AUTORITÉ DE SÛRETÉ NUCLÉAIRE

ASN GUIDE N°4
MEDICAL

Guide to risk self-assessment in external beam radiotherapy

Version number: 0 • Version date: 15/01/2009

Foreword

This guide to the self-assessment of radiotherapy risks results from the joint work conducted by the ASN's Nantes Division and by radiotherapy professionals in Brittany and the "Pays de la Loire" region, with the backing of the French Society of Radiation Oncology (SFRO - Société Française de Radiothérapie Oncologique) and the French Society of Medical Physics (SFPM - Société Française de Physique Médicale).

It comprises:

1. a set of instructions aimed at radiotherapy centres, which should be read before completing the "Failure Mode, Effects and Criticality Analysis" (FMECA) table
2. a "Failure Mode, Effects and Criticality Analysis" table, to be completed by each radiotherapy centre
3. the report issued by the task force led by the ASN's Nantes Division, explaining the methodology used to establish this guide.

The Nuclear Safety Authority (ASN) has developed this self-assessment guide to complement the "Radiotherapy Safety and Quality Management" guide. Its purpose is above all educational. It is designed to evolve and grow with the input and contributions of radiotherapy centres. Although it is voluntary, its objective is to encourage radiotherapy centres to formalise the assessment of risks incurred by patients during radiation therapy. However, radiotherapy centres are free to choose another means of assessing these risks. It should be pointed out that risk assessment is one of the requirements set forth in technical decision no. 2008-DC-0103 of 1st July, 2008 (article 8), which the ASN submitted to the Minister of Health, Youth Affairs, Sport and Associations in order to develop the culture of safety within radiotherapy services. This requirement is also specified in the above-mentioned "Radiotherapy Safety and Quality Management" guide (point 4.1.A).

The report issued by the multidisciplinary task force under the leadership of the ASN's Nantes Division is annexed to this document, to give readers an insight into the context of the work conducted, the methodology employed and the results achieved in educative terms.

As indicated in the attached report, the task force decided to use "Failure Mode, Effects and Criticality Analysis" (FMECA) because it is easy to implement and allows actions to be prioritised according to the criticality of each risk. Although it is difficult to address the multi-causality of potential failures with this method, and its implementation was not preceded by and based on a functional analysis of the care process, it has nevertheless resulted in an initial list of potential failures, which should be updated in the future.

The failures referred to in this document include only the anomalies that may occur during the planning and implementation of a radiotherapy programme. Neither the expected adverse effects resulting from a concerted strategy implemented by the medical practitioner and the patient, nor the unexpected

effects arising from individual radiosensitivity or from unforeseeable changes in the patient's condition, are taken into consideration.

The success of this self-assessment relies in particular on the participation of the entire radiotherapy team. Therefore, a multidisciplinary group must be set up within each radiotherapy centre to identify all the failures likely to be generated by each phase of the clinical process (from treatment to post-treatment follow-up), and to propose measures to improve the safety of patients during treatment. This action is fully in line with the risk management and continuous quality improvement procedures implemented in radiotherapy. In order to optimise the work done in this area, the multidisciplinary group should be composed of the same people as the task force set up to analyse internal malfunction or adverse event reports (as per article 11 of technical decision no. 2008-DC-0103, dated 1st July 2008, and requirement 5.2.A in the Radiotherapy Safety and Quality Management guide).

The self-assessment procedure should enable each centre to draw up a personalised map of radiotherapy risks and to prioritise the measures needed to improve treatment safety. Some of these actions may already have been identified during discussions held within individual radiotherapy centres as part of the procedure - overseen by the MeaH[1] - to conduct a safety audit and to establish an "experience feedback committee in radiotherapy" (CREX), with a view to implementing corrective measures. These actions must be constantly improved and enhanced in line with the development of the risk management culture in radiotherapy centres, with the additional aim of identifying solutions for detecting failures and/or mitigating their effects as soon as they occur.

The use of this assessment tool by all medical staff (radiation therapists, radiation physicists, dosimetrists, operators, technicians, secretaries, etc.) should fuel discussions on how to improve radiotherapy safety and thus increase patient confidence in this method of treatment.

This guide is designed to evolve over time in response to the extent and outcome of its implementation nationwide, and to feedback on reports of actual or potential malfunction. It must also be updated according to ongoing international research, which may provide new insights towards the end of 2010. Nevertheless, the ASN is likely to amend the guide substantially in the months following its publication. Therefore, it is recommended that this first version be published electronically, in order to facilitate the revision process.

This document is available for viewing on the ASN's website - http://www.asn.fr - where the latest version can be downloaded.

❋ ❋ ❋

[1] The actions taken by the French National Hospital Expertise and Audit Agency (Mission nationale d'expertise et d'audit Hospitalier - MeaH) in regard to radiotherapy are described on its website: http://www.meah.sante.gouv.fr, under "radiotherapy."

Contents

Instructions for use

Firstly, the "Failure Mode, Effects and Criticality Analysis" table in this document provides examples of potential failures, which may be used by radiotherapy centres. Over sixty possible failures were identified by the task force and have been organised into 3 main categories, each of which has been further broken down into several sub-headings:

1. **Patient Itinerary (PI)**
2. **Installations and Equipment (E)**
3. **Human and Organisational Factors (HOF)**

Hence, after setting up a multidisciplinary group[2], the next step for each radiotherapy centre is to accept or reject the potential failures listed in the above-mentioned table and to explain any rejection decision (on the grounds of its specific organisational characteristics).
It is possible that a radiotherapy centre will identify one or more additional potential failures, as the list provided in the table is not exhaustive. In this case, the centre must establish which category and sub-heading the potential failure belongs to, identify possible causes and effects, and determine its severity level and frequency of occurrence in order to assign a criticality score to the associated risk(s). To do this, it is recommended that the centre use the tables below, which are taken from the report annexed to this document. This will ensure that the same scoring criteria are used, and hence that the document remains consistent throughout.

Determining the severity of a failure		
Level	**Criterion**	**Severity score (S)**
Not very critical	Temporary discomfort, malaise, unpleasantness	1
Critical	Prolonged discomfort Reversible damage or impairment Medical treatment required Temporary handicap	2
Very critical	Delayed consequences, but marked for the patient Irreversible damage or impairment Permanent handicap Not life threatening	3
Serious	Short-term fatal outcome for the patient Life threatening	4

2 As indicated in the foreword, it is recommended that this group be composed of the same people as the task force set up to analyse internal malfunction or adverse event reports (as per requirement 5.2.A in the Radiotherapy Safety and Quality Management guide, and article 11 of ASN decision no. 2008-DC-0103, dated 1st July 2008).

Determining the frequency of a failure		
Level	**Criterion**	**Frequency score (F)**
Very rare	Once every 5 years	1
Rare	Once a year	2
Frequent	Once a month	3
Very frequent	Once a session	4

Note: the criticality score (C) of the risk associated with a failure is given as follows:

C= S*F

The "Failure Mode, Effects and Criticality Analysis" table shown hereafter will be completed[3] with the following information:

1. identification of the failure,
2. possible effect(s)
3. possible cause(s)
4. severity score (S)
5. frequency score (F)
6. risk criticality score (C)

Secondly, the purpose of this table is to enable radiotherapy centres to formalise[4] the organisational and technical measures taken to detect, monitor and prevent failures inherent to radiation therapy, and to limit the consequences of such failures. Healthcare professionals within radiotherapy centres have already discussed and implemented such measures, but have not always taken the time to document them. As a result, some measures may have been changed without anyone noticing or without relevant explanation.

3 In line with the aim to jointly and continuously improve patient safety, the centre identifying the new failure(s) is invited to notify the learned societies, the other radiotherapy centres and the ASN via an information-sharing and improvement network, which it is suggested that it set up deliberately for this purpose.

4 Once these measures have been recorded in the table, more personnel will be able to consult them and to use this document for internal reference purposes (in the event of a memory lapse) or for training new recruits. It will ensure that the transfer of information is accurate and reliable.

Therefore, for each failure identified, the above-mentioned multidisciplinary group should record (in the Failure Mode, Effects and Criticality Analysis table) all the measures taken or planned to:

1. detect its occurrence,
2. prevent its occurrence,
3. limit its consequences if it occurs despite all the precautions taken.

The introduction of measures relating to the above three points constitutes a "defence in depth" approach, and is one of the improvement actions specified in the "Radiotherapy safety and quality management" guide:

IMPROVEMENT ACTIONS:

Set of actions taken to:

1. correct a malfunction, an adverse situation or a non-conformity (corrective action), or to authorise their acceptance by special dispensation,
2. remove the cause(s) of a malfunction, an adverse situation or a non-conformity, where this/these cause(s) can be attributed to the health facility (corrective action),
3. remove the cause(s) of a potential malfunction, adverse situation or non-conformity, where this/these cause(s) can be attributed to the health facility (preventive action),
4. reduce the actual or potential effects of a malfunction, adverse situation or non-conformity, or even remove such effects if they are not caused by the health facility.

The implementation of such an approach must be accompanied by discussions on the introduction of new measures to permanently improve treatment safety. As part of this continuous improvement strategy, the impact of any new measure aiming to modify existing arrangements must be assessed. The aim is to take into consideration the possible transfer of risks covered by these modifications, and to prioritise the implementation of measures to deal with them.

Therefore, once the radiotherapy centres have completed this process, every legal affairs manager, department head or radiotherapy department worker will be aware of the measures taken or planned to offset the risks inherent in radiotherapy care or in their specific radiotherapy centre, and will be able to refer to these measures whenever necessary.

Failure Mode, Effects and Criticality Analysis table

EXTERNAL BEAM RADIOTHERAPY									
Patient Itinerary	Failure mode	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
1 Admission and first consultation	**PI-1** Patient identification error during the administrative process	Patient integrity is significantly jeopardised (treatment error)	Name mix-up Communication difficulties with the patient (confusion, sensory impairment) Multiple electronic registrations	4	3	12			
	PI-2 Poor transfer of the clinical data in the patient's records Mix-up of one patient's records with those of another patient	Patient integrity is significantly jeopardised (treatment location error)	Secretarial error Missing data on the patient's condition and on ongoing treatments (chemotherapy, major surgery, etc.) Iodine allergy or presence of a pacemaker not taken into account	2	3	6			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
Patient Itinerary	Failure mode	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
1 Admission and first consultation	**PI-3** Lack of information or loss of the patient's records	Need to begin the admission procedure again (including some radiation examinations)	Error or inattention on the part of the staff handling the patient's records Incomplete medical records	1	3	3			
2 Patient information	**PI-4** Accident-provoking behaviour on the part of the patient during medical imaging procedures	Unsatisfactory acquisition of the patient's anatomical data	Inadequate patient information	4	4	16			
	PI-5 Accident-provoking behaviour on the part of the patient during treatment	Imprecise treatment delivery	Inadequate patient information	4	4	16			
	PI-6 Patient identification error	Patient integrity is significantly jeopardised (treatment error)	Name mix-up Communication difficulties with the patient (confusion, sensory impairment)	4	3	12			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
Patient Itinerary	Failure mode	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
2 Patient information	**PI-7** Incorrect patient position on the couch during examinations	Patient integrity is significantly jeopardised Treatment definition error	Lack of information on the patient's position on the couch, in the treatment definition file Use of another patient's immobilisation device Accident-provoking behaviour on the part of the patient (see point IP-4)	4	4	16			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
Patient Itinerary	Failure mode	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
2 Patient information	**PI-8** Error in the acquisition of "patient" parameters (for each imaging system [CT scanner, MRI, PET scanner])	Patient integrity is significantly jeopardised (treatment error)	The coding / direction / magnification of images differ (emitter vs. receptor), particularly if external images. Error in the laser movement direction (reverse direction) Inconsistency between the laser system indication and the actual position of the slice plane	4	3	12			
	PI-9 Incorrect image selection	Patient integrity is significantly jeopardised (treatment error)	Data transfer fault between the virtual simulation system (scanner) and the dosimetry system	4	3	12			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
Patient Itinerary	**Failure**	**Possible effects**	**Possible causes**	**S**	**F**	**C**	**Preventive measure**	**Detection or monitoring measure**	**Impact reduction measure**
3 Acquisition of morphological data	**PI-10** Error in the acquisition of "patient" parameters (if a simulator is used)	Patient integrity is significantly jeopardised (treatment error)	Contouring magnification error (existence of a pantograph)	4	3	12			
4 Use of images in the definition of volumes of interest	**PI-11** Image fusion error (CT scanner/MRI/PET scanner)	Patient integrity is significantly jeopardised (treatment error)	Difference in the patient's position between two examinations No initial or periodic verification of image fusion software Accident-provoking behaviour on the part of the patient (see point IP-4)	4	3	12			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
Patient Itinerary	Failure	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
4 Use of images in the definition of volumes of interest	**PI-12** Failure to take into account all the volumes to treat	Risk of unplanned overlap between radiation beams treating different target volumes Double irradiation of the overlapping area Patient integrity is jeopardised The patient is endangered	Lack of attention Failure to consider the treatment volumes as a whole Incomplete medical records Incomplete scanner image acquisition	4	2	8			
	PI-13 Inadequate knowledge of previously treated irradiation volumes	Risk of unplanned overlap between radiation beams treating different target volumes Double irradiation of the overlapping area Patient integrity is jeopardised The patient is endangered	Incomplete technical file Missing medical records	4	2	8			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
Patient Itinerary	Failure mode	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
5 Definition of ballistics	**PI-14** Incorrect treatment data (due to manual data input)	Patient integrity is significantly jeopardised (treatment error)	Positioning - immobilisation Error in the transcription of beam dimensions and parameters	4	3	12			
6 Calculation of dose distribution and of monitor units	**PI-15** Scan examination error (images used to define target volumes, when there are several series of examinations)	Patient integrity is significantly jeopardised (treatment error)	Inattention on the part of the operator Lack of information or incorrect information on the images available	4	3	12			
	PI-16 Error of calculation	Patient integrity is significantly jeopardised (treatment error)	Incorrect data input Inadequate software ergonomics Shortage of time / inadequate operator training Electron density / Hounsfield number conversion tables not available (in the calculator) for the scanning images, or not defined for the scanner being used	4	3	12			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
Patient Itinerary	Failure mode	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
7 Treatment room	**PI-17** Patient identification error	Patient integrity is significantly jeopardised (treatment error)	New patient Confusion when selecting the patient's name from the pull-down menu Name mix-up Communication difficulties with the patient (confusion, sensory impairment) Lack of organisation	4	4	16			
	PI-18 Use of another patient's immobilisation device	Patient integrity is significantly jeopardised (treatment error)	Inattention on the part of the operator Incorrect referencing of immobilisation devices	3	3	9			
	PI-19 Use of another patient's shield	Patient integrity is significantly jeopardised (treatment error)	Inattention on the part of the operator Incorrect referencing of shields	3	3	9			
	PI-20 Shield positioning error	Patient integrity is significantly jeopardised (treatment error)	Design fault Incorrect definition of the shield position	3	3	9			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
Patient Itinerary	Failure mode	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
7 Treatment room	**PI-21** Patient positioning error, immobilisation error	Patient integrity is significantly jeopardised (treatment error)	Inattention on the part of the operator Inadequate references for correctly positioning the patient	3	3	9			
	PI-22 Referencing error (tattoos/markers/images) Beam positioning error	Patient integrity is significantly jeopardised (treatment error)	Inattention on the part of the operator Confusion about reference points (previously interrupted treatment process, operation, etc.)	3	3	9			
	PI-23 Change in the patient's position during treatment	Patient integrity is significantly jeopardised	Patient behaviour Patient breathing	4	4	16			
	PI-24 Irradiation field sizing error	Patient integrity is significantly jeopardised	Maladjusted equipment Unit problem Beam programming error (incorrect transfer of centring data, or data input error)	3	3	9			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
Patient Itinerary	Failure	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
7 Treatment room	**PI-25** Failure to protract the dose correctly	Patient integrity is significantly jeopardised	Inattention on the part of the operator Incorrect data input R&V software not used Lack of organisation R&V software not configured correctly	3	2	6			
	PI-26 Failure of the operator to detect an incident during the treatment session	Patient integrity is significantly jeopardised	Inadequate supervision of the patient during the treatment session	3	3	9			
	PI-27 Failure to spot a dosing error in the treatment chain	Possibility of over-dosage or under-dosage	No overall verification of the treatment chain	4	3	12			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
Patient Itinerary	Failure	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
8 Follow-up visits	**PI-28** No weekly visit	Failure to spot side effects (see following point)	Shortage of time Lack of organisation	3	3	9			
	PI-29 Appearance of unexpected side effects during treatment	Adverse effects	Individual radiosensitivity Error in planning and/or delivering the treatment	4	2	8			
	PI-30 No end-of-treatment visit	Failure to spot side effects (see following point)	Shortage of time Lack of organisation	4	3	12			
	PI-31 No post-treatment follow-up visit	Failure to spot side effects (see following point)	Shortage of time Lack of organisation	4	3	12			
	PI-32 Appearance of unexpected side effects after the end of treatment	Adverse effects	Error in planning and/or delivering the treatment	4	2	8			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
Equipment	Failure	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
9 Dose planning TPS (Treatment Planing System)	**E-1** Incorrect data input Incorrect interpretation of some parameters Confusion between two data input parameters	Inappropriate treatment The patient is endangered	Inadequate training of staff The data input interfaces used in dose planning are not user-friendly Text in a foreign language unfamiliar to the operator Units not indicated for some parameters Operator fatigue	4	3	12			
	E-2 Computer bugs (occurrence of adverse effects due to the software)	The patient is endangered Uncontrollable effect on the distribution of the delivered dose	Software/hardware No record of possible errors (rarely catalogued)	4	2	8			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
Equipment	Failure	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
9 Dose planning TPS (Treatment Planing System)	**E-3** No procedure to verify the dose delivered per measurement in complex treatment plans	The patient is endangered Over- or underdose of the tumour and/or the adjacent critical organs Short-term, medium-term or long-term side effects of the treatment	Failure to take into consideration: Regions where electronic equilibrium is not established Dose under shields Penumbral regions Tangential beams Heterogeneity Techniques using intensity modulation (IMRT) Techniques based on dynamic arc therapy, using stereotactic positioning	4	3	12			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
Equipment	Failure	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
9 Dose planning TPS (Treatment Planing System)	**E-4** Error between calculated delivered dose and measured delivered dose Dose distribution error in a plane or a volume	Over- or underdose of the tumour and/or the adjacent critical organs Short-term, medium-term or long-term side effects of the treatment The patient is endangered	Inadequate training of staff Not enough time to perform thorough checks (not allowed for in the schedule of work on the accelerator) Error in the measurement or input of basic parameters used to create or verify models: - dose / reference monitor unit - variation in dose when the collimator opens - depth dose (percentage depth dose or tissue-to-medium ratio), dose profiles, dose rate depending on the opening - reference parameters for performing calculations with accessories (filters, additional shields, etc.) Inadequate or incorrect modelling	4	3	12			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
Equipment	Failure mode	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
9 Dose planning TPS (Treatment Planing System)	**E-5** Incorrect scale used in the delineation (contouring) of target volumes, critical organs, external contours	Inappropriate treatment The patient is endangered	Inadequate training of staff Scale not validated for the equipment or the current version	4	3	12			
	E-6 Errors in the printing formats of dosimetry data	Inappropriate treatment Errors in the dose delivered, due to inaccurate interpretation of data	Inadequate training of staff Scale not validated for the equipment or the current version	4	3	12			
	E-7 Incorrect calculation of the dose to deliver, due to inaccurate estimation of tissue density	Over- or under-dosage Inappropriate treatment of areas where variations in tissue density are high	Inaccurate and/or ill-defined Hounsfield/density conversion tables	4	3	12			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
Equipment	Failure mode	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
10 R&V network equipment (Record and Verify coupled with the Radiotherapy Information System)	**E-8** Incorrect data input Incorrect interpretation of some parameters Confusion between two data input parameters	Inappropriate treatment The patient is endangered	Inadequate training of staff Lack of ergonomy of: -the treatment data input interface -the treatment delivery interface (accelerator controls) -text in a foreign language unfamiliar to the operator -units not indicated for some parameters -operator fatigue	4	3	12			
	E-9 Computer bugs (occurrence of adverse effects due to the software)	The patient is endangered Uncontrollable effect on the distribution of the delivered dose	Software problem Hardware problem No record of possible errors (rarely catalogued)	4	2	8			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
Equipment	Failure mode	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
10 R&V network equipment (Record and Verify coupled with the Radiotherapy Information System)	**E-10** Problem with the transfer of information, related to the user: images	Inappropriate treatment The patient is endangered	Incorrect input of "patient" data, leading to incompatibility with other data relating to the same patient in the Radiotherapy Information System (RTIS) Images not acquired in the correct order (if several series of slices) Inadequate optimisation of image viewing parameters (poor quality image) Some DICOM data missing User fatigue or inadequate training	4	3	12			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
Equipment	Failure mode	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
10 R&V network equipment (Record and Verify coupled with the Radiotherapy Information System)	**E-11** Problem with the transfer of information, related to the user: treatment plan information	Inappropriate treatment The patient is endangered	Incorrect input of "patient" data, leading to incompatibility with other data relating to the same patient in the Radiotherapy Information System (RTIS) Beam parameters not entered or partly incorrect Incorrect dose per beam, number of fractions, etc. User fatigue or inadequate training	4	3	12			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
Equipment	Failure mode	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
10 R&V network equipment (Record and Verify coupled with the Radiotherapy Information System)	**E-12** Problem with the network transfer of information, related to the procedure (CT scanner, MRI, PET scanner etc. to the TPS): images	Inappropriate treatment The patient is endangered	Incompatibility between the software versions used Failure to preserve image orientation Failure to preserve CT numbers (link with the physical/electron density of the tissues) Image data deformation in the case of scan acquisitions with a variable inter-slice distance	4	3	12			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
Equipment	Failure mode	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
10 R&V network equipment (Record and Verify coupled with the Radiotherapy Information System)	**E-13** Problem with the network transfer of information, related to the procedure (TPS to R&V/RTIS, R&V/RTIS to accelerators): treatment parameters	Inappropriate treatment The patient is endangered	Incompatibility between the software versions used Inconsistent interpretation of the data transferred between two systems The exchange of data in DICOM format: - the attributes exist in the patient's DICOM file, but the service provider software does not assign the same value to them or the user software is unable to read them - the attributes exist in the DICOM object definitions, but they are not or cannot be defined in the dose planning system or the RTIS (e.g..: DSP, position on the couch, number of fractions, etc.) - the attributes exist in the patient's administrative records, but do not correspond to a technical radiotherapy procedure The exchange of data with proprietary standards for each piece of equipment (creation of gateways): the same type of risks, but very considerably magnified	4	3	12			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
Equipment	Failure mode	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
10 R&V network equipment (Record and Verify coupled with the Radiotherapy Information System)	**E-14** Problems encountered further to the upgrading or modification of software by the manufacturer	Inappropriate treatment The patient is endangered	Incompatibility between the software versions used Inconsistent interpretation of the data transferred between two systems	4	3	12			
11 Immobilisation devices / Markings / Shields	**E-15** Immobilisation device design fault	Inappropriate treatment Patient discomfort Positioning problem	Immobilisation device too tight The patient has lost weight Immobilisation device too loose Position too difficult to maintain for the patient	3	3	9			
	E-16 Immobilisation device error	Inappropriate treatment	Wrong choice of immobilisation device during the manufacturing Incorrect referencing of the immobilisation device Mix-up of one patient's immobilisation device with that of another patient	3	2	6			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
Equipment	Failure mode	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
11 Immobilisation devices / Markings / Shields	**E-17** Shield design fault (wrong thickness or shape)	Inappropriate treatment	Error or inattention on the part of the operator The alloy used is of inappropriate density Choice of material	3	3	9			
	E-18 No positioning reference points (on the patient or the immobilisation device)	Difficulties in positioning the patient Treatment not reproducible	Oversight during simulation Markings erased	3	2	6			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
Equipment	Failure mode	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
12 Portal imaging device Patient positioning imaging device	**E-19** Poor image quality	Inappropriate treatment	Incorrect calibration of the sensor Imaging device off-centre	3	2	6			
	E-20 No reference images, or poor-quality reference images (matching system)	Inappropriate treatment	Patient identification error Incorrect choice of digital filter or of image type (MV/kV)	3	2	6			
	E-21 shift error	Inappropriate treatment	Misunderstanding of the direction of the offsets needed Incorrect tattooing point set-up	3	2	6			
13 Accelerator	**E-22** Internal quality control not completed	Dose received by the patient different to the planned dose Treatment parameters not met The patient is endangered	Some parameters not verified often enough Shortage of time Shortage of staff Dosimetry equipment inadequate to perform certain verifications	4	2	8			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
Equipment	Failure	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
14 Whole treatment chain	E-23 Accessory damaged or not functioning properly (filter, laser, telemeter, repositioning system, etc.)	Inappropriate treatment	Data transfer problem Human factors Failure to follow instructions	3	2	6			
	E-24 Calibration drift	Over- or under-dosage The patient is endangered	No daily check of the monitor unit value. Problem with the accelerator's ionisation chamber Faulty test equipment Failure to follow instructions Error in the calibration procedure	3	2	6			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
Equipment	Failure	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
14 Whole treatment chain	**E-25** No start-up procedure for any of the devices in the treatment chain	Over- or under-dosage of all treatments The patient is endangered	Failure to follow instructions Shortage of time Shortage of staff Confusion between the different tests to be performed	3	2	6			
15 Metrology	**E-26** Calibration or dose control error	Over- or under-dosage of all treatments The patient is endangered	Malfunction in the measurement chain Failure to adhere to a regular equipment calibration schedule Failure to comply with the calibration protocol Malfunction in the water tank	4	2	8			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
General organisation	Failure mode	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
16 Human and organisational factors	**HOF-1** Rate of work Pressure due to the work schedule Failure of the management to see the situation as it actually is and to act accordingly Failure of the management to take into account the introduction of new treatment equipment and/or techniques	Stress leading to errors at all levels of decision-making Not enough time for maintenance and inspections Risk-taking due to shortage of time Risks for the patient Disorganisation within the department	Shortage of staff due to holidays and sick leave Poor organisation within the department, from the booking of appointments to the management of patient records at the post-treatment stage Poor organisation of maintenance work (e.g. difficulties in restarting the accelerator after daily testing of the emergency stop device during operation) Failure to verify the adequacy between the workload and the human resources available Poor distribution of tasks and responsibilities	3	3	9			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
General organisation	Failure mode	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
16 Human and organisational factors	**HOF-2** Temporary unavailability of a medical physicist in the department	Impact on the preparation and validation of patient files Failure to identify possible treatment malfunctions Impossibility of taking action in the event of a treatment problem	Shortage of staff Holidays / Sickness leave Training External meetings Installation - testing - commissioning of a new machine	3	3	9			
	HOF-3 Temporary unavailability of the department's radiation therapist	Impact on the preparation and validation of patient files Impossibility of taking action in the event of a treatment problem	Shortage of staff Holidays / Sickness leave Training External meetings	3	2	6			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
General organisation	Failure mode	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
16 Human and organisational factors	**HOF-4** Lack of communication	Risk of treatment or patient identification errors	Poor relationship between co-workers Rate of work Bad working atmosphere	3	3	9			
	HOF-5 Inattention of an operator while working	Risk of treatment or patient identification errors	Attempt by a third party to gain the attention of an operator while s/he is working, for non-essential reasons or regarding other tasks	3	3	9			
	HOF-6 Unclear definition of responsibilities	Unclear verification and validation procedures Conflicts of interest between those in charge Dangerous situations	Ill-defined hierarchical links / responsibilities Relationship between the radiation therapist / radiation physicist / dosimetrist / operator / technician Complex distribution of responsibilities between the radiation physicist and the biomedical engineer	3	3	9			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
General organisation	Failure mode	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
16 Human and organisational factors	HOF-7 No harmonisation of treatment practices within the same facility (for a given organ)	Potential source of errors for: - the physician - dosimetrists - operators	Lack of cooperation between radiation therapists Lack of leadership from the head of department	4	3	12			
	HOF-8 No validation of treatment protocols per organ type, or of amendments to protocols	Ill-defined treatment plan. Risk of over-dosage or under-dosage	Shortage of time Lack of organisation	4	3	12			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
General organisation	Failure mode	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
17 Archiving and Filing	**HOF-9** Incorrect archiving / filing - of the patient's medical records - of the radiotherapy file	Filing of data concerning patient X in the file of patient Y Treatment definition error	Shortage of time File not completed correctly Name mix-up	2	3	6			
	HOF-10 Missing documents (consultation report, etc.)	Waste of time Loss of information that could be instrumental in defining the treatment plan	Archiving error Failure to inform the medical secretarial office of the documents required (from the patient's GP, etc.)	2	3	6			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
General organisation	Failure mode	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
18 Identification of discrepancies / Feedback	**HOF-11** Failure to detect unexpected events or incidents caused by the radiation	Occurrence of serious adverse events Discrepancy between the treatment doses planned and those actually delivered	Lack of response from the medical team to side effects or to patient concerns Follow-up visits not carried out	4	3	12			
	HOF-12 Inadequate assessment of the radiotherapy process during treatment (in terms of radiation protection)	Failure to spot malfunctions or anomalies during treatment planning and delivery Impossibility of evaluating the overall quality of the treatment	No regular meetings of the medical team Follow-up visits not carried out Follow-up visits not traceable	4	3	12			
	HOF-13 Inadequate post-treatment follow-up / failure to spot delayed effects	Failure to spot possible treatment malfunctions Impossibility of evaluating the overall quality of the treatment	Patients do not have regular appointments with their radiation therapist No regular meetings between the radiotherapist and the treatment team Clinical examination not carried out	4	4	16			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
General organisation	Failure mode	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
18 Identification of discrepancies / Feedback	**HOF-14** Poor organisation of experience feedback	Failure to spot possible treatment malfunctions Impossibility of evaluating the overall quality of the treatment	No statistical analysis of treatment data per organ type and patient type No regular assessment of treatments by the medical team	4	4	16			
	HOF-15 Inadequate preparation of changes (to the treatment, equipment or organisational set-up)	Occurrence of unexpected events due to the incorrect implementation of the treatment process Failure to take a change (and all its consequences) into account	No risk assessment No change implementation and management procedure Failure to comply with IAEA requirements No procedure for tracking the changes implemented	4	3	12			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
General organisation	Failure mode	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
18 Identification of discrepancies / Feedback	**HOF-16** Failure to inform users when equipment is changed (software upgrades, etc.)	Failure to take the change into account Treatment planning or delivery errors	Isolated decision Poor communication within the department	4	3	12			
	HOF-17 Failure to inform concerned parties when a treatment variable is changed	Failure to take the change into account Treatment planning or delivery errors	Isolated decision Poor communication within the department	4	3	12			
19 Training	**HOF-18** Skills management Individual and team training sessions	Inadequate knowledge of tools, equipment and software Treatment planning or delivery errors	Shortage of time No skills management No training plan No resources Training postponed or cancelled, with no further action	4	2	8			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
General organisation	Failure mode	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
19 Training	**HOF-19** Personnel management Management of new recruits	Inadequate knowledge of tools, equipment and software Treatment planning or delivery errors	Shortage of time No skills management No training plan No resources Training postponed or cancelled Poor relationship between co-workers	4	2	8			
	HOF-20 Skills management Authorisation of personnel to use specific techniques and upgraded equipment	Inadequate knowledge of tools, equipment and software Treatment planning or delivery errors	No definition of the skills needed by the department Shortage of resources and/or time No job descriptions	4	2	8			
	HOF-21 No common language within the medical team	Inadequate knowledge of tools, equipment and software Treatment planning or delivery errors	No definition of the skills needed by the department Shortage of resources and/or time	3	2	6			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

EXTERNAL BEAM RADIOTHERAPY									
General organisation	Failure mode	Possible effects	Possible causes	S	F	C	Preventive measure	Detection or monitoring measure	Impact reduction measure
20 Quality assurance	**HOF-22** No validation of key points in the treatment plan by the medical team	Treatment carried out without validation	No dialogue No validation procedure in force No medical practitioner Too much or too little unwritten delegation of responsibilities	4	2	8			
	HOF-23 Lack of self-assessment indicators	Failure to detect possible treatment malfunctions	No quality manager No record of risks	3	2	6			
	HOF-24 Inadequate document management system	Loss of information Waste of time No possibility of drawing up summaries or providing experience feedback Failure to detect possible treatment malfunctions	Lack of organisation Quality procedure not implemented	3	2	6			

Frequency: 1= very rare – once every 5 years, 2= rare – once a year, 3 = frequent – once a month, 4 = very frequent -- daily
Severity: 1 = not very critical, 2= critical, 3= very critical, 4= serious

Appendix

Multidisciplinary task force report on which this guide is based

FOREWORD

Radiation therapy is one of the three main methods of treating cancer in France, along with surgery and chemotherapy. Around 200,000 cancer patients benefit from radiotherapy every year.

Although this technique is very safe, the number of incidents and accidents reported to the Nuclear Safety Authority is rising. These events serve as a reminder that, although radiotherapy contributes significantly to improving the treatment of patients, it can also, when used incorrectly, have serious consequences for their health.

Following the very first incidents reported to the ASN in 2005, the Nantes division came up with the idea of establishing a regional, multidisciplinary task force composed of radiotherapy professionals from Brittany and the "*Pays de la Loire*" region. The purpose of this task force would be to promote experience sharing and improve treatment safety, notably through the more efficient identification of risks. This proposal was submitted to the general management of the ASN and received its approval on 13th June, 2006.

The work of the task force has culminated in the development of a guide to risk assessment and analysis in radiotherapy. The use of this guide* - which covers everything from the patient's admission to the treatment process and post-treatment follow-up - by all medical staff (radiation therapists, radiation physicists, dosimetrists, operators, technicians, secretaries, etc.) should help improve treatment safety and hence increase patient confidence in and satisfaction with radiotherapy.

This is what the members of the task force, the French Society of Radiation Oncology (SFRO), the French Society of Medical Physics (SFPM) and the Nuclear Safety Authority (ASN) are hoping for.

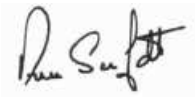
(*) The guide will be updated periodically

The leader of the task force

Pascal Fourrier

The head of the Nantes division

Pierre Siefridt



I. INTRODUCTION

Radiation therapy is one of the three main methods of treating cancer, along with surgery and chemotherapy. In France, around 200,000 cancer patients benefit from it every year.

Although this technique is, on the whole, very safe, the number of incidents and accidents reported to the Nuclear Safety Authority is rising. These events serve as a reminder that, although radiotherapy contributes significantly to improving the treatment of patients, it can also, when used incorrectly, have serious consequences for their health.

Such events are reported within the framework of the networks established by the ASN for the purpose of sharing knowledge and information about significant events ("radiovigilance"), and in accordance with the public health law of 9th August, 2004, relating to serious adverse reactions to treatment. The reporting of these events provides an opportunity to improve radiotherapy safety by promoting experience sharing and more efficiently identifying risks.

Some fifteen incidents and accidents have been reported in France since 2005, the main causes of which were as follows:

- failure to communicate treatment parameters due to a software design fault, which resulted in the serious overexposure of a patient in Grenoble and required corrective surgery;
- an error in the size of the irradiation field during stereotactic radiotherapy, which led to the death of a patient in Lyon;
- incorrect use of software, leading to the overexposure of 24 patients in Epinal, and the death of 5 of these patients;
- unplanned overlapping of irradiation fields, leading to the serious overexposure of a patient in Tours;
- a beam calibration error due to the use of inappropriate measuring equipment in Toulouse;
- patient identification errors involving patients being treated for the same disease. These errors occurred in several facilities and led to expected consequences in some cases.

Following the first events reported to the ASN in 2005, the Nantes Division came up with the idea of developing quality assessment and improvement tools, in collaboration with radiotherapy professionals in Brittany and the *"Pays de la Loire"* region. This proposal was submitted to the general management of the ASN and received its approval on 13th June, 2006.

A regional, multidisciplinary task force was therefore set up, composed of members of the medical community and experts from the ASN. This task force performed a risk analysis using methods that are widely used in industry and in the aeronautics sector.

The purpose of this report is to explain the background to the analysis, the methodology used and the results achieved.

BACKGROUND TO THE ANALYSIS

The task force was set up against the following backdrop:

- several serious accidents and incidents have been reported to the Nuclear Safety Authority since 2005,
- discussions are taking place within several healthcare facilities, regional hospitalisation agencies and national organisations, with a view to better identifying and controlling the risks associated with radiotherapy.

Hence the health facility accreditation procedure[5] now requires facilities to establish a "Risk Management Programme" covering all areas of activity. As a result, discussions are taking place in health facilities, but do not seem to be very coordinated as far as radiotherapy is concerned.

At the same time, the MEAH has conducted a study on the organisation of radiotherapy care, leading to the publication of a document entitled "*Recueil de bonnes pratiques organisationnelles en radiothérapie*" (Good Organisational Practices in Radiotherapy). The main purpose of this document is to "conduct an external investigation of the internal organisation of radiotherapy departments, using an obvious and relevant indicator: the time to treatment"[6]. It does not specifically take into consideration either the safety or the quality of radiotherapy care. However, these issues should be addressed more specifically in a second document, which is currently being drawn up.

As the Nuclear Safety Authority (ASN) is directly responsible for matters relating to the radioprotection of patients, the Nantes Division (with the support of the ASN) set up a regional task force on the risks incurred by patients during radiotherapy. The purpose of this task force was to draw up a guide to the assessment of risks in radiotherapy: identification of failure modes, quantification of the consequences, proposition of preventive measures, evaluation of risk reduction measures.

[5] Foreword of the "Manuel de certification HAS V2-2007" (the National Health Board's Certification Handbook, V2, 2007), reference 33 a in particular

[6] Foreword of "*Recueil des bonnes pratiques organisationnelles en radiothérapie*" (Good Organisational Practices in Radiotherapy), MEAH 2005

COMPOSITION OF THE TASK FORCE

The task force brought together representatives of voluntary organisations already involved in discussions and activities concerning the safety of radiotherapy care. It comprised:

- professionals from the medical community, from all stages of the treatment chain (radiation therapists, radiation physicists, dosimetrists, electroradiology technicians, repair and maintenance technicians);
- experts from the Nuclear Safety Authority, selected for their competence in this area of activity.

Hence, the task force was made up of the following people:

CRLCC Eugène Marquis (35)

Jean-Pierre Manens .....Radiation physicist
Hervé Cadiou.....Electroradiology technician - Dosimetrist

CRLCC René Gauducheau (44)

Professor Marc-André Mahe.....Radiation therapist
Albert Lisbona .....Radiation physicist
Nathalie Guillaume .....Electroradiology technician - Dosimetrist

Centre Catherine de Sienne (44)

Dr Zineb Douadi Gaci.....Radiation therapist

CHD, La Roche sur Yon (85)

Sylvain Crespin .....Radiation physicist
Cyrille Le Maguer .....Technician

Nuclear Safety Authority

Pascal Fourrier, Pascal Guillaud, Pierre Siefridt, ASN/ Nantes
Philippe Menechal..... ASN/ Bordeaux
Marc Valero..... ASN/ Ionising Radiation and Health Division

The task force was led by: Pascal Fourrier (ASN – Nantes Division), with the help of Pascal Guillaud – (ASN – Nantes Division)
It met 7 times, on the following dates: 26th September 2006, 19th December 2006, 22nd February 2007, 18th April 2007, 13th June 2007, 20th September 2007, 12th December 2007.

Members from Brittany and the "*Pays de la Loire*" region, taking part in proofreading and improving the document:

Jacques Lescrainier, radiation physicist, Clinique Armoricaine, ST BRIEUC (22)
Nathalie Chapel, radiation physicist, Clinique Pasteur, BREST (29)
Cyril Leleu, radiation physicist, QUIMPER hospital (29)
Philippe Bergerot, radiation therapist, Centre Etienne Dolet, ST NAZAIRE (44)
Olivier Dupuis, radiation therapist, and M. Tep, radiation physicist, Centre Jean Bernard, LE MANS (72)

WORK METHODOLOGY

The task force based its work on several risk analysis methods, which have been widely used in industry and in the aeronautical and agri-food sectors for several years: (1) Failure Modes, Effects and Criticality Analysis (FMECA), (2) Hazard Analysis Critical Control Point (HACCP), (3) the 5 M method (Machinery, Manpower, Material, Measurement and Method), (4) Problem solving methods, etc.).
The methodological approach consisted in:

- breaking a system down into basic parts (for example, the fundamental stages of a process
- or the components of a system);
- identifying generic failure modes for each basic part,
- insofar as the risk assessment or analysis was not associated with a specific facility or
- piece of equipment;
- establishing the causes and effects of each failure mode;
- evaluating the initial criticality of the event using a scoring system;
- identifying ways of controlling the risks;
- suggesting monitoring indicators;
- evaluating the final criticality of the event using a scoring system.

This method was selected because of its many advantages:

- it is easy to understand and implement;
- preventive measures can be prioritised depending on
- the severity of the event, the probability of occurrence, etc.

The severity assessment table was compiled using the "Common Terminology Criteria for Adverse Events (CTCAE)" issued by the National Cancer Institute (USA) and the "Toxicity Criteria" issued by the Radiation Therapy Oncology Group.

However, it differs from these criteria in the following respects:

- unlike the CTCAE and the "Toxicity Criteria", which are defined for each specific location, the severity assessment table is generic for all organs;
- the severity assessment table uses 4 levels of severity (unlike the CTCAE, which uses 5), in order to prevent "median" effects.

The task force selected and used the following system to score the severity of events:

Determining the severity of a failure		
Level	**Criterion**	**Score (S)**
Not very critical	Temporary discomfort, malaise, unpleasantness	1
Critical	Prolonged discomfort Reversible damage or impairment Medical treatment required Temporary handicap	2
Very critical	Delayed consequences, but marked for the patient Irreversible damage or impairment Permanent handicap Not life threatening	3
Serious	Short-term fatal outcome for the patient Life threatening	4

The task force selected and used the following system to score the probability of events:

Determining the frequency of a failure		
Level	**Criterion**	**Score (F)**
Very rare	Once every 5 years	1
Rare	Once a year	2
Frequent	Once a month	3
Very frequent	Once a session	4

The task force will invite health facilities in the "*Pays de la Loire*" region and Brittany to self-assess their performance by comparing initial and final severity scores.

The task force organised its work around the following 3 main themes:

- ***patient itinerary:*** analysis of failure modes at each stage of the care process, from the first consultation to the end of treatment;
- ***equipment:*** analysis of failure modes associated with the devices used at each stage of the care process;
- ***human and organisational factors***: analysis of failure modes associated in particular with organisational factors, information circulation and the training of staff.

Thanks to the structure adopted, a single failure mode can be approached from various angles. When the final risk analysis tables were drawn up, any failure modes appearing for a second time under a different theme were removed: hence, if an event appeared both in the "patient itinerary" table and another table, it was erased from the second table. The "equipment" and "human and organisational factors" tables contain mainly cross-discipline failure modes.

THE SCOPE OF THE TASK FORCE

Radiotherapy-related risks, the effects of which are generally deferred, may have several causes:

- side effects resulting from a concerted strategy implemented by the medical practitioner and the patient during treatment;
- unexpected effects that may derive from abnormalities occurring during the treatment **planning** phase;
- unexpected effects that may derive from abnormalities occurring during the treatment **delivery** phase;

Lastly, some unexpected effects may be caused by imponderable factors (individual radiosensitivity, unforeseeable changes in the patient's condition, etc.) rather than by abnormalities in the treatment process.
The task force investigated only the risks deriving from abnormalities in the treatment planning and delivery phases. Risks associated with individual radiosensitivity were addressed briefly and partly taken into consideration.

ANALYSIS OF RISKS RELATED TO THE PATIENT ITINERARY

a) Identification of the different stages and key processes

The task force identified several particularly important stages in the treatment planning and delivery process. This facilitated the identification of failure modes likely to occur at each stage (see appendix).

Hence, the treatment process can be broken down into 7 key stages, which occur in the following chronological order:

1. Multidisciplinary Consultation Meeting (MCM)

   This meeting brings together all the different medical disciplines associated with the patient's condition (surgery, radiotherapy, chemotherapy, organ specialists, etc.). Its role is to examine the case of each patient following diagnosis, and to define the best possible treatment strategy, i.e. a personalised treatment programme.

2. Initial announcement consultation with medical and paramedical staff – Patient information

   When the treatment strategy involves radiotherapy, the patient is referred to the radiation therapist, who will define a personalised treatment plan. The secretarial office in the radiotherapy department will arrange an appointment and put together a file for the patient (containing biological test results, scans and information on the patient's general health). At the announcement consultation, the radiation therapist will explain the treatment modalities to the patient and tell him/her about the side effects likely to occur.

   The success of the treatment and the limitation of side effects will partly depend on the patient's behaviour during the different stages of the treatment process. Patients must therefore be advised on the appropriate behaviour to adopt (for example, they should be told not to move and should be given advice on post-treatment skin care, diet, etc.). They should also be made aware of the importance of following this advice. The patient will be given this information by the radiotherapy technicians during the announcement consultation.

3. Acquisition of morphological data and definition of treatment ballistics

   This is a vital part of the treatment planning process. It can be broken down into several basic steps:

   - acquisition of morphological data: to define the treatment plan, a number of anatomical images (X-rays, CT scans, MRI scans, PET scans, US scans) and/or functional images (PET scans) must be available. These images must be clear, and must show the area requiring treatment and the vital organs to protect. Therefore, the patient may be required to undergo several additional examinations for non-diagnostic purposes;

   - use of the images to define volumes of interest: the images of the area to be treated are superimposed, repositioned and fused in order to obtain a single image containing all the information needed for the treatment planning process and the dosimetry software. On

these images, the radiation therapist defines the target volume(s) to be treated and the organs that need to be protected;

- definition of the treatment ballistics: depending on the volume to be treated, the radiation therapist, the radiation physicist and the dosimetrist define the radiation type and energy to be used and the number and direction of the beams.

4. Calculation of dose distribution and of monitor units

This stage involves the use of a dose planning system, which - based on the modelling of the radiation beams produced by the accelerators and on treatment data (number and direction of beams, radiation energy, etc.) - will calculate the dose distribution to the target volume (as defined by imaging during the planning stage). As a result, it will be possible to specify the contribution of the different radiation beams and to perform any beamforming necessary (wedge filters, multi-leaf collimator, intensity modulation, etc.). Treatment plans are optimised through the selection of several parameters: the type and energy of the radiation beam, and ballistics (number and direction of the beams, the shape of the radiation fields and the dose weighting of each beam).

These calculations provide information on the dose delivered to the tumour and to the adjacent organs: 2D/3D dose distributions, dose-volume histograms.

5. The treatment room

Once the treatment plan has been defined, the patient must undergo one or more irradiation sessions, during which the full dose or a fraction of the full dose is delivered according to the prescription (protraction = total length of treatment, number of weekly sessions; fractionation = daily dose delivered). This stage involves electroradiology technicians, who welcome the patient, install him/her on the treatment couch, set up the equipment and accessories and start the irradiation session. At the end of the session, the treatment data are recorded in the patient's electronic record (radiotherapy information system) and/or noted in the "hard" copy of the patient's record. The technicians then release the patient, who can either go home or return to a specific medical care service.

6. Weekly follow-up visits

During the treatment phase (which lasts for several weeks), the patient is monitored by the radiation therapist. The latter monitors treatment tolerance and identifies any side effects. Should any unexpected, early or exaggerated reactions occur, s/he may also look for the causes and identify any problems. Further to these consultations, the treatment may be modified or even temporarily interrupted.

7. Post-treatment visits

Similarly, post-treatment visits are conducted in order to monitor the patient's clinical condition, detect any recurrence of the disease and identify delayed side effects.

b) Risk analysis summary

The task force focused on 7 stages of the radiotherapy care process, as described below. The analysis tables describing failure modes, their causes and effects, their level of criticality and corrective measures are annexed to this document. The main conclusions are presented below.

1. Multidisciplinary Consultation Meeting (MCM)

Failures occurring at this stage are connected with medical decisions, which only a doctor is qualified to judge. Therefore, the task force deliberately chose not to investigate potential failures at this stage.

Such failures are addressed by the National Health Board (HAS), through the evaluation of healthcare practices and the certification of health establishments.

2. Initial announcement consultation with medical and paramedical staff – Patient information

Patient identification errors can occur from this stage onwards. Furthermore, incorrect or incomplete information in the patient's file can impact on the radiation therapist's prescription and on the definition of the treatment plan. It is therefore essential to set up redundant identification systems and to ensure that data are accurate and exhaustive.

During the initial consultation, the radiation therapist must establish whether there are several volumes to treat at the same time and whether the patient has already had radiotherapy in the past, in order to take into account any doses already received (and prevent risks associated with the overlapping of radiation fields).

Most courses of treatment last for 4 to 7 weeks and involve several sessions a week. The patient's position must be identical at each treatment session. A reproducible patient position is essential to successful treatment and is ensured by the use of immobilisation devices designed to suit the patient's morphology and the part of the body being treated, and with the patient's "comfort" in mind. These devices take into account the position of both internal and external structures.

However, some organs (such as the lungs, breasts, bladder, rectum, etc.) possess a certain degree of mobility, which can be quite difficult to control. Nevertheless, it is very important to take such movement into account in highly-targeted radiotherapy or when the cancerous volume is close to sensitive organs. The radiation therapist systematically takes these factors into consideration when defining margins, which are adjusted according to the mobility of some target or at-risk organs.

The radiation therapist must tell the patient about immediate and deferred side effects. Information must be delivered in writing, so that the patient can refer to it at any time.

The patient must also be informed of the conditions that must be met during the acquisition of morphological data and the delivery of treatment. Besides the necessity of remaining still (hence the importance of immobilisation devices), such information may relate to the bladder (whether it should be full or empty), the intestines (should the patient have an empty stomach or not) and

breathing control. The patient is given this information by the doctor or by the radiotherapy technician during the announcement consultation.

3. Acquisition of morphological data and definition of treatment ballistics

The issues mentioned above regarding patient identification must also be taken into consideration at this stage. Indeed, an identification error would result in inappropriate treatment and could have serious consequences for the patient. Similarly, particular attention must be paid to the patient's position on the examination couch and to the immobilisation devices, which must be identical to those used during treatment delivery.

Several equipment-related errors may also occur during the image acquisition and analysis phase. This point will be examined in greater detail in chapter VI. However, we would like to point out that problems can arise from the use of images provided by other establishments, bearing in mind that morphological data are essential to the treatment planning process. Radiotherapy technicians must cast a critical eye over any images taken by an external organisation, using equipment that they are not familiar with (verification of coding standards, movement directions, sources, etc.). If images are being provided by an external organisation (which is often the case for MRI and PET images), the radiotherapy technician must be informed of the patient's condition when the images were acquired (empty/full bladder, etc.), in order to reduce the risk of error in locating target volumes and volumes to protect.

Finally, the information provided by the radiation therapist must be detailed enough to guide technicians in the choice and acquisition of images.

4. Calculation of dose distribution and of monitor units

As dose distribution is calculated electronically, errors may occur due to the selection of the wrong image, a data input error or incorrect use of the software. It is therefore important to clearly identify images and to verify and validate calculations (by performing the calculation twice or, for example, by in-vitro dosimetry [= simulation of a generic treatment in an anthropomorphic phantom, with dose distribution determination]). The skill and qualifications of the people using the software are also important, and will be discussed in the chapter on human and organisational factors.

Finally, from a reliability point of view, it is important to introduce tools for improving the detection of systematic global errors in the calculation chain (in-vivo dosimetry).

5. The treatment room

Firstly, the patient identification errors referred to above can also occur during a treatment session. Staff must therefore be particularly vigilant so that this type of confusion does not arise. A number of steps can be taken to reduce the risk of error (digital photo of the patient, bar codes, portal imaging, biometrics, etc.), but these measures will only really be effective if radiotherapy technicians remain highly vigilant (asking questions, communicating, etc.). This important point will be discussed in greater detail in the chapter on human and organisational factors.

Failures may also occur during patient and equipment set-up (shield selection or positioning error, immobilisation device error, patient positioning error, etc.). Only a limited amount of time is allocated to each treatment session. Therefore, it is important to minimise the risk of confusion by correctly and unequivocally identifying shields and immobilisation devices, accurately describing the position of both the patient and the immobilisation device, and defining adequate reference points (in terms of number and location) to ensure that the patient is positioned correctly.

Once the radiotherapy session has begun, it is also important to supervise the patient to ensure that s/he does not move. This means that radiotherapy technicians must remain vigilant at all times, hence the importance of having appropriate supervision equipment in the treatment room (quality and position of cameras, possibility of zooming in and out).

The task force concluded that, when in the treatment room, radiotherapy technicians should focus their attention exclusively on delivering the treatment.

Despite the above precautions, it is recommended that in-vivo dosimetry be carried out at the first or second treatment session, to ensure that any global errors in the treatment planning and delivery chain are detected.

6. Weekly follow-up visits

We would like to stress how important it is to ensure the traceability of patient follow-up during the treatment programme. The primary purpose of this follow-up is to assess tolerance to treatment and, above all, to identify side effects (which may be due to treatment planning or delivery errors) as soon as possible.

7. Post-treatment visits

We would like to point out the necessity of post-treatment follow-up. The primary purpose of this follow-up is to assess treatment outcome, detect any recurrence of the disease and identify delayed side effects.

ANALYSIS OF RISKS RELATED TO "EQUIPMENT"

a) Identification of the different types of equipment

Radiotherapy treatments are increasingly technical, involving more and more complex equipment and software. This has improved treatment quality, but can also lead to errors that are sometimes difficult to detect. Because of this, the task force decided to identify and analyse failure modes connected specifically with the equipment used.

As a result, several categories of equipment were identified:

1. the Treatment Planning System (TPS), the system for recording and verifying treatment parameters (Record and Verify) and the associated data transfer networks, including the image network;
2. immobilisation devices and shields;
3. on-board imaging systems;
4. the linear electron accelerator.

b) Risk analysis summary

1. The Treatment Planning System, Record and Verify, and data transfer networks

The first failure mode to be identified concerns data input errors. Generally speaking, user interfaces need to be improved. They should show the units for all parameters, and labels should be clear and arranged in order of severity for the patient. It would also be useful to have good French translations of both software and instruction manuals. These improvements cannot be made directly by the users, but require the collaboration of equipment manufacturers and AFSSAPS.

However, users can reduce data input errors by considering the compatibility and networkability of equipment when drawing up specifications and evaluating responses to Requests for Proposals. This would reduce, or even remove altogether, the need to enter or re-enter data manually.

The second failure mode concerns the amount and diversity of equipment in the system. Any changes in equipment or software may upset the operation of the system, which is qualified for use in a given configuration. The following problems have been identified (list not exhaustive):

- alteration in the scale of images when a printer or monitor is changed;
- if a new imaging device is used: changes in image direction, movement direction, inter-slice distance, data coding, etc.

In any case, the system must be checked regularly and re-qualified every time a component is changed or software is upgraded.

The third failure mode concerns the transfer of data between system components. These failures may be caused either by operator error (incorrect or incomplete data input) or by the

communication standards used. Corrective action can be taken on two levels: firstly, the equipment selected should use recognised communication formats, such as those defined by the DICOM-RT standard; secondly, data transfer functions should be checked regularly, and every time a system component is changed.

The above failure modes illustrate the need to extend quality controls to all the devices in the treatment chain (computer link-ups, machine-machine interfaces, etc.).

Lastly, software abnormalities can occur for no apparent reason. The appearance of these bugs should be monitored and their causes identified with the help of the manufacturer. It should be pointed out that it is important to report such malfunctions to AFSSAPS, for the purposes of medical device vigilance.

At present, computer bugs can be considered as one of the most dangerous failure modes in radiotherapy treatment.

2. Immobilisation devices and shields;

In chapter V above, we saw that the correct positioning of the patient on the treatment couch plays an important role in the safety of external beam radiation therapy. Indeed, recent equipment allows for highly-precise beam targeting and hence for the delivery of larger and larger doses to target volumes without exceeding tolerance limits for healthy tissues. The benefits of this precision can be completely erased if the patient's position on the treatment couch cannot be reproduced for each treatment session.

Great care must be taken in designing and developing immobilisation devices, as they play a key role in positioning the patient. It may also be necessary to create new immobilisation devices during the course of treatment, for example if the patient has lost weight. This means repeating the whole treatment planning phase beforehand.

Special care must also be taken in developing additional shields or collimators. Sizing checks and portal imaging should be performed to make sure that these devices are appropriate.

3. On-board imaging systems

Accelerators can be fitted with two different types of system:

- MV imaging systems: an image of the X-rays emitted by the accelerator is taken with a digital image sensor, in order to verify the shape and position of the therapy beams. The quality of this image is mediocre, due to the use of high-energy radiation which causes a loss of image contrast. However, it is good enough to "see the therapy beam" as it will be delivered to the patient.

- kV imaging systems: some accelerators are fitted with X-ray generators identical to those used in conventional radiology. They provide a 2D or 3D image of the patient's position.

In this case, good image quality is essential for detecting patient positioning errors. So these devices should be checked regularly, and the dose delivered during these examinations should be taken into account.

4. Treatment device

Although accelerator quality controls are obligatory and their content is regulated by AFSSAPS, inspections conducted by the ASN as part of its efforts to ensure the radiation protection of both staff and patients show that these controls are not always fully carried out due to lack of time or equipment, or even, in some cases, to the failure of users to appreciate their utility. This is why the task force deemed it important to consider incomplete quality controls as a failure mode.

Given this situation, discussions should be held with AFSSAPS in view of updating the list of compulsory controls, keeping only those which are really beneficial. In addition, health establishments should continue their efforts to procure equipment for the purpose of carrying out these controls. The necessary human resources should also be made available.

Provisions should also be made regarding fail-soft operation, as faults in the treatment device do not necessarily lead to the interruption of treatment. Therefore, a specific procedure must be defined and appropriate back-up measures introduced. However, fail-soft operation should only be used as a last resort, and only in the case of minor and clearly-defined operating faults.

ANALYSIS OF RISKS RELATED TO "HUMAN AND ORGANISATIONAL FACTORS"

a) Identification of the areas explored

Besides analysing the most visible risks (relating to the patient care process and to the use of complex equipment), we also need to look at the deeper causes of failure, which may include a heavy workload, poor organisation, inadequate training and bad relations between co-workers. These failure modes, which are studied in the "Human and Organisational Factors" table, could be described as transversal, as they can impact on several different stages in the treatment chain.

The failure modes identified cover the following areas:

1. general organisation;
2. archiving and filing;
3. identification of discrepancies/feedback;
4. change management;
5. skills;
6. quality assurance.

b) Risk analysis summary

1. General organisation

The main failure mode is related to the work rate and the frequency of treatment sessions. Although it would be too simplistic to suggest that the solution lies in taking on more staff, it is important for each establishment to assess the adequacy between their workload and the human resources they have available. In doing this, they should take into account all the extra tasks that staff have to deal with in addition to treatment delivery (regular checks, maintenance operations, training, discussions between technicians/patients and between technicians/doctors/physicists, reception of patients, updating of files, organisation of appointments and schedules, drawing up of the medical physics plan, etc.).

For want of a more relevant benchmark, establishments should refer to the circular DHOS/SDO/01/no.2002/299 of 3rd May 2002 relative to the organisation of cancer care, and to the recommendations approved by the "European Federation of Organisations for Medical Physics – EFOMP" in September 1997, specifying the criteria which a medical physics unit must meet.

In addition to this, time can be saved by planning and scheduling tasks more efficiently.

Fail-safe operation should also be provided for by addressing the following points:

- organisational hitches: lack / absence of a radiation therapist, radiation physicist or technicians, the presence of a trainee in the department, audits, etc.;
- equipment problems: unavailability or failure of a piece of equipment, etc.

Another potential source of errors is a lack of clarity in the way health establishments providing radiotherapy care are organised. For example, in many establishments, the hierarchical position of radiation physicists, dosimetrists and maintenance technicians is not clear or is not consistent with the attributes of the different players.

Lastly, the adoption of different treatment practices by different radiation therapists is a source of confusion and therefore of error. Therefore, each practitioner should clearly define a treatment plan for each patient and practices should be harmonised both within individual establishments and on a national level wherever possible (given the clinical context). [A guide to external beam radiotherapy procedures has just been published (SFRO)].

2. Archiving and filing

Archiving errors, if they go unnoticed, can lead to a loss of information or the use of incorrect information. For example, if the test results of patient X are filed in patient Y's records, the radiation therapist may draw up an inappropriate treatment plan as a result. This can happen if two patients have the same name.

The archiving system must be comprehensive and efficient.

3. Identification of discrepancies/feedback

A great deal of progress remains to be made in this area. The following key points must be taken into consideration:

- firstly, regular follow-up visits must be arranged during the treatment phase, along with check-ups in the post-treatment phase;
- secondly, appropriate tools should be introduced to analyse data both individually and collectively: traceability of observations made, keeping of records, definition of indicators, etc.;
- lastly, all the data collected should be analysed, and relevant conclusions should be drawn from these data at all stages of the treatment chain. It is important to ensure that all concerned parties are involved in this process, regardless of their position in the hierarchy.

4. Change management

Changes, if they are not managed properly, can lead to numerous errors. To reduce the risk of accident, the following basic principles should be applied:

- all changes must be made according to a formal procedure that is proportionate to the issues at stake; it is important to analyse the overall consequences of a change (in equipment or in the treatment plan), and to qualify these consequences according to a formal procedure;
- the internal change management procedure must include provision about informing all concerned parties and, if necessary, a validation process.

5. Skills

The importance of appropriate skills no longer needs to be demonstrated, in an area where the techniques used are increasingly complex. According to the task force, three issues deserve special attention:

- the pro forma management of skills;
- teamwork training and the empowerment of new recruits;
- the maintaining and updating of skills further to the introduction of new equipment or techniques.

6. Quality assurance

Of course, all the processes implemented in radiotherapy care must be formalised, and all the data collected must be traceable and analysed. In particular, the development of treatment validation and delivery processes must be clarified, i.e. individual roles and responsibilities must be clearly specified and treatment protocols must be harmonised.

It is also essential to implement a continuous improvement policy. This means defining relevant performance indicators beforehand, as discussed above in point 3.

IDENTIFICATION OF AREAS REQUIRING QUALITY CONTROL

The Minister of Health has asked the Nuclear Safety Authority (ASN) to develop a quality management guide based on the ISO 9000 family of standards.

The ASN's technical decision introducing quality assurance requirements for external beam radiotherapy is currently being drawn up. It should be accompanied by application guidelines, providing further information and recommendations regarding its implementation.

Based on the requirements of the ISO 9000 family of standards, the task force identified 5 fundamental and essential strategies for facilitating the implementation of a permanent programme⋆ of quality improvement in radiotherapy care:

⋆ (such as that which is already partially implemented in some centres).

1 - foster commitment and responsibility among managers;
2 - introduce a document management system (record keeping and traceability);
3 - effectively manage human resources (training, skills), equipment and working conditions;
4 - effectively manage treatment planning and delivery processes;
5 - measure, analyse and continuously improve.

The future guide will enable health establishments to self-assess their performance by conducting a risk analysis (as suggested above in point 5).

CONCLUSION AND SUGGESTED FURTHER ACTION

Improving safety in external beam radiotherapy is a long-term task and involves a whole team of people working for the patient's best interest (radiation therapists, radiation physicists, dosimetrists, operators, technicians, secretaries, etc.).

To improve safety in external beam radiotherapy, such teams must be built on solid foundations (i.e. an efficient quality assurance policy). The best interests of the patient are a priority, from his/her first visit to treatment delivery and post-treatment follow-up. The regular assessment of internal practices should improve quality and thus highlight the benefits of such a procedure. As a result, satisfaction among patients and radiotherapy staff alike should increase.

The task force hopes that the tools proposed will facilitate the achievement of this goal.

GLOSSARY

Quality policy: set of measures implemented by the establishment to improve customer satisfaction.

Guide: set of written quality requirements used for assessment purposes. Guides are based on statutory provisions, good practice guidelines, etc.

Corrective action: action to eliminate the cause of non-conformity or of an adverse situation. This should not be confused with preventive action, which prevents a problem occurring.

Preventive action: action to eliminate the cause of potential non-conformity or of a potentially adverse situation. Preventive action is taken to prevent the occurrence of problems, while corrective action is taken to prevent their re-occurrence.

Efficiency: relationship between the results achieved and the resources used.

Quality management: coordinated measures taken to guide and manage quality achievement within an establishment.

Procedure: specific means of performing an activity or process (ISO 9000: 2000).

Process: set of correlated or interactive activities which convert input into output (ISO 9000: 2000).

Protocol: description of the techniques to use and /or the instructions to follow.

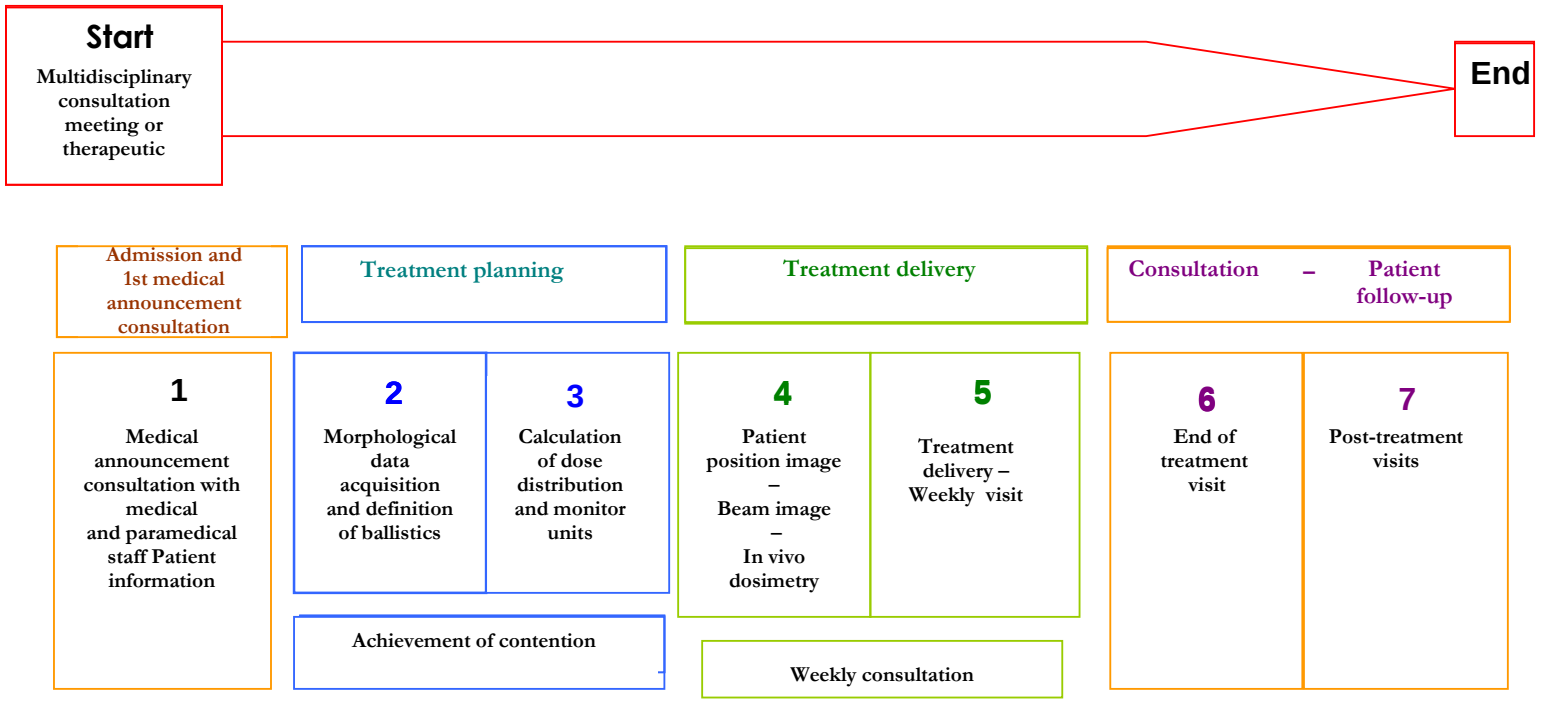
ABBREVIATIONS

DIC: Electronic oncology file
R/V: Record & Verify system
TPS: Treatment Planning System
DICOM-RT: A standard for transferring medical image and technical data in radiotherapy
MCM: Multidisciplinary Consultation Meeting
RTIS: Radiotherapy Information System

ACRONYMS

IAEA: International Atomic Energy Agency
AFSSAPS: French Health Products Safety Agency
ASN: French Nuclear Safety Authority
CRLCC: Regional Cancer Centre
DHOS: French Directorate for Hospitals and the Organisation of Care
FOMP: European Federation of Organisations for Medical Physics
HAS: French National Health Board
MEAH: French National Hospital Expertise and Audit Agency
SFPM: French Society of Medical Physics
SFRO: French Society of Radiation Oncology

Description of the clinical process in external beam radiotherapy



Probability: 1= very rare – once every 5 years, 2= rare – once a year, 1 = frequent – once a month, 4 = very frequent -- daily
Severity: 1=minor= not very critical, 2= significant= critical, 3= very critical, 4= serious= catastrophic

Description of the clinical process in external beam radiotherapy

Start (Multidisciplinary Consultation Meeting or Therapeutic Decision)

End

Admission and 1st medical announcement consultation

Treatment planning

Treatment delivery

Consultation – patient follow-up

1. **Medical announcement consultation with medical and paramedical staff**
   Patient information

2. **Morphological data acquisition and definition of ballistics**
   Development of immobilisation devices

3. **Calculation of dose distribution and monitor units**

4. **Patient position image – Beam image – In-vivo dosimetry**

5. **Treatment delivery**
   Weekly visit

6. **End-of treatment visit**

7. **Post-treatment visits**

Probability: 1= very rare – once every 5 years, 2= rare – once a year, 1 = frequent – once a month, 4 = very frequent -- daily
Severity: 1=minor= not very critical, 2= significant= critical, 3= very critical, 4= serious= catastrophic

Main Failure Modes and Corrective Measures in External Beam Radiotherapy

EXTERNAL BEAM RADIOTHERAPY											
Patient Itinerary	Failure mode	Possible effects	Causes	S	P	iCI	Possible corrective measures	S	P	fCI	Optimisation
1 Admission and first consultation	**PI-1** Patient identification error during the administrative process	Patient integrity is significantly jeopardised (treatment error)	Name mix-up Communication difficulties with the patient (confusion, sensory impairment) Multiple electronic registrations	4	3	12	Compare 2 sources of information ("carte vitale" [health insurance card] and national identity card) Assign an identification number	4	2	8	
	PI-2 Poor communication of the clinical data in the patient's records Mix-up of one patient's records with those of another patient	Patient integrity is significantly jeopardised (treatment location error)	Secretarial error Missing data on the patient's condition and on ongoing treatments (chemotherapy, major surgery, etc.) Iodine allergy or pacemaker not taken into account	2	3	6	Set up a double verification system (secretarial office + doctor): - When an ID number is assigned to the patient, make a card with the number on it and give it to the patient	2	2	4	
	PI-3 Lack of information or loss of the patient's records	Need to begin the admission procedure again (including some radiation examinations)	Error or inattention on the part of the staff handling the patient's records Incomplete medical records	1	3	3	Improve archiving procedures Make sure that staff are aware of the importance of efficient file management Keep the patient's file and the appointments schedule up to date Make sure that the file is complete before any therapeutic decisions are made	1	2	2	Create an electronic file with a unique identifier, assigned to the patient on admission
2 Patient information	**PI-4** Accident-provoking behaviour on the part of the patient during medical imaging procedures	Unsatisfactory acquisition of the patient's anatomical data	Inadequate patient information	4	4	16	Systematically remind patients of how important it is not to move during the examination and to control their breathing. Inform patients of the conditions that must be met prior to the image acquisition procedure (bladder/stomach full or empty, etc.)	4	3	12	This issue should be addressed during the MCM or the announcement consultation Make sure the patient has an information sheet Draw up a special procedure for dealing with restless patients
	PI-5 Accident-provoking behaviour on the part of the patient during treatment	Imprecise treatment delivery									

EXTERNAL BEAM RADIOTHERAPY											
Patient Itinerary	Failure mode	Possible effects	Causes	S	P	iCI	Possible corrective measures	S	P	fCI	Optimisation
3 Acquisition of morphological data	**PI-6** Patient identification error	Patient integrity is significantly jeopardised (treatment error)	Name mix-up Communication difficulties with the patient (confusion, sensory impairment)	4	3	12	Call the patient by his/her name Introduce an appointments card Check the patient's date of birth	4	2	8	Introduce an electronic identification number (PPI - permanent patient ID) If in doubt, check the number
	PI-7 Incorrect patient position on the couch during examinations	Patient integrity is significantly jeopardised Treatment definition error	Lack of information on the patient's position on the couch, in the treatment definition file Use of another patient's immobilisation device Accident-provoking behaviour on the part of the patient (see point CP-4)	4	4	16	Make the immobilisation device just before image acquisition Describe in detail the patient's position on the treatment couch: - Take a photo of the patient's position on the couch - Make sure that the position of tattoos is noted in the patient's file, etc.	4	2	8	Introduce standard description protocols
	PI-8 Error in the acquisition of "patient" parameters (for each imaging system [CT scanner, MRI, PET scanner])	Patient integrity is significantly jeopardised (treatment error)	The coding / direction / magnification of images differ (emitter vs. receptor), particularly if external images. Error in the laser movement direction (reverse direction) Inconsistency between the laser system indication and the actual position of the slice plane	4	3	12	Verify standards on coding and on data transfer between the emitter and the receptor Perform quality controls New imaging equipment / new software: - Make sure that the direction of the slices has not changed - Make sure the zero positions of the laser and the scanner are aligned Train staff to use new equipment or software	4	2	8	Check the direction and accuracy of the laser's movement Take an image to check the position of the selected isocentre
	PI-9 Incorrect image selection	Patient integrity is significantly jeopardised (treatment error)	Data transfer fault between the virtual simulation system (scanner) and the dosimetry system	4	3	12	Keep an electronic or written record of the treatment planning parameters	4	2	8	

Probability: 1= very rare – once every 5 years, 2= rare – once a year, 1 = frequent – once a month, 4 = very frequent -- daily
Severity: 1=minor= not very critical, 2= significant= critical, 3= very critical, 4= serious= catastrophic

EXTERNAL BEAM RADIOTHERAPY											
Patient Itinerary	Failure mode	Possible effects	Causes	S	P	iCI	Possible corrective measures	S	P	fCI	Optimisation
3 Acquisition of morphological data	**PI-10** Error in the acquisition of "patient" parameters (if a simulator is used)	Patient integrity is significantly jeopardised (treatment error)	Contouring magnification error (existence of a pantograph)	4	3	12	Check the system regularly	4	2	8	Stop using the system
4 Use of images in the definition of volumes of interest	**PI-11** Image fusion error (CT scanner/MRI/PET scanner)	Patient integrity is significantly jeopardised (treatment error)	Difference in the patient's position between two examinations No initial or periodic verification of image fusion software Accident-provoking behaviour on the part of the patient (see point CP-4)	4	3	12	Conduct the examinations under treatment conditions Introduce a common image fusion protocol with the PET scan and MRI departments	4	2	8	Access to a PET scan and/or an MRI scan
	PI-12 Failure to take into account all the volumes to treat	Risk of unplanned overlap between radiation beams treating different target volumes Double irradiation of the overlapping area Patient integrity is jeopardised The patient is endangered	Lack of attention Failure to consider the treatment volumes as a whole Incomplete medical records Incomplete scanner image acquisition	4	2	8	Specifically identify patients with several volumes to treat, at their very first visit Plan for irradiated volume overlap and inform the patient	4	1	4	Create an index number - reference number on the patient's file Ensure that the radiation therapist validates all the volumes at once
	PI-13 Inadequate knowledge of previously treated irradiation volumes	Risk of unplanned overlap between radiation beams treating different target volumes Double irradiation of the overlapping area Patient integrity is jeopardised The patient is endangered	Incomplete technical file Missing medical records	4	2	8	Interview the patient Look for previous tattoos	4	1	4	Introduce electronic medical/technical files compliant with the DICOM-RT standard

Probability: 1= very rare – once every 5 years, 2= rare – once a year, 1 = frequent – once a month, 4 = very frequent -- daily
Severity: 1=minor= not very critical, 2= significant= critical, 3= very critical, 4= serious= catastrophic

EXTERNAL BEAM RADIOTHERAPY											
Patient Itinerary	Failure mode	Possible effects	Causes	S	P	iCI	Possible corrective measures	S	P	fCI	Optimisation
5 Definition of ballistics	**PI-14** Incorrect treatment data (due to manual data input)	Patient integrity is significantly jeopardised (treatment error)	Positioning - immobilisation Error in the transcription of beam dimensions and parameters	4	3	12	Describe in detail the treatment position Describe in detail the immobilisation device and the position used Set up a written data transfer system - double verification Keep a record of the number of times data is re-entered, and set up a verification system	4	2	8	Create an electronic link between the simulation tool and the record and verify system, to prevent the need for manual data re-entry Create a link with the network
6 Calculation of dose distribution and of monitor units	**PI-15** Scan examination error (images used to define target volumes, when there are several series of examinations)	Patient integrity is significantly jeopardised (treatment error)	Inattention on the part of the operator Lack of information or incorrect information on the images available	4	3	12	Make sure that the images used are those which were approved for treatment planning Make sure data is transferred in writing if several scanners are used Provide exhaustive information in the image files	4	2	8	Establish image identification and validation rules (procedure)
	PI-16 Error of calculation	Patient integrity is significantly jeopardised (treatment error)	Incorrect data input Inadequate software ergonomics Shortage of time / inadequate operator training Electron density / Hounsfield number conversion tables not available (in the calculator) for the scanning images, or not defined for the scanner being used	4	3	12	Check the orders of magnitude based on the initial experimental data Have the radiation physicist check and validate the calculations (dose distribution + monitor units) Have the radiation therapist validate the dose distribution (overall dose, fractionation, number of beams, filters, etc.) Check the orders of magnitude based on the initial experimental data	4	1	4	Identify the limitations of the calculators Carry out in-vitro dosimetry measurements in a phantom matching the patient's morphology, for some techniques (IMRT) and/or all risky, complex clinical situations (taking into consideration the limitations of some algorithms and of their implementation) Double check using in-vivo dosimetry if technically feasible Establish an intervention level based on an analysis of uncertainties, according to the technique/ballistics (eg. above 5%)

Probability: 1= very rare – once every 5 years, 2= rare – once a year, 1 = frequent – once a month, 4 = very frequent -- daily
Severity: 1=minor= not very critical, 2= significant= critical, 3= very critical, 4= serious= catastrophic

EXTERNAL BEAM RADIOTHERAPY											
Patient Itinerary	Failure mode	Possible effects	Causes	S	P	iCI	Possible corrective measures	S	P	fCI	Optimisation
7 Treatment room	**PI-17** Patient identification error	Patient integrity is significantly jeopardised (treatment error)	New patient Confusion when selecting the patient's name from the pull-down menu Name mix-up Communication difficulties with the patient (confusion, sensory impairment) Lack of organisation	4	4	16	Make sure that a photo of the patient is available Establish a patient traceability system which does not rely on the patient's name (bar code, number, etc.) Make sure that the patient's file (data, photo) is in the treatment room and on the control desk Make sure that the patient gives his/her appointment card to the operator Check the location of tattoos Make sure that the immobilisation device is suitable for the patient	4	2	8	Have the operator double check the identity of the patient before s/he enters the treatment room, by asking the following question: What's your name? Insert the images of the treatment area
	PI-18 Use of another patient's immobilisation device	Patient integrity is significantly jeopardised (treatment error)	Inattention on the part of the operator Incorrect referencing of immobilisation devices	3	3	9	Make sure that the immobilisation device belongs to the patient (code or index number)	3	2	6	
	PI-19 Use of another patient's shield	Patient integrity is significantly jeopardised (treatment error)	Inattention on the part of the operator Incorrect referencing of shields	3	3	9	Visually check that the right shield is being used Enable the accelerator's automatic detection system, if it has one	3	2	6	Wherever possible, purchase machines that have a system for automatically detecting shield errors Assign reference codes to shields (R&V)
	PI-20 Shield positioning error	Patient integrity is significantly jeopardised (treatment error)	Design fault Incorrect definition of the shield position	3	3	9	Use imaging to check the position of the shield	3	2	6	Purchase multileaf collimators Shorten the interval between test images

Probability: 1= very rare – once every 5 years, 2= rare – once a year, 1 = frequent – once a month, 4 = very frequent -- daily
Severity: 1=minor= not very critical, 2= significant= critical, 3= very critical, 4= serious= catastrophic

EXTERNAL BEAM RADIOTHERAPY											
Patient Itinerary	Failure mode	Possible effects	Causes	S	P	iCI	Possible corrective measures	S	P	fCI	Optimisation
7 Treatment room	**PI-21** Patient positioning error, immobilisation error	Patient integrity is significantly jeopardised (treatment error)	Inattention on the part of the operator Inadequate references for correctly positioning the patient	3	3	9	Check alignment with tattoos Describe the treatment position in detail Describe in detail the immobilisation and positioning devices used Define an adequate number of reference points Communicate information in writing Take a test image (if in doubt, perform another simulation)	3	2	6	During treatment, make sure that the patient is able to adopt and maintain the required position
	PI-22 Referencing error (tattoos/markers/images) Beam positioning error	Patient integrity is significantly jeopardised (treatment error)	Inattention on the part of the operator Confusion regarding reference points (Previous treatments interrupted surgery, etc.)	3	3	9	Draw up a common tattooing protocol Set up an imaging-based verification system Perform an imaging test before each new treatment session	3	2	6	
	PI-23 Change in the patient's position during treatment	Patient integrity is significantly jeopardised	Patient behaviour Patient breathing	4	4	16	Remind operators to be particularly vigilant regarding patient position Try to find the most comfortable positions	4	3	12	Purchase a respiratory gating system for some treatments
	PI-24 Irradiation field sizing error	Patient integrity is significantly jeopardised	Maladjusted equipment Unit problem Beam programming error (incorrect transfer of centring data, or data input error)	3	3	9	Review the accelerator quality control procedure (frequency) Perform an imaging test	3	1	3	

Probability: 1= very rare – once every 5 years, 2= rare – once a year, 1 = frequent – once a month, 4 = very frequent -- daily
Severity: 1=minor= not very critical, 2= significant= critical, 3= very critical, 4= serious= catastrophic

EXTERNAL BEAM RADIOTHERAPY											
Patient Itinerary	Failure mode	Possible effects	Causes	S	P	iCI	Possible corrective measures	S	P	fCI	Optimisation
7 Treatment room	**PI-25** Failure to protract the dose correctly	Patient integrity is significantly jeopardised	Inattention on the part of the operator Incorrect data input R&V software not used Lack of organisation R&V software not configured correctly	3	2	6	Make sure that the treatment plan complies with the prescription: (number and frequency of treatment sessions, total dose, dose per volume) Review the management of access rights to the R&V system in the treatment room (the operator should not be able to change the treatment ballistics, the monitor units (MU) delivered per beam, the fractionation parameters or the dose protraction parameters) Check the dose per beam and per session	3	1	4	Make sure that the R&V system takes into account the dose/beam/session ratio
	PI-26 Failure of the operator to detect an incident during the treatment session	Patient integrity is significantly jeopardised	Inadequate supervision of the patient during the treatment session	3	3	9	Introduce a procedure for monitoring what patients say and how they look during the treatment session Optimise the position of cameras to detect patient movement. Make sure that cameras are able to zoom in on the patient.	3	2	6	Introduce automatic movement detection systems
	PI-27 Failure to spot a dosing error in the treatment chain	Possibility of over-dosage or under-dosage	No overall verification of the treatment chain	4	3	12	Introduce in-vivo dosimetry Set up a training course (man-machine) Train staff to use computer equipment	4	2	8	

Probability: 1= very rare – once every 5 years, 2= rare – once a year, 1 = frequent – once a month, 4 = very frequent -- daily
Severity: 1=minor= not very critical, 2= significant= critical, 3= very critical, 4= serious= catastrophic

EXTERNAL BEAM RADIOTHERAPY											
Patient Itinerary	Failure mode	Possible effects	Causes	S	P	iCI	Possible corrective measures	S	P	fCI	Optimisation
8 Follow-up visits	**PI-28** No weekly visit	Failure to spot side effects (see following point)	Shortage of time Lack of organisation	3	3	9	Make weekly visits standard procedure	3	2	6	Create a weekly visit information sheet with indicators, so that patient data can be recorded quickly and effectively
	PI-29 Appearance of unexpected side effects during treatment	Adverse effects	Individual radiosensitivity Error in planning and/or delivering the treatment	4	2	8	Check the treatment chain Discontinue treatment if necessary, either temporarily or definitively Provide reinforced medical follow-up of the patient	4	2	8	
	PI-30 No end-of-treatment visit	Failure to spot side effects (see following point)	Shortage of time Lack of organisation	4	3	12	Make end-of-treatment visits standard procedure	4	1	4	Create an end-of-treatment visit information sheet with indicators, so that patient data can be recorded quickly and effectively
	PI-31 No post-treatment follow-up visit	Failure to spot side effects (see following point)	Shortage of time Lack of organisation	4	3	12	Make post-treatment visits standard procedure	4	1	4	Draw up a post-treatment follow-up schedule for each treated site Create a post-treatment visit information sheet with indicators, so that patient data can be recorded quickly and effectively
	PI-32 Appearance of unexpected side effects after the end of treatment	Adverse effects	Error in planning and/or delivering the treatment	4	2	8	Remind the patient of the importance of regular follow-up visits	4	2	8	Make sure that the doctor in charge of following up the patient liaises with the radiation therapist Draw up a form for communicating and monitoring clinical / disease indicators

Probability: 1= very rare – once every 5 years, 2= rare – once a year, 1 = frequent – once a month, 4 = very frequent -- daily
Severity: 1=minor= not very critical, 2= significant= critical, 3= very critical, 4= serious= catastrophic

EXTERNAL BEAM RADIOTHERAPY											
Equipment	Failure mode	Possible effects	Causes	S	P	iCI	Possible corrective measures	S	P	fCI	Optimisation
9 Dose planning TPS (Treatment Planing System)	**E-1** Incorrect data input Incorrect interpretation of some parameters Confusion between two data input parameters	Inappropriate treatment The patient is endangered	Inadequate training of staff The data input interfaces used in dose planning are not user-friendly Text in a foreign language unfamiliar to the operator Units not indicated for some parameters Operator fatigue	4	3	12	Draw up a procedure to indicate the units used for each measurable parameter (dosimetric or non-dosimetric) Use the French version of the software, if available Keep a translated glossary of the parameters within the reach of users	4	2	8	Make data input and treatment delivery interfaces more user-friendly: Indicate the units used for each measurable parameter (dosimetric or non-dosimetric) Clarify the designation of certain parameters Install a French version of the software
	E-2 Computer bugs (occurrence of adverse effects due to the software)	The patient is endangered Uncontrollable effect on the distribution of the delivered dose	Software/hardware No record of possible errors (rarely catalogued)	4	2	8	Keep an up-to-date record of the bugs encountered Keep this record within the reach of operators Introduce a system for alerting an expert if a new bug is encountered Suspend treatment until the situation is resolved	4	1	4	Set up a procedure for dealing with new bugs
	E-3 No procedure to verify the dose delivered per measurement in complex treatment plans	The patient is endangered Over- or underdose of the tumour and/or the adjacent critical organs Short-term, medium-term or long-term side effects of the treatment	Failure to take into consideration: Regions where electronic equilibrium is not established Dose under shields Penumbral regions Tangential beams Heterogeneity Techniques using intensity modulation (IMRT) Techniques based on dynamic arc therapy, using stereotactic positioning	4	3	12	Introduce a procedure for verifying the dose delivered per measurement	4	2	8	Periodically review the procedure

Probability: 1= very rare – once every 5 years, 2= rare – once a year, 1 = frequent – once a month, 4 = very frequent -- daily
Severity: 1=minor= not very critical, 2= significant= critical, 3= very critical, 4= serious= catastrophic

EXTERNAL BEAM RADIOTHERAPY											
Equipment	Failure mode	Possible effects	Causes	S	P	iCI	Possible corrective measures	S	P	fCI	Optimisation
9 Dose planning TPS (Treatment Planing System)	**E-4** Error between calculated delivered dose and measured delivered dose Dose distribution error in a plane or a volume	Over- or underdose of the tumour and/or the adjacent critical organs Short-term, medium-term or long-term side effects of the treatment The patient is endangered	Inadequate training of staff Not enough time to perform thorough checks (not allowed for in the schedule of work on the accelerator) Error in the measurement or input of basic parameters used to create or verify models: - dose / reference monitor unit - variation in dose when the collimator opens - depth dose (percentage depth dose or tissue-to-medium ratio), dose profiles, dose rate depending on the opening - reference parameters for performing calculations with accessories (filters, additional shields, etc.) Inadequate or incorrect modelling	4	3	12	Introduce a protocol for verifying the quality of the dose delivered: monthly and six-monthly tests	4	2	8	
	E-5 Incorrect scale used in the delineation (contouring) of target volumes, critical organs, external contours	Inappropriate treatment The patient is endangered	Inadequate training of staff Scale not validated for the equipment or the current version	4	3	12	Adjust scales (on printers, monitors, software) each time equipment is changed or upgraded	4	2	8	Define test protocols Allocate time for conducting these tests

Probability: 1= very rare – once every 5 years, 2= rare – once a year, 1 = frequent – once a month, 4 = very frequent -- daily
Severity: 1=minor= not very critical, 2= significant= critical, 3= very critical, 4= serious= catastrophic

EXTERNAL BEAM RADIOTHERAPY											
Equipment	Failure mode	Possible effects	Causes	S	P	iCI	Possible corrective measures	S	P	fCI	Optimisation
9 Dose planning TPS (Treatment Planing System)	**E-6** Errors in the printing formats of dosimetry data	Inappropriate treatment Errors in the dose delivered, due to inaccurate interpretation of data	Inadequate training of staff Scale not validated for the equipment or the current version	4	3	12	Adjust scales (on printers, monitors, software) each time equipment is changed or upgraded	4	2	8	Define test protocols Allocate time for conducting these tests
	E-7 Incorrect calculation of the dose to deliver, due to inaccurate estimation of tissue density	Over- or under-dosage Inappropriate treatment of areas where variations in tissue density are high.	Inaccurate and/or ill-defined Hounsfield/density conversion tables	4	3	12	Create conversion tables each time equipment is changed or upgraded	4	2	8	
10 R&V network equipment (Record and Verify coupled with the Radiotherapy Information System)	**E-8** Incorrect data input Incorrect interpretation of some parameters Confusion between two data input parameters	Inappropriate treatment The patient is endangered	Inadequate training of staff Lack of ergonomy of: -the treatment data input interface -the treatment delivery interface (accelerator controls) -text in a foreign language unfamiliar to the operator -units not indicated for some parameters -operator fatigue	4	3	12	Make data input and treatment delivery interfaces more user-friendly: - indicate the units used for each measurable parameter (dosimetric or non-dosimetric) - clarify the designation of certain parameters - use a French version of the software - keep a translated glossary of the parameters within the reach of users	4	2	8	Create a direct link between the TPS and the R&V system

Probability: 1= very rare – once every 5 years, 2= rare – once a year, 1 = frequent – once a month, 4 = very frequent -- daily
Severity: 1=minor= not very critical, 2= significant= critical, 3= very critical, 4= serious= catastrophic

EXTERNAL BEAM RADIOTHERAPY											
Equipment	Failure mode	Possible effects	Causes	S	P	iCI	Possible corrective measures	S	P	fCI	Optimisation
10 R&V network equipment (Record and Verify coupled with the Radiotherapy Information System)	**E-9** Computer bugs (occurrence of adverse effects due to the software)	The patient is endangered Uncontrollable effect on the distribution of the delivered dose	Software problem Hardware problem No record of possible errors (rarely catalogued)	4	2	8	Keep an up-to-date record of the bugs encountered Keep this record within the reach of operators Introduce a system for alerting an expert if a new bug is encountered - wait for the expert's conclusions Suspend treatment if the quality of treatment may be affected	4	1	4	Set up a procedure for dealing with new bugs
	E-10 Problem with the transfer of information, related to the user images	Inappropriate treatment The patient is endangered	Incorrect input of "patient" data, leading to incompatibility with other data relating to the same patient in the Radiotherapy Information System (RTIS) Images not acquired in the correct order (if several series of slices) Inadequate optimisation of image viewing parameters (poor quality image) Some DICOM data missing User fatigue or inadequate training	4	3	12	Verify the content of protocols and their application by users In the absence of a router, keep the hard copy: this copy constitutes the independent quality control needed to authorise the first irradiation session Make sure that the procedures are kept within the reach of users.	4	2	8	Update / complete / establish quality control procedures applicable to data transfers Introduce a regular training protocol on data transfer Implement data transfer verification procedures: - when new equipment is installed - when a component in the communication system is upgraded - after each recorded "error" Keep an up-to-date record of "errors" and their causes

Probability: 1= very rare – once every 5 years, 2= rare – once a year, 1 = frequent – once a month, 4 = very frequent -- daily
Severity: 1=minor= not very critical, 2= significant= critical, 3= very critical, 4= serious= catastrophic

EXTERNAL BEAM RADIOTHERAPY											
Equipment	Failure mode	Possible effects	Causes	S	P	iCI	Possible corrective measures	S	P	fCI	Optimisation
10 R&V network equipment (Record and Verify coupled with the Radiotherapy Information System)	**E-11** Problem with the transfer of information, related to the user treatment plan information	Inappropriate treatment The patient is endangered	Incorrect input of "patient" data, leading to incompatibility with other data relating to the same patient in the Radiotherapy Information System (RTIS) Beam parameters not entered or partly incorrect Incorrect dose per beam, number of fractions, etc. User fatigue or inadequate training	4	3	12	Verify the content of protocols and their application by users In the absence of a router, keep the hard copy: this copy constitutes the independent quality control needed to authorise the first irradiation session Make sure that the procedures are kept within the reach of users.	4	2	8	Update / complete / establish quality control procedures applicable to data transfers Introduce a regular training protocol on data transfer Implement data transfer verification procedures: - when new equipment is installed - when a component in the communication system is upgraded - after each recorded "error" Keep an up-to-date record of "errors" and their causes
	E-12 Problem with the network transfer of information, related to the procedure (CT scanner, MRI, PET scanner etc. to the TPS): images	Inappropriate treatment The patient is endangered	Incompatibility between the software versions used Failure to preserve image orientation Failure to preserve CT numbers (link with the physical/electron density of the tissues) Image data deformation in the case of scan acquisitions with a variable inter-slice distance	4	3	12	Make sure that the softwares accurately interpret the data exchanged, as on paper Verify the content of protocols and their application by users In the absence of a router, keep the hard copy: this copy constitutes the independent quality control needed to authorise the first irradiation session	4	2	8	Implement data transfer control procedures: - when new equipment is installed - when a component in the communication system is upgraded - after each recorded "error" Keep an up-to-date record of "errors" and their causes Prefer equipment which complies with the DICOM standard or which allows for "straightforward" temporary solutions Proceed in a step-by-step manner, starting with each new piece of equipment The specifications of each new piece of equipment must take into account all the functionalities in the network

Probability: 1= very rare – once every 5 years, 2= rare – once a year, 1 = frequent – once a month, 4 = very frequent -- daily
Severity: 1=minor= not very critical, 2= significant= critical, 3= very critical, 4= serious= catastrophic

EXTERNAL BEAM RADIOTHERAPY											
Equipment	Failure mode	Possible effects	Causes	S	P	iCI	Possible corrective measures	S	P	fCI	Optimisation
10 R&V network equipment (Record and Verify coupled with the Radiotherapy Information System)	**E-13** Problem with the network transfer of information, related to the procedure (TPS to R&V/RTIS, R&V/RTIS to accelerators): treatment parameters	Inappropriate treatment The patient is endangered	Incompatibility between the software versions used Inconsistent interpretation of the data transferred between two systems The exchange of data in DICOM format: - the attributes exist in the patient's DICOM file, but the service provider software does not assign the same value to them or the user software is unable to read them - the attributes exist in the DICOM object definitions, but they are not or cannot be defined in the dose planning system or the RTIS (e.g..: DSP, position on the couch, number of fractions, etc.) - the attributes exist in the patient's administrative records, but do not correspond to a technical radiotherapy procedure The exchange of data with proprietary standards for each piece of equipment (creation of gateways): the same type of risks, but very considerably magnified	4	3	12	Make sure that the software accurately interpret the data exchanged, as on paper Verify the content of protocols and their application by users In the absence of a router, keep the hard copy: this copy constitutes the independent quality control needed to authorise the first irradiation session	4	2	8	Implement data transfer control procedures: - when new equipment is installed - when a component in the communication system is upgraded - after each recorded "error" Keep an up-to-date record of "errors" and their causes Prefer equipment which complies with the DICOM standard or which allows for "straightforward" temporary solutions Proceed in a step-by-step manner, starting with each new piece of equipment The specifications of each new piece of equipment must take into account all the functionalities in the network

Probability: 1= very rare – once every 5 years, 2= rare – once a year, 1 = frequent – once a month, 4 = very frequent -- daily
Severity: 1=minor= not very critical, 2= significant= critical, 3= very critical, 4= serious= catastrophic

EXTERNAL BEAM RADIOTHERAPY											
Equipment	Failure mode	Possible effects	Causes	S	P	iCI	Possible corrective measures	S	P	fCI	Optimisation
10 R&V network equipment (Record and Verify coupled with the Radiotherapy Information System)	**E-14** Problems encountered further to the upgrading or modification of software by the manufacturer	Inappropriate treatment The patient is endangered	Incompatibility between the software versions used Inconsistent interpretation of the data transferred between two systems	4	3	12	Obtain a list of the modifications made by the manufacturer Perform a further quality control of the features changed	4	2	8	Ask the manufacturer for a full list of the parameters affected by the changes (points requiring vigilance).
11 Immobilisation devices / Markings / Shields	**E-15** Immobilisation device design fault	Inappropriate treatment Patient discomfort Positioning problem	Immobilisation device too tight The patient has lost weight Immobilisation device too loose Position too difficult to maintain for the patient	3	3	9	Improve the immobilisation device development process Make sure that the staff in charge of creating the immobilisation device are aware of its importance Train staff to create different immobilisation devices If necessary, create a new immobilisation device during treatment	3	2	6	Draw up a procedure for the development of different immobilisation devices
	E-16 Immobilisation device error	Inappropriate treatment	Wrong choice of immobilisation device during the manufacturing Incorrect referencing of the immobilisation device Mix-up of one patient's immobilisation device with that of another patient	3	2	6	Make sure that the staff in charge of creating the immobilisation device are aware of its importance Train staff to create different immobilisation devices Enhance traceability	3	1	3	
	E-17 Shield design fault (wrong thickness or shape)	Inappropriate treatment	Error or inattention on the part of the operator The alloy used is of inappropriate density Choice of material	3	3	9	Make sure that the person who develops the shield checks its size and thickness Use imaging to check new or modified shields, at least before each treatment session Be vigilant regarding radio-opaque immobilisation devices	3	2	6	

Probability: 1= very rare – once every 5 years, 2= rare – once a year, 1 = frequent – once a month, 4 = very frequent -- daily
Severity: 1=minor= not very critical, 2= significant= critical, 3= very critical, 4= serious= catastrophic

EXTERNAL BEAM RADIOTHERAPY											
Equipment	Failure mode	Possible effects	Causes	S	P	iCI	Possible corrective measures	S	P	fCI	Optimisation
11 Immobilisation devices / Markings / Shields	**E-18** No positioning reference points (on the patient or the immobilisation device)	Difficulties in positioning the patient Treatment not reproducible	Oversight during simulation Markings erased	3	2	6	Draw up a written procedure Always check reference points before beginning treatment Realign if necessary	3	1	3	Promote the use of on-board imaging systems (verification of the patient's position by aligning the "on-board image" with the reference image)
12 Portal imaging device Re-positioning imaging device	**E-19** Poor image quality	Inappropriate treatment	Incorrect calibration of the sensor Imaging device off-centre	3	2	6	Comply with recommendations regarding imaging device calibration intervals Regularly check image quality Reduce positioning tolerances	3	1	3	Set up a preventive maintenance procedure
	E-20 No reference images, or poor-quality reference images (matching system)	Inappropriate treatment	Patient identification error Incorrect choice of digital filter or of image type (MV/kV)	3	2	6	Clearly identify the patient Select the patient who is actually lying on the treatment couch Always check the patient's file before commencing treatment	3	1	3	Maintain a critical stance regarding the images obtained Traceability of the checks performed
	E-21 shift error	Inappropriate treatment	Misunderstanding of the direction of the offsets needed Incorrect tattooing point set-up	3	2	6	Harmonise the recommendations and information from different doctors Establish a written record of these recommendations and information Check the couch set-up	3	1	3	Take another test image If inconclusive, take another scan or carry out another simulation

Probability: 1= very rare – once every 5 years, 2= rare – once a year, 1 = frequent – once a month, 4 = very frequent -- daily
Severity: 1=minor= not very critical, 2= significant= critical, 3= very critical, 4= serious= catastrophic

EXTERNAL BEAM RADIOTHERAPY											
Equipment	Failure mode	Possible effects	Causes	S	P	iCI	Possible corrective measures	S	P	fCI	Optimisation
13 Accelerator	**E-22** Internal quality control not completed	Dose received by the patient different to the planned dose Treatment parameters not met The patient is endangered	Some parameters not verified often enough Shortage of time Shortage of staff Dosimetry equipment inadequate to perform certain verifications	4	2	8	Make a list of the checks required and note how often they should be performed, depending on the potential risk of failure associated with the parameter in question Expand the team in charge of these checks Purchase the equipment needed to perform these checks Comply with decisions issued by AFSSAPS	4	1	4	Classify parameters according to risk type Optimise the organisation of human resources Develop a quality policy as opposed to a performance policy Establish a record of failures leading to a loss of quality
14 Whole treatment chain	**E-23** Accessory damaged or not functioning properly (filter, laser, telemeter, repositioning system, etc.)	Inappropriate treatment	Data transfer problem Human factors Failure to follow instructions	3	2	6	Keep a record - traceability of communications between operators	3	1	3	Implement a fail soft procedure in certain cases
	E-24 Calibration drift	Over- or under-dosage The patient is endangered	No daily check of the monitor unit value. Problem with the accelerator's ionisation chamber Faulty test equipment Failure to follow instructions Error in the calibration procedure	3	2	6	Set up an inspection traceability system Have the travelling-wave tube checked every day by a qualified technician	3	1	3	Introduce in-vivo dosimetry

Probability: 1= very rare – once every 5 years, 2= rare – once a year, 1 = frequent – once a month, 4 = very frequent -- daily
Severity: 1=minor= not very critical, 2= significant= critical, 3= very critical, 4= serious= catastrophic

EXTERNAL BEAM RADIOTHERAPY											
General organisation	Failure mode	Possible effects	Causes	S	P	iCI	Possible corrective measures	S	P	fCI	Optimisation
14 Whole treatment chain	**E-25** No start-up procedure for any of the devices in the treatment chain	Over- or under-dosage of all treatments The patient is endangered	Failure to follow instructions Shortage of time Shortage of staff Confusion between the different tests to be performed	3	2	6	Conduct the following compulsory tests in chronological order: - acceptance tests with the manufacturer - non-dosimetric and dosimetric commissioning tests	3	1	3	Perfect knowledge of software limitations TPS - expression of algorithm variations / tolerances Periodically conduct tests pertaining to specific clinical situations
15 Metrology	**E-26** Calibration or dose control error	Over- or under-dosage of all treatments The patient is endangered	Malfunction in the measurement chain Failure to adhere to a regular equipment calibration schedule Failure to comply with the calibration protocol Malfunction in the water tank	4	2	8	Repair the fault / correct the calibration error Systematically check that measurements are consistent with previous values	4	1	4	Verify the response of the measurement chain against a constant source Have a calibrated reference source of radiation

Probability: 1= very rare – once every 5 years, 2= rare – once a year, 1 = frequent – once a month, 4 = very frequent -- daily
Severity: 1=minor= not very critical, 2= significant= critical, 3= very critical, 4= serious= catastrophic

EXTERNAL BEAM RADIOTHERAPY											
General organisation	Failure mode	Possible effects	Causes	S	P	iCI	Possible corrective measures	S	P	fCI	Optimisation
16 Human and organisational factors	**HOF-1** Rate of work Pressure due to the work schedule Failure of the management to see the situation as it actually is and to act accordingly Failure of the management to take into account the introduction of new treatment equipment and/or techniques	Stress leading to errors at all levels of decision-making Not enough time for maintenance and inspections Risk-taking due to shortage of time Risks for the patient Disorganisation within the department	Shortage of staff due to holidays and sick leave Poor organisation within the department, from the booking of appointments to the management of patient records at the post-treatment stage Poor organisation of maintenance work (e.g. difficulties in restarting the accelerator after daily testing of the emergency stop device during operation) Failure to verify the adequacy between the workload and the human resources available Poor distribution of tasks and responsibilities	3	3	9	Conduct an audit Invest in a task scheduling tool Optimise test procedures (e.g. conduct emergency stop tests during maintenance periods) Verify the adequacy between the workload and the human resources available Conduct a feasibility study before purchasing equipment	3	2	6	Identify optimal solutions and test them Act on the results of the workload / human resources analysis (recruitment, definition of indicators, etc.) If necessary, consult with an outside specialist in organisation – National Hospital Expertise and Audit Agency (MEAH)
	HOF-2 Temporary unavailability of a radiation physicist in the department	Impact on the preparation and validation of patient files Failure to detect possible treatment malfunctions Impossibility of taking action in the event of a treatment problem	Shortage of staff Holidays / Sickness leave Training External meetings Installation - testing - commissioning of a new machine	3	3	9	Hire another radiation physicist Draw up a duty schedule or an accessible on-call schedule Establish the minimum requirements of the contract (knowledge of equipment and software, regular meetings, etc.)	3	2	6	Delegate some quality control tasks to qualified technical staff, in order to relieve the radiation physicist's workload Draw up an agreement with a neighbouring establishment, ensuring that another radiation physicist will be available in the event of problems
	HOF-3 Temporary unavailability of the department's radiation therapist	Impact on the preparation and validation of patient files Impossibility of taking action in the event of a treatment problem	Shortage of staff Holidays / Sickness leave Training External meetings	3	2	6	Draw up a duty schedule or an accessible on-call schedule	3	1	3	

Probability: 1= very rare – once every 5 years, 2= rare – once a year, 1 = frequent – once a month, 4 = very frequent -- daily
Severity: 1=minor= not very critical, 2= significant= critical, 3= very critical, 4= serious= catastrophic

EXTERNAL BEAM RADIOTHERAPY											
General organisation	Failure mode	Possible effects	Causes	S	P	iCI	Possible corrective measures	S	P	fCI	Optimisation
16 Human and organisational factors	**HOF-4** Lack of communication	Risk of treatment or patient identification errors	Poor relationship between co-workers Rate of work Bad working atmosphere	3	3	9	Improve internal organisation Work on the management Foster dialogue Avoid sources of conflict Organise communication between the different members of the radiotherapy team See HOF-1	3	2	6	Draw up a code of conduct
	HOF-5 Inattention of an operator while working	Risk of treatment or patient identification errors	Attempt by a third party to gain the attention of an operator while s/he is working, for non-essential reasons or regarding other tasks	3	3	9	Make sure that operators are not interrupted while working, for reasons unrelated to their current task	3	2	6	Draw up a code of conduct Consult the MEAH's work on this subject
	HOF-6 Unclear definition of responsibilities	Unclear verification and validation procedures Conflicts of interest between those in charge Dangerous situations	Ill-defined hierarchical links / responsibilities Relationship between the radiation therapist / radiation physicist / dosimetrist / operator / technician Complex distribution of responsibilities between the radiation physicist and the biomedical engineer	3	3	9	Clarify the position of radiation physicists, dosimetrists and technicians in the hierarchy Ensure that staff working under the supervision of a given person report directly to this person Formalise organisation charts and job descriptions	3	2	6	
	HOF-7 No harmonisation of treatment practices within the same facility (for a given organ)	Potential source of errors for: - the physician - dosimetrists - operators	Lack of cooperation between radiation therapists Lack of leadership from the head of department	4	3	12	Promote dialogue Draw up a protocol per organ type, applicable at least to the entire establishment Comply with the protocol (exceptions possible for quality assurance reasons)	4	2	8	Draw up common protocols between radiation therapists

Probability: 1= very rare – once every 5 years, 2= rare – once a year, 1 = frequent – once a month, 4 = very frequent -- daily
Severity: 1=minor= not very critical, 2= significant= critical, 3= very critical, 4= serious= catastrophic

EXTERNAL BEAM RADIOTHERAPY											
General organisation	Failure mode	Possible effects	Causes	S	P	iCI	Possible corrective measures	S	P	fCI	Optimisation
16 Human and organisational factors	**HOF-8** No validation of treatment protocols per organ type, or of amendments to protocols	Ill-defined treatment plan Risk of over-dosage or under-dosage	Shortage of time Lack of organisation	4	3	12	Introduce a validation procedure, including dosimetry, for each treatment protocol	4	2	8	Check the protocols regularly
17 Archiving and Filing	**HOF-9** Incorrect archiving / filing - of the patient's medical records - of the radiotherapy file	Filing of data concerning patient X in the file of patient Y Treatment definition error	Shortage of time File not completed correctly Name mix-up	2	3	6	Set up a filing procedure Always check the patient's name and number	2	1	2	
	HOF-10 Missing documents (consultation report, etc.)	Waste of time Loss of information that could be instrumental in defining the treatment plan	Archiving error Failure to inform the medical secretarial office of the documents required (from the patient's GP, etc.)	2	3	6	Draw up a list of the documents in the patient's medical file	2	1	2	Make sure that the examinations prescribed are consistent with the results obtained
18 Identification of discrepancies / Feedback	**HOF-11** Failure to detect unexpected events or incidents caused by the radiation	Occurrence of serious adverse events Discrepancy between the treatment doses planned and those actually delivered	Lack of response from the medical team to side effects or to patient concerns Follow-up visits not carried out	4	3	12	Observe the patient's general condition Listen to the patient's concerns Organise systematic follow-up visits	4	2	8	Obtain access to the radiation therapists' appointment schedules, in order to be able to organise appointments quickly

Probability: 1= very rare – once every 5 years, 2= rare – once a year, 1 = frequent – once a month, 4 = very frequent -- daily
Severity: 1=minor= not very critical, 2= significant= critical, 3= very critical, 4= serious= catastrophic

EXTERNAL BEAM RADIOTHERAPY											
General organisation	Failure mode	Possible effects	Causes	S	P	iCI	Possible corrective measures	S	P	fCI	Optimisation
18 Identification of discrepancies / Feedback	**HOF-12** Inadequate assessment of the radiotherapy process during treatment (in terms of radiation protection)	Failure to spot malfunctions or anomalies during treatment planning and delivery Impossibility of evaluating the overall quality of the treatment	No regular meetings of the medical team Follow-up visits not carried out Follow-up visits not traceable	4	3	12	Set up a regular meeting to discuss files Define a vigilance indicator Organise systematic follow-up visits Make sure that follow-up visits are traceable	4	2	8	Record side effects and their level of severity in a management chart Circulate the indicators internally
	HOF-13 Inadequate post-treatment follow-up / failure to spot delayed effects	Failure to spot possible treatment malfunctions Impossibility of evaluating the overall quality of the treatment	Patients do not have regular appointments with their radiation therapist No regular meetings between the radiotherapist and the treatment team Clinical examination not carried out	4	4	16	Set up a procedure for systematically monitoring all patients Keep an up-to-date record of patient follow-up information	4	2	8	Record side effects and their level of severity in the end-of-treatment report or the post-treatment follow-up reports.
	HOF-14 Poor organisation of experience feedback	Failure to spot possible treatment malfunctions Impossibility of evaluating the overall quality of the treatment	No statistical analysis of treatment data per organ type and patient type No regular assessment of treatments by the medical team	4	4	16	Create a record of discrepancies	3	2	6	Conduct a periodic review of treatment protocols, with a view to updating and improving them

Probability: 1= very rare – once every 5 years, 2= rare – once a year, 1 = frequent – once a month, 4 = very frequent -- daily
Severity: 1=minor= not very critical, 2= significant= critical, 3= very critical, 4= serious= catastrophic

EXTERNAL BEAM RADIOTHERAPY											
General organisation	Failure mode	Possible effects	Causes	S	P	iCI	Possible corrective measures	S	P	fCI	Optimisation
18 Identification of discrepancies / Feedback	**HOF-15** Inadequate preparation of changes (to the treatment, equipment or organisational set-up)	Occurrence of unexpected events due to the incorrect implementation of the treatment process Failure to take a change (and all its consequences) into account	No risk assessment No change implementation and management procedure Failure to comply with IAEA requirements No procedure for tracking the changes implemented	4	3	12	Conduct a risk assessment before making a change Set up a change management procedure Make sure that changes are being applied by staff Conduct implementation tests Organise change traceability procedures, and the information and training of staff	4	2	8	Conduct risk assessments for each piece of equipment, in collaboration with the manufacturers Allocate staff time to coordinating quality in the radiotherapy department Verify compliance with IAEA requirements
	HOF-16 Failure to inform users when equipment is changed (software upgrades, etc.)	Failure to take the change into account Treatment planning or delivery errors	Isolated decision Poor communication within the department	4	3	12	Set up a system for informing all users when equipment or software is changed Make sure that changes are traceable	4	2	8	Allocate staff time to coordinating quality in the radiotherapy department
	HOF-17 Failure to inform concerned parties when a treatment variable is changed	Failure to take the change into account Treatment planning or delivery errors	Isolated decision Poor communication within the department	4	3	12	Set up a system for informing all concerned parties when a treatment parameter is changed Make sure that changes are traceable	4	2	8	Allocate staff time to coordinating quality in the radiotherapy department

Probability: 1= very rare – once every 5 years, 2= rare – once a year, 1 = frequent – once a month, 4 = very frequent -- daily
Severity: 1=minor= not very critical, 2= significant= critical, 3= very critical, 4= serious= catastrophic

EXTERNAL BEAM RADIOTHERAPY											
General organisation	Failure mode	Possible effects	Causes	S	P	iCI	Possible corrective measures	S	P	fCI	Optimisation
19 Training	**HOF-18** Skills management Individual and team training sessions	Inadequate knowledge of tools, equipment and software Treatment planning or delivery errors	Shortage of time No skills management No training plan No resources Training postponed or cancelled, with no further action	4	2	8	Develop a training plan for all staff likely to be working on new equipment Reinforce the notion of teamwork	4	1	4	Draw up a training programme self-assessment guide
	HOF-19 Personnel management Management of new recruits	Inadequate knowledge of tools, equipment and software Treatment planning or delivery errors	Shortage of time No skills management No training plan No resources Training postponed or cancelled Poor relationship between co-workers	4	2	8	Develop a process for welcoming and training new recruits Conduct a skills assessment Draw up a job description	4	1	4	Evaluate and validate training courses
	HOF-20 Skills management Authorisation of personnel to use specific techniques and upgraded equipment	Inadequate knowledge of tools, equipment and software Treatment planning or delivery errors	No definition of the skills needed by the department Shortage of resources and/or time No job descriptions	4	2	8	Re-assess collective work practices (periodically and following the implementation of changes) / conduct internal and external cross audits Set up an information/training programme for all equipment and software upgrades and all new techniques	4	1	4	Develop cross audits with other establishments / specific techniques Promote one-off staff exchanges between establishments

Probability: 1= very rare – once every 5 years, 2= rare – once a year, 1 = frequent – once a month, 4 = very frequent -- daily
Severity: 1=minor= not very critical, 2= significant= critical, 3= very critical, 4= serious= catastrophic

EXTERNAL BEAM RADIOTHERAPY											
General organisation	Failure mode	Possible effects	Causes	S	P	iCI	Possible corrective measures	S	P	fCI	Optimisation
20 Quality assurance	**HOF-21** No common language within the medical team	Inadequate knowledge of tools, equipment and software Treatment planning or delivery errors	No definition of the skills needed by the department Shortage of resources and/or time	3	2	6	Train concerned members of staff to correctly reformulate the procedures to be implemented	3	1	3	Conduct a periodic assessment of the terms employed by staff
	HOF-22 No validation of key points in the treatment plan by the medical team	Treatment carried out without validation	No dialogue No validation procedure in force No medical practitioner Too much or too little unwritten delegation of responsibilities	4	2	8	Define a validation process (who, when, how) Introduce validation indicators at each key step in the treatment process	4	1	4	Set up a daily consultation and validation meeting
	HOF-23 Lack of self-assessment indicators	Failure to detect possible treatment malfunctions	No quality manager No record of risks	3	2	6	Introduce indicators to measure activity and progress in radiation protection	3	1	3	Introduce a self-assessment procedure
	HOF-24 Inadequate document management system	Loss of information Waste of time No possibility of drawing up summaries or providing experience feedback Failure to detect possible treatment malfunctions	Lack of organisation Quality procedure not implemented	3	2	6	Record and update all monitoring procedures and indicator data in a quality manual	3	1	3	Conduct a periodic review of the department's activities, based on the indicators used

Probability: 1= very rare – once every 5 years, 2= rare – once a year, 1 = frequent – once a month, 4 = very frequent -- daily
Severity: 1=minor= not very critical, 2= significant= critical, 3= very critical, 4= serious= catastrophic

Addendum

Please note that, on 27th January 2009, just when the layout of this document had been completed, the World Health Organisation (WHO) published a report on risk assessment in radiotherapy, based on feedback from the international community.

This technical report is available in English via the WHO's website:
http://www.who.int/patientsafety/activities/technical/radiotherapy_risk_profile.pdf

6, place du Colonel Bourgoin
75012, Paris
Telephone: +33 (0)1 40 19 86 00
Fax: +33 (0)1 40 19 86 69