTEE: CONTACT: FUNCTION: STREET + N°: POSTCODE: LOCALITY: TEL: E-MAIL:

Training organised by XXX

Caution: The training program of the company is not a registration form.

Indicate in the table below, the training for which you intend to register staff and which are organised by external training companies, manufacturers or suppliers.

Title of training	Trainer	Number	Period

4.2 Specific trainings with the department

Specific training in the department is training which is organised wholly or partly tailored by a company. It should not always be given by an external trainer. It is therefore in-house training and the trainer can be a staff member. Here below is a template of an in-house training program for newly arrived/hired personnel with the different items that need to be seen.

Approval of the person in charge	Name	Signature

			Level??	
	Checklist new arrival	EGQ	Revision 1	
			Date	
Name:	Date of arrival:			
Type of contract:				
Information/formations	Person in charge	realized	Not carried out	Comments
Card-index personal data filled/CV/character reference/rules of procedure				
Schedule and general organisation				
Tour of the department and Presentation of Team Leader				
Training in the workplace				
Presentation of safety instructions				
Radiation protection training				

Signature of the person in charge	Signature of the trained staff

4.3 Skills matrix

Here below is a skills matrix which specifies the skills and knowledge of all team members for different tasks. It displays the members' expertise/aptitude in those tasks.

Skills matrix															
DATE	Phycisian			Physicist			RTT			Secretariat			QM		
	Contouring	Simulation	Consultation	Dosimétry	machies QA	...	Machines	Simulation	...	Encode commads	Patients	make en appointment	documents management	incidents management	general management
0. in progress															
1. under surveillance															
2. Autonomus															
3. Responsible															
4. Manager / director															
NAME															

Chapter 10: Communication Management

1 General Definitions

1.1 Theory of communication

Communication is an evolving process in which there is an exchange of information between two or more individuals. It is a system made up of several elements which are connected to each other, and which gives sense to the messages exchanged by the participants. Communication is a complex process involving people either within the same department, or from other departments or from other sites with which the radiotherapy department works (55). Communication is an evolving process in which there is an exchange of information between two or more individuals.

The theory of information is based on the Shannon model. This model was designed to develop effective communication between a sender and a receiver. It identifies different elements (see Fig 11) “an information source, which produces a message; a transmitter, which encodes the message into a signal; a channel, to which signals are adapted for transmission; a receiver, which decodes (reconstructs) the message from the signal; and a destination, to which the message arrives (56).

Shannon model

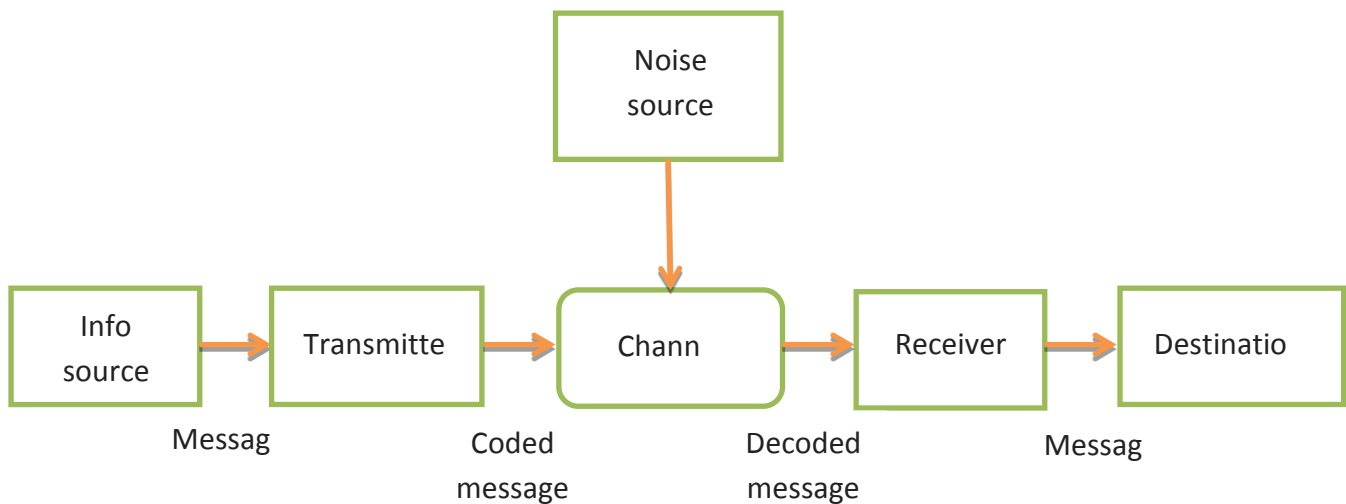


Figure 11- Shannon Model

1.2 Types of communication

Different types of communication exist (56):

Downward vertical communication: Communication from a higher hierarchical level towards a lower hierarchical level (example: the head of department informs his staff).

Ascending vertical communication: Communication from a lower hierarchical level (e.g. a staff member) to a higher hierarchical level (example: a subordinate returning a report, an agenda, or reporting an incident to his manager...).

Horizontal communication: Communication between colleagues without the intervention of the hierarchy (examples: communication between RTTs, RO or between physicists).

Internal communication: communication within a department or a hospital, or amongst the various participants of a process.

External communication: Communication by the radiotherapy department towards one or more departments of the hospital, other hospital sites or towards outside organisations, auditors, etc. It can be also made from the outside (firms, Federal agency for Nuclear Control (FANC), Controlatom, internal or external auditors at the hospital) towards the department itself.

2 Theoretical framework

It is important to note that the communication must be embedded into the hospital communication management. The tools used are those provided by the hospital to observe consistency in all departments. Several different types of communication exist:

2.1 Internal communication

2.1.1 Organisation of meetings

A structured quality management system (QMS) needs to foresee the organisation of regular meetings. The frequency of the meetings is based on a mutual agreement between the various members in each team and the quality manager (depending on the type of meeting). It is also necessary to take into account the activities of the department, on-going or future projects and the type of meeting needing to be organised.

The meetings that are generally organised in a radiotherapy department vary but may include the following:

- Quality meetings
- Team meetings (example: nurse/RTT, medical, medical physics)
- Departmental/ management meetings

Staff meetings for contouring and dosimetric reviewing

- Project management meetings
- Risk management / incidents report management meeting

2.1.2 Communication between all teams

The communication between the different teams is important and must be structured especially in a radiotherapy department where several teams must work together. Medical, technical, and treatment information as well as administrative support must make its way through the different radiotherapy sub processes and through the professional teams while minimising the risk of loss or distortion of information (57).

The existence of different professional groups in a radiotherapy department does lead to a complex approach of communication. Each professional group has specific tasks and responsibilities. And each group needs to interact with each other with a common objective: providing overall optimal patient care (55).

2.1.3 The communication of adverse error events (also see Chapter 11: Risk Management System)

Quality breaches, adverse error events must be communicated to the quality manager through an incident reporting platform (PRISMA-RT, ENNOV, Patient Safety...). The QM will be informed of the event either by the reporter or by consulting the platform or through the reception of an automatic mail generated by the platform, the process depend on the procedure established in the service. The QM must then gather the necessary information needed to carry out the retrospective analysis. This allows him/her to determine the classification of the primary causes and “root causes” and to attribute the proper context variables. In the majority of existing systems, the reporter may be informed of the status of his report (new, to analyse, completed, re-opened).

2.2 External communication

2.2.1 Communication with other departments of the hospital

The radiotherapy department is a medical-technical department and not an inpatient department. However, some patients, depending on their clinical status or treatment, need to be hospitalised on a ward. When the ward and the radiotherapy department are located in the same hospital, transportation to and from the radiotherapy department needs to be organized. The radiotherapy department must be able to communicate with the ward of the patient, the internal patient transportation department and also with other departments likely to intervene in the patient’s care (medical imagery, laboratory, inpatient or outpatient chemotherapy ...). This is also applicable if the patient is hospitalised in another hospital. In this case, communication also needs to be established with the patient transportation companies (ambulances, shuttles ...).

The radiotherapy department also communicates with the other department through the organisation of MOC (Multidisciplinary Oncological Consultations) meetings. These meetings are held between “various specialists, (*oncologists, radio-oncologists, surgeons, gynaecologists, urologists,...*) within the framework of the diagnosis and treatment of a new oncologic affection” (58). These consultations ensure that all newly diagnosed or on-going patients are discussed in a multidisciplinary setting.

2.2.2 Communication with other radiotherapy centres

Extra-muros (extra-mural) transfer of medical and treatment specific (dosimetry, treatment chart,...) information also needs to be organised. A patient can consult a radiation oncologist in one radiotherapy department and have his/her treatment administered in another department. In this case, the disclosure of medical information is crucial for patient care in another department.

The same applies to patients having benefited from treatments in one department and needing a subsequent treatment in a different department (that is for example closer or has a particular technique).

Computer systems that centralize the various medical data, exams and protocols within the same database allows for physicians from different hospitals to easily and rapidly consult the data (59). This data management helps avoid experts from performing interventions and exams that were already carried out. This also prevents patients from having to undergo the same types of procedures multiple times.

2.2.3 Communication concerning adverse error events/large scale incidents

If a report seems to meet the inclusion criteria for a FANC declaration of incident, it is crucial to inform the person in charge of the professional groups (medical, physical, and nurse/RTT) and to mutually decide if the authorities (FANC, Controlatom) need to be informed.

If the decision is made to inform the authorities, this incident will be reported following the rules and through a form available on the FANC website:

<http://www.fanc.fgov.be/GED/00000000/2400/2493.pdf>.

Similarly, if the event concerns a medical device or product, the incident should be reported to the FAMHP (Federal Agency for Medicines and Health Products). This can be done through the completion of the form found on their website:

http://www.fagg-afmps.be/en/notification_effets/

2.2.4 Communication with firms

Collaboration between radiotherapy departments and the companies/firms responsible for machines and the technical installations, is important for the smooth progress of treatments - this specifically during the management of breakdowns and preventive machine maintenances. Therefore, it is important to optimize these types of communications while keeping a hard copy of the important information submitted to the firms and by the firms.

Communication must also be established between outside organisations and the radiotherapy department. The other sites, departments, firms, national institutions, regional and international entities,... must be able to easily communicate with the radiotherapy department and the transmitted information must directly arrive to the appropriate recipient. (physicist, technician,...depend on department organization). This avoids the generation of distorted messages due to the existence of intermediaries.

2.3 Communication with patients

2.3.1 Patient specificities

It is necessary to take into account the characteristics of the patients in order to adapt the communication system and the type of information to be transmitted to the patient. In this way, the information transmitted to the patient will be well understood and not a source of apprehension (55).

Patient characteristics that need to be taken into account can be as follows:

- Age: communication needs to be adapted if the patient is a child, teenager, adult or an elderly person;
- Cultural and religious values ;
- Language ;
- Handicaps (vision or hearing impaired/patient with physical mental disabilities);
- ...

Information transmitted verbally to patients can be accompanied by written information in the form of booklets, posters, DVDs etc.... in order to improve patient understanding and cooperation.

2.3.2 Contact with the department

The first contact made with the radiotherapy department is generally established through a medical specialist or general practitioner and sometimes by the patient himself. The ease with which facilities make contact with the department is important so as to give the patient access to the necessary information for his/her care with eventually the establishment of service level agreements between radiotherapy departments and referrers.

2.3.3 Services offered

It is necessary to understand “services offered to the patients” as the different levels of support/assistance to the patient. This can be social (welfare service), psychological (psychological follow-up), dietary (dietician, nutritional monitoring), paramedical (wound

care, physiotherapy, occupational and speech therapy,...), and oncological(follow up by a nurse, cancer care coordinator, ...) support.

Communication with these services must be established through a member of the radiotherapy department (doctor, nurse/RTT, secretaries). The patient can also contact the appropriate services if he has the necessary contact information or if consultations are organised regularly.

The department may also use posters or TV screens e.g. in waiting rooms or distribute booklets with general or disease specific information and the available support services accessible to them.

3 Practical modalities

3.1 Communication tools

In order to transmit a message, various tools exist and the selection of the appropriate tool is based upon various criteria: characteristics of the transmitter and the receiver as well as the type of message. These various tools must be used in the most adequate possible way (55).

The various communication tools that exist are as follows (57):

- Paper media (booklet, posters, reports, agenda, meeting's minutes...)
- Electronic media (e-mail, Power Point...)
- Telephone/fax
- Data-processing platform (Internet, websites, Intranet, software...)

3.2 Internal communication

3.2.1 Meetings

The practical organisation of meetings is specific to each department and should ideally be defined in a procedure.

An example of the organisation of a meeting can be as follows:

- A few days before the meeting, a proposal of an agenda is communicated to the concerned members. It must contain the subjects to be discussed and the date, time, location and title of the meeting.
- During the meeting, the organiser and the person who is taking the minutes are identified.
- Following the meeting, the minutes are drafted up by the appointed person. The draft must contain the date and the time of the meeting, the title, the number of pages, the participants, the absentees and the topics discussed.
- The draft of the minutes is reviewed by the participants of the meeting and feedback is given if needed(in many cases the minutes are officially approved at the start of the next meeting)
- The approved minutes of the meeting are then broadcasted.

If corrective, preventive or other actions need to be put into place, the person in charge as well as deadlines will be clearly stipulated and transmitted to the supervisors.

3.2.2 Communication between teams

In the presence of too many communication tools, communication between different teams can quickly become too complex. The choice of the tool to be used is crucial and must be selected according to the transmitter, the type of message to be communicated and the receiver.

It can also be useful and facilitating, to define various “communication procedures” including areas such as type of data to be transmitted, type of communication channel to be used and personnel involved.

Example of a procedure that could be defined in a department: how to communicate the existence of an isocentric shift - following treatment planning -from the medical physics’ team towards the RTTs and RO. Type of communication (oral/written, type of tools to be used? When the information should be given...).

It is important to keep in mind that the traceability of transmitted information is important. Therefore oral transmission of information is often insufficient.

In the recent years, workflow management systems have arisen which have allowed the facilitation and traceability of information communication. These can be externally made systems (ARIA, MOSAIQ...) or in house made systems. They allow a systemic vision of the RT workflow and processes and gives the user access to the useful information when this is needed and it improves the transmission of this information.

3.2.3 Communication of adverse error events

It is important to communicate to staff members, the results of analyses carried out for the various events that are reported. The information given should include the decisions that were made, the suggested improvement actions to be put into place and the immediate actions that have been put into place. This information can also include statistical analyses that were realized on a reported event. This communication also includes quantitative data such as the statistical analysis of a reported event, root causes and context variables (see Chapter 11: Risk Management System for more information concerning communication of incidents).


3.2.4 Other type of communication

“Quality” dashboards can also be implemented within the department. This type of interface allows for staff members to easily visualise progress reports, quality indicators or the current status of projects. This can be displayed on a white board, digital board or on a web interface. It is continuously updated and enables the staff to be informed of trends, actions to be carried out and/or to be sensitized of security barriers (see Chapter 5: Quality Indicators for more information).

4 Templates

4.1 Agenda of a meeting

Template of the agenda of a meeting

	TITLE		
	DATE	TIME	LOCATION
	TOPICS : - - - - -		

Chapter 11: Risk Management System

1 General definitions

Risk management is “the discipline which attempts to identify and treat” in a methodological manner“, the risks related to the activities of an organisation” (2). The aim of the process is to analyse, assess and control risks. The term "risk" is defined as the combination of the probability that an event occurs and the severity of the harm it causes (60).

In radiotherapy, "risk management aims to prevent (a priori approach) the occurrence of adverse error-events associated with treatment (or with the entire radiotherapy process). In case of occurrence of such an event, risk management aims to identify, analyse its causes, mitigate or eliminate its harmful effects on the patient and to implement measures to prevent it from happening" (61).



Figure 12 - Risk management (8)

The risks can have an impact on 4 types of resources (62):

- Management, people, skills
- Planning (time)
- Technologies, materials, environment
- Financing

Risk is characterized by two components (61):

- An "objective" component -which is related to the frequency of occurrence of the risk and the severity of its consequences (Criticality Index = Frequency * Severity)

- A "subjective" component- which is related to the manner in which the risk is perceived (= unique to each individual personal assessment of the risk of occurrence of the event).

Risk can be "proven", "potential", "emerging" or "future". Over time, certain risks occur and others disappear; hence the importance of being able to manage risks.

Risk management is an iterative approach that involves four steps: Identification, Prioritization, Prevention and Follow-up (Fig. 2).



Figure 13- Risk management iterative steps

During this iterative process, preventive or protective measures can be developed.

In other words, decreasing the frequency of risk is prevention and decreasing the level of risk is protection:

- **Prevention:** A set of measures to avoid the occurrence of an incident.
- **Protection:** A set of measures to limit the extent and / or severity of the consequences of a phenomenon or dangerous events, without changing the probability of occurrence.

Along with the proactive and retroactive analysis of risk events, integrated QMS measures should be considered to reduce the risk of errors (7). They are listed in the hierarchy of the effectiveness of preventive measures defined by the "Institute for Safe Medication Practice" as demonstrated in the diagram below (Fig. 14) (63).

The three items at the top of the scale are effective systemic strategies in reducing the risk of errors. Strategies at the bottom of the scale have moderate efficacy and a human component. The error prevention requires the implementation of action at all levels of the hierarchy (63).



Figure 14- Effectiveness of preventive measures

The use of consistent terminology is of uttermost importance in order to properly assess and analyse risks. In this document we will therefore use the terminology defined in the RP 181 in which the terms used are as follows (8):

- **A near-miss:** An event that could have potentially led to the harm of the patient but did not affect the patient directly.

Example: table position move not performed before treatment, but detected before initiating treatment after checking the table settings. The displacement is carried out and treatment is delivered as usual - there is no incident.

- **Adverse-error event (AEE):** An event that results in unintended harm (minor or serious) to the patient by an act of commission or omission (all treatment-related side effects are excluded).

Example: the displacement of the table position is not performed and not detected before starting the treatment.

- **A significant event/incident:** An adverse error event that involves accidental or unintended exposures of the patient or medical staff and implicates the notification of the national authorities.

2 Theoretical framework

2.1 Content

Risk management is primarily aimed at improving the safety of patients, visitors and staff. The approach aims at reducing preventable risks and optimising prevention mechanisms and protection. A good risk management system in a radiotherapy department is based on four main pillars (8):

1. An established comprehensive quality assurance and quality management system
2. The application of lessons learned from international major accidental exposures (IAEA, ICRP) and national incidents (FANC).
3. The establishment of an adverse error event reporting and management system, which enables security monitoring and continuous improvement practices.
4. The quantification and proactive anticipation of latent risks

Points 3 and 4 mainly lead to the identification and the analysis of the existing risks in the system and aim at decreasing the likelihood of adverse error-events.

Risk management should ideally be balanced by two approaches: a prospective and a retrospective approach.

Retrospective approach	Prospective approach
= Analysis of near-miss or adverse error event reporting → Investigate → Analyse → Improve → Evaluate	= Analysis of process failures/defaults Search for causes → Prevent → Improve → Evaluate
Objective: To prevent the recurrence of incidents	Objective: To prevent the occurrence of incidents

2.2 Format

2.2.1 Retrospective approach

The retrospective approach in risk management is thus the analysis of adverse error-events (AEE) and near-misses reported through the use of a reporting system (computerized or not).

To make the event reporting platform the most ideal possible, it is important to follow some basic rules such as the (63) (4):

- Implementation of a multidisciplinary team for the analysis of events and the determination of corrective and preventive actions.
- Promotion the non-punitive nature of the reporting system by respecting the concept of "Just Culture" (64).

Some rules can be applied to encourage the reporting of events in the reporting platform (63):

1. Encourage the active involvement of the management team;
2. Avoid a reproach policy upon the declaration of an adverse event;
3. Implement an anonymous and confidential reporting system;
4. Use the parameter "Number of encoded events" as a quality indicator;
5. Actively educate staff members on safety and security manners;
6. Make the reporting system user friendly;
7. Facilitate access to the reporting system;
8. Provide timely feedback to users/reporters;
9. Search for solutions and not guilty individuals/staff;
10. Monitor the implementation of corrective actions.

A detailed analysis of a reported event (AEE or near-miss) must be carried out following its declaration in order to determine the root causes and to identify the corrective and preventive actions needing to be implemented in order to reduce the severity and occurrence of this event. As stipulated in Action 16 of the National Cancer plan, the methodology used for the analysis of events in radiotherapy is the PRISMA (**P**revention and **R**ecovery **I**nformation **S**ystem for **M**onitoring and **A**nalysis) method and the use of the Eindhoven classification system (4). The modalities pertaining to the PRISMA methodology is described in the chapter "Practical Modalities". Action 16 has also permitted the creation of a PRISMA-RT.be benchmark environment – which allows for the analysed data and their context variables to be anonymously transferred into a database allowing for the statistical analysis and inter-comparison of data between different radiotherapy departments.

As required by the Ministry of Health, the declaration of events in radiotherapy also needs to be integrated within the institutional event declaration system. In this context, the events are classified using the WHO taxonomy and allow for coherence and exchangeability of data between the different hospitals (65). Furthermore, the incorporation of radiotherapy related event with the institutional system allows for the proper integration of the radiotherapy risk management within the overall hospitals risk management system.

As a result, all radiotherapy events not only need to be analysed using the PRISMA methodology but also need to be integrated within the institutional system in order to classify them using the WHO taxonomy.

When an event involves accidental or unintended exposures of the patient or medical staff and implicated the notification of national authorities, then it is also important that these authorities be notified as defined by the practical measures put in place in the radiotherapy department and institution's management (see Chapter 10: Communication Management). In general terms, significant events need to be declared to:

- The FANC (Federal Agency of Nuclear Control) if the significant event concerns a patient/patients or personnel (inclusion criteria can be found on the FANC website: link:<http://www.fanc.fgov.be/fr/page/directives-afcn-relatives-aux-modalites-et-criteres-de-declaration-a-l-afcn-des-evenements-significatifs-dans-le-domaine-de-la-radioprotection-en-radiotherapie/1029.aspx> (French, Dutch and English version available)
- The FAMHP (Federal Agency for Medicines and Health Products) if the event concerns a medical device or product (http://www.fagg-afmps.be/en/notification_effets/)

2.2.2 Prospective approach

Several prospective approaches do exist and these include: **risk maps**, **risk assessment visits**, **scenario analysis** and **FMEA (Failure Mode and Effect Analysis)**.

Each department can choose its own approach. The one recommended by the ASN (Autorité de Sûreté Nucléaire) for radiotherapy departments is FMEA methodology. They have recently published a specific risk analysis grid "Guide d'auto-évaluation des risques encourus par les patients en radiothérapie externe " (60). The AAPM task group 100 (TG100) has also recently published its report on using the FMEA methodology (66).

- FMEA method (Failure Mode Analysis, Effects and Criticality)

General principles of the method (61) (60):

It is a prospective analysis method that identifies potential failures of care processes and that evaluates the critical points of the process to prevent failure occurrence.

The aim of this approach is to identify potential failures and evaluate them to define priorities.

Its goal is not only to analyse but also to draw preventive measures and action points by searching for malfunctions and areas of improvement. Before carrying out a **FMEA** analysis, it is first of all necessary to define how the studied system operates by defining and drawing out the activity process.

At each stage of the process, failures and its causes and effects will be estimated (qualitative analysis). The evaluation will assess the severity, frequency and existing means of failure detection (quantitative analysis).

Severity, frequency and detection scales should be defined within the department (or possibly the institution if a global comprehensive risk management is done or planned) prior to FMEA analysis.

In conclusion, the combination of retrospective and prospective methods of risk analysis is beneficial to optimise risk management in a radiotherapy department.

3 Practical modalities

3.1 The PRISMA methodology

As mentioned in the previous section, in Belgium, the Radiotherapy College and the Cancer Plan recommends the use of the same methodology for the analysis of reported adverse events in order to allow for the benchmarking of data between different departments (52). The recommended method is the PRISMA methodology (**P**revention and **R**ecovery **I**nformation **S**ystem for **M**onitoring and **A**nalysis) and the use of the Eindhoven classification of root causes (64). As a result, this chapter is devoted to this type of analysis although other approaches do exist, such as:

- Ishikawa diagram (5M)
- ALARM (Association of Litigation and Risk Management)
- HFACTS (Human Factor Analysis and Classification System)
- ORION
- SIRE (Systematic Incident Reconstruction and Evaluation)

The purpose of the PRISMA analysis is to acquire a deeper understanding of the occurrence of incidents. In this case, it is necessary to know the context of the occurrence of an event in order to analyse the root causes.

If the content of the report is not clear enough, the QM can carry out an investigation to understand the circumstances of the event. This information can be collected through site visits, collection of evidence or by interviewing the staff. It is important to note that the information collected should be based on facts and not emotions or feelings. When all the elements necessary to the understanding of the event are collected, the reported event can then be analysed and the causal tree can be established.

3.1.1 Causal tree

3.1.1.1 Information analysis

- When analysing the reported adverse event, it is important to ask the following questions:
- What happened and what are the consequences for the patient?
- How should things have proceeded?
- Does a formal procedure exist
- What were the errors that occurred and at what phase of the process?
- What errors occurred during the different phases of the process?
- What happened at the last phase?
- What is the damage for the patient?

Information analysis is crucial in order to get the most comprehensive and complete view of the reported event.

i. Establishment of the causal tree:

The first step of an adverse event analysis is its description through a causal tree. This causal tree gives an objective view of events that led to the adverse event occurrence (near-incident / incident).

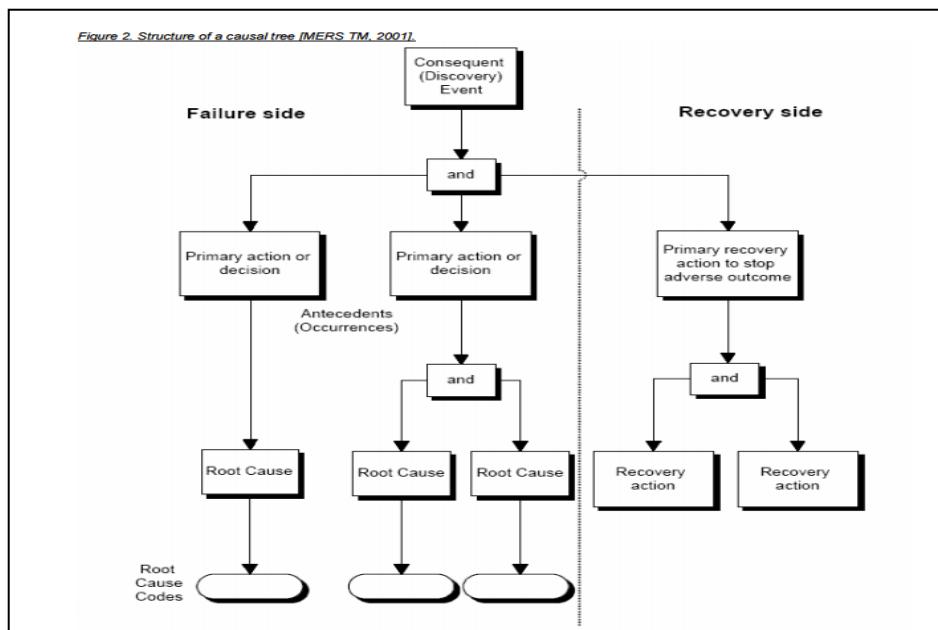


Figure 15- Causal tree (64)

If the event is an incident, the tree provides failure analysis and if it is a near-incident, it also allows for the analysis of recovery actions (planned or non-planned), which prevented the incident from occurring.

Methodology used for the establishment of the causal tree:

1. Find the starting point of the event: Identify the event, what happened
 - **Direct Causes**: situated immediately below the proximal event. 2 or 3 causes that together explain the proximal event.
 - **Secondary Causes**: there are often several secondary causes under primary causes. The direct cause is often the result of underlying secondary causes.

2. To find secondary causes, we must ask the question: Why?
 - Stopping Rules:
 - When there are no new objective facts;
 - If the cause is external to the context or responsibility of the organization
 - if the cause is outside of the RT scope of activity (in this case, transmit the information to the institution's other working groups)
 - Verification Rule:
 - To verify the consistency of the causal tree, use the following rule: "Since root causes 1 and 2 were present, secondary cause of the upper level may have occurred."

- **AND Links**: 2 or 3 causes TOGETHER cause an event. The incident could have happened because the cause 1 and 2 were present and the combination of the two caused the event.

- **OR Links**: there still remains uncertainty about what actually happened. It is possible that either cause 1 OR 2 caused the event. Therefore, it is necessary to obtain more information in order to eliminate OR links. In the final causal tree, there shouldn't be any OR links.

Missing information can never be filled in if it is not based on a fact. Information should be based on facts, not judgements or assumptions.

For near-incident analysis, in which the proximal end event has not occurred, it is important to define the recovery / prevention measures; i.e., the measures that allowed for event recovery and prevented an incident from occurring.

The purpose of causal trees is to find the primitive or root causes -as acting upon them will allow for process improvement and the decrease in the occurrence of adverse events.

3.1.2 Classification of the root causes: The Eindhoven Classification Model

Once the root causes are identified, it is possible to assign a code using the classification of Eindhoven. This allows for the identification of dominant latent causes and to translate them into structural measures (matrix classification / action).

The Eindhoven Classification Model (causes profile) allows for a classification of the root cause and categorizes them as (64) (67):

- Technical (T) failures;
- Organizational (O) failures;
- Human (H) failures;
- Patient related (PRF) failures;
- Other (X)

These different categories of failures can further be subdivided:

∅ **Technical failure (T)** can be subdivided into:

- **External (T-EX):** refers to any technical failures beyond the control and responsibility of the investigating organisation
- **Design (TD):** failures due to poor design
- **Construction (TC):** correct design which was not followed accurately during the construction phase
- **Materials (TM):** category for other material defects, not classifiable under TD or TC

∅ **Organisational failure (O)** can be subdivided into:

- **External (O-EX):** any failures at an organisational level beyond the control and responsibility of the investigating organisation
- **Transfer of Knowledge (OK):** refers to failures resulting from inadequate measures taken to ensure that situational or domain specific knowledge or information is transferred to all new or inexperienced staff
- **Protocols (OP):** failures related to the quality and availability of the protocols within the department (too complicated, inaccurate, unrealistic, absent, poorly presented)
- **Management priorities (OM):** refers to failures resulting from management decisions in which safety is relegated to an inferior position when faced with conflicting demands or objectives
- **Culture (OC):** refers to failures resulting from a collective approach and its attendant modes of behaviour to risks in the investigating organisation

Ø Human failure (H) can be subdivided into:

- **External (H-EX):** refers to human failures originating beyond the control and responsibility of the investigating organisation
- **Knowledge (HKK):** refers to the inability of an individual to apply their existing knowledge to manage novel situations
- **Qualifications (HRQ):** refers to the incorrect fit between an individual's qualifications, training or education and its task
- **Co-ordination (HRC):** refers to a lack of task co-ordination within the organisation or team
- **Verification (HRV):** concerns failures in the correct and complete assessment of a situation including relevant conditions of the patient and materials to be used before starting the intervention
- **Intervention (HRI):** applies to failures that result from faulty task planning and execution
- **Monitoring (HRM):** pertains to failures during the monitoring of process or patient status during or post-intervention
- **Slips (HSS):** refers to failures in the performance of fine motor skills
- **Tripping (HST):** refers to failures in whole body movements

Ø Other failure (H) can be further refined as:

Patient related:

- **Patient related factor (PRF):** Failures related to patient characteristics which are beyond the control of staff and influence treatment

Unclassifiable:

- **Unclassifiable (X) :** Category for failures that cannot be classified in any other category

Context variables

It is also possible to assign context variables to root causes in order to assign a context/setting to the causes. These context variables have been validated and approved by the PRISMA Board of Experts and have been integrated within the PRISMA platform. They are grouped according to their scope within different categories:

- General (general information and implicated process of the root cause (+ planned improvement))
- Technical (context variables assigned to technical root causes)
- Organisational (context variables assigned to organizational root causes)
- Human (context variables assigned to human root causes)

More information concerning the Belgian context variables can be found in a separate document by the PRISMA board of experts ([see pdf](#)).

3.1.3 Determination of improvement actions

The root cause analysis provides interesting information, which provides help in defining improvement actions. These actions must be determined by the RT department PRISMA task group (multidisciplinary safety team) and approved by the management (ie: heads of staff), prior to release. The monitoring and evaluation of the improvement actions should be formalised at the time of implementation. The period of review, the indicators and means of assessment must also be determined beforehand.

The possible actions can be grouped according to the areas affected by failures.

A matrix has been designed, in order to guide the user in putting into place the appropriate corrective actions. The choice of corrective actions will depend on the assigned Eindhoven classification of the root cause, as shown in the matrix below (Fig.16) (64).

Classification code	Technology / Equipment	Procedures	Information and Communication	Training	Motivation	Escalation	Reflection
T-EX						x	
TD	x						
TC	x						
TM	x						
O-EX						x	
OK						x	
OP		x					
OM						x	
OC							x
H-EX						x	
HKK			x		NO		
HRQ				x			
HRC				x			
HRV				x			
HRI				x			
HRM				x			
HSS	x				NO		
HST	x				NO		
PRF ¹							
X							

¹If particular patient related factors (such as language problems) that cannot be prevented by the patients themselves recur, then these problems should be solved at an organisational level (i.e. escalation).

Figure 16- Classification matrix-Action

The corrective actions can then be categorized as being related or acting upon :

- **Technology/Equipment area:** new or redesign of machines and software that require interfaces with a person.
- **Procedures:** completion or development of procedures that promote efficiency and safety in the performance of tasks

- **Information and communication:** enhancement of the sources of information and means of communication.
- **Training:** improvement of the level of voluntary compliance towards the general rules by the application of the principle of positive encouragement of behavioural change
- **Escalation:** transfer of the problem to a higher level of management.
- **Reflection:** promote self-awareness by encouraging the use of critical behavioural self-evaluation.

3.2 The FMEA prospective analysis

3.2.1 Practical methodology (60) (61)

3.2.1.1 Process selection and description of sub-processes

In order to carry out FMEA, it is necessary to define the activity/process that will be analysed and to have a common understanding of the sub-processes associated with it. A step-by-step description of the process needs to be clearly defined and structured in a tabular format. Ideally, this step should be formalised with the department or institution's management.

3.2.1.2 Establishment of a (multidisciplinary) analysis team

The choice of members to be included in the analysis must be strategic and allow the implementation of actions. Preferably, the head of the department and the head of the medical physics and RTT team should be present. Experienced personnel or process experts should also be included in the task group. The QM's main task will be to lead the task group and to ensure the proper implementation of the FMEA methodology.

3.2.1.3 Definition of the measurement scales

The measurement scales that will be used for failure evaluation needs to be defined beforehand. Generally, two types of scales are used:

- Severity scale – “what is the consequence of the identified possible failure”
- Occurrence scale – “what is the probability of the event occurring”

The detection (“how well is the failure detected”) or acceptability (“is the department willing to accept this type of failure”) scale may also be added in order to prioritise actions.

Scales give rise to scores that need to be multiplied in order to obtain a “risk priority level” (RPN) Risk level = Frequency * Severity * Detection (66).

As an example for the calculation of a risk level for a failure (61) (60):

Severity: Severity Scale from 1 to 5 (from the least to the most serious)

Frequency scale of 1 to 4 (from the least to the most frequent common)

Detection: scale 1 to 4 (1 means preventive measures are in place; 4 means no measures are in place)

Risk level of 1-30 = minor risk

Risk level of 31-60 = moderate risk

Risk level of 61-80 = major risk

Ideally, this measurement scale should be approved by the department's or institution's management.

3.2.1.4 FMEA analysis

Before the analysis, the table framework to be used is established. At each stage of the process, one identifies failures (undesirable events), possible causes, and possible consequences and assesses the risk level. The risk level assessment should be based on a consensus. At the end of the analysis, a proposal for improvement actions should be made.

3.2.1.5 Validation of the analysis by all participants and the management team (of the department or institution - depending on the context).

The analysis, risk prioritization and risk prevention must be validated by the task group members (multidisciplinary team) and, by the institutional management committee (if required or needed as stated by internal organization regulations).

The actions needing to be taken and their deadlines are to be determined during this step. The practical implementation of these actions needs to be discussed and decided upon.

3.2.1.6 Presentation of the analysis and action plan to staff members involved in the process

The analysis and action plan are to be presented to the entire staff.

3.2.1.7 Planning, implementation and monitoring of improvement actions

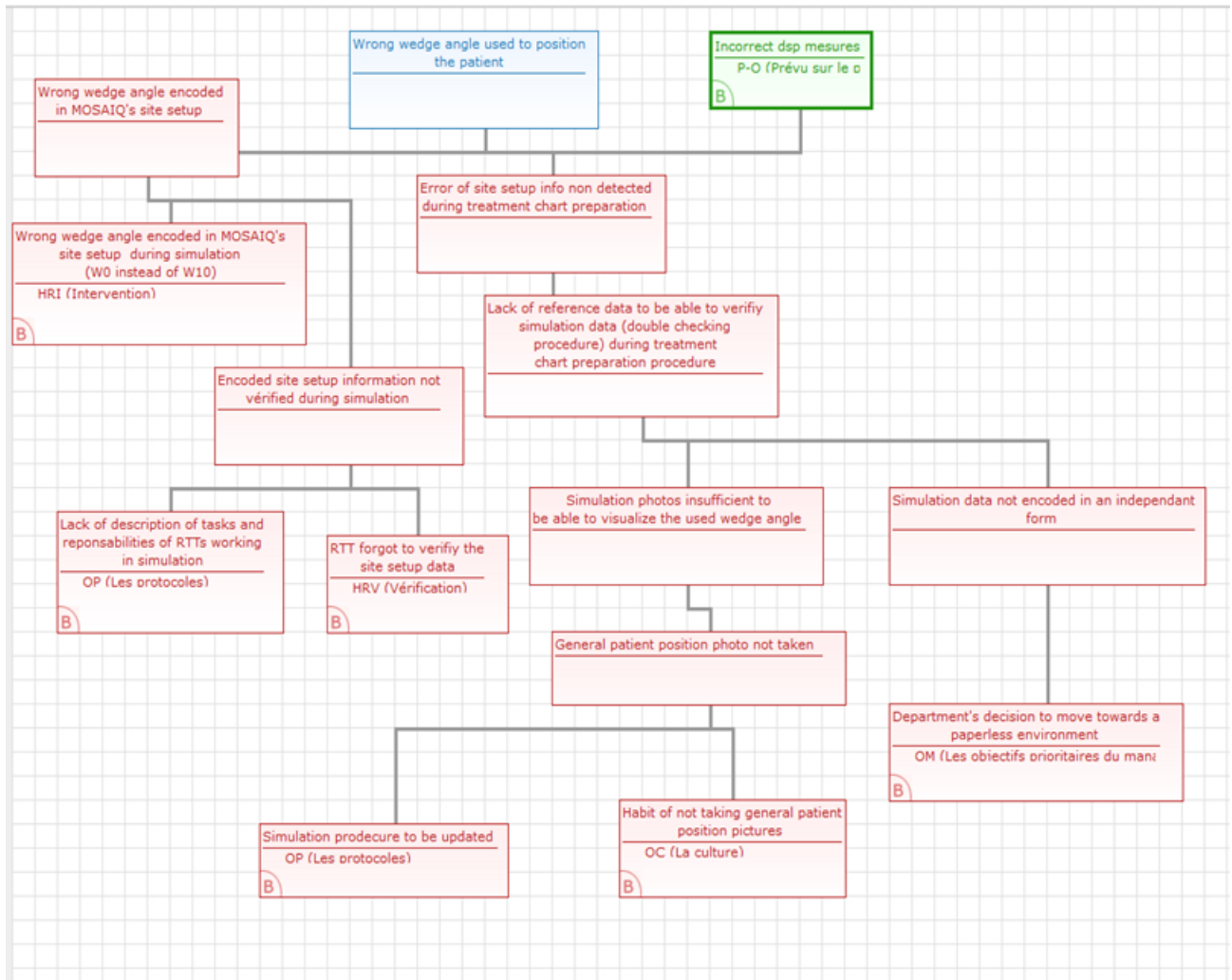
The staff members, responsible for each action, need to be identified and a timeline for the implementation of actions need to be established.

It is necessary to determine who is responsible for tracking these actions (verification of adherence to deadlines, used methods...). The responsibility for monitoring the entire project should not solely rely on the quality or risk manager.

4 Templates

4.1 Causal tree of a reported adverse error-event

Here below is an example of a root cause analysis of a near incident using the PRISMA methodology. . In blue is the event, in red the causal factors having favoured the occurrence of the near-incident and in green the recovery factor.



4.2 Belgian Context variables

The PRISMA board of expert have developed Belgian context variables document. These are readily available through the QMRT.be group (68).

Chapter 12: Management of breakdowns

1 General Definitions

Machine and treatment interruptions can be due to two factors:

Unplanned interruption due to machine breakdowns (a breakdown is defined as being an error or a dysfunction in a mechanical, electrical or computer device).

Planned interruptions due to preventive machine maintenance (Preventative maintenance is defined as interventions performed in an attempt to avoid or minimise machine failures and allows for the medical device to maintain its function).

Depending to those two factors, two types of managements need to be set up:

- Management of equipment breakdown: its aim is to document breakdowns at the time of occurrence, in order to facilitate their resolution and to reduce the rate of reoccurrence. It can also lead to define the correct procedures to maintain an optimal patient workflow during the period of a dysfunction.
- Management of treatment interruption (maintenance): those interruptions are planned in advance, to plan the machine's preventive maintenance. The aim of managing this period is minimise its effect on patient treatment and workflow.

In other words, breakdown management deals with implementing procedures which, will guide the team in dealing with unplanned treatment interruption while preventive maintenance management allows for the implementation of planned machine interruptions with the aim of minimizing its effect on patients' treatments and the occurrence of unplanned treatment interruptions.

This chapter will only deal with unplanned treatment interruptions (breakdowns). However, it is important to keep in mind that machine maintenance need to foreseen and planned with the implicated staff and company responsible of the maintenance. The maintenance program needs to be discussed in a multidisciplinary matter (including RO and RTTS) in order to avoid conflicts with other events such as vacations or planned meetings.

Proper communication between the field service engineers and the RT technical/physics team is of crucial importance. In all cases, preventative maintenance interventions need to be documented and need to be approved by the physics team. These interventions should also be followed by technical and dosimetric QCs before the device is made available to clinical work.

2 Theoretical framework

2.1 Format

Breakdowns must be reported by the staff that detects them in order to evaluate the downtime of the implicated device/machine and the type of breakdowns that are recurrent. This is realized with the aim of implementing corrective actions necessary to avoid their reoccurrence.

The management of breakdowns on treatment machines/modalities in radiotherapy implies that continuity of patient care must be ensured. In order to guarantee continuity of care, a procedure needs to be established in order to determine the priority levels of each type of treatment and the selection criteria during a breakdown event.

The management of breakdowns in radiotherapy also involves the management of patient workflow after a breakdown event. In this case, the procedure needs to define the actions that need to be taken in order to re-establish proper patient workflow and to guarantee that patients receive the planned number of fractions/dose in the proper time span.

To do so, it is imperative to define the duration of breakdown from which the workflow of patients must be modified (rescheduling of a treatment session to another time on the same day, on the same or another treatment modality or treatment session postponed to another day). It is also important to determine the level of priority of the different type of treatments schemes, so as to optimise the management of the patients to be treated. This is needed when a choice between two patients needs to be made, when the department is unable to treat all patients on the day of a breakdown or the on the days following a breakdown. Therefore, this can be included in a written procedure.

The collection of information concerning breakdowns can be centralized in a :

- Paper or electronic logbook;
- Appointment scheduling or Management system used in the department;
- CAMM system (Computer Assisted Management of Maintenance) - *if this system is available in the department or the hospital.*

2.2 Content

The items that could be included when collecting information in the breakdown database :

- Date of breakdown
- Time at start of breakdown
- Time at end of breakdown
- Duration of the breakdown (estimate)
- Name of the reporter

- Name of individuals implicated in the intervention
- Identification of the affected workstation (linear accelerator, simulator, CT,...)
- Type of breakdown (machine, computer system, imagery system, in vivo dosimetry system or other)
- Description of the breakdown
- Curative or corrective action taken
- Possible impact of the breakdown on the patient, the staff and the activity of the department

3 Practical modalities

3.1 Defining the procedures

The following steps are important when defining the procedures (69):

1. Defining and classifying the different types of breakdowns

Example of types of breakdown: computer network breakdown, power outage, accelerator breakdown, simulator/CT breakdown

2. Categorizing the different duration of breakdowns.

Example: breakdown of less than one hour, less than 24 hours, more than 24 hours.

3. Defining the guidelines that need to be followed for each type of breakdown,

Example:

- *Accelerator breakdown of less than one hour with established breakdown diagnosis and internal solution: the planned patients are preserved but informed about the expected delay and the reason of delay.*
- *Accelerator breakdown of less than one hour but with absence diagnosis and internal solution: need to contact the manufacturer by physics' team with the aim to establish a diagnosis + modification of patient schedules following the patient priority levels.*
- *Accelerator breakdown of more than one hour but less than 24 hours: management of patient workflow following the patient priority levels and accessibility of other treatment modality.*
- *Accelerator breakdown of more than 24 hours: rescheduling on other treatment modalities, with reviewing of treatment plans according to chosen treatment modality.*

4. A written procedure can be established in order to clarify and formalize the proceedings (See appendix).

3.2 Recording of breakdowns

Any breakdown must be recorded in order to allow for its inclusion in the complete analysis of types of breakdowns and downtime per machines/device. This data can be recorded via a logbook, appointment scheduling/management system or a MMCA.

3.3 Follow-up of curative and corrective actions

Any action carried out by the medical physics or technical department or the manufacturer must be documented in a paper or electronic logbook so as to have a precise recording of the various interventions and to allow for the feedback of frequency of certain types of breakdowns. In any case, the medical physics team must be informed of any planned or on-going intervention in order to set up the necessary QC (if needed) and this before resuming clinical activities following the breakdown.

The medical physics department must regularly analyse breakdowns logbook in order to follow up on possible trends and to diminish, if possible, the rate of reoccurrence of certain types of breakdowns.

In the case of “non-avoidable” breakdowns, it is important to define the actions needed to be taken in order to solve them as soon as possible. Instructions need be written down for known breakdowns including in-house solutions/action plans. This facilitates the transmission of information to the whole medical physics/technical team.

3.4 Management of patient workflow following a breakdown

The categories of patient priority levels must be defined in order to manage the workflow of the patients in an optimal manner during a breakdown.

It is important to define the actions that need to be taken for all patients according to their “type” of treatment. This allows the department to determine which patient’s session can be cancelled and which patients need to be treated or rescheduled in a restricted time period according to the patient’s priority level (hypofractionated treatments versus hyperfractionated treatment, new patients versus on-treatment patients, concomitant versus no chemotherapy...).

3.5 Recording of the intervention reports

All the interventions reports produced internally or issued by the manufacturer must be analysed and stored by the medical physics or technical department in order to encourage traceability of the realized corrective and preventive actions.

3.6 Statistical analysis of the data

A yearly statistical analysis must ideally be carried out by an appointed member of the medical physics /technical team. This analysis gives rise to information pertaining to downtime measurements for each machine/modality, types of breakdowns recorded and the corrective actions put into place. The frequency at which this is done is defined by the RT management team.

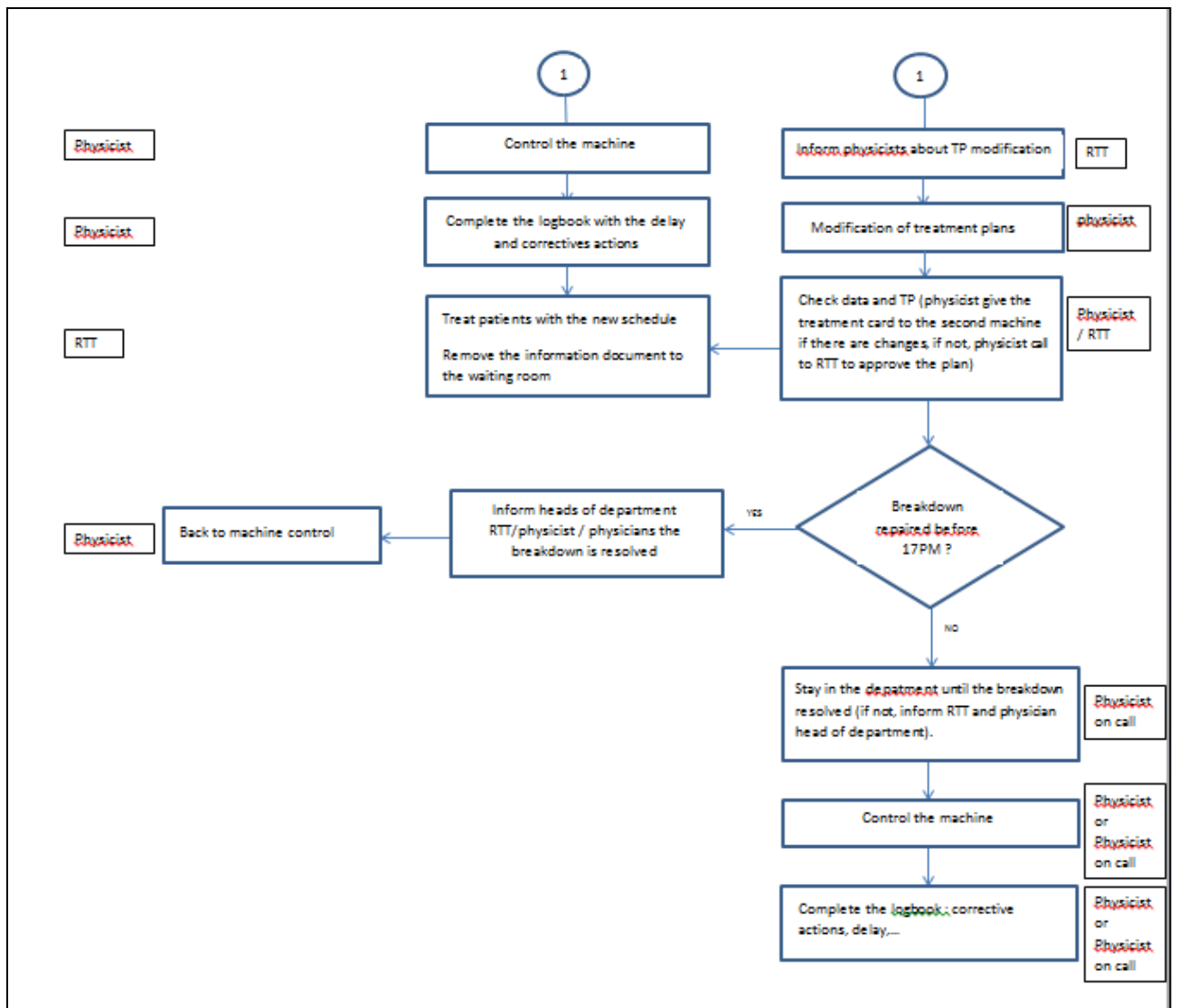
3.7 Preventive actions

The analysis of breakdown data allows the medical physics department to carry out preventive actions in order to avoid future breakdowns or minimise downtimes. These preventive actions could include putting into place additional maintenances or performing additional mechanical checks.

4 Templates

4.1 Example of breakdown workflow

Example of a process diagram depicting the different steps needing to be followed in order to manage workflow upon the occurrence of a breakdown.



4.2 Electronic logbook of machine breakdowns

Example of a computer based software allowing for the recording and monitoring of breakdowns (downtime monitoring).



Source - iTherapy Process, Version 0.2 - Process management software in Oncology Copyright Radiation (C) 2010-2012, Maxime Coevoet

Chapter 13: Patient satisfaction

1 General definitions

Patient satisfaction is a parameter that takes into account patients' expectations AND their perception of the quality of healthcare they received. Patient satisfaction is evaluated by the implicated healthcare department through the use of patient feedback and by listening to patients.

Patient satisfaction can be evaluated through the:

- Identification of patients' needs and expectations;
- Distribution and collection of patient satisfaction surveys
- Claims department if one exists in the healthcare institution.

The quality of care provided by the department cannot entirely reflect the quality expected by the patient as requirements constantly change over time. Therefore, it is very helpful to regularly conduct surveys and collect patient claims, opinions or feedback. The purpose of this assessment is to continuously improve patient care within the department.

Taking into account patient feedback thus leads to quality improvement and increased patient satisfaction. This is confirmed by the Scientific Institute of Public health, which states that *"the collection of information on patient's satisfaction is warranted for 3 important reasons"* (70):

- It provides a description of the patient's perspective of care,
- It makes it possible to identify problematic areas and to suggest solutions,
- It allows the evaluation of care.

Patient satisfaction surveys can thus be conducted in radiotherapy departments in order to evaluate the patients' impressions. The analysis of the collected surveys can help the department in identifying certain weak points, which if worked on, can help improve the service provided and increase patient satisfaction (Fig. 17).

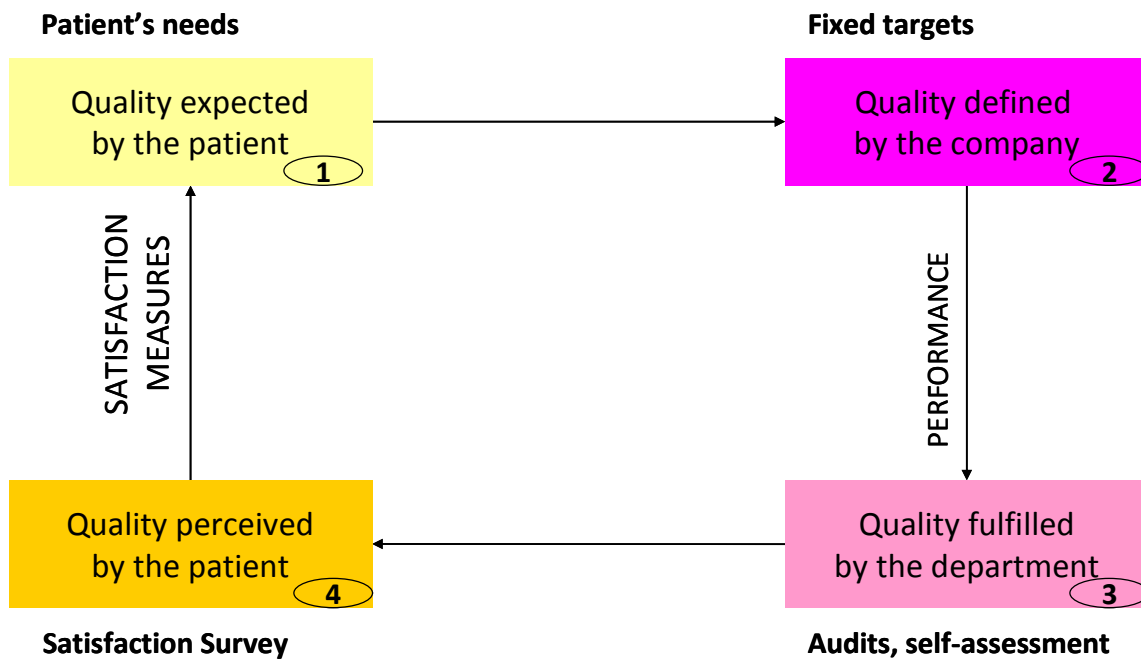


Figure 17- Quality cycle: the patient-department interrelation

2 Theoretical framework

Satisfaction surveys come in many different shapes and forms. These may be written surveys, personal interviews, face to face meetings or by contacting the patient by telephone. This type of survey chosen will depend on the scope of the survey within the department, the level of staff/patient involvement, the desired response rate, the type of patient etc. The majority of radiotherapy departments will opt for the written survey.

In all cases, the design of the survey will be based on:

- The objectives of the study
- The targeted population (patients, carers, family...);
- The sample characteristics (inclusion of all the patients or patients who received a certain type of treatment technology...);
- The method of data collection (survey, phone call, personal or face to face interview...);
- The type of data analysis;
- The presentation of the results;

3 Practical modalities

Steps for setting up of a patient satisfaction survey (30) (71):

1. Before making patient satisfaction survey, the hospital must be involved.
2. Establish a working group: the diversity within the group allows people to consider the patient as a whole, including his treatment and needs.
3. Define the objectives that the institution or department would like to attain such as the desired overall satisfaction level.
4. Define the sample: Consider whether the survey will include all patients treated with external beam radiotherapy or brachytherapy or only those patients treated with a specific technique or within a specific clinical workflow. At this stage, the inclusion criteria will also need to be defined.
5. Define the duration of the survey (survey methods): Specify if patient satisfaction will be evaluated at a given moment in time (a few days per year) or continuously (all year).
6. Develop the survey: The design of the survey is based on three major points:
 - The overall satisfaction of the health care services provided;
 - The different sub processes of patient care needing to be assessed (consultation, simulation, treatment ...).
 - The various topics needing to be covered and evaluated for each of the sub processes (schedule adherence, quality of the reception, respect for privacy, explanations given ...).

As an example, the survey established by the EORTC covers the following different topics: reception, medical care, nursing care, services and organization of the department level of comfort, paramedical and medical support, and continuity of care,... (4)

It is also important to inform and /or involve the institution's quality department/committee and communication department. This also includes informing them of the results of the survey and the difficulties that are being pointed out.

The choice of questions and the answer mode must be considered both in terms of ease of understanding for the patient and at the level of encoding of responses. General questions can also be included (age, sex, date, waiting time at the 1st consultation, simulation, treatment modality ...) to establish the general profile of respondents.

In parallel, the rate of respondents will be determined by the number of completed surveys compared to the number of surveys distributed.

7. The workgroup should decide how the questionnaire will be distributed: online, on paper... consider the patient population
8. Pre-designate the person in charge of the analysis and the methodology used. Different types of software do exist in order to facilitate the analysis of the surveys ("the sphinx, webquest, survey manager").
9. Test the survey: the survey should be distributed to a small sample of respondents and the survey should be modified accordingly to the feedback given.
10. Distribute the survey: Distribute the survey by defining the most appropriate time for its distribution and agree on the person who will be responsible for this.
11. Collection of the survey: Set the time, the means used (mailbox, mail, email ...) and the person in charge of the collecting the surveys.
12. Analysis of the survey:
13. Communicate the results of the analysis:
 - Determine how often the results are to be communicated (monthly, bi-yearly or yearly basis...)
 - Identify the group of people (recipients) to which this information is destined and communicated
 - Define the format in which results will be communicated (orally, paper or electronic format).
14. Implement improvement actions based on the results of the analysis:
 - Set priorities for action,
 - Define the methodology,
 - Define the individual(s) (working group) who will participate in the implementation of improvement actions.
15. Describe the methodology implemented in a general procedure.

It is important to make a link between patient satisfaction measured in surveys and registration of complaints to the hospital. This process helps to develop highly targeted improvement actions.

There are other methods to measure patient satisfaction. Contrary to the questionnaire, most of these methods require much more resources in time and personnel. Include the following methods:

- Telephone interview
- Semi-structured face to face interview
- Focus group

4 Templates

4.1 EORTC satisfaction survey

An example of a satisfaction survey was published in 2006 by the EORTC in the context of a multicentre study entitled "multicentric Validation of a survey of satisfaction of the care during a treatment of chemotherapy or ambulatory radiotherapy" (72).

4.2 Patient satisfaction survey – CHU de Charleroi

The following template can be used as example and be adapted accordingly the specificities of each radiotherapy department.

"Dear Patient,

To help us improve our quality of service, please take a few minutes to complete this questionnaire. We would like to know how you feel about the health care you received during your radiotherapy treatment. Your feedback is very important to us so that we can continue to improve the quality of service to our patients. All responses are anonymous. We thank you in advance for completing this questionnaire. When you have finished please drop the questionnaire in the "Satisfaction Survey" box located near the secretary's office.

General information:

Sex: Female - Male

Age: __ years

Were you hospitalized during your treatment: YES - NO

Date: __/__/__

Access to the hospital and the radiotherapy department:

From which hospital did you come?

- ...
- ...
- ...
-

By what means of transport did you come to the hospital?

- by car
- By public transport
- By ambulance

- By a transport organized by your medical insurance company
- Other (*please specify*).....

Is the access to the hospital easy?

YES - NO

Did you easily find your way to the radiotherapy department?

YES - NO

Why did you choose to have your treatment here?

- The hospital is close to your home
- The hospital has a good reputation
- The hospital is easily accessible
- It was recommended to you

.....

Regarding the questions below, you could say that you are:

😊 : Very satisfied

😊: Satisfied

😞 : Not very satisfied

😞😞 : Dissatisfied

NC: Not concerned (perhaps replaced by “Neutral”)

Reception

The reception staff is friendly 😊😞😞😞😞NC

The reception staff answered your questions 😊😞😞😞😞NC

The reception staff gave you clear and precise explanations 😊😞😞😞😞NC

Did you receive an information booklet? YES - NO

First contact consultation with your doctor

Your appointment time was respected YES - NO

You received information about your health 😊😞😞😞😞NC

You received information about the proposed treatment and the side-effects ☺☹☹☹☹NC

The doctor answered your questions clearly and accurately ☺☹☹☹☹NC

The simulation (s)	
The timing for your appointment was respected	YES - NO
You received information concerning the proceedings of simulation	☺☹☹☹☹ NC
The staff was friendly	☺☹☹☹☹NC
You received clear and precise answers to your questions	☺☹☹☹☹NC
Were you informed about the number of treatment sessions/fractions you will have?	YES –NO
You have been advised on how to deal with possible side effects?	☺☹☹☹☹NC
Your feedback/input was taken into account for the scheduling of the radiation sessions	☺☹☹☹☹NC
Your privacy was respected	☺☹☹☹☹NC

A radiology scanner	
The department was easily found	☺☹☹☹☹NC
Your appointment time was respected	YES - NO
You received information concerning the conduct of the examination	☺☹☹☹☹NC
The nurses and radiotherapist doctor were present	YES – NO
Your privacy was respected	☺☹☹☹☹NC

The treatment	
How many days have elapsed between the first consultation and the first day of treatment?	__ days
Generally, appointment times were respected	☺☹☹☹☹ NC
The nursing staff was friendly	☺☹☹☹☹ NC
You received information about your treatment sessions/fractions	☺☹☹☹☹ NC
Your privacy was respected	☺☹☹☹☹ NC
You received advice for dealing with side effects.	☺☹☹☹☹ NC
You have regularly seen your doctor (radiation oncologist)	☺☹☹☹☹ NC
Comfort of the waiting room (TV, cleanliness/neatness, toilets...)	☺☹☹☹☹ NC
If you were hospitalized, quality of the transport system/department	☺☹☹☹☹ NC

End of treatment	
On your last day of treatment did you see a radiation oncologist (doctor)?	YES - NO
You received advise for dealing with side effects	☺☹☹☹☹ NC
You received an appointment for a follow-up visit	☺☹☹☹☹ NC

Other	
Did you use a transportation service? Which one?	YES – NO
-If so, which one? Transport from your insurance – ambulance – other:	
The appointments/schedule were/was respected	☺☹☹☹☹ NC
Quality of care by staff (friendliness, courtesy...)	☺☹☹☹☹ NC
Did you contact other services?	YES – NO

-If so, which one? Psychologist – social worker – dietician – other:.....	
Overall quality of care	☺☹☹☹☹ NC
You have received the help you needed	☺☹☹☹☹ NC

Overall satisfaction regarding your care in our radiotherapy department	☺☹☹☹☹ NC
Would you recommend our service to a family member or friend?	YES - NO

Do you have any suggestions/comment to add:

1 General Definitions

1.1 Audit

An audit is a methodical, independent and documented process, to verify conformance to standards and to evaluate them objectively to determine the extent to which the audit criteria are fulfilled (73).

An audit is performed by a person (or more than one person) who is (are) skilled in audit methodology, allowing for the evaluation of the organisation's status and operational methods and this according to its quality policies.

1.1.1 Types of audits:

Various types of audits exist, distinguished by:

- **Its goal**
 - Improvement: audit that focalises on a department/ branch of a company that is unable to meet its objectives. His aim is to encourage the company to improve his practices
 - Control: It verifies if the company's regulations are respected.
 - Certification/ accreditation: it evaluates if an organisation is qualified to obtain to the certification/accreditation requested. This type of audit is conducted by a certification/accreditation or standardisation body.
 - Peer review: is performed by individuals within the same field of work, who evaluate in a constructive manner, the activities of their colleagues (their « peers »). These audits can be conducted on specific activities of the group being audited and/or on a more global level.
- **The auditors**
 - Internal: Sometimes called « first party audit ». It is an audit conducted by the organisation itself, or on its behalf, for internal purposes. It can be the basis for organisation's self-declaration of conformity. It can be operational or strategic depending on its approach.
 - Interdepartmental: that allows for the better understanding of the role of each individual and allows for the improvement of team work. It is conducted by employees from other departments within the same company.
 - Internal cross
 - : is an internal audit conducted by another company that is external to the audited company. This system allows for both companies to have an unbiased

objectives and constructive exchanges. It allows for quality management issues to be seen from a new perspective (74)

- External: also referred to as « second or third party audits». Second party audits are conducted by parties such as shareholders or customers, having an interest in the organisation or by other persons on their behalf. Third party audits are conducted by independent auditing organisations (usually certified) that evaluate the organisation's conformity to the standard/requirements.
- **Its organisation**
 - Planned: it is announced and planned by the company to be audited
 - Unplanned: is not announced. It is either conducted by professionals or by the managers of the company.

2 Theoretical framework

2.1 General principles of an audit

The general principles that apply to an audit are the following (73) (74)

- The audit is performed in an objective, independent and systematic manner;
- The audit is a management tool in which the results obtained allow the company to identify areas of improvements;
- The audit is authorised by the company's management according to its quality policies, legislation or other;
- The planning and efficient conduct of an audit give rise to conclusions that are reliable and credible ;
- The methodology and organisation of the audit allow it to have significant and reproducible results;
- The scope, the objectives and the criteria of the audit must be defined and approved prior to the audit;
- The person carrying out audit needs to have technical skills and proper competencies

The principles applicable to the AUDITORS are the following (11):

- Professional integrity: The basis of professionalism, required to encourage confidentiality and discretion;
- Impartiality: The audit's findings and conclusions as well as the audit report need to reflect the audit's activities in a truthful and accurate manner;
- Professionalism: The auditors should act in accordance with the importance of the tasks they perform and the trust placed in them by the clients;
- Independence: The auditors are independent from the activity being audited; they are neither biased nor have any conflicts of interest. The auditors

are impartial to ensure that the observations and conclusions are based on audit evidence;

- Evidence based approach: Audit evidences are verifiable, based on sample data that are available. Trust is linked to the appropriate use of the sampling.

2.2 Objectives of an audit

The objectives are determined according to the (73):

- Management priorities (including, amongst others, quality management);
- Background experience of the company;
- Management system requirements;
- Legal requirements
- Potential for improvement areas.

Objectives of an internal audit

- Identify potential areas of improvement in the processes and in the departments;
- Identify dysfunctions in the quality management system;
- Assess the level of satisfaction according to the quality management system requirements;
- Verify the attainment of levels of achievement planned;
- Ensure that the audit does not become a control tool, which could hinder any collaboration during future audits.

Objectives of an external audit

- Verify the conformity according to reference documents provided, regulations, etc...;
- Assess the performance of the quality management system;
- These audits can either lead to “certifications”, “accreditations” or recommendations.

2.3 Audit criteria

Audit criteria are elements that will be verified during an audit in order to determine if the process complies with the standards followed by the auditee. For a quality audit, the criteria can generally take two forms; the first type of criterion is based on patient requirements (explicit or implicit), the second type is based on existing or applicable regulations. The

auditor needs to have these criteria in order to compare and establish whether or not they are being implemented (11).

2.4 Audit evidence

When the auditor finishes auditing the perimeter that he has been asked to audit, he/she will record some deviations (known as “observations” in ISO 19011), which will be acknowledged to be accurate by the persons being audited. These recordings, statements of facts are audit evidences, which need to be verifiable. The auditor will then present the audit report with the conclusions of the audit to the department, during the exit briefing (11).

3 Practical modalities

3.1 Management of audits

In an institution, internal and external audits can be planned at regular intervals to determine if the [quality] management system is (11) (75):

- Compliant to the planned dispositions, standard institutional and QMS requirements;
- Implemented and maintained in an effective manner;
- These audits are organised by the department or according to the organisation, by the institution, based on the results of the previous audits, to verify the implementation of actions put in place following the previous audit;
 - An audit program is preferably made prior to its conduct;
 - The auditors are chosen as needed;
 - The area/activity to be audited is defined for every audit programme;
 - The criteria, the field, the rate of recurrence and the methods used for the audit must be defined;
 - The choice of the auditors and the conduct of the audit must ensure the objectivity and impartiality of the audit process;
 - The auditors should not audit their own work - for an internal audit, a person outside the department is needed to conduct the audit;
 - A documented procedure should be established to define the responsibilities and the requirements needed to plan and conduct the audits, to establish the recordings and to report the outcome;
 - The recordings of the audits and their results must be conserved.

Since 2010, external QUATRO audits are conducted and organised by the Belgian college of radiotherapy. In this framework, 5 radiotherapy departments are audited every year. As a

result, all of the departments have been audited as of end of 2015. In fact, these QUATRO audits are peer audits whereby the auditors are made up of a radiation oncologist, a medical physicist and a RTT. These audits lead to recommendations and not to a certification. The audited departments will take into account the recommendations in order to improve their practices and optimise the quality and safety of the treatments.

Starting from 2017, it is planned to include a Quality Manager (QM) in the team of auditors of the Belgian College of radiotherapy. The role of the QM auditor will be to supplement the QUATRO audits with the QMRT checklist focusing on the structure of the QMS itself.

3.2 Audit process

To conduct an audit, it is preferable to follow the six following steps (11) (6):

1- Initiating the audit: following an audit request, an audit program is defined before the audit is launched. The area/activity to be audited is determined, the auditors are chosen and the audit criteria are defined.

2- Document review: All the reference and necessary documents are reviewed. The necessary checklists are prepared.

3- On-site audit preparation: A proposal of an audit plan is made based on the topics to be audited, the people to be interviewed and their availabilities. In the presence of multiple auditors, a pre-meeting is organised to define the objectives of the audit, the methodology to follow and to ensure optimal coordination

4- On-site conduct of the audit: An entrance briefing is organised at the beginning of the audit to inform the auditee of the audit modalities. The audit is then carried out over a pre-selected period of time and ends with a review meeting and exit briefing ([see point 3](#)).

5- Audit report: The audit report is written either the same day or a few days later but must include all the points discussed during the exit briefing

6- Completion of the audit: The audit report is distributed and improvement action are proposed

3.3 On-site conduct of an audit (external - internal)

3.3.1 Entrance briefing

The entrance briefing allows for the participants (the auditors, the auditees as defined in the audit plan) to introduce themselves and define their role within the framework of the audit. The objective of the audit is pointed out; the audit plan is confirmed or modified according

to the organisation of the audited department. It is during this meeting that it is advisable to underline the goal of the audit. It is necessary to insist on the fact that the audit does not give rise to judgements but is a tool that allows for the department to progress, improve and accomplish one's job under the best possible conditions.

The entrance briefing is often followed by a visit of the department/organization in order for the auditor's to become familiar with the environment and the various installations.

3.3.2 Audit

The audit is carried out in the department and on-site. The audit in the department allows for the auditors to examine existing documents and to evaluate peoples' practices. The on-site audit in the radiotherapy department is a technical and clinical audit carried out by the various professionals in RT. It is necessary to organise discussions with people of different levels and functions. The list of staff members needing to be met and questioned is defined in the audit plan. But once the audit has begun the auditor can question other staff members depending on the questions he/she has or depending on his/her observations. For example, he/she can also meet the recently employed personnel, the trainees and/or other personnel.

The principle of the audit is to collect tangible data and/or evidence of functional or dysfunctional processes in the system. This evidence can be:

- Consulted documents;
- Outcomes of the interviews with the individuals/employees;
- The observations of the practices and situations;

The comparison between the audit's collected data and the audit's criteria allows for the auditors to establish the audit's observations.

3.3.3 Review meeting

The review meeting allows the auditor's team to prepare a report on the observed deviations prior to presentation at the exit briefing. During this meeting, the auditors may invite the individuals responsible for each professional group (head of staff) to ensure that there exists a good understanding of the observed deviations prior to presenting the conclusion work to the department/institution.

3.3.4 Exit briefing

This meeting takes place in the presence of the head of department (radiation oncologist), the team leaders (physicist, RTT/nurse), the Quality manager (QM), and all of the available staff members from the audited department. If possible the management staff of the institution is also invited.

During this meeting, the auditor will start by presenting the strong points of the department. The auditor will make sure to inform the participants as to the observations that were made during the audit and will ensure that these are well understood - this, in order to facilitate the implementation of the corrective actions. Subsequently, the areas of improvement/recommendations will be presented and discussed.

3.3.5 The audit report

The audit report includes the various points observed and the conclusions of the auditor.

3.3.6 Distribution of the audit report:

The report is communicated to the head of department, team leaders and the QM. The QM, in agreement with the head of the department, can then proceed with the distribution of the report, internally or externally to the department (for example, to the different managements of the institution, members of the department...).

3.3.7 Follow-up:

During the follow-up, an action plan- composed of corrective actions - is developed addressing the areas of improvement pointed out by the audit. Their effectiveness is followed up and evaluated (76). And in some cases, a re-audit might be recommended.

4 Templates

4.1 Example of an audit report (EpiCURA)

Template of an audit report with the main points needing to be included in the report (courtesy of EpiCURA, Mons)

- | |
|--|
| <ol style="list-style-type: none"><u>1. GENERALITIES</u><u>2. AUDITORS</u><u>3. AUDITEE (S)</u><u>4. AUDITEED DEPARTMENT</u><u>5. DATE OF THE REPORT</u><u>6. OBJECTIVES AND AREA OF APPLICATION OF THE AUDIT</u><u>7. DOCUMENTATION USED AND CHECKED</u> |
|--|

8. IMPARTIALITY

The auditor examines the situations without judging the persons on their skills. He bases himself on facts. His aim is to highlight any deviations, to understand them and to allow the department that is audited to improve itself.

9. DATE OF AUDIT

10. AUDIT PLAN

Day 1

Hour1: Meeting with the Department Director

Hour2: Official opening meeting for the audit (as many people as possible from the department should attend) which will take place in the meeting room of the department. During the meeting, we will have given the audit schedule and specified the persons who will be interviewed and in which order.

Day 2

Hour1: Continuation and end of the audit

Hour 2: Closing meeting

11. DESCRIPTION OF INSTALLATIONS

12. CONTENT OF REPORT

a. Strong points

Radiations therapy staff

RTT/Nurses :

Physicist staff

Secretariat staff

b. Areas for improvement

c. Action proposal

13. SUMMARY AND CONCLUSION OF THE AUDIT

4.2 Example of an audit checklist used to audit a radiotherapy department

Here below is a audit check list (Check it Out) used to verify various point of a radiotherapy department (courtesy of AZ Turnhout)

Check it Out: Radiotherapie		29-01-2016		
Ingevoerd door	xxxxxx (ONCOLOGIE RT)			
Datum verstuurd	xx-xx-xxxx			
Organisatie eenheid	Radiotherapie			
<hr/>				
Indien u problemen ondervindt bij het uitvoeren van de Check it Out, mag u steeds contact opnemen met XXXX (xxxx). Om te voorkomen dat steeds dezelfde medewerkers de Check it Out uitvoeren, willen wij vragen aan de hoofdverpleegkundige om een lijst bij te houden wie de Check it Out reeds heeft uitgevoerd op zijn/ haar afdeling.				
DEEL 1: BEVRAGING MEDEWERKERS				
1. Elke medewerker van de afdeling draagt zijn badge zichtbaar, op ooghoogte met volledige weergave van voor- en achternaam.				
		Ja	Nee	Opmerkingen
★	Medewerker 1			
★	Medewerker 2			
★	Medewerker 3			
★	Medewerker 4			
★	Medewerker 5			
★ Is iedereen 100 % in orde voor medewerkersidentificatie?				
Pagina 1				



2. Alle aanwezige zorgverleners die men tijdens de Check it Out heeft gezien, houden zich aan de voorgeschreven hygiëneregels.

	Ja	Nee	Opmerkingen
★ De juwelen (ringen, armbanden, polshorloge,...) zijn afgedaan.			
★ De nagels zijn in orde (schoon, kort, geen kunstnagels of nagellak).			
★ De dienstkledij wordt op de voorgeschreven manier gedragen (korte of 3/4de mouwen, geen vest over de kledij).			

★ 3. Staat op het moment van het uitvoeren van de Check it Out C2M, C-eHealth portal, Q-doc of I-plan open zonder een bevoegd persoon achter de computer?

Opmerkingen

★ 4. Werd de controlelijst van de reanimatiekoffer de voorbije maand gecontroleerd?

Opmerkingen

★ 5. Controleer of de houdbaarheidsdatum van alle aangebroken ontsmettingsstoffen nog niet verstreken is. Zijn er vervallen ontsmettingsstoffen terug te vinden?

Opmerkingen

6. Volgende vragen dienen aan de medewerker gesteld te worden:

		Ja	Nee	NVT	Opmerkingen
★	De medewerker heeft in Infoland nog documenten staan die een leesbevestiging vragen.				
★	De medewerker kan in Infoland de noodprocedure terugvinden.				
★	De medewerker weet de noodstop van het simulatietoestel staan.				
★	De medewerker weet de noodstop van de bestralingstoestellen staan.				

Pagina 3

		Ja	Nee	NVT	Opmerkingen
★	De medewerker weet met welke producten de hulpstukken mogen gereinigd worden.				
★	De medewerker vindt het resultaat van de labo-uitslagen (bv. wissers, bloedwaarden en nierfunctie) terug in C-eHealth portal.				
★	De medewerker kent het REA-nummer.				
★	De medewerker kent het brandnummer.				
★	De medewerker kent de verschillende stappen van de BLS-reanimatie.				
★	De medewerker kan 4 rechten van de patiënt opsommen.				

Rechten van de patiënt:

1. Ontvangen van een kwaliteitsvolle dienstverstreking. 2. Vrij kiezen van de beroepsbeoefenaar. 3. Geïnformeerd worden over zijn gezondheidstoestand. 4. Vrij toestemmen in een tussenkomst, met voorafgaande informatie. 5. Over een zorgvuldig bijgehouden patiëntendossier beschikken, met mogelijkheid tot inzage en afschrift. 6. Verzekerd zijn van de bescherming van zijn persoonlijke levenssfeer. 7. Neerleggen van een klacht bij een ombudsdienst. De brochure over patiëntenrechten kan men hier terugvinden.

Pagina 4

		Ja	Nee	Opmerkingen
★	De medewerker weet wat voor hem/ haar de stralingsbron is.			
★	De medewerker weet wat ALARA betekent.			
★	De zorgverlener draagt de dosimeter op de correcte manier.			
★	De zorgverlener weet de richtlijnen bij zwangerschap.			

Bedankt voor uw deelname!

Vragen, opmerkingen, suggesties, interpretatieproblemen,... bij het uitvoeren van de Check it Out? Noteer ze hier. ! Vergiet niet op de knop 'Verzenden' te klikken om de ingevulde vragenlijst door te sturen.

Pagina 2

DEEL 2: AFDELINGSSPECIFIEKE VRAGEN

7. De medewerker controleert op de correcte manier de identiteit van de patiënt nl. 'Kan u uw naam en geboortedatum even zeggen?'.

		Ja	Nee	NVT	Opmerkingen
★	Medewerker 1				
★	Medewerker 2				
★	Medewerker 3				
★	Medewerker 4				

8. Volgende vragen dienen aan de medewerker gesteld te worden:

		Ja	Nee	Opmerkingen
★	De medewerker kent de vluchtwegen en locatie van branddekens, brandblussers,....			
★	De plaats van het reanimatiemateriaal is gekend.			
★	De naaldcontainers zitten te vol (> 75%).			
★	De vuilnisbakken zitten te vol.			
★	Er zit nog voldoende handalcoholgel in de flacons (op voldoende locaties).			

Pagina 1

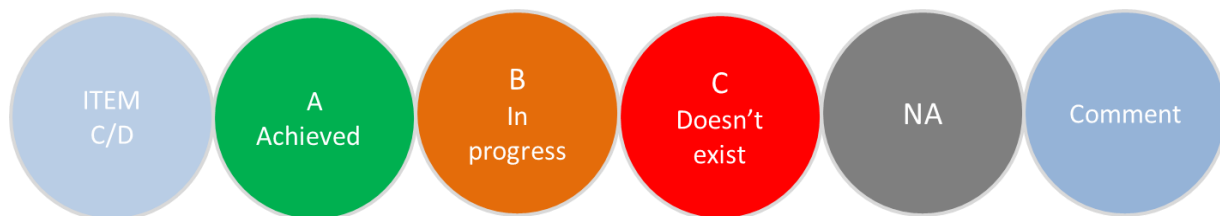
QMRT check list



The checklists are tools that are designed to structure the work of auditors but also to help departments to know what is desired in a standardized quality management system. It is also a tool for the quality manager to best prepare this audit.

In this manual, we have developed a checklist based on what is described in our guide of 14 chapters. Each check-list is composed by 5 to 18 questions per chapter.

The checklist is developed to help auditors/ auditee to quickly assess if the different evaluated items are completed or not and is presented in this way:



The items are firstly classified as either by C = Compulsory/required or D: non-compulsory (Desired). Indeed, in a quality management system, some elements are required, either by the law or according to different standards followed by the radiotherapy department, or by the institution.

The other 4 columns are used to classify the proposals according to the progression of the quality management in the various projects.

The assessment will be **A** if a project has been **completed**, **B** if the project is **underway**, **C** if the project is **not programmed** which will then enable the department to quickly evaluate its progress and review its goals to improve the Quality Management System. As some proposals are not relevant to all departments, a "Not Applicable" category was also created.

Comments can also be added to give more information concerning the evaluated items or to emit recommendations.

The possibility of integrating this checklist within a modified QUATRO checklist – taking into account Belgian radiotherapy specificities - is currently being discussed. The combination of both checklists will then become known as B-QUATRO

Checklists

Items	C/D	Evaluation				Comments
		A= Achieved	B= In progress	C= Doesn't exist	N/A	
Is a QMS implemented in the department?	C					
Is the QM included in the department's organizational chart?	C					
Are the responsibilities and missions of the QM defined?	C					
Are the QMS' processes and interactions identified?	C					
Is there an existing document management system?	C					
Are the legal requirements and regulations applied?	D					
Is quality management system planning Implemented to maintain the integrity of the quality management system (audits, document/procedure review, projects...)?	D					
Are changes within the department (TPS, change in TPS/treatment units...) properly planned and documented?	C					
Are the necessary resources required for QMS implementation, maintenance and continuous improvement available?	D					
Are the corrective and preventive actions monitored and follow-up?	C					
Are analyses of the results periodically performed (audits, customer satisfaction, indicators ...)?	D					
Are specific meeting set up to analyze the results over time and define the actions and objectives of the following period?	D					
Are the results and the actions taken reported in the department	C					
Are tools applied for the implementation of continuous improvement (Kaizen, 5M, lean ...)?	D					
Does a risk management system exist in the department?	C					

Additional comments

Document management system						
Items	C/D	Evaluation				Comments
		A= Achieved	B= In progress	C= Doesn't exist	N/A	
Is there an existing document management system (departmental level or hospital level)?	C					
Is there an existing procedure concerning document management?	D					
Does it insure that documents are approved for prior its distribution?	D					
Does it describe the renewal/update process for distributed documents?	D					
Are changes and current revision statuses of documents identified?	D					
Are relevant versions of the applicable documents available at points of use?	D					!! Coherence between existing procedure and what is done at the points of use (are the procedures up to date?)
Are documents legible and readily identifiable?	D					
Are documents of external origin identified and controlled?	D					
Are the different types of documents easily identifiable?	D					
Are there department specific document models?	D					
On the approved documents						

Is it possible to identify the person involved in the verification and/or approval of the document?	C					
Is it possible to identify the reference number, the version and the date of approval?	C					
Are the documents regularly updated/revised?	C					
Is there an existing system to disseminate the documents?	D					
Is there an existing archiving system for outdated documents?	D					
Are outdated documents inaccessible?	D					! Verify the coherence between the versions existing in the document management system and those existing at the points of use
Is it possible to track the different versions of a document?	D					
Additional comments						

Quality manual		Evaluation				Comments
Items	C/D	A= Achieved	B= In progress	C= Doesn't exist	N/A	
Is there a quality manual?	D					
Is the scope of the quality manual properly defined?	D					
Is the quality manual periodically revised?	D					
Is the quality manual readily available and approved?	D					
Is the quality manual properly structured?	D					

Does the quality Manuel represent /reflect the actual practices?	D					
Additional comments						

Quality Policy		Evaluation				Comments
Items	C/D	A= Achieved	B= In progress	C= Doesn't exist	N/A	
Is there a quality policy in the department?	D					
Is the quality policy broadcasted to and known by the department?	D					Is the Quality Policy "followed" in the department?
Does the quality policy include the department's objectives?	D					
Is the Quality Policy included in the quality Manuel?	D					
Is the quality policy approved/validated by the head of department?	D					
Is the quality policy made accessible to the patients? (visible)	D					
Is the quality policy updated?	D					Is the Quality Policy respected the documents management rules?
Additional comments						

Quality Indicators						
Items	C/D	Evaluation				Comments
		A= Achieved	B= In progress	C= Doesn't exist	N/A	
Are there defined QI in the department?	C					Which ones?
Are the QI evaluated/measured?	C					
Are the defined QI in accordance with the quality policy?	D					
Are the QI SMART?	D					
Are the QI periodically reviewed?	D					
Are improvement actions put into place after QI analysis?	D					
Are the QI measures communicated?	D					
Are the QI measures conserved?	D					
Additional comments						

Process management						
Items	C/D	Evaluation				Comments
		A= Achieved	B= In progress	C= Doesn't exist	N/A	
Are the treatment processes clearly defined?	C					
Are the sub processes logically defined?	D					
Are the processes approved and readily available?	C					
Is the involved personnel clearly identified at each sub process?	D					
Are the processes linked to the department's procedures?	D					
Additional comments						

Organisational chart						
Items	C/D	Evaluation				Comments
		A= Achieved	B= In progress	C= Doesn't exist	N/A	
Is there a defined organisational chart defined (in the department)?	D					
Does the organizational chart clearly represent the actual status of the department's organisation?	D					
Is the connection between the RT QM and the rest of institution clear?	D					
Is the QM included in the department's organizational chart?	D					
Is the organisational chart clear enough?	D					
Additional comments						

Tasks and responsibilities						
Items	C/D	Evaluation				Comments
		A= Achieved	B= In progress	C= Doesn't exist	N/A	
Are the job descriptions of the radiation oncologist clearly defined?	C					
Are the job descriptions of the medical physicists clearly defined?	C					
Are the job descriptions of the nurses/RTT clearly defined?	C					
Are the job descriptions of the quality manager clearly defined?	C					
Are the job descriptions of the administrative department clearly defined?	C					
Are the job descriptions of the logistics personnel clearly defined (technical support, engineers,...)?	C					

Are the job descriptions of the supportive personnel clearly defined (nurse specialists, psychologists, social worker, dieticians...)?	C				
In the RT process					
Are the radiation oncologist's tasks clearly defined?	D				
Are the medical physics' tasks clearly defined?	D				
Are the RTT's tasks clearly defined?	D				
Are the technical-engineer's tasks clearly defined?	D				
Are the administrative personnel's tasks clearly defined?	D				
Are the logistic personnel's tasks clearly defined?	D				
Additional comments					

Resource management						
Items	C/ D	Evaluation				Comments
		A= Achieved	B= In progress	C= Does n't exist	N/A	
Training plan						
Is there an existing formalized training plan for new recruits?	D					
Is there an existing formalized training plan for interns?	D					
Is internal training organized?	D					Is the personnel trained in the principles underlying QMS?
Is external training organized?	D					
Are the personnel's competencies monitored?	D					
Is the defined in a plan/evaluation system?	D					
Is a list of equipment established?	D					
Does this list coincide with the needs of the department?	D					
Is there a specific person appointed to coordinate formalized internal training?	D					
Is external training funded by the department/by the hospital?	D					
Are minimal numbers of staff for external training/ meetings defined?	D					

Additional comments	

Communication						
Items	C/D	Evaluation				Comments
		A= Achieved	B= In progress	C= Doesn't exist	N/A	
Are meetings organized in the department?	D					Specify de types of meetings Does the department easily communicate with other departments inside the hospital?
Is an agenda proposed for all meeting?	D					Does the department easily communicate with other hospitals?
Are minutes generated after meetings?	D					Does the department easily communicate with outside companies/suppliers?
Are the meetings' agenda and minutes archived?	D					Does management communicate in an optimal matter with the department's personnel?
Are communication tools implemented into the department?	D					Do the different disciplines communicate with each other in an optimal matter?
Are improvement actions communicated?	D					
Are department's memos communicated?	D					
Are significant incidents communicated to the department?						
Are significant incidents communicated to the management of the hospital??						
Are significant incidents communicated to authorities?	D					

Is there an existing dashboard?	D					
Additional comments						

Risk management						
Items	C/D	Evaluation				Comments
		A= Achieved	B= In progress	C= Doesn't exist	N/A	
Does a risk management system exist in the department?	C					
Is there an existing event reporting and analysis system?	C					
Is it easily accessible?	D					
Is proactive risk analysis carried out?	D					
Is the department's event report and analysis system integrated into the hospital's system?	D					
Are the improvement actions carried out on the basis of event reporting and analysis?	C					
Are the improvement actions from this system stocked with others actions?	C					
Are there regular meetings held for event analysis and determination of improvement actions?	D					
Is this a multi-disciplinary team?	D					
Is feedback given to the reporter of the event?	D					
Is feedback given to the RT team (feedback on event declaration, dashboard, use of newsletter,...)	D					
Are there regular safety training sessions organized?	D					
Is the PRISMA methodology used for event analysis?	C					
Are context variables used?	D					
Does the department participate in the benchmark database?	D					
Additional comments						

Breakdown management						
Items	C/D	Evaluation				Comments
		A= Achieved	B= In progress	C= Doesn't exist	N/A	
Is there an existing breakdown managing system (incl loss of treatment time, types of fault/errors...)?	D					
Is an analysis of existing data regularly carried out?	D					
Are corrective and preventive actions defined in accordance with breakdown data analysis?	D					
Is there a defined procedure for patient workflow in case of breakdowns?	D					
Are specific QI put into place?	D					
Additional comments						

Patient satisfaction						
Items	C/D	Evaluation				Comments
		A= Achieved	B= In progress	C= Doesn't exist	N/A	
Is patient satisfaction considered in the department?	D					
Are statistical analyses of patient satisfaction carried out?	D					
Are patient satisfaction surveys distributed to the patients	D					Is the duration of patient survey distribution limited?
Are statistical analysis carried out on the data?	D					

Are these results of the analysis communicated?	D					
Do improvement actions originate for the results of the patient satisfaction surveys?	D					
Additional comments						

Audits						
Items	C/D	Evaluation				Comments
		A= Achieved	B= In progress	C= Doesn't exist	N/A	
Are internal audits carried out in the department?	D					
Are internal audits planned?	D					
Are there existing internal audit procedures?	D					
Are external audits carried out in the department?	D					
Are external audits planned?	D					
Are there existing external audit procedures?	D					
Is the QM involved in the internal audits?	D					
Is the QM involved in the external audits?	D					
Are the recommendations following the audits stocked and managed?	D					
Are the results of the audits conserved?	D					
Do improvement actions originate from the results of the audits?	D					
Additional comments						

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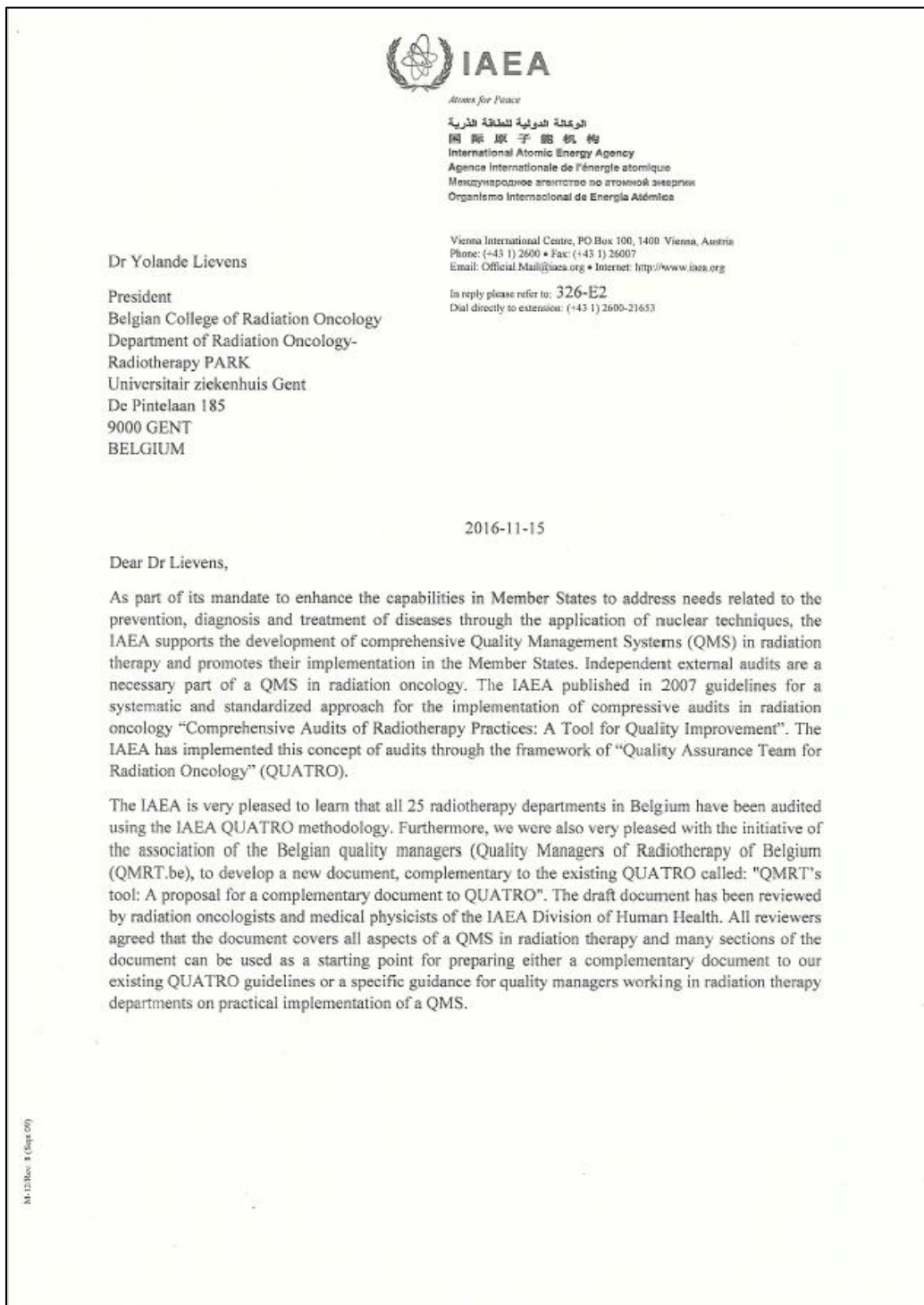
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Appendix

1 IAEA Letter of support



Page 2

I am writing to express support of the IAEA for your document "QMRT's tool: A proposal for a complementary document to QUATRO" and trust that you, or one of your colleagues, will join our drafting committee for the review of IAEA QUATRO guidelines in 2017.

Yours sincerely,

A handwritten signature in blue ink, consisting of a capital letter 'A' followed by a stylized, cursive flourish.

Ahmed Meghzi
Section Head
Dosimetry and Medical Radiation Physics Section
Division of Human Health
Department of Nuclear Sciences and Applications