AUTORITÉ DE SÛRETÉ NUCLÉAIRE

ASN GUIDE N°5

Management guidelines for safety and quality in radiotherapy

Index 1 • Version 10/04/2009

Notice

This guide is intended to make it easier to apply the statutory requirements that ASN wants to bring into effect in safety* and quality* management of radiotherapy (external radiotherapy and brachytherapy). It does not give rules that can be enforced. It is available to establishments that want to implement quality assurance, and provides guidelines about areas to prioritise and how best to organise the work, whatever the type of healthcare facility.

It is intended for those legally responsible for all public or private healthcare facilities in which all or part of radiotherapy treatment is carried out, and clinical oncologists, all healthcare* professionals and all other healthcare* staff that assist in radiotherapy.

The guide is adapted from the NF EN ISO 9001: 2000 international quality management standard, and sets out to organise radiotherapy into a series of specific, well-managed processes, with the ultimate aim of continuous improvement of safety and quality in radiotherapy.

It also takes account of the requirements of the French Health Authority (HAS) certification guide, that enables healthcare facilities to meet their obligation for continuous improvement* of the quality of healthcare, as specified by Article L. 6113-3 of the French Public Health Code.

International studies by WHO*, PAHO*, and especially the European Society for Therapeutic Radiology and Oncology (ESTRO*) and the IAEA* are considered too. The guide also takes into account work done in France since 2006 by the MeaH* to support healthcare facilities wanting to improve the organisation and safety of their radiotherapy departments. A number of documents are available in French on their website: http://www.meah.sante.gouv.fr as articles on radiotherapy.

This management guide was prepared between April 2007 and April 2008, working with government health entities (INCa*, HAS*, Afssaps*) and the IRSN*, and professional bodies (SFRO*, SFPM* et AFPPE*). It is intended to change with time, especially as a result of its assessment in 2012 by a working group comprising representatives of the groups listed above. However, ASN is likely to make significant changes in the months following publication, so, in order to facilitate the revision of this first version, we recommend using it in soft copy.

The document can be consulted on the ASN website http://www.asn.fr, where the latest version can be downloaded.

* The definitions of words marked with an asterisk are found in Annex 1.

Foreword

Quality management in radiotherapy is detailed in Article R. 1333-59 of the French Public Health Code concerning the obligation in quality assurance needed to optimise doses during exposure to ionising radiations for medical purposes. However, to date, this generic provision has not been explained in detail, and is not understood well enough, even by radiotherapy healthcare professionals. The Ministry of Health has commissioned the French Nuclear Safety Authority (ASN) to draw up a quality management reference document based on ISO 9000: 2000 standards, to increase safety* in radiotherapy. So this guide can be adopted on a voluntary basis as a radiotherapy safety and quality management reference document[1].

These guidelines are usually a reminder of statutory requirements and organisational procedures that already exist in many healthcare facilities that already have a quality management system. The document aims to consolidate a safety culture in organising radiotherapy, a major part of oncology, It takes greater account of the organisational and human aspects of radiotherapy department.

Because I am convinced that good organisation of all the steps contributing to radiotherapy* is one of the prerequisites for the quality and safety of patient care, my hope is that this document will make it easier to apply the statutory requirements for quality assurance* that ASN advocates, and that it will become one of the vectors for a stronger culture of risk management.

[1] This document is based on the guide XP CEN/TS 15224 for use of the ISO 9001:2000 standard for healthcare.

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ANNEXES

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Introduction

The safety* and quality* management system model developed in this guide can be illustrated by the diagram below. It shows the interaction between the processes described in the following chapters. It is a practical application of "Deming's Wheel", with its "Plan, Do, Check, Act (PDCA)" that applies to all activities. Deming's Wheel is described as follows:

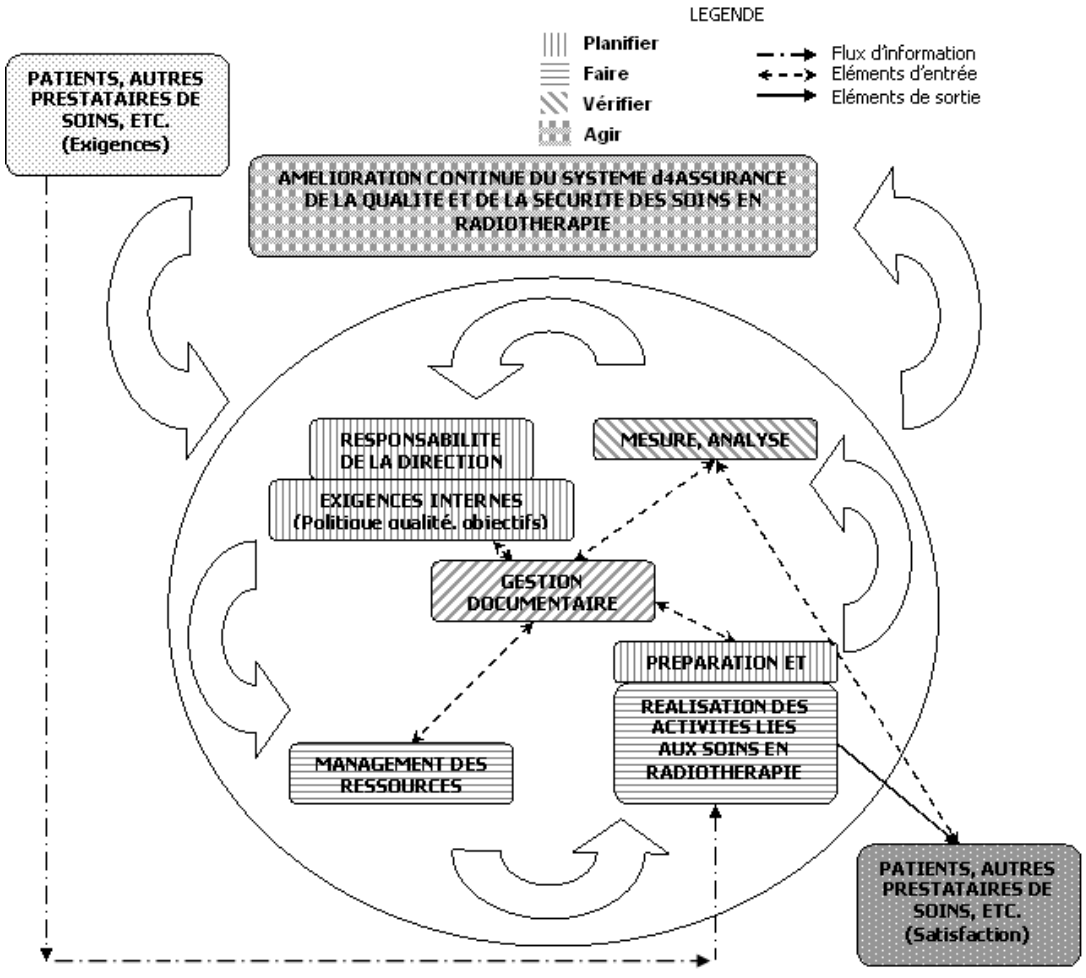
Plan: Define the objectives and processes needed to produce results* that correspond to the policy of the healthcare facility* and the requirements* of patients or other health service providers, and even, if applicable, insurance companies that require the services of the health facility (vertical hatching).

Do: Implement the processes (horizontal hatching)

Check: Monitor and measure the processes and results* of activities compared with internal requirements and be accountable for results* (right oblique hatching).

Act: Implement actions necessary to make continual improvements to the system (cross hatching).

A MODEL OF QUALITY MANAGEMENT SYSTEM FOR ENSURING SAFETY AND QUALITY OF CARE IN RADIOTHERAPY



* The definitions of words marked with an asterisk are found in Annex 1.

FRANCAIS	ANGLAIS	FRANCAIS	ANGLAIS
Legende	Key	Amélioration continue du système d'assurance de la qualité et de la sécurité des soins en radiothérapie	Continuous improvement of the quality and safety assurance system for radiotherapy treatment
Planifier	Plan	Responsabilité de la direction	Management Responsibility
Faire	Do	Mesure, Analyse	Measure, Analyse
Vérifier	Check	Exigences internes	Internal requirements
Agir	Act	(Politique qualité, objectifs)	(Quality policy, aims)
Flux d'information	Information flow	Gestion documentaire	Document management
Eléments d'entrée	Input	Préparation et réalisation des activités liées aux soins en radiothérapie	Preparing and implementing actions related to radiotherapy treatment
Eléments de sortie	Output	Management en ressources	Resource management
patients ou des autres prestataires de soins	patients or other health service providers		
(Exigences)	(requirements)	(Satisfaction)	(Satisfaction)

This guide is in 23 leaflets, one or several pages long, divided into three parts:

- The first part is shown as a box. It sets out the requirements to be met and is added to as appropriate.
    - References to the requirements of the HAS Certification Manual (version 2007), which corresponds to the subject(s) dealt with in the leaflet (except for reference 33 which applies to all leaflets);
    - Approval criteria for practising external radiotherapy fixed by the INCa for authorising oncology treatment.
    - A note about the possibility of MeaH support with INCa funding. Healthcare facilities must first apply to INCa for support for organising their radiotherapy department*. The MeaH support lasts for 12 months and the recipient healthcare facility must implement these measures for the long term to meet the requirements of this guide.
- The second part specifies what is expected in general requirements, and the regulations (if any) that apply to the subject(s) in the leaflet.
- The third part gives guidelines for choosing one or more areas of work and helping implement the quality system.

All these leaflets provide radiotherapy centres with a framework for creating a quality management process, as required by the ASN Technical Decision 2008-DC-0103, dated 1 July 2008. The Decision adds to the regulations by specifying the quality assurance* obligations of radiotherapy centres as given in Article R. 1333-59 of the French Public Health Code, especially to develop a culture of risk management, including risk of human error, in the centres. The Decision was taken after widespread consulting with stakeholders, and was sent for certification to the Minister of Health.

The guide has eight annexes.

- Annex 1 defines the terms used, and marked with an asterisk in this guide.
- Annex 2 shows how the guidelines given here correspond to ISO 9001: 2000 standards on quality management systems.
- Annex 3 is a table showing how these guidelines correspond to the general references of the 2007 version of the HAS certification manual, which also has a specific section (33a) on quality assurance in radiotherapy.
- Annex 4 shows which pages of this guide correspond to INCa accreditation criteria for using external radiotherapy.
- Annex 5 is a suggested timetable for implementing the safety and quality management system.
- Annex 6 is the timetable for implementing Decision 2008-DC-103 that sets radiotherapy quality assurance obligations.
- Annex 7 shows how the above mentioned obligations correspond to these ASN guidelines.
- Annex 8 is the text of the decision dated 1 July 2008 defining radiotherapy quality assurance obligations.

N.B.

All suggestions of these ASN guidelines can be applied to brachytherapy, by adding specific aspects about source management and adapting the provisions concerning radiation protection of staff and the public.

Chapter 1	Requirements of the quality management system[2]
Section 1.1	General requirements

1.1.A **All healthcare facilities* that offer radiotherapy* must have a quality management system* intended to ensure the safety* and quality of radiotherapy treatment. The system must be documented, applied and continually maintained, so that the quality and safety of treatment improves all the time.**

1.1.B **Checklist for organising a quality management system for healthcare facilities:**

- **Identify the strategic, operational and support processes* that cover the whole area of radiotherapy treatment.**
- **Analyse and define the order in which processes occur and the relationships between them. This is to ensure that they function correctly, optimise interactions and reduce risks.**
- **Determine the criteria and methods needed to asses how well these processes function and are controlled.**
- **Ensure that the necessary human and material resources and information* are available for the functioning and monitoring of the processes.**
- **Monitor, assess and analyse the processes.**
- **Set up the actions needed to obtain the results* planned and continued improvement of the processes.**

1.1.C **When a healthcare facility decides to outsource all or part of one or several processes impacting patient management in radiotherapy, the facility remains responsible for their control. This must be specified in the quality management system and the contract between the parties.**

HAS requirements covered	1b, 3a, 3b, 4a, 4b, 6, 7, 10b, 10d, 10e, 11, 18c, 28

MeaH	INCa funded support is available for radiotherapy centres to implement the quality and safety approach.

More information

Organisation of public healthcare facilities

The organisation of public healthcare facilities is detailed in the French Public Health Code in Articles L. 6141-1 to 6148-8. It should be noted that public healthcare facilities are legal entities under public law, with administrative and financial autonomy. They are run by a Board of Directors and managed by a Chief Executive. Article L. 6143-1 of the French Public Health Code specifies that the Board of Directors decides on the general policy of the healthcare facility, and after consulting the healthcare facility's medical commission, decides on the policy for continuing improvement of the quality and safety of care. Article L. 6143-7 of the French Public Health Code specifies that the Chief Executive represents the healthcare facility in law and in all aspects of civilian life. S/he prepares the work for the Board of Directors and

[2] The definitions of words marked with an asterisk are found in Annex 1.

presents the development project to them. S/he is responsible for carrying out Board decisions and implementing its policies, after approval by the Chief Executive of the Regional Hospital Agency. S/he has authority to manage the affairs of the healthcare facility other than those listed in Article L. 6143-1. S/he is responsible for its management and general running, and keeps the Board of Directors abreast of things. S/he has authority over all personnel in terms of ensuring that they comply with the ethical or professional codes for healthcare professionals, with responsibilities in administering treatment and with the professional independence of practitioners in exercising their skills. The Chief Executive may delegate his/her signature under the terms set by Order.

Article L. 6146-1 of the Public Health Code gives details on the internal organisation of public healthcare facilities into clinical centres and internal care or medical-technical structures known as services or functional units.

Article L. 6146-3 of the Public Health Code specifies

1) Conditions for appointing Heads of clinical or medico-technical centres (Tenured practitioners enrolled on an accreditation list, joint decision of the Chief Executive and President of the healthcare facility's medical commission, the Board of Directors decides in case of disagreement),
2) The length of term of office of these Heads, and of those in charge of the internal structures, and the conditions for renewing terms of office,
3) Conditions for appointing heads of centres other than clinical or medico-technical (decision of the Chief Executive).

Articles L. 6146-4 and L. 6146-5 of the French Public Health Code specify conditions for appointing heads of department (Tenured practitioners enrolled on a list of accreditation, joint decision of the Chief Executive and President of the healthcare facility's medical commission) and conditions for appointing heads of functional units (Tenured practitioners, appointed by the head of the clinical or medico-technical centre to which they belong).

Article L. 6146-5-1 of the French Public Health Code specifies that the heads of internal structures ensure that the tasks assigned to the structure for which they are responsible are carried out, and they coordinate the medical team working there.

Article L. 6146-6 of the French Public Health Code specifies that the practitioner in charge of a clinical or medico-technical centre implements the general policy of the healthcare facility and uses the resources defined by the contact made with the Chief Executive and president of the healthcare facility's medical commission to meet the objective set by the centre. S/he organises the medical, care and management teams of the centre, over which s/he has operational authority, and also the operation of the centre, applying the code of ethics of each practitioner, and the tasks and responsibilities as laid out in the centre's development project. For radiotherapy, s/he is assisted by a "cadre de santé" (middle ranking healthcare professional) for the organisation, management and assessment of activities under his/her charge, and by an administrative manager.

In the light of these articles, a hierarchy exists between the Chief Executive, the head of the clinical or medico-technical centre and the heads of departments or heads of functional units concerning the general organisation of healthcare.

Organisation of private healthcare facilities

The French Public Health Code provides no framework for the organisation of private healthcare facilities. Therefore these healthcare facilities are governed more by the commercial code and company law. Commercial contracts may bind a non-hospital doctor to a private healthcare facility, but no hierarchical relationship exists between the doctor and the person legally responsible for the healthcare facility.

Common definition for organisation

In the light of the very different rules given above for the organisation of public and private healthcare facilities, the ASN considers that the Chief Executive of a public healthcare facility or the appropriate equivalent of a private healthcare facility or the General Secretary of an interhospital union or the administrator of a healthcare cooperative is responsible for setting up and developing a quality management system to ensure the safety and quality of radiotherapy treatment. In the rest of these guidelines, the person in charge is defined as "the highest management level* of the healthcare facility". S/he must ensure that the system is appropriate and determine a quality policy with the aim of continually improving the quality and safety of radiotherapy care.

It should be remembered that this model, in all public and private healthcare facilities, has also been selected for establishing a system to ensure the quality of sterilisation of medical devices, as specified in Article L. 6111-1 of the French Public Health Code and defined by Articles R.6111-18 to R.6111-21 of the code.

Who organises the quality management system for ensuring the quality and safety* of radiotherapy treatment?

In principle, the quality management system is organised as explained above:

- In public healthcare facilities, by the Chief Executive after consultation with the Board of Directors and the healthcare facility's medical commission;
- In private healthcare facilities, by the appropriate person, with advice from the medical conference or the medical commission;
- In interhospital unions, by the General Secretary after consultation with the Board of Directors and the healthcare facility's medical commission;
- In healthcare cooperatives, by the group administrator, with advice from the General Assembly.

This system takes account of strategic preferences in radiotherapy treatment, especially as defined in the SROSS and implemented in the *contrat pluriannuel d'objectif et de moyens* (CPOM – long term contract of goals and resources), the policy for managing risks* inherent to radiotherapy, local conditions, needs and expectations of the interested parties*. The way the healthcare facility* is organised results from this, especially in terms of human and material resources.

The processes* necessary for the quality management system described in this guide, intended to ensure the safety and quality of radiotherapy treatment, include processes* involving:

1) Creating and maintaining a document system
2) The details of management
3) Resource availability
4) Provision of treatment
5) Quality system measures and improvements.

Chapter 1	Requirements of the quality management system*
Section 1.2	Documentation requirements
Sub-Section 1.2.1	General remarks

1.2.1.A **The healthcare facility must define a documentation system that contains:**
- **A quality manual including a policy with quality objectives and a description of the processes and how they interact,**
- **Work procedures and instructions,**
- **All necessary records***
- **A study of the risks incurred by patients during the clinical process of radiotherapy.**

1.2.1.B **The documentation system must be kept up to date and must correspond to real practice.**

HAS requirements covered	6a, 10b, 10e

MeaH	INCa funded support is available for radiotherapy centres to implement the quality and safety approach.

More information

Documentation requirements are summarised in the quality management system presented in Deming's Wheel above: Determine documentation needs -> Write -> Circulate -> Apply -> Check -> Analyse -> Note gaps -> Modify -> Write -> Circulate ->…

The extent of documentation on the quality management system designed to ensure the safety and quality of radiotherapy treatment can differ from one healthcare facility to another, due to:

1) the size of the facility,
2) the complexity of processes* and their interactions,
3) the competence of the staff.

Documentation can exist in any form that suits the needs of the healthcare facility.

Recommendation

Documentation should comprise at least:

1. A quality policy and aims:

   The Chief Executive or qualified entity or General Secretary or administrator must write and circulate a quality policy on radiotherapy treatment, especially in order to reduce the risks inherent in the process*, both for personnel and third parties.

   The quality policy must:

   1. be adapted to the final purpose of the healthcare facility (including its role in the local, regional or national healthcare system)
   2. be consistent with the risk management* policy,

* The definitions of words marked with an asterisk are found in Annex 1.

3. be known and understood within the healthcare facility,
4. be reviewed periodically to ensure that it is always relevant,
5. include an undertaking to satisfy the requirements*, and continually improve the effectiveness of the quality management system.

Management* must also provide a framework for creating and reviewing quality objectives whenever needed, so that they:

remain consistent with quality policy,

are measurable and cover the main objectives of the healthcare facility's processes*,

cover the key issues on effectiveness and safety in radiotherapy

are drawn up for the functions and staffing levels in the facility and define their responsibilities in using them.

2. A quality manual:

The healthcare facility creates a quality manual comprising a general description of how radiotherapy is carried out, and especially a description of the processes* and how they are related and interact.
The processes* are divided into basic steps. For each step of the process, there must be at least a risk assessment for patients, users and third parties, including the intensity and frequency of the risk.
Each of the processes* also refers to documented procedures. The procedures are drawn up following a fixed schedule, beginning with the steps involving the highest risk.

3. Procedures*, instructions and records*

Procedures, protocols, instructions for work, checklists, record* forms, etc. must be systematically organised and managed. For each document, the healthcare facility must appoint a person responsible for matching content with real practice.
Procedures, methods of operation and forms must not be fixed forever but rather altered as practice, understanding and technical data change.
The written, applied and updated documented procedures required in the guide must:

1. describe the scope of the procedure,
2. contain specific information* at an early stage,
3. explain the respective responsibilities of the people involved,
4. briefly describe the actions necessary,
5. refer to regulatory documents (work instructions and/or record forms for the traceability of actions as part of the quality management system).

Work instructions must explain, in detail and separately, each action performed in a procedure,
Record forms must enable the traceability of actions described in the instructions or procedures and guarantee that the quality management system is functioning correctly.
Chapter 4 Section 1 of this guide describes procedures or instructions needed to set out the actions performed in radiotherapy.

4. A study of risks, especially risks to patients as specified in section 4.1 of this guide.

Chapter 1	Requirements of the quality management system*
Section 1.2	Documentation requirements
Sub-Section 1.2.2	Document control

1.2.2.A The healthcare facility must create a documented procedure* for document management, to enable the following:

1) **approving the suitability of documents before circulating them, making sure they are easy to use;**
2) **reviewing, updating if necessary and re-approving documents;**
3) **ensuring that modifications and the status of the current document version is identified;**
4) **ensuring that the current versions of the regulatory documents are circulated and available in the places they are to be used;**
5) **ensuring that the documents remain readable and easily identifiable;**
6) **ensuring that documents from outside sources are identified and controlling how and where they are circulated;**
7) **preventing accidental use of out of date documents, and ensuring that they are clearly labelled as old if they need to be kept for any reason.**

HAS requirements covered	10e
MeaH	INCa funded support is available for radiotherapy centres to implement the quality and safety approach.

More information

All quality system documents must be reviewed regularly and adapted with regard to risks encountered and to changes in organisation or techniques to ensure that they match real practice

Recommendation

Any change to a document must be recorded and a new version must be produced, with no erasures or alterations, as per provisions in the document management procedure. Modifications must be approved by the people in charge of the quality management system or their representative, and the staff concerned must be trained in the new procedure, if necessary.

The document management procedure should specify the measures to be taken for approving the suitability of documents before they are circulated, and particularly all internal or external documents, including forms and checklists that are important for the process*.

* The definitions of words marked with an asterisk are found in Annex 1.

Documents should be reviewed during internal audits, ensuring that the scope and number of audits enable a regular, complete review of the quality System documents relevant for their risk level. For the lower risk procedures and instructions, document reviews should be no less than every 5 years.

N.B.: It is quite usual for document management procedure to be called "Procedure for procedures".

Chapter 1	Requirements of the quality management system*
Section 1.2	Documentation requirements
Sub-Section 1.2.3	Record* management

1.2.3.A **Healthcare facilities must set up a documented procedure* for managing records*, to ensure that quality records* are identified, accessible, stored, protected, archived for the correct length of time and then destroyed.**

1.2.3.B **Quality records and/or information* contained in patient records must remain readable, easy to identify and accessible, while maintaining confidentiality*.**

1.2.3.C **A specific procedure must define the method of creating patient medical records, their content, circulation and storage, in compliance with relevant regulations.**

1.2.3.D **Hard or soft copy archives must be stored in suitable dedicated premises.**

1.2.3.E **All appropriate measures must be taken to ensure that named data remains confidential*.**

1.2.3.F **If the documents are stored as soft copy, a storage procedure must be set up and backup and safeguard facilities chosen to avoid accidental data loss, especially during the statutory storage period.**

HAS requirements covered	4b, 10e, 28, 29
MeaH	INCa funded support is available for radiotherapy centres to implement the quality and safety approach.

More information

Records* (patient medical records*, checklist*, measurement results, etc.) must prove that the process went as planned and that the formal procedures were followed.

Patient medical records

As regards the patient medical records mentioned in Article R. 1112-2 of the French Public Health Code, order no. 2006-6 dated January 4, 2006, published in the Official Gazette dated January 5, 2006 and Article R1112-7 of the same code stipulate that, whether in hard or soft copy, records must be kept for twenty years as from the date of the last hospital stay or the last outpatient appointment at the healthcare facility. If the twenty year period finishes before the patient's 28th birthday, the records must be kept until the later date. In all cases, if a patient dies less than ten years after the last visit to the healthcare facility, the medical record is kept for ten years after the date of death. These dates are suspended in the case of any informal appeal or legal proceedings involving the medical responsibility of the healthcare facility or healthcare professionals due to their work in the healthcare facility.
After the storage time mentioned above, and, if necessary, after returning stored data covered by Article L. 1111-8, the patient medical record can be destroyed. The Chief Executive of the healthcare facility

* The definitions of words marked with an asterisk are found in Annex 1.

takes the decision to destroy the record, after consulting the practitioner responsible for medical information. In public healthcare facilities and private facilities that participate in public hospital service, the archive administration also needs to approve the destruction, after removing records that are to be kept indefinitely due to their scientific, statistical or historical interest.

Reminder: Articles R. 1112-2 and R. 1112-3 of the French Public Health Code specify that a patient medical record must be created for each patient hospitalised in the public or private healthcare facility, and must contain at least the following items, classified as follows:

1. The information noted during outpatient visits to the healthcare facility, the accident and emergency (A&E) department, or at admission to hospital and during the hospital stay, particularly:

a) Doctor's letter initiating the appointment or admission;
b) Reasons for hospitalisation;
c) Previous history and risk factors;
d) Conclusion of the initial clinical examination;
e) Type of management planned and instructions given on admission;
f) Type of treatment given and instructions given during outpatient appointment or visit to A&E;
g) Information about management during hospitalisation: clinical status, treatment received, paraclinical examinations, especially imaging;
h) Information about the medical approach adopted under conditions specified in Article L. 1111-4;
i) Anaesthesia record;
j) Surgery or childbirth report;
k) Written informed consent for situations in which this is required for legal or statutory reasons.
l) Record of blood transfusions and, when applicable, a copy of the transfusion incident form mentioned in the second line of Article R. 1221-40;
m) Information about the medical instructions, their administration and other examinations;
n) Nursing report, or, failing this, information on nursing given;
o) Information on care by other healthcare professionals;
p) Correspondence between healthcare professionals;
q) The advance directives mentioned in Article L. 1111-11, or, when applicable, mention of their existence and the contact details of the person holding a copy.

2. Information noted when the patient is discharged. This includes:

a) The hospital report and the letter written at the time of discharge;
b) Instructions at discharge and copies of prescriptions;
c) Patient destination (home, other facilities);
d) Liaison nurse information;

3. Information stating that it has been collected from a third party not intervening in patient management, or concerning such third parties.

Information in categories numbered 1 and 2 only can be communicated. The record contains the patient identity and, if applicable, the name of the trusted person defined in Article L. 1111-6 and that of the contact person.
Each item in the record is dated and has the first and last names of the patient, date of birth or identity number, and the name of the healthcare professional who recorded or produced the information. Medical instructions are annotated with the date and time, and signed. The name of the signatory practitioner is written legibly.

Recommendation

Medical Archives

Archived information must be accessible for consultation throughout the time of storage. For ASN, this storage duration for medical records should be longer than current regulations require, given the possible long term consequences of irradiation, especially of children and post-adolescents, for whom information in medical records is often useful 50 to 70 years later. The interministerial instruction n°DHOS/E1/DAF/DPACI/2007/322 an DAF/DPACI/RES/2007/014 dated 14 August 2007 specifies that the durations defined in Article R. 1112-7 of the French Public Health Code are minimum durations, and therefore each healthcare facility needs to assess each case individually to decide whether all or part of the medical information on a given patient should be kept longer, because it is likely to be of interest after the deadline, or whether it can be destroyed.

This is why it is important for each healthcare facility to create a policy for keeping medical records for the medical conditions treated by radiotherapy.

It is also important to guarantee the longevity and integrity of electronic documents for at least the statutory storage duration, by storing them appropriately. As applicable, during this minimum storage time, the documents should also be stored as hard copy, taking care to ensure that they remain legible.

In addition, conditions in the archives room should be carefully monitored (temperature, humidity, fire risk) to ensure that documents will not be damaged.

Chapter 2	Management responsibilities*
Section 2.1	Management commitments

2.1.A **To show their commitment to developing and implementing a quality management system, the management of healthcare facilities must:**

a) Create a quality policy and the schedule for implementing the quality management system;

b) Instil in the healthcare personnel the importance of meeting legal and statutory requirements* as well as the demands of patients and other healthcare providers needing the services of a healthcare facility;

2.1.B

c) Define measurable quality objectives that are coherent with quality policy;

d) Ensure that the quality objectives mentioned above are detailed at all hierarchical and organisational levels and for each area of work;

2.1.C

e) Ensure that the necessary human and material resources are available;

f) Formally assess the quality system to ensure that it meets quality policy and objectives ("Management review"*).

HAS requirements covered	1a, 2c, 3b, 5a, 6a, 7b
MeaH	INCa funded support is available for radiotherapy centres to implement the quality and safety approach.

More information

Using the principles of quality management:

The healthcare facility must be run and managed so as to improve its quality and safety in radiotherapy treatment. This needs method and transparency. One of the factors for success is for Management* to apply the following 6 major principles:

1) Create and maintain an atmosphere within the healthcare facility that allows all staff to take a full part in meeting objectives,
2) Use the aptitudes of all healthcare personnel at whatever level,
3) Manage resources and activities as processes* that work together to achieve expected results*,
4) Identify, understand and manage all dependent processes* as a system, so that interactions are better controlled.
5) Aim at permanent, continual improvement in the overall performance of the healthcare facility,
6) Base decisions on analysis of data and information, and prefer facts to theories.

* The definitions of words marked with an asterisk are found in Annex 1.

The commitment and involvement of Management* of the healthcare facility are vital for developing and maintaining a quality management system for ensuring the safety and quality of radiotherapy treatment.

Recommendation

To implement the above principles, Management* must work at points such as:

1) Creating a vision, a policy and strategic objectives that are consistent with the aims of the healthcare facility in radiotherapy treatment,
2) Running the healthcare facility so as to develop trust among the personnel,
3) Communicating values and an organisational focus based on quality and the quality management system,
4) Participating in projects to improve radiotherapy treatment, and research into new methods of patient management and new treatments,
5) Obtaining direct feedback on the effectiveness of the quality management system by encouraging people to report non-conformities spontaneously, etc.,
6) Identifying processes* of delivering radiotherapy treatment,
7) Identifying support processes* impacting the effectiveness and efficiency of the treatment processes*,
8) Creating an environment that encourages staff involvement and development (Cf. II.3.2),
9) Making available the structures and resources that are needed to support the strategic plans of the healthcare facility,
10) Having performance measurement tools for the healthcare facility, to test whether objectives have been met, concentrating on methods of measuring the performance of processes*, external methods such as third party assessments and satisfaction assessments by patients, personnel and other interested parties*.

Laying the foundations

The commitment of Management is the key to the success of the quality and safety management system for radiotherapy treatment. The Management undertakes actions that prove its commitment to quality. Management is very involved in effective communication that must put the patient back in the centre of things. This commitment should be formalised in a written document (usually called the commitment letter). The information in this document sets out the general approach and methods used.

The commitment letter should start by setting the broader context in which the healthcare facility works, and summarise its strategic policy for radiotherapy treatment. Then should come a summary of the major safety and quality objectives. The commitment letter usually has an overview of operational objectives, so that each person can measure the individual contribution expected from their staff level in terms of "statutory and legal requirements". This paragraph is very important for the safety of patients and other stakeholders. It requires healthcare professionals to be vigilant. Management then commits to providing resources to meet objectives and set up continuous assessment that demonstrates the coherence of the steps taken. It should end with a commitment to permanent improvement in managing the quality and safety of radiotherapy treatment, for its long term development. Improvement is best when the stakeholders have been involved, so the commitment letter often ends with an overview of the healthcare facility's involvement with outside entities, and the expected benefits of these exchanges.
Although the letter is often taken for a statement of intent that has no great use, in fact it stresses the importance for Management* of safety and quality management in radiotherapy, and thus its sustainability. This is why it should be made available to all staff, patients and other stakeholders.

Chapter 2	Management responsibilities*
Section 2.2	Needs and expectations of interested parties

2.2.A **In order to identify the needs and expectations of interested parties* and translate them into requirements* so that the quality system organisation can be documented, the Management of the healthcare facility should carefully consider the following:**

1. **Organisational requirements it wants to meet voluntarily;**
2. **Legal and statutory requirements applying to radiotherapy in the healthcare facility. So the legal and statutory requirements must be identified and implemented in the quality management system;**

2.2.B

3. **Demands of patients, other healthcare providers, and, as applicable, National Health insurance or mutual benefit societies that need the services of the healthcare facility. So procedures must be drawn up for collecting information* about their needs and expectations and monitoring* satisfaction.**

HAS requirements covered	10a, 11a, 24b

More information

Some points that healthcare facility Management* needs to consider, in addition to these guidelines, to streamline the identification of needs and expectations of interested parties* and spell them out as requirements*:

1) Needs and expectations of healthcare professionals dealing with patients,
2) Needs and expectations of staff, especially in terms of recognition, professional satisfaction and personal development, to ensure optimum involvement and motivation, and in order to organise social dialogue.
3) Needs and expectations of service providers and suppliers,
4) Needs and expectations of society at large – the local community and public involved in the healthcare facility,
5) Sources of outside information that can help develop the skills of the healthcare facility.

N.B.: Information from healthcare professionals previously involved in managing a given patient must be available when the patient arrives. All exchanges of data between those professionals and the ones working in the healthcare facility must be identified at the time of treatment and after treatment. This guarantees continuity of management and reporting of any adverse event in good time.

* The definitions of words marked with an asterisk are found in Annex 1.

2.3.A **The Management of the healthcare facility takes responsibility for defining and complying with the actions and the timetable for implementing the quality management system of the internal structure*.**

HAS requirements covered	10b, 10d

More information

Implementation planning

The planning role of the person legally responsible for the healthcare facility is vital for managing continual improvement of healthcare quality and safety.
The following are some of the sources of information that the healthcare facility management can consider for correct planning of the management system:

1) The Management Review,
2) Strategies of the healthcare facility,
3) Organisational objectives,
4) Needs and expectations of patients and other interested parties,
5) Assessment of legal and statutory requirements,
6) Assessment of data on radiotherapy quality and process* quality,
7) Lessons learned from past experience, opportunities for improvement noted,
8) Risk assessment and reduction data.

In general, quality planning requires Management* to define the processes* necessary for delivering and supporting radiotherapy treatment, in the following areas:

a) Skills and knowledge needed for the healthcare facility,
b) Responsibility and authority for implementing plans to improve processes*,
c) Resources needed, e.g. financial and infrastructure,
d) Setting indicators to assess improvement in performance of the healthcare facility,
e) Needs for improvement, including methods and tools,
f) Documentation needs, including records*
g) Control of emergencies and potential accidents likely to impact the process* of radiotherapy treatment.

* The definitions of words marked with an asterisk are found in Annex 1.

Recommendation

Any changes in the quality management system must not affect its consistency, and Management* must systematically review the points listed above on a regular basis to guarantee permanent planning. To this end, planning results* can be included as input in the Management review* [Cf. chapter 2 section 5].

Chapter 2	Management responsibilities*
Section 2.4	Responsibility, authority, communication
Sub-Section 2.4.1	General remarks

2.4.1.A Healthcare facility Management* sets the responsibilities, authority and delegation of staff at all levels, and makes them known to everyone.

HAS requirements covered	1c
MeaH	INCa funded support is available for radiotherapy centres to implement the quality and safety approach.

More information

Defining responsibilities and authority at all levels of the healthcare facility means that job and/or role descriptions must be defined for all staff who influence the quality and safety of the radiotherapy process*.

Recommendation

Job and/or role descriptions generally comprise skills, responsibilities and conditions for delegating authority.
Management* must be able to prove that staff know the remit and responsibilities of those with authority.

For the healthcare facility to be able to guarantee and cover its own institutional responsibility, Management* is advised to organise relationships with outside professionals focussing on patient health.

In terms of internal communication, Management* defines and implements a process* to communicate to the whole staff, about its quality policy, requirements, aims and results* and actively encourages feedback and communication between healthcare facility staff in order to involve them more.

In terms of traceability, healthcare facility Management* records and keeps the elements on which decisions are based, especially management reviews and also quality management system planning and communication, to build up a document history to make it easier for assessment.

* The definitions of words marked with an asterisk are found in Annex 1.

Chapter 2	Responsibilities of management*
Section 2.4	Responsibility, authority, communication
Sub-section 2.4.2	Responsibility of the person responsible for quality management

2.4.2.A **All healthcare facilities must make available to the internal radiotherapy structure* a line manager for the healthcare quality and safety management system. S/he must have the requisite training, skills and experience. S/he must have the necessary time and resources to manage the system, liaising where necessary with Quality Management.**

2.4.2.B **The line manager for the quality management system of the internal structure, who has the role of ensuring safety and quality of care in radiotherapy must in particular be responsible for and authorised to:**

a) ensure that the processes required for the quality management system are established, implemented and maintained;

b) report to Management on the functioning of the quality management system and on any improvements needed;

c) ensure that staff at the healthcare facility in question are aware of the needs of patients and other health service providers requiring the services of the healthcare facility;

d) be the first point of contact for the competent authorities.

HAS requirements covered	1d

MeaH	INCa funded support is available for radiotherapy centres to implement the quality and safety approach.

More information

Line manager of the healthcare safety and quality management system (SMSQ)

The manager of the quality management system for radiotherapy treatment is responsible for checking that the processes* required for the quality management system are established, implemented and maintained.

Recommendation

Prerequisites and qualities of the SMSQ line manager

The line manager for the quality management system of the internal structure* may be recruited either from radiotherapy professionals or from the "quality, security and environment" sector so long as s/he can demonstrate a high degree of involvement in the running of this project and be the driving force

*The definitions of words marked with an asterisk are found in Annex 1.

behind sharing the quality and safety cultures with the healthcare and medical cultures. Before appointment, s/he is to be trained appropriately in quality and safety management according to his/her needs and university qualifications, so as to be capable of explaining the objectives of quality management and to be aware of the requirements of the ISO 9001:2000 standard and the principles of risk management tools.
In public healthcare facilities, the line manager of the quality management system for the internal structure* should, subject to the provisions of Articles L. 6146-4 and L. 6146-5 of the French Public Health Code, be appointed by the Chief Executive of the facility or the General Secretary of the interhospital union. The manager should be appointed by the administrator in the case of healthcare cooperatives, and by the appropriate person in private healthcare facilities.

Work of the SMSQ line manager

To check that the processes* needed for the quality management system are established, implemented and maintained, the manager of the quality management system for radiotherapy treatment can check, for instance:

1) On personnel:
- that operating procedures relating to staff health and safety are being implemented,
- that all operations in the radiotherapy department are carried out by operating personnel with the appropriate qualifications*, training and experience,
- that staff are made aware of the concept of quality assurance* and trained in using "quality" practices.

2) On procedures*, methods of operation and records*:
- that they are checked, validated and available,
- that they are being used or completed as evidence of compliance with the prescribed provisions,
- that staff have been informed whenever a procedure, method of operation or record has been set up or modified.
- Preferably, these modifications should be in writing and easy to identify in any new version of the document, which is then approved, dated and circulated to personnel. Staff are then trained in how to apply it,
- that the person responsible for training in a new procedure or for modifying the procedure, method of operation or record ensures that personnel responsible for applying it have understood the contents of the document (testing of theoretical knowledge) and how to use it (testing of practical knowledge, for example by simulation),
- that all versions of quality documents are stored in a chronological file,
- that records are stored and made accessible for easy evaluation.

3) On quality* control* and audits:
- that the calibration, standardisation or maintenance of equipment is planned and carried out in accordance with this plan and any prescribed provisions,
- that the internal and external quality* control* programme for medical equipment requiring this is drawn up and followed,
- that internal audits are conducted in accordance with a schedule defining dates, areas audited, period and audit team,
- that the results of quality controls or internal audits, and any inspections by supervisory authorities, are actually used as input data, especially to correct any anomalies,
- that the managers of the radiotherapy department* are kept informed of findings and observations concerning the quality assurance system,

- that measures following any withdrawal of a medical device by the Agence française de sécurité sanitaire des produits de santé [French agency for the safety of health products] are correctly applied,
- that traceability documents, especially those relating to the management of medical equipment, including software, are properly maintained,
- that any other imaging services collaborating with the radiotherapy department*, to which patients are referred, apply a quality assurance system meeting any requirements of this document that apply to them, while respecting their rights.

4) On the information system:

- that any operating procedures relating to data security are implemented,
- that access procedures remain confidential and are followed,
- that regulations are complied with and patients are kept informed,
- that telecommunication and electronic transmission procedures are followed,
- that files, records, documentation and information system data are retained.

Chapter 2	Responsibilities of Management*
Section 2.4	Responsibility, authority, communication
Sub-section 2.4.3	Internal communication

2.4.3.A **The Management of the healthcare facility must set up appropriate communication processes for:**

1. **increasing the amount of feedback regarding non-conformances observed, malfunctions discovered or undesirable situations encountered,**
2. **finding out why and how the organisation of the quality management system can be improved and in particular explaining any corrective and/or preventive action taken,**
3. **encouraging staff to be interested and involved in sharing and exchanging experience,**
4. **benefiting from feedback from and handling of precursor* events* so as to anticipate any modifications in the event of harm* being caused.**

HAS requirements covered	5a

MeaH	INCa funded support is available for radiotherapy centres to implement the quality and safety approach.

More information

Internal communication must give staff quick and useful access to information on any new regulatory requirements and other requirements relating to the provision of care, modifications to medical or technical equipment, hazardous situations* and risks*.

Recommendation

Communication within the healthcare facility can be fostered by organising meetings and providing opportunities for discussion in the internal structure* and, within the healthcare facility, between the internal structures and with Management, on improving quality.

* The definitions of words marked with an asterisk are found in Annex 1.

Chapter 2	Responsibilities of Management*
Section 2.5	Management review*

2.5.A **The Management of the healthcare facility must carry out management reviews at regular intervals to ensure that the quality management system remains relevant, adequate and effective. This review must include an assessment of opportunities for improvement and of any changes needed to the quality and safety management system.**

2.5.B **Records* must be kept of management reviews*.**

HAS requirements covered	44d

More information

Ascertaining the functioning of the quality management system and quality of treatment

The Management of the healthcare facility must demonstrate how the management review process benefits the healthcare facility and the procedure for taking new decisions and initiatives on:

1) improving the effectiveness of the quality management system and processes including the quality policy and "quality" objectives,
2) improving radiotherapy treatment in relation to requirements, especially in safety terms,
3) resources needed.

Information on the functioning of processes* and on the conformity of radiotherapy treatment, for use as input data for the management review*, can generally be obtained by recording and analysing the rates of complications, near-accidents and actual accidents, including significant elements and other undesirable incidents.
In general, data on which new decisions are based during the management review constitute the output of the management review process*.

Recommendation

Management reviews should be conducted at intervals of no longer than 1 year without due reason. Partial, more frequent management reviews can also be arranged.

Those at the highest management level of the healthcare facility are strongly encouraged to get personally involved in the review so as to be directly informed of the performance of the processes* of performing and supporting radiotherapy treatment.

Decisions to improve or modify the quality management system that are made during the management review should take account of:

1. the functioning of the processes and the conformity of the radiotherapy treatment,
2. the results* of having made previous improvements or modifications to the quality management system earlier than planned,

* The definitions of words marked with an asterisk are found in Annex 1.

3. the status of preventive and corrective action,
4. the results of internal and external audits and of visit reports from regulatory bodies, if any, and/or recommendations made in their annual report where available,
5. action arising from previous management reviews,
6. changes that might affect the quality management system,
7. recommended improvements,
8. feedback from patients, other health service providers or, where appropriate, health insurance funds or mutual benefit societies requiring the services of the healthcare facility, with regard to the information-gathering procedures set up.

Decisions taken during the management review and factors taken into consideration should be recorded, as indicated in Chapter 1 section 2 sub-section 2.

Chapter 3	Management of resources
Section 3.1	General points

3.1.A **Management must identify and make available, at the appropriate time, the resources needed in order to implement and support processes needed for the quality management system and for ongoing improvements to their effectiveness.**
These resources include people, infrastructures, work environment, information*, suppliers and partners, and funding.

3.1.B **Management must also ensure that the identification and availability of resources enhance the safety and quality of radiotherapy treatment for patients requiring the services of the healthcare facility.**

HAS requirements covered	3a, 3c, 7b, 15a

MeaH	INCa funded support is available for radiotherapy centres to implement the quality and safety approach.

*The definitions of words marked with an asterisk are found in Annex 1.

Chapter 3	Management of resources
Section 3.2	Human resources
Sub-section 3.2.1	Obligations of Management*

3.2.1.A **The Management of the healthcare facility is responsible for choosing appropriate personnel. It must ensure that jobs in the healthcare facility are allocated correctly in terms of assigning responsibilities, providing the necessary resources for checks* and assessing how tasks for which staff are responsible have been performed.**

3.2.1.B **The Management of the healthcare facility must use a documented procedure* to define responsibilities and authorisations so that:**

- **any non-conformances observed, malfunctions discovered or undesirable situations encountered can be dealt with, or that radiotherapy treatment that does not meet requirements can be discontinued or terminated,**
- **and they can be resumed once it is clear that the problem has been eliminated, or carried out despite one or more requirements not being met, after a risk/benefit analysis.**

3.2.1.C **Arrangements must be specified and applied for arranging recruitment and external or internal continuing professional development, and for checking that knowledge and professional skills are kept up to date. The results of this action must be recorded and retained.**

HAS requirements covered	3b, 3d, 8a, 8b, 8c, 8d, 10c
INCa criteria to be considered	**4)** A specialist radiotherapy practitioner and a specialist in medical radiation physics are to be present at the centre throughout the period when patients are being treated. **5)** Each patient is to be treated by two radiographers at the treatment station. **7)** A multi-year training plan, including training in the use of equipment, is to be drawn up for all members of radiotherapy teams. **8)** The radiotherapy centre is to ensure that the list of staff trained in using its radiotherapy equipment is up to date.
MeaH	INCa funded support is available for radiotherapy centres to implement the quality and safety approach.

* The definitions of words marked with an asterisk are found in Annex 1.

More information

It should be noted that, when analysing and allocating tasks likely to expose workers to ionising radiations, the head of the facility must assess work stations in accordance with Article R. 4451-11 of the French Labour Code. Work stations must be assessed again at regular intervals and whenever there is a change in conditions that might affect the health and safety of workers. This assessment takes account of the collective and individual doses to which personnel may be exposed when working in a restricted area. This allows personnel to be categorised in accordance with Articles R. 4453-1 to 3 of the French Labour Code.

Analysing personnel requirements

To analyse current and future skills requirements and be more confident of having them available, the Management* of the healthcare facility is to take into account:

a) changes in the processes*, tools and equipment of the healthcare facility,

b) the results of assessing the proficiency of individuals in performing pre-defined activities.

The Management* of the healthcare facility should also determine and then take into account:

c) future requirements in terms of strategic and operational objectives and plans,

d) the anticipated need to replace managerial and other staff,

Furthermore, the Management* of the healthcare facility is to encourage the development of its staff. To achieve this it can, for instance:

- propose career plans,
- carry out a periodic review of the needs of personnel,
- pass on the suggestions and opinions of staff,
- measure the satisfaction of its staff,
- find out why people join and leave the healthcare facility.

As regards personnel doing work that impacts the quality of radiotherapy treatment, Management is to ensure, amongst other things, that the various processes and interactions have been identified in order to compile a list of all personnel with training needs, and that this training is suitable for their needs and their knowledge level. It is therefore usual to include health professionals* that have direct contact with patients, but also other healthcare staff* that have direct or indirect contact with patients, as well as support staff where their jobs have an impact on the safety and quality of radiotherapy treatment.

Recruiting personnel

To justify the appropriate choice of personnel whose work impacts the quality and safety of radiotherapy treatment, Management needs to:

1) identify the necessary skills, including in the area of quality, depending on the jobs that are filled or are to be filled,

2) be aware of their competence,

3) provide training or take other action to meet these needs, including teaching about quality matters at a level suited to the individual jobs,

To organise the recruitment of personnel whose work impacts the quality and safety of radiotherapy treatment, Management needs to:

4) organise the recruitment, induction and integration of all this category of personnel,

5) establish the measures for qualification* of personnel,

6) make arrangements for maintaining acquired skills,

7) assess the efficacy of action taken,

8) ensure that members of staff are aware of the relevance and importance of their work and the contribution they make to achieving quality goals,

9) keep the appropriate records*, including records of initial training and professional development, the content of any continuing development provided, assessments of knowledge acquired and know-how (particularly job descriptions, copies of diplomas, appraisal forms, training programmes, records of tutoring, certificates of qualifications* obtained etc.) (see Chapter 1, Section 2, Sub-section 2)).

Maintaining and developing staff skills

External and internal continuing professional development is to include training prior to the application of any procedures, protocols or operating methods, whether new or amended.

Management is to ensure that the continuing development and learning of its personnel, including staff in non-clinical departments, are planned and implemented whenever this training seems relevant to the quality and safety of patient care. The benefit of planning the training lies in the fact that the organisation of care can be planned in the light of resources available and that the training is appropriate to the maintenance and development of the professional competence of personnel, improving their know-how and also maintaining motivation and behaviour that is favourable to the quality and safety of treatment.

Initial training and professional development, know-how, experience and the fact that the work has to be performed in accordance with legislation, the requirements of professional healthcare facilities and other agreed requirements, generally represent appropriate criteria for judging the competence of individuals.

The Order of 18 May 2004 on the obligation to train healthcare professionals in radiation protection for patients exposed to ionising radiations, as stated in Article L. 1333-11 of the French Public Health Code, requires that the objectives and content of specific programmes for radiographers and radiography managers in medical radiology ensure that these members of staff are trained in preparing a quality assurance programme.
This training obligation is effective from 19 June 2009 with regard to all professionals practising at the publication date of this legislation or when they start to practise if their initial training does not include teaching on radiation protection for patients and training must be updated every ten years as a minimum.

It should be noted that, as concerns training and in accordance with Articles R. 4453-4 to 7 of the French Labour Code, the head of the facility must organise training in the risks involved in using ionising radiation, for workers likely to be operating in restricted areas. This training must be refreshed whenever necessary and, in any event, at least every 3 years. It should also make personnel aware of special instructions applicable to pregnant women under Articles D.4452-5 and D.4153-34 of the Code. In addition to this training, if personnel sometimes have to work in a controlled area, the head of the facility must give them a notice about the special risks linked with the job held or the action to be taken, in accordance with Article R. 4453-9 of the French Labour Code.

Recommendation

Encouraging personnel to get involved

To get individuals involved and encourage them to take part in improving the quality management system, Management* can, initially, seek the trust and encourage the development of people who are able to influence the processes* of providing radiotherapy treatment by:

1) defining responsibilities and authority (organisation chart, job description for position holders or substitutes, delegation of authority where appropriate),
2) setting individual and team goals, managing the performance of processes* and assessing results,
3) continuing development,
4) recognition and, where appropriate, reward,
5) setting up a dialogue with staff concerned to develop a "whistleblower's charter" and undertaking to respect it,
6) encouraging the open exchange of information,
7) encouraging involvement in goal-setting and decision-making,
8) encouraging access by personnel to, and informing them about, statutory and regulatory requirements and reference documents affecting the healthcare facility and interested parties,
9) assessing working conditions and improving them by reducing occupational risks as far as possible,
10) ensuring effective teamwork.

Management* should also establish a timetable for training activities in the light of the impact of staff jobs on the quality and safety of radiotherapy treatment for patients, and keep records of when they are carried out.

Personnel qualification

Arrangements should be specified (procedures and instructions) for ensuring that people are qualified* to perform the tasks required at their work stations and for monitoring qualifications regularly. One of the prerequisites for any qualification is the specification of all tasks to be performed at the work station. For this reason, individual job descriptions should be prepared in sufficient detail.

Qualification should be declared once personnel have been recruited, with regard to pre-defined criteria of competence, including in the area of quality, depending on the jobs to be filled. This competence is to be acquired through certificate courses as a prerequisite at the time of recruitment where appropriate, previous professional experience and more specific knowledge to be acquired within the radiotherapy department* in order to adapt to the job, the internal organisation of the department and the physical resources used. The type and number of training courses required before a job is taken up can vary depending on the level of competence of the people appointed, so whenever someone is recruited, the facility should set out the individual training path that needs to be followed in order to declare the person qualified for the tasks to be performed at their work station.

Training or validation* of the required competence should be given for each procedure or instruction allowing one or more task(s) to be performed at a work station.

Whether or not knowledge has been acquired following training in one or more procedure(s) or instruction(s) allowing one or more task(s) to be performed can be tested by simulation, if necessary on a dummy/phantom, recording the important parameters and/or the behaviour of the person being tested, based on target results and defined areas of progress.

Arrangements should also be specified for assessing whether people's job skills are being maintained (supervision, audit etc.) Depending on the complexity of the work and associated risks, these arrangements should lay down the type and frequency of assessments, the criteria for qualification and subsequent, systematic disqualification after a given period of time when a task is not being practised.

After amending any procedure(s) or instruction(s) for carrying out one or more task(s) at a work station, arrangements should be made for informing, training and assessing the people responsible for implementing them, depending on the complexity of the change(s) made and how dangerous they are.

Complex changes to procedures or instructions and those involving greatest risk should entail further qualification or requalification of those responsible for carrying them out.

A record of assessments for judging whether the necessary skills have been acquired or maintained, together with copies of the required diplomas and service certificates as evidence of the acquisition of either a certain level of knowledge or experience should be used to support a decision on qualification or continued qualification.

When the healthcare facility uses tutoring in order to equip its personnel with skills specific to a particular work station, it should be provided in an appropriate manner so as to allow enough time beforehand to organise the qualification of the required number of tutors before undertaking the qualification of the student(s).
For this purpose, the healthcare facility should set out, for the tutor, the criteria required for professional competence, experience and learning, as appropriate, should arrange for the acquisition of corresponding knowledge and should record training given as well as checking* that these criteria have been met before deciding on the qualification of each tutor. The healthcare facility should also specify measures for assessing whether the tutor(s) have maintained their own competence and decide how frequently to assess this, together with the criteria for systematic disqualification, especially where tutoring has not been practised for a given period or where qualification for a particular job has been partially or completely withdrawn.
As regards the student(s), the healthcare facility should set out, in one or more tutoring programme(s), the knowledge to be acquired for each student, and should then record the type of teaching and the order in which it is to be given during the tutoring, and the arrangements for checking* the knowledge acquired and/or that the student(s) have become self-sufficient.

Chapter 3	Management of resources
Section 3.2	Human resources
Sub-section 3.2.2	Obligations of personnel

3.2.2.A **Staff at the healthcare facility must comply with all current procedures and operating methods in the quality management system of the internal structure.**

3.2.2.B **When the application of a quality document proves problematic for staff, they should report this according to the measures adopted for amending quality documents, as set out in the document management procedure.**

HAS requirements covered	N/A

Chapter 3	Management of resources
Section 3.3	Physical resources

1)

3.3.A **The healthcare facility must define and manage the conditions in which work is carried out, including physical, environmental and other factors.**

3.3.B **The arrangements made to ensure the security of the information* system and to ensure quality control* for the data required or generated at every stage of the provision of radiotherapy treatment must be laid down and carried out. The relevant records* must be kept.**

3.3C **The technical approval*, maintenance, quality* control* or benchmarking and the decommissioning of the medical devices and the inspection, measurement and test equipment used in radiotherapy must be performed in controlled conditions using documented specifications and procedures in order to ensure that this equipment functions correctly.**

3.3.D **Records* must be kept of operations, measurements or tests performed.**

3.3.E **The healthcare facility must define, provide and maintain the physical resources (including buildings, installations, equipment, software, logistics, communication means etc.) in controlled conditions, to achieve the safety and quality of radiotherapy treatment. It must keep the associated records*, particularly those relating to maintenance and checking* correct functioning.**

HAS requirements covered	14c, 16a, 16c, 18a, 18c

More information

Working conditions

It should be borne in mind that the conditions under which work is carried out include the physical work environment, the arrangement of the premises, the ergonomics of equipment, the way the workforce and their skills are managed, any time constraints or production pressures etc. These organisational and human factors have a significant impact on the performance of the system and therefore on the safety and quality of care provided.

Management of physical resources

The security of the information system refers to the arrangements made to ensure the integrity and availability of the information system, as well as the confidentiality* of the data it contains and the traceability of access.

The documented specifications and procedures used for standard radiotherapy techniques are to be validated in line with good professional practice.

* The definitions of words marked with an asterisk are found in Annex 1.

In general, the healthcare facility is to make ad-hoc arrangements to comply with the recommendations for installation, operation and maintenance in the instructions from manufacturers of hardware and equipment in the radiotherapy department*. However, the healthcare facility may depart from these on its own responsibility. Similarly, any use of equipment for longer than recommended by the supplier is to be on the responsibility of the healthcare facility.

Obligations connected with the operation of certain medical devices

Points to remember:

1) the existence of an obligation to maintain and supervise* the quality* of certain medical equipment pursuant to Article L. 5212-1 of the French Public Health Code and stated in the Order dated 3 March 2003 published in the Official Journal of the French Republic on 19 March 2003. In any case, all radiotherapy departments* must be provided, as a minimum, with the medical equipment mentioned in Article R. 6123-93 of the French Public Health Code, unless they meet the conditions for derogation contained in that article. This equipment must always be maintained in good working order, pursuant to Article R. 5212-25 *et seq.* of the French Public Health Code.
   Consequently, to apply the equipment management and tracking policy in practice, the Management* of the healthcare facility should describe the measures adopted in terms of managing and tracking equipment, especially medical devices used for radiotherapy and the inspection, measurement and test equipment (IM&TE) that is used for commissioning and operating these devices, from purchase right through to decommissioning.

2) the existence of recommendations on technical approval of radiotherapy installations, issued by the *Agence française de sécurité sanitaire des produits de santé* [French agency for the safety of health products] dated 8 April 2008 and available on its website under "*Dispositifs médicaux de radiothérapie* [medical radiotherapy devices]" at the following address: http://afssaps.sante.fr/htm/10/dm/inddm.htm

3) the existence of an obligation to conduct technical inspections of radiation protection and environment in accordance with Articles R.4452-12 and R.4452-13 of the French Labour Code using the procedures defined in the Order of 26 October 2005. The results of these inspections for medical devices may be recorded in the register required in Article R. 5212-28, para. 5 of the French Public Health Code, in which all maintenance and quality control operations can also be recorded. In this case a reference to this register must be made in the single document on risk assessment. The latter document should also contain an up-to-date list of sources and equipment emitting ionising radiations that are used and stored in the facility, and information on any modifications made to each item of emitting equipment or source, and to each protective device, pursuant to Article R.4452-20 of the French Labour Code.

Recommendation

Promoting the harmonisation of equipment

Within any one internal structure, the equipment or hardware used should be standardised for easier use and management.

Supervising the information system

Within the internal structure, a manager and deputy should be appointed to manage the security of the information system used for the radiotherapy treatment; an inventory of the various resources* making up or used for the information system (documents, data, hardware, software etc.) should be prepared and kept up to date; and procedures and charters for using IT resources* should be drawn up and applied, as should procedures for managing access to the information system (definition of access rights), backups and the destruction of data.

The relevant records* should make it possible to demonstrate compliance with the above-mentioned quality documents in day-to-day use.

The arrangements made to ensure quality control for the data required or generated by the information system at every stage of the provision of radiotherapy treatment should be laid down in the form of test instructions. The records* of tests carried out as part of this inspection must provide evidence of the reliability, relevance and protection of the data.

Supervising the management of medical devices;

Within the internal structure, a manager and deputy should be appointed to manage the medical devices used for radiotherapy, and they will be lead persons responsible for:

- preparing and applying procedures and charters for accessing medical radiotherapy equipment (hardware, software etc.), for use by the department responsible for managing the medical equipment and in particular for maintaining it, so as to be able to coordinate the effective performance of quality control and maintenance operations, and the recovery and storage of data that can be used for the traceability of these operations, or else
- if the healthcare facility does not have a department responsible for managing medical equipment and in particular for maintaining it, specifying and requiring the application of organisational arrangements and selected means for carrying out technical approval, maintenance and quality control activities, in order to comply, at the very least, with regulatory obligations.

The relevant records* should make it possible to demonstrate compliance with the above-mentioned quality documents in day-to-day use.

When the healthcare facility decides to depart from manufacturers' recommendations, for instance as regards maintenance, it should nevertheless record its reasoning for making this choice when this measure is not explicitly stated in the regulations.

For computer systems, the healthcare facility should check in particular that the versions of software or the hardware to be installed have sufficient capacity and are compatible with the other software and hardware used. Any modification of information or programs must be made only by an authorised, identified person. Changes to a program must be traceable.

The measures adopted for management and tracking of inspection, measurement and test equipment (IM&TE) should also preferably make it possible to:

- ensure that the number of items of IM&TE is sufficient for the volume of inspection activity and particularly with the time periods assigned for completion of these inspections,
- catalogue and list each piece of IM&TE,
- draw up specific documentation on the maintenance, calibration and benchmarking of each piece of IM&TE, including the instruction manual, technical documentation and calibration procedures where these take place within the healthcare facility,
- record* and store records of all maintenance, calibration and benchmarking operations for each piece of IM&TE on suitable media, together with the results of calibration and benchmarking, for traceability purposes.

Therefore, for medical devices and the inspection, measurement and test equipment used in radiotherapy treatment, the measures used by the healthcare facility should allow it:

At the time of purchase

- to put together a purchase file including:
  - a description of the product to be purchased and a statement of need including, as appropriate:
    - the requirements for certification and/or compatibility of equipment,
    - the requirements for installation, usability, maintainability and, where necessary, updating of software, benchmarking and maintenance of equipment,
    - the requirements for training and qualification* of personnel,

- the specifications sheet, including the desired features and specifications and, where necessary, requirements in terms of radiation protection,
    - administrative items (including evidence of compliance with regulations),
    - test reports or visit reports prior to the decision to purchase,
    - the sales points for the proposed choice,
    - the final choice
    - the minutes of all meetings, especially between the radiotherapy department* and the medical physics department and, where they exist, the biomedical department, the IT department and the technical department, in order to assess constraints and prepare the specifications sheet.

At the time of installation

- to check that each piece of equipment complies with the order and with current regulations,
- to check that the equipment and, where appropriate, its installation is compatible with its intended use,
- to catalogue and, where appropriate, identify each piece of equipment, particularly in the case of medical devices subject to obligations with respect to maintenance and quality control,
- to inspect documentation submitted by the supplier, especially the existence of instructions on use in French, and a technical manual,
- to check that the equipment is working properly, particularly any safety features and accessories. Where necessary, competent personnel of the supplier, the user departments and the support services involved in the maintenance of equipment can define one or more protocol(s), depending on the complexity of the devices and with regard to the manufacturer's recommendations. All the checks* made must be recorded* in an acceptance document together with the inspection and measurement equipment used, where necessary, duly calibrated and/or benchmarked,
- before any equipment is used, to plan and carry out the training of users and maintenance personnel in the commissioning and handling of equipment. All training carried out must be recorded*,
- to draw up protocols for maintenance, and for checking that medical devices work properly and have been inspected before they are used on patients, stating among other things the type of tasks, their frequency and the people responsible for carrying them out,
- to draw up protocols and programmes for maintenance, calibration and benchmarking of IM&TE,
- to commission the equipment in the presence of competent personnel of the supplier, the user departments and the support services involved in the installation and maintenance of the equipment. This commissioning consists of checking that all the functions and operating conditions have been presented to and are understood by the various users. All records* including, where appropriate, the lifting of non-conformances identified at the time of acceptance (acceptance document, any non-conformance sheets, records of trained personnel and the training received by each person), together with maintenance, checking* or inspection protocols for which users are responsible, are then reviewed to check that they are complete. This review is recorded on suitable media, validated by the above-mentioned people, who were present on the date of commissioning.

At the time of operation

- to put together documentation relating to maintenance and quality control, including:
    - a description of the measures adopted for conducting these two activities,

- specific documentation in relation to maintenance and quality control for each medical device, including the instruction manual, or a copy of it, and the technical documentation,
- in particular, for medical devices subject to compulsory maintenance and quality control, records kept for at least 5 years after decommissioning of all maintenance and quality control operations for each medical device, on suitable media, also comprising data making it possible to trace items or components or changed software versions and to track the test and measurement equipment used.
- a record of bugs encountered in software, stating the type and date of occurrence so that they can be analysed and, at the very least, reported to the manufacturer where not mentioned in the operating instructions.

- to negotiate benchmarking contracts for IM&TE and internal or external quality control or maintenance contracts for medical devices, suited to the needs of the user departments and support services, especially in terms of availability, know-how and qualification* and in relation to the quality and safety objectives set.

At the end of operation (retirement)

- to decommission the equipment used for radiotherapy so as to ensure safety and contribute to the improvement of performance using criteria of obsolescence arising from developments in scientific knowledge and technical data, service time and cost in relation to regulatory requirements. The measures adopted must make it possible to:
  - give prior notice to the user department and the support services of the date of decommissioning of each piece of equipment and the reason for this,
  - specifically identify and isolate each piece of equipment, especially medical equipment, including any accessories, as soon as it is decided to decommission it, pending its actual physical removal from the healthcare facility,
  - record this retirement operation in the inventory of the facility for both accounting and technical reasons,
  - give notice to the user departments by the support services of the decommissioning report.

Specific nature of planning and processing software used in radiotherapy

The healthcare facility is also recommended to ensure that the software used for defining, planning and delivering radiotherapy treatment is protected at each stage of the process from any unauthorised intrusion and is compliant with any developments in scientific knowledge and technical data.
In connection with this software and/or the equipment required for defining, planning and delivering radiotherapy treatment, maintained by an external service provider, it is usual to sign an agreement or contract with service providers selected for maintenance. Generally, this document will state, amongst other things that:

- the staff of these service providers are subject to rules of professional secrecy and that they have the requisite knowledge to work on the equipment covered and mentioned in the document,
- the necessary means are used to ensure protection of confidential data,
- the service provider undertakes to be responsible for the functioning of software in terms of the specifications covered by the terms and conditions of purchase or any updates,
- all work done on site or by remote maintenance may be carried out only at the written request of one of the two parties, by authorised, identified personnel from within either of the parties, and must be covered by a detailed report, including:

- type of work and reason,
- level of performance achieved,
- possible changes in functioning as a result of this work,
- date performed,
- result as concerns the conformance of the device,
- identity of the individual doing the work and his employer, if any,

- after the work is completed, the specialist in medical radiation physics responsible for the software or equipment must check that the latter is in a condition suitable for clinical use. S/he must take the necessary steps to check that the values of parameters that might have been altered during the work do actually correspond to the reference levels within predefined tolerances and agree with the data contained in the sign-off report.

N.B. The sign-off report mentioned above is to be signed, dated and sent to the legal representative of the healthcare facility or his/her deputy. In this case, the name and contact details of the deputy are also to be mentioned in the above-mentioned agreement or contract. Particularly in the case of medical devices subject to compulsory maintenance, the report is to be co-signed and attached to the maintenance record as provided in Article R. 5212-28 of the French Public Health Code. A copy of the sign-off report should be given to the specialist in medical radiation physics* if s/he is not the deputy.

It should be noted that the results of maintenance and quality control operations for radiotherapy accelerators required by Article R. 5212-28, para 5 of the French Public Health Code and the results of technical inspections of radiation protection for this equipment required by Article R. 231-84 of the French Labour Code can be put together on the same media for each accelerator, as long as there is a reference to the media in the single document.

Chapter 4	Preparation for and performance of activities connected with patient management, from first consultation to follow-up after treatment
Section 4.1	Control of the preparation for and performance of activities connected with patient management, from first consultation to follow-up after treatment.

4.1.A The healthcare facility must:

1) Carry out an analysis of the risks* for patients. This analysis should at least cover any risks that might lead to an error in the dose delivered, volume treated or dose fractionation, during the treatment. The study of risk must include a risk assessment* and measures taken to reduce the risks.
2) also use the above-mentioned risk assessment as a basis for developing:
   a) procedures for ensuring that the dose delivered, volume treated, dose fractionation and the organs irradiated or protected are in accordance with the medical prescription,
   b) operating methods that allow equipment to be used correctly.
   Personnel in all work zones must have access to these documents at all times.

4.1.B

3) have personnel who are trained and qualified, particularly in quality assurance,
4) as a minimum, plan and carry out the whole radiotherapy process in controlled conditions consistent with the medical radiation physics organisation plan [*plan d'organisation de la radiophysique médicale* (PORPM)],
5) implement appropriate measures (especially to train personnel in radiation protection for patients), and preventive measures (alarms, safety devices etc.) to ensure personal safety.

4.1.C The documented risk assessment required in point 4.1.A 1) above must be re-evaluated regularly, especially in the light of feedback, whether internal or external, and modifications made (equipment, personnel, organisation etc.)

4.1.D The healthcare facility must control the support processes* that contribute to the performance of the clinical radiotherapy process. These processes must be planned and carried out under controlled conditions with respect to procedures and operating methods that are in writing, dated and validated. Records* should be kept by personnel who are trained and qualified, particularly in quality assurance.

HAS requirements covered	11b, 11c, 11d, 17b, 19b, 20a, 24a, 24b, 27a, 30b, 37a, 37b, 41a

INCa criteria to be considered	10) When preparing treatment, the radiotherapy centre is to use three-dimensional imaging. It should have a dedicated scanner for this, or else access during time slots dedicated to the preparation of the treatments. 11) Software used for calculating and planning doses should take systematic account of beam measurements validated in the centre. 12) The number of monitor units is to be checked by a second calculation system for each beam before treatment. 13) The treatment parameters are to be recorded and checked using a dedicated computer system. 14) All the geometric characteristics of each new beam are to be checked when first used. 15) In vivo dosimetry is to be used for each technically measurable beam, during the first or second irradiation session, and whenever treatment is modified. 16) For any one treatment sequence, all the beams are to be used at each session. 17) Patient positioning is to be checked at least once a week by imaging performed on the treatment equipment.
MeaH	INCa funded support is available for radiotherapy centres to implement the quality and safety approach.

More information

Main requirements of the authorisation for radiotherapy treatment of cancer

It should be noted that if an organisation holds the authorisation mentioned in Article L. 6122-1 of the French Public Health Code it is deemed to comply with the requirements of Article R.6123-88 of the French Public Health Code. This implies that the authorisation holder:

1. Is a member of a cancer care coordinating body, either a regional network recognised by the French National Cancer Institute or else a local network with a constitution approved by the director of the regional hospitalisation agency;
2. Is organised in such a way, and where appropriate jointly with other cancer treatment authorisation holders, as to ensure that each patient is given:
   a) A statement of diagnosis and proposed therapy based on multidisciplinary cooperation using methods complying with the reference documents on treatment. These documents are defined by the French National Cancer Institute under Article L. 1415-2, para. 2 and reflected in an individual care programme given to each patient;
   b) Treatment given in accordance with the reference documents on good clinical practice defined by the French National Cancer Institute pursuant to Article L. 1415-2, para. 2 or else based on recommendations issued by consensus between learned societies; this measure also applies when treatment is given under conditions covered by Article R. 6123-94;
   c) Access to the care and support required by patients throughout their illness, especially pain management, psychological support, greater access to social services and, where necessary, palliative care;
3. Complies with the approval criteria set out by the French National Cancer Institute pursuant to Article L. 1415-2, para. 2 on the quality of cancer treatment.
4. Provides patients with access to innovative treatment and clinical trials. This can be done either by the facility itself, together with a structure based abroad where necessary, or under an agreement with

other healthcare facilities holding the authorisation mentioned in the first paragraph. Support may be had from the relevant organisation under the regional healthcare organisation scheme.

Analysing risks

When analysing the risks arising from a radiotherapy installation, the risks for workers should be dissociated from those run by patients.

This guide is not intended to cover radiation protection for workers; however, it should be remembered that Articles L. 4121-1 to L. 4121-4 of the French Labour Code require an assessment of risks to the health and safety of workers; the results* of this must be transcribed and updated by the employer in a single document covered by Articles R. 4121-1 to 4 and R. 4452-5 of the same code. In accordance with Article R. 4452-4 of the French Labour Code, the head of the facility should ensure that the regulatory zoning around sources is appropriately defined, having made an assessment of the risks from ionising radiation; s/he should also obtain the opinion of the competent person for radiation protection as mentioned in Article R. 4456-1 of the same code. On the basis of this assessment, the zoning defined, the monitoring of dosage levels for workers and also access to the premises can be confirmed or reconsidered. The employer can take inspiration from the working papers below when carrying out a risk assessment for workers:

- the report of the French Institute for Radiation Protection and Nuclear Safety (IRSN), ref. DRPH/DIR no. 2007-6, *Guide pratique pour la réalisation des études dosimétriques de poste de travail présentant un risque d'exposition aux rayonnements ionisants* [Practical guide to conducting dosage studies of work stations with a risk of exposure to ionising radiation] (downloadable from the IRSN website)
- the brochure ED 4246 *Radiothérapie externe, accélérateur de particules* [External beam radiotherapy, particle accelerator], also available from the INRS website.

As concerns the risks run by patients, no account should be taken of the risks of any side effects, however serious, resulting from a strategy agreed between the practitioner and the patient and accepted in the light of the expected benefits of treatment, taking account of the principles for justification and optimisation. Account should be taken of risks that might lead to an error in irradiated volumes or dose delivered at each stage of the clinical radiotherapy process*, including:

1) patient identification,
2) input of morphological and anatomical data,
3) use of imaging to determine volumes of interest,
4) calculation of dose distribution and determination of monitor units (MUs),
5) definition of ballistics,
6) checking* all parameters before the start of treatment,
7) giving the treatment and validation* of the first session,
8) the next treatment sessions and monitoring during treatment,
9) the end-of-treatment verification after the last treatment session,
10) planning and providing post-treatment consultation.

Next, this study of risk should also include biological risks (nosocomial infection), wounds, electric shock, the patient falling, allergy, intolerance etc.

The assessment of risks run by patients should also take into consideration the various pieces of medical equipment used at each stage of the clinical radiotherapy process*, especially:

a) the treatment planning system (TPS),
b) the "record and verify" system,
c) immobilisation equipment, shields,

d) verification imaging (portal imaging for verification of beams and verification of patient positioning; the latter type of verification can also be done with other imagers (Cone Beam CT etc.))

e) the accelerator,

f) measurement and verification equipment.

The healthcare facility should customise the assessment of systemic risks mentioned above to the specific needs of a given patient whenever his condition gives rise to fears of potential adverse reactions or events connected with the procedures applied, the drugs or equipment involved etc. so as to be able to identify them. Depending on this appraisal, the healthcare facility must assess the need for additional services and follow-up, and identify these.

Managing treatment

To validate the various stages of treatment, the healthcare facility can choose methods and/or tools for validating* processes* depending on the stages to be validated. These methods and/or tools can be, for example, tools for demonstrating errors in hardware or human error, and/or for setting tolerances for the results of verification of the various stages; other examples are risk analysis, theoretical experiments, analyses of tolerance and a failure mode, effects and criticality* analysis.

Procedures for giving radiotherapy treatment include rules on the presence of and consultation between patients and/or, where appropriate, their families, and the various medical and paramedical personnel involved, in order to obtain informed consent from patients before any treatment is given. These procedures must also include rules on coordination between the personnel mentioned above and technical personnel, to ensure continuity of care.

Modifying treatment

There are two different situations that could lead to treatment being modified. One relates to the modification of a treatment protocol, which involves rethinking the procedures and/or operating methods and, if necessary, the associated records, and validating these modifications. The other involves adapting a patient's treatment as a departure from the general rule, in which case this particular case needs to be handled with due formality.
An example of this is changing a protocol aimed at going from an isocentre on the skin surface to an isocentre on the tumour as distinct from a modification of treatment for a patient that involved replanning dosimetry because of a morphological change.

Where a treatment protocol is modified, the healthcare facility should re-assess the common risks* and should modify or develop procedures and/or operating methods aimed at ensuring the safety and quality of the radiotherapy treatment. In particular, if this modification is made as a result of a risk-reduction measure, the facility must track the effectiveness of implementing this measure in its records.
A re-assessment of individual risks will prove necessary while a patient is being treated if changes arise, especially changes related to his/her state of health, new results of laboratory tests or any other information, for example, information about a change in the patient's morphology. These steps should be viewed as an integral part of the provision of radiotherapy treatment.
Where a patient's treatment is modified, the healthcare facility should re-assess individual risks. The healthcare facility should use this to determine any exemptions to be requested from the manager of the quality management system Any exemptions that are likely to modify a patient's treatment require the approval of the prescribing physician* before the modification is implemented; the approval should be documented, including in the patient's medical record*, in order to avoid erroneous interpretation.

Recommendation

Analysing the risks for patients.

Once processes have been identified and mapped, the risks for the patient that are inherent in carrying out the processes should be analysed. The generic tool recommended by the ASN as a starting point for this

analysis is the "*Guide d'auto-évaluation des risques « patients » en radiothérapie externe*" [Guide to self-assessment of "patient" risks in external radiotherapy]; this will help internal radiotherapy structures to assess the risks for patients, which might lead to an error in irradiated volumes or dose delivered, or fractionation of treatment. For this, it is up to each internal radiotherapy structure to get hold of the tool and its explanatory notes, to analyse the inherent risks in its system and define the hardware, human and/or organisational measures to be put in place in order to reduce the criticality* of the failure modes identified.

Managing the documentation system

To be certain that the part of the documentation system relating to preparation and administration of radiotherapy treatment has been properly developed and maintained, the following should take place:

1) procedures for managing radiotherapy patients should be laid down, checked, approved, dated and implemented by trained, qualified staff,
2) any change in these procedures should be justified in writing, recorded, approved, dated and notified,
3) after any change to procedures that impacts radiotherapy treatment, training should be given to all personnel responsible for applying it, and a review of risk management* should be carried out,
4) after any change to procedures likely to modify the treatment received by a patient, the prescribing physician* should be given information on treatment reports, in order to avoid erroneous interpretation,
5) any malfunction or any danger* that arises following the implementation of the procedures should lead to an investigation into causes and action to be take to correct the situation and prevent its recurrence. Records should be kept of any corrective measures taken for this purpose and an assessment of their results.

Planning and providing care

The conditions that demonstrate that the planning and provision of radiotherapy treatment are being properly managed include:

a) holding an authorisation to provide treatment pursuant to Article L. 6122-1 of the French Public Health Code.
b) holding an authorisation of use or a receipt of declaration pursuant to Article L. 1333-4 of French Public Health Code, depending on the medical device used for the radiotherapy treatment,
c) the availability of information describing the features of each process*,
d) the availability of the documents required for patient management, from first consultation with a clinical oncologist to post-treatment review, as mentioned in the various service documents, for example the medical physics organisation plan, workflows, procedures, work instructions, check-lists, treatment protocols etc.,
e) the availability and use of appropriate resources,
f) knowledge of the relationships between the successive stages of the radiotherapy treatment process* and a description of the verification scheduled for each stage, allowing the continuity of care provided for in Article D. 6124-132 of the French Public Health Code,
g) the availability and use of the monitoring and measurement devices required for controlling processes*, including inspection, measurement and test equipment (IM&TE),
h) the availability of the physical resources required for carrying out the process*, including medical devices, with respect to the arrangements adopted for carrying out maintenance and, where appropriate, quality control,
i) the carrying out of monitoring and measurement while the service is being provided in order to supervise critical activities and check the availability of resources and information that are described as being necessary. Apart from this supervision* and these checks*, it would be useful

for the healthcare facility to supervise the processes* in order to comply with the requirements applicable to each patient,

j) evidence that the patient accepts the radiotherapy proposed under the individual care plan (Article D. 6121-133 of the French Public Health Code) at the initial consultation, while being monitored and at the end of treatment.

Promoting the harmonisation of practices

Within any one internal structure, therapeutic procedures and the specifications of clinical oncologists and/or medical physics specialists that are used for standard radiotherapy techniques should be made consistent, to make them easier to implement and adapt to circumstances.

In general, the procedures and operating methods that need to be developed and applied for the purposes of providing radiotherapy treatment relate especially to the arrangements made by the healthcare facility for:

1) receiving the patient,
2) prescribing the radiotherapy (**defining the volume** to be treated, **prescribing the dose** to be delivered and the **delivery methods** (dose per session, number of sessions, intervals and frequency of sessions), **setting out** acceptable **dose limits** for **at-risk organs**, generally located in the immediate vicinity of or at some distance from the volume to be treated),
3) identifying the patient, his/her patient record and any accessories used (immobilisation, shield, bolus etc.),
4) doing the simulation (centring and scanning),
5) producing the dosimetric plan,
6) validating the dose by another means, independent of the dose planning system,
7) coordinating the joint validation of the prescribing clinical oncologist and the specialist in medical radiation physics, to encourage the exchange of opinions,
8) planning the treatment sessions,
9) where necessary, producing immobilisation devices, shields, impressions and mouth guards,
10) ensuring that equipment is available (use, maintenance, repair, benchmarking, checking, including the obligation to notify the medical physics specialist before use is resumed),
11) positioning the patient and checking all the geometric characteristics of each new beam before first use,
12) giving the treatment and describing the protocol used. It is important for this method to be adapted to the theoretical knowledge and technical data available at the time. Wherever possible, it should be in line with the recommendations of national or international radiotherapy groups,
13) verifying the dose delivered for each technically measurable beam, with the in vivo dosimetry,
14) providing medical reviews for the patient throughout treatment (monitoring for the onset of iatrogenic complications),
15) passing on information about treatment and describing the operating methods used,
16) providing or coordinating long-term medical reviews for patients after the end of treatment (monitoring for the onset of iatrogenic complications),
17) ensuring health and safety in the radiotherapy department*,
18) managing IT systems,
19) managing malfunctions and emergency situations during treatment or malfunctions detected subsequently and informing the competent personnel of the healthcare facility and, where necessary, the patient(s),

20) recording events and incidents and analysing their cause(s),

21) taking note of feedback on events inside and outside the department and what can be learned from this to improve the safety of treatment,

22) notifying an event/incident to the competent authority as soon as possible (Afssaps*, ASN*, ARH* etc.).

The length of the long-term follow-up of patients should comply with the recommendations of national or international radiotherapy groups or the INCA*; in particular it should comply with criteria for safety of treatment, specifically criteria for approval of the practice of external radiotherapy.

Chapter 4	Preparation for and performance of activities connected with patient management, from first consultation to follow-up after treatment
Section 4.2	Validation*of the preparation for and performance of activities connected with patient management, from first consultation to follow-up after treatment

4.2.A **The results of measurements and tests carried out for the purpose of the technical approval*, maintenance or quality control of the medical devices used in radiotherapy must be reviewed and validated in particular by the specialist in medical radiation physics. Where the results do not conform to the expected specifications of the equipment, the specialist in medical radiation physics must give the Management of the healthcare facility a reasoned proposal, depending on the circumstances, for not using this equipment or for new conditions of use and, if necessary, must follow the arrangements made for the facility to make the obligatory notification to Afssaps and/or ASN.**

4.2.B **Having studied the proposal of the specialist in medical radiation physics, Management should consult the clinical oncologists and personnel responsible for maintaining the medical equipment and, if appropriate, the technical and/or IT departments. It should then reach a decision about which medical devices can be used, depending on the type of treatment provided or possible restrictions on the use of this equipment, or indeed putting it out of service and discontinuing treatment with this equipment.**

4.2.C **According to their responsibilities and in accordance with regulations, all members of staff must validate each stage of the clinical radiotherapy process, from first consultation with the clinical oncologist to follow-up after treatment, so as to achieve the desired result*.**

4.2.D **According to their responsibilities and in accordance with regulations, all members of staff must ensure that data transmission takes place within periods consistent with proper clinical use and in conditions of confidentiality* to as to maintain professional secrecy.**

4.2.E **Apart from the validations made, the healthcare facility must organise or coordinate post-treatment follow-up of patients, including long-term follow-up, to assess the quality of care provided.**

4.2.F **The healthcare facility must validate the support processes that contribute to the performance of the clinical radiotherapy process when it is not possible to measure the results* of these processes in real time.**

HAS requirements covered	Not applicable

* The definitions of words marked with an asterisk are found in Annex 1.

INCa criteria to be considered	
	11) Software used for calculating and planning doses should take systematic account of beam measurements validated in the centre. 18) Follow-up, and traceability of follow-up, is organised for each patient treated by irradiation, by agreement with the patient. A once-yearly radiotherapy consultation is to be provided for at least 5 years; this frequency can be modified in line with data on the patient's clinical condition and/or follow-up examination, or as part of a clinical research programme. Late toxicity is assessed according to the classification currently in use at the US National Cancer Institute, entitled Common Toxicity Criteria.

More information

Validation is useful for demonstrating the capability of the radiotherapy treatment process* to produce the planned results* since it is difficult to measure radiotherapy outcomes directly in the organs treated and in real time while radiotherapy is being carried out; another reason is that some deficiencies only become apparent once the session, or indeed the treatment, is finished.

The various stages of the clinical process of radiotherapy treatment can be validated by signing, dating and authenticating the records, especially records of:

1) the prescription or treatment plan,
2) preparation of the treatment (simulation),
3) contouring of the target volume(s) and at-risk organs,
4) dosimetric planning: double calculation of monitor units by an independent system and double validation by the clinical oncologist and the medical physics specialist,
5) patient positioning images and checking of beams (initial, periodic and in case of a modification of ballistic parameters or patient positioning),
6) the dose actually delivered, for each technically measurable beam, on the basis of the in vivo dosimetry,
7) the end of the sessions (change of sequence and/or end of treatment).

When support processes require validation*, the healthcare facility should make specific arrangements for these processes, including, as appropriate:

a) criteria defined for the review and validation* of processes;
b) the qualification* of equipment and qualification of personnel;
c) the use of specific validation procedures and methods;
d) the requirements for records (see Chapter 1, Section 2, Sub-section 2);
e) circumstances that would require revalidation of these processes.

Recommendation

As regards good practice, account should be taken of the recommendations made in the external radiotherapy procedures guide* published by the SFRO*; however, this guide is not binding.

Chapter 4	Preparation for and performance of activities connected with patient management, from first consultation to follow-up after treatment
Section 4.3	Identification and traceability*

4.3.A **The healthcare facility must use suitable means to identify and ensure the traceability* of each step in the radiotherapy treatment process, and the stage it has reached. It must determine the level of identification and traceability, especially by taking into consideration the results of the risk analysis and must set out the methods for validation, as hard copy and/or by electronic means, used for each category of personnel.**

4.3.B **It must also make arrangements to:**

a) ensure, after each task in the radiotherapy treatment process, that the planning of the remaining tasks can be examined;

b) keep up-to-date records* of the identification, traceability and review of the remaining tasks, and make them available if necessary;

c) ensure reliable, unique and relevant identification of each patient, documents relating to him/her and, where appropriate, his/her immobilisation or shield(s), so as to limit the risk of confusion;

d) keep up-to-date records* of the identification and traceability of installation, calibration and/or benchmarking operations, and of maintenance and, where necessary, quality control of the equipment used.

4.3.C **The healthcare facility must design its medical records* so as to provide a history of services received, times, dates and personnel authorised to administer treatment, medication or other services, together with the results of these services.**

4.3.D **Reports of treatment must include the statements required by regulations and must be validated by the clinical oncologist,**

HAS requirements covered	18b, 28a, 28b, 28c, 37b
INCa criteria to be considered	3) Before starting any treatment, the centre is to have available the patient's records, especially the minutes of the multidisciplinary team meeting and all information necessary for establishing the treatment plan. …/…

* The definitions of words marked with an asterisk are found in Annex 1.

INCa criteria to be considered	6) The report on the end of radiotherapy is to include the following details: - the start and end dates of the radiotherapy, - identification of the target volumes, - specification of the type and power of the beams, - doses delivered, including the dose delivered to the critical organs, - fractionation, protraction, - assessment of acute morbidity using the classification currently in use at the US National Cancer Institute, entitled Common Toxicity Criteria, - indication of the next therapeutic stage, where appropriate, and monitoring methods.
MeaH	INCa funded support is available for radiotherapy centres to implement the quality and safety approach.

More information

Identification

Identification includes the administrative and clinical information concerning the patient, organs, fluid and tissue samples, the healthcare professionals involved, the equipment, devices and hardware used, associated with the department and the stage of treatment.

It should also be noted that identification of the progress of the stages as they are completed can, in particular, ensure that no treatment stages are forgotten or added.

Dosimetric information to be included in a radiotherapy treatment report*

Article 6 of the order of 22 September 2006 on the dosimetric information that must be included in a report on a procedure (treatment report*) using ionising radiation also states that, in the case of external radiotherapy, this information is to comprise:

1) Identification of the patient and the doctor carrying out the procedure;
2) Date when the procedure was performed,
3) Reasons for performing the procedure, taking account of the prescription guides and procedure guides mentioned in Articles R. 1333-69 and R. 1333-70 respectively of the French Public Health Code;
4) Identification of the equipment used for the most irradiating techniques: interventional radiology, computed tomography and radiotherapy;
5) the dose delivered to the various target volumes and to the critical organs included in the volume concerned when the treatment is given. These items must be also give information on the fractionation and protraction of the dose administered.

Recommendation

Medical records should be standardised as far as is necessary to ensure continuity of the care given to the patient by the various health service providers.

Chapter 5	Assessment, analysis and improvement
Section 5.1	Monitoring and assessment of the performance of the management system
Sub-section 5.1.1	Monitoring and assessment of the processes and their results*

5.1.1.A **The healthcare facility must plan and implement the processes of monitoring, assessment, analysis and continuous improvement required in order to:**

a) measure the characteristics of patient care, at appropriate stages in the process, so as to check that the requirements are met;
b) demonstrate that the treatment delivered complies with the patient's treatment plan;
c) ensure the conformance of the quality management system and, in particular, check that the radiotherapy treatment is carried out according to the treatment specifications as mentioned in the quality documentation;
d) provide significant data for decision-making;
e) and, on the basis of the above data, continually improve the effectiveness of the quality management system.

5.1.1.B **The healthcare facility must:**

1. **set up procedures stating the reason or objective, methods, tools and time of assessing the data for the monitoring and assessment of the processes and their results*, and the use of this information*,**
2. **make arrangements for planning and implementing this monitoring.**

5.1.1.C **Evidence of compliance with acceptance criteria must be stored together with the traceability of the operations and information on who carried them out. The records* in the patient's medical record must mention the person(s) who supervised each treatment session and the process as a whole.**

HAS requirements covered	10b, 40a, 43 a, 43b, 43c, 44c, 44d, 44e
INCa criteria to be considered	9) Self-assessment of radiotherapy practice is to be carried out annually in the facility, using indicators defined by the French National Cancer Institute, and in the context of monitoring the quality of practice as provided in Article R. 6123-95 of the French Public Health Code. The anonymised data is to be sent to the French National Cancer Institute for collation on a national scale.
MeaH	INCa funded support is available for radiotherapy centres to implement the quality and safety approach.

* The definitions of words marked with an asterisk are found in Annex 1.

More information

Providing evidence of the conformity of treatment

The result of treatment is usually considered the most important indicator of success for demonstrating the conformity of the result obtained; however, in radiotherapy the result may not be immediate. Therefore, account should be taken of patients' long-term follow-up data.

The healthcare facility should use appropriate methods for monitoring and measuring radiotherapy treatment processes, in order to demonstrate the capability of the processes to achieve the planned results*. Formal arrangements must be made for implementing these methods. When the planned results are not achieved, corrective action must be taken to ensure that the treatment delivered complies with the patient's treatment plan. The analysis of the reasons for these results and any decisions taken to remedy them must be recorded.

Special attention on the part of the Management of the healthcare facility must be paid to the methods for monitoring and measuring critical processes* in relation to the functional goals. As soon as the quality plan is developed, the attention paid will give a clear indication of the nature of the various requirements, the areas that need to be supervised and the level of this supervision. It will then be easier to define and describe the methods for monitoring and measuring these processes*.

Recommendation

Publishing the results of treatment promotes transparency and makes for easy comparisons within the healthcare facility and between healthcare facilities.

It is recommended that methods such as, and especially, self-assessment and quality control of equipment should be used for monitoring and measuring the treatment processes.

The healthcare facility should identify methods allowing it to obtain and analyse information about how well it is meeting the requirements of any person or body requiring its services (patients, other health service providers or, where necessary, the State or National Health insurance).

The most common method is a satisfaction survey. For patients, this consists in providing a satisfaction questionnaire at the end of treatment, to get information on the various criteria seen as significant in relation to the quality policy and the preset goals. Using the same method, applied regularly to other healthcare professionals working with the patients, it will be possible to take stock of their satisfaction level where their needs differ from patient needs.

Once the monitoring and measurement methods have been defined and described, the second stage is to determine the anticipated results of other processes*, so that the monitoring and supervision of the quality management system apply to all radiotherapy treatment processes*. If the goals of a process* are not attained, the process* should be improved until the desired results are achieved.

An additional method for monitoring and measuring processes* consists particularly of recording events likely to impair the radiotherapy treatment process* and of setting up the appropriate organisation, using the necessary skills, to analyse how these events were caused. This organisation can take the form of a task force or a feedback unit for analysing events, and proposing and implementing solutions for improvement as indicated in Chapter 5, Section 3 below.

Chapter 5	Assessment, analysis and improvement
Section 5.1	Monitoring and assessment of the performance of the management system
Sub-section 5.1.2	Internal audit*

2)

5.1.2.A **The healthcare facility must set up a documented procedure and internal audit* programme looking at the status and importance of the processes and fields to be audited, and at the results* of previous audits**

5.1.2.B **The healthcare facility must carry out planned internal audits at regular intervals and record the results find out whether the quality management system:**

a) meets the requirements of this guide and the requirements of the quality management system laid down by the healthcare facility;

b) **is being implemented and maintained effectively.**

HAS requirements covered	10b
MeaH	INCa funded support is available for radiotherapy centres to implement the quality and safety approach.

More information

In general, quality planning should allow the field (identification of process(es)* audited), frequency and methods of audit to be set in advance with respect to the criteria.
The objective of the audit is to ensure that formal arrangements are made for the tasks carried out, using procedures and instructions, and that these arrangements are respected. The aim of the audit is, therefore, to check the application of a procedure or instruction and not to check the relevance of its contents. One of the ways of checking whether these documents have been followed is to check* the corresponding records (evidence-based checking).
The information or methodology laid down in a procedure or instruction must, where necessary, be reviewed with regard to any non-conformances recorded and the setting up of corrective or preventive action.

The healthcare facility should set out in a documented procedure* the arrangements made, responsibilities and requirements for:

1) setting up a group of auditors who have made individual undertakings to be objective and impartial during the audit process, if it has not been possible to select them from outside the internal structure;
2) planning internal audits;
3) carrying out internal audits and reporting the results*;
4) keeping records;
5) dealing with any non-conformances detected and their causes within a predetermined period;

* The definitions of words marked with an asterisk are found in Annex 1.

6) checking the action taken;

7) preparing and distributing reports of the results of this check.

It should be noted that performing internal and external quality control of the medical devices used for radiotherapy treatment, setting up the in vivo dosimetry at the first or second session, and carrying out regular self-assessment, all constitute monitoring and measurement methods; however, they are no substitute for internal audits.

Recommendation

Criteria should defined for use with planning, such as the criticality* of a process* or the scale of the associated activity, and a procedure should be developed to describe the method of carrying out internal audits.
To ensure the objectivity and impartiality of the audit process*, the healthcare facility should take special care that auditors do not have to assess their own work.
It is advisable to put the supervisory staff responsible for the area being audited in charge of arrangements, responsibilities and requirements for eliminating any non-conformances detected and their causes. Where difficulties are encountered in eliminating any non-conformances detected and their causes, care should also be taken that the supervisory staff responsible for the area being audited can report these to the quality management system manager so that the necessary measures can be taken, referring where necessary to the Management of the healthcare facility.

Assessment, analysis and improvement

Management of malfunctions, adverse situations or non-compliant results*found in connection with patient management, from first consultation with a clinical oncologist to the end of treatment

5.2.A **The Management of the healthcare facility must set up:**

1) training addressed to all personnel whose work impacts the quality and safety of radiotherapy treatment, ensuring, as a minimum, that they are able to:

- **detect non-conformances* or adverse situations* or malfunctions*, in terms of organisational as well as hardware or human matters, among day-to-day events,**
- **and declare these in what is referred to below as an "internal declaration";**

2) a specific organisation for analysing internal declarations and planning any action necessary to improve the safety and quality of radiotherapy treatment, referred to below as improvement action*.

3) procedures for informing the patient or his/her legal representatives, if the event triggering the internal declaration has led to his/her death, is life-threatening, or has left him/her disabled or handicapped. This information must be provided, even after the patient has left the facility.

5.2.B **All personnel whose work impacts the quality and safety of radiotherapy treatment must declare each non-conformance observed, adverse situation encountered or malfunction detected, whether relating to organisational, hardware or human matters, to the organisation described in 5.2.A 2).**
Anyone making a declaration must, as a minimum, record the date of the declaration, a description of the event triggering it, the circumstances in which this event arose and a description of its consequences, as soon as possible after its discovery.

5.2.C **The organisation mentioned in point 5.2.A 2) must analyse internal declarations within an appropriate period in view of their criticality*; this should either happen as soon as possible after the declaration when there is an obligation to declare the triggering event to the competent authorities under the heading of due diligence or the recording of serious adverse events, or should take place at regular intervals in the case of other internal declarations.**
The analysis should, as a minimum, cover the skills of the various professionals directly involved in the therapeutic management of radiotherapy patients.
It must:

1) assess each internal declaration,

2) analyse the internal declarations involving greatest risk, especially when there is an obligation to declare the events to Afssaps or ASN;

3) for every declaration analysed, propose action to be taken for improvement:

a) allowing the malfunctions detected or adverse situations encountered to be corrected, or authorising them to be accepted by exemption;

b) allowing the causes of the malfunctions detected or adverse situations encountered to be eliminated, where the causes originate with the healthcare facility;

c) that may lessen or even overcome the actual or potential effects of the malfunctions or adverse situations, especially where the causes do not originate with the healthcare facility.

4) propose to Management a timetable for carrying out each of the improvement

* The definitions of words marked with an asterisk are found in Annex 1.

actions, a person responsible for implementing each one and a person responsible for checking* its effectiveness,

5) propose to check that the actions are carried out and assess their effectiveness.

Where difficulties are encountered in implementing improvement actions, these must be referred to the Management of the healthcare facility, who are responsible for fixing the timetable for improvement actions and for following them up.

5.2.D The healthcare facility must set up a documented procedure for managing non-conformances, malfunctions or adverse situations and must have procedures allowing it to discontinue or suspend any treatment that does not meet the requirements; the procedures should allow treatment to be resumed once it is clear that the problem has been eliminated, or carried out despite one or more requirements not being met, after a risk/benefit analysis.

5.2.E For each non-conformance, adverse situation or malfunction dealt with, the minimum records to be kept are: name of the person making the declaration, date of the declaration, description of the event, circumstances in which it arose and description of its consequences. This declaration, in any format, constitutes one of the records* in the documentation system.
For each declaration processed, the minimum records to be kept are: names of the people involved in the assessment, acceptance by exemption or request for corrective and/or preventive action, and provisional date set for carrying out the proposed action.
Records must also be kept at least of the nature of the proposed action, together with the date when it must take place, the name of the people appointed to carry out and follow up the action, and a record of how effective it was.
This information, in any format, constitutes one or more record(s)* in the documentation system.
All these records* must be easily accessible for any one event.
Where appropriate, links between these records must be identified and maintained.

5.2.F For each declaration analysed, the following records must also be kept, as a minimum: names of the people involved in identifying possible causes and justifying any that are discarded, defining improvement action and deciding how it should be planned; nature of the proposed action; date by which it has to take place; names of the people appointed to carry out and follow up the action; and a record of the fact that it took place. These records must be kept.

HAS requirements covered	12b, 12c, 12d, 19d

MeaH	INCa funded support is available for radiotherapy centres to implement the quality and safety approach.

More information

Dealing with malfunctions

A material error, an unjustified delay in providing care or a fault observed in the radiotherapy process* or other processes* such as benchmarking, maintenance of equipment, training of personnel, or indeed the result* of a process* (dose received, fractionation etc.) are all examples of non-conformances where requirements had been established previously, or adverse situations where there are no requirements. If no formal requirement had been established but nevertheless the facts observed lead to a situation that is unwanted or abnormal, these facts are described as malfunctions. These malfunctions* may be observed before, during or after the use of a medical device or piece of equipment. The documentation required for every malfunction includes records of the nature of the malfunction and all subsequent action taken, including any exemptions obtained.

The documented procedure for managing malfunctions or adverse situations or non-compliant results must describe the arrangements made for:

1. defining the appropriate inspections (review of documentation, measurement etc.) in order to detect non-compliant treatment;
2. making use of appropriate skills and knowledge in relation to the area of the non-conformances or adverse situations detected;
3. notifying the competent authorities of some non-conformances or adverse situations (serious adverse events*, medical device vigilance, radiovigilance*), depending on the legislation in force;
4. reviewing malfunctions or adverse situations at defined intervals, depending on their criticality*;
5. determining the causes of non-conformances or adverse situations, using an agreed methodology;
6. authorising acceptance by exemption or identifying and implementing the curative action* necessary to overcome the malfunction;
7. assessing the need to take corrective action* to ensure that non-conformances or adverse situations do not recur;
8. recording the results of action taken (see Chapter 1, Section 2, Sub-section 2);
9. reviewing the curative and corrective action taken.

Details of specific malfunctions

It should be stated that as regards the legislation or regulations in force, the competent authorities (the InVs*, l'Afssaps*, and/or ASN* respectively) must be notified without delay of certain adverse situations or malfunction or serious non-conformances such as serious adverse* events*, risk of accidents or serious incidents or serious accidents or incidents of materiovigilance/medical devices vigilance or significant radioprotection* events*.
When a serious event as specified above causes injury* to a patient, the health facility must also ensure that the patient or his/her beneficiaries are informed in compliance with the legal provisions (L. 1142-4 of the French Public Health Code), and at the latest within 15 days of discovery of the injury*.
Some internally-declared malfunctions (within the health facility), must be notified to the competent authorities if they fulfil the criteria for obligatory external reporting. As a result, prior analysis of each report will facilitate identification of those that fulfil the criteria for external reporting. These malfunctions that fulfil the criteria for obligatory external reporting, including significant radioprotection* events* (ESR), must be the subject of a more detailed investigation in order to identify the underlying causes. To do this, special care must be taken with documenting the situation that allowed them to happen and establishing a causal hierarchy will rank the causes in order of importance.

Contribution and scope of the support coordinated by the MeaH and financed by INCa

In order to improve the quality and safety of treatment, INCa and the national mission for Hospital Expertise and Audit (MeaH) have developed tools to support the radiotherapy centres. Within this framework, a method is proposed to the centres based on studies relating to safety in the aviation sector. This method is based on the systematic use of precursor events. Continuous analysis of these precursor events allows the safety of an organisation to be tested and reinforced. To date, 51 centres have benefitted from this support. A best practice committee, known as CREX, was created within the radiotherapy centres. This committee meets once a month. It is charged with analysing and exploiting at regular frequencies certain malfunctions known as "precursor* events*", and particularly those that do not fulfil the criteria for obligatory notification to the competent institution(s). Within the framework of the CREX, the post-reporting collection of facts should include the entire chronology of the event and challenge the robustness of the various precautions that the organisation has put in place.
The approach of these CREX committees fulfils the obligations established by resolution n°2008-DC-0103 of the ASN of 1st July 2008. However all centres that are supported by the MeaH should distinguish the methods for managing the events that are the subject of an internal report from those that fulfil the criteria for reporting of a significant radioprotection* event* (ESR). Hence, any ESR that does not meet the obligations for notification to the ASN and to the state representative must be subject to analysis, appropriate corrective measures and a report addressed to the authority within two months (guide ASN/DEU/03).

Recommendation:

Encouraging reporting

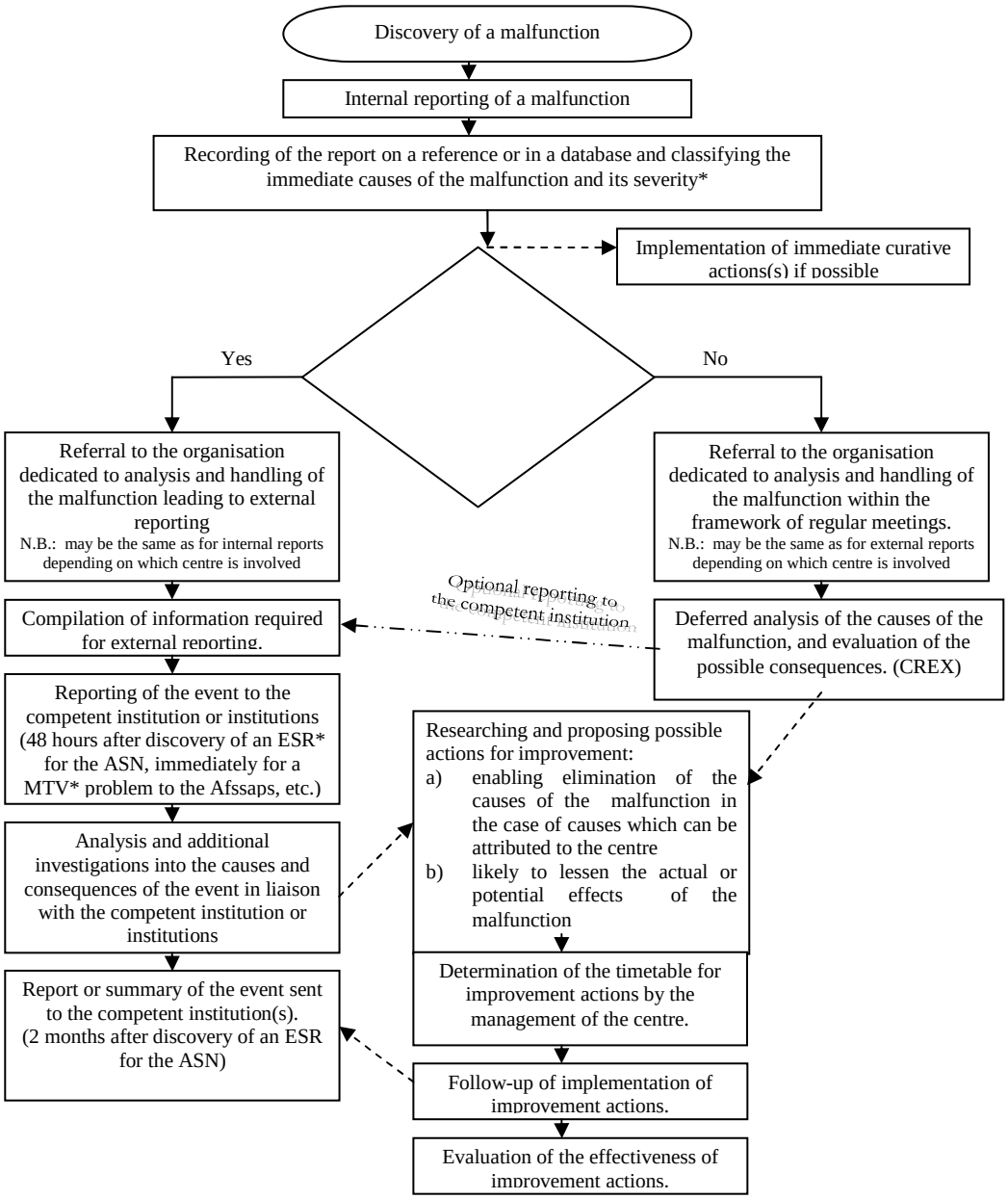
In order to facilitate the implementation of internal reporting of malfunctions, Management can adopt a whistle-blower protection charter to ensure a climate of confidence and safety between Management and staff. Actions to improve reporting are also desirable. These steps are a precursor to sharing experience taken from a risk situation and therefore lead to an improvement in the quality and safety of the processes*, and hence treatment.

One or several organisations that manage malfunctions

Depending on the importance of the health facility and its structure in the area of quality and risk management, it may be valuable to have a different structure to that responsible for analysing the causes of internal reports, responsible for determining the actions for improvement or for fixing the timetable for implementation of actions for improvement and ensuring their follow-up. The analysis of causes requires specific skills, especially for drafting the causal hierarchy, and some individuals in the healthcare facility may have these. Researching the actions for improvement must be multidisciplinary to expand the skills of the organisation mentioned in 5.2.A 2), in order to cover all the skills necessary to carry out any work which impacts on the safety and quality of radiotherapy treatment. When the facility has skills available, especially in the areas of biomedical engineering, information technology, or even construction engineering, energy installations and networks, it is strongly advisable to make as much use of these as necessary. It is also advisable if appropriate to include specific skills to improve the management of patients (admission, care when they return home, and patient comfort). It is Management's responsibility to ensure a timetable is drawn up for implementing the improvement actions and for following these up. Therefore Management may wish to participate in these meetings. It is also a good idea to formally organize the structure or structures responsible for analyzing the malfunctions, the adverse situations or non-conformances, to determine the actions for improvement, to establish the timetable for implementation and to follow them up. Finally the necessary skills and the personnel responsible should be documented in a systematic manner, defining the jurisdiction of this structure or structures or their attributions and their accountability with respect to the other structures in the health facility. Their work should be recorded, follow-up of the implementation of actions for improvement evaluated on a regular basis and if appropriate any difficulties encountered reported to Management. Records should be kept throughout.

Procedure for handling malfunctions

It is strongly advisable to carry out an evaluation of the report shortly after the report is made, and to ask the individual reporting the event to take part in reproducing the events to make him/her specify any information that he/she may have omitted on the report. Mentioning the name of the individual on the report, accompanied by a whistle-blower's charter for the individual enables greater involvement of personnel and makes analysis easier, hence the pertinence of improvement actions. In addition, it is also essential to meet all the individuals concerned, and to visit their workplace to analyse the organisational and human factors that might influence overall performance of the system and to establish the causal hierarchy without loss of information.



Flowchart of the procedure for handling a malfunction

The structure mentioned in 5.2.A 2) should be organised in such a way that every internal report can be evaluated and classified so that those subject to the obligation to report to the Afssaps or the ASN can be analysed as soon as possible and the time between detection and reporting to the competent authorities does not exceed 48 hours.

Use of a tool such as the causal hierarchy that enables graphic representation of the logical sequence of the facts can facilitate analysis of the causes of the malfunction. This analysis must be based on the precise

and objective collection of concrete facts and examine all the elements of the situation, including organisational-type or underlying causes, by going back as far as possible into the causes for non-conformance. Analysis is facilitated if the inquiry takes place as early as possible in the location where the malfunction took place and with all the individuals concerned. It is advisable to ask several questions (How did this happen? Is it necessary? Is it sufficient?) for each fact identified, to be able to go back as far as possible in researching the causes.

Analysis of the reporting of an ESR must allow identification of all the causes of the event, including indirect causes, which might have contributed to its appearance and all contributory factors, including the organisational and human factors.

When the internal report does not originate from a situation that leads automatically to the obligation for external reporting (radiovigilance* and materiovigilance), the reported event can be considered as a risk precursor event*. It is advisable to analyse precursor* events* according to a method of analysis focused on precursor events where the risk is equal to or greater than a pre-determined level of risk. In the event of a reduction in the number of reported precursor events, the risk level that must lead to analysis of a precursor event should be decreased in order that the number of events is more indicative of the problems encountered.
This methodology for analysis of precursor events most at risk allows one to become detached from the accident context or incident, and focus on the analysis, the improvement actions, the timetable for implementation and follow-up. Regular implementation of this methodology enables one to smooth the workload. Which is why the structure mentioned in 5.2.A 2) should carry out at specified intervals (minimum monthly) for a specified time (each health facility should fix the time to be allotted to this task) an analysis of the precursor events most at risk by formalizing the level of risk that must lead to analysis. This structure should keep an up-to-date statement of the number of reported precursor events in order to be able to revise downwards the level of risk that must lead to an analysis.

When establishing how long each member of the structure(s) responsible is to spend on this, account should be taken of individual and group preparation time and follow-up activities. Which is why it is advisable to set up a scheme that enables evaluation of the working time of these members so that the time allocated to the associated workload can be adjusted.

Chapter 5	Assessment, analysis and improvement
Section 5.3	Analysis of data

5.3.A **The health facility must determine, collect and analyse the data resulting from the monitoring and measurement activities to demonstrate the pertinence and effectiveness of the quality management system and to evaluate the possibilities for improving its effectiveness.**

HAS requirements covered	43a, 43c , 44e
MeaH	INCa funded support is available for radiotherapy centres to implement the quality and safety approach.

More information:

In general, the analysis of data initially provides as a minimum the following information:

1) conformance of the outcome of radiotherapy treatment compared with the pre-established requirements,
2) and details of the development in processes* and treatment outcomes,

In the years following the implementation of the ASN technical resolution specifying the nature of the obligations relating to quality assurance in radiotherapy, the analysis of data can also provide information on the following:

3) opportunities for preventive action enabling a development in processes* and treatments,
4) patient satisfaction and satisfaction of the other interested parties,
5) if appropriate, the satisfaction of suppliers.

Chapter 5	Assessment, analysis and improvement
Section 5.4	Improvement, corrective action*, preventive action*

5.4. A **The health facility must take curative action* to correct non-conformance* an adverse situation* or a known malfunction* if it is possible to make a correction.**

5.4.B **The health facility must take corrective* action to eliminate the cause or causes of non-conformance* or of an adverse situation* or a known malfunction* if this cause (or these causes) can be attributed to the health facility, in order to prevent any recurrence. This correction involves pertinent identification of the cause and elimination of the latter.**

5.4.C **The documented procedure* defined in chapter 5 section 2 D item iv) must be followed in order to define the requirements leading to a review of all reported non-conformances or malfunctions or adverse situations (including the complaints of the patient or of other interested parties). This procedure must be applied in order to determine and manage each non-conformance.**

5.4.D **The institution must establish a documented procedure* to determine and manage the preventive actions that will enable elimination of the cause or causes of a potential non-conformance or a potential adverse situation or potential malfunction in order to prevent them from happening.**

5.4.E **The corrective actions must be adjusted to the effects of the non-conformances encountered and be based in all cases on the analysis of causes of the non-conformance.**

5.4.F **The preventive actions* must be adjusted to the effects of the potential problems.**

HAS requirements covered	17b, 32c, 41a, 43a, 43b, 43c, 44b
MeaH	INCa funded support is available for radiotherapy centres to implement the quality and safety approach.

More information:

Continuous improvement is a basic requirement of the quality management system and can be implemented by applying the Deming wheel cycle. This cycle includes planning and action as prerequisites to the prevention of malfunctions or non-conformances, as well as the reaction to these events via the intermediary of corrective action.

The analysis and identification of the causes of malfunctions or non-conformances must be documented to create a foundation for the corrective action.

* The definitions of words marked with an asterisk are found in Annex 1.

The facilities that work on the so-called "precursor" events can more easily implement so-called "preventive action" enabling them to detect at risk areas before the event produces a situation which involves an injury to an individual (patient, professional, third party).

A documented* procedure* for managing preventive action must define the requirements for:

1) accessing appropriate skills and knowledge relating to the area of potential non-conformance;
2) determining potential non-conformances and their causes;
3) evaluating the need to undertake actions to prevent the appearance of non-conformances;
4) determining and implementing the necessary actions;
5) recording the outcome of implemented actions (see chapter 1 section 2 subsection 2) ;
6) reviewing implemented preventive actions.

Recommendation:

From risk analysis to preventive actions

Preventive actions should be both predicted and maintained in order to reduce the risks, both those associated with the radiotherapy treatment processes and those not associated with them, such as fires, environmental risks. This approach requires initial identification of the potential risks and evaluation of their probability of occurrence, as well as their possible consequences. Which is why this malfunction prevention approach is the logical continuation of the risk analysis approach, and especially of the risks posed to patients.

It is also desirable within the framework of this prevention approach to take into account feedback from malfunctions that have occurred, on a national as well as international level (ASN, ROSIS, CIPR, AIEA, PAHO, OMS, etc.) as inputs into the process of improvement of the quality and safety of radiotherapy treatment. This information should be taken into account by the structure in charge of analysing the internal reports and for planning the actions for improvement as part of its everyday activities.

The health facility may also have a legitimate interest within the context of its management of the risks posed to a patient, to carry out actions to reduce the actual or potential effects of the malfunctions or adverse situations or non-conformances when their cause or causes are not attributed to them, in order to limit the consequences to the patient. The opportunity to study the implementation of such actions therefore comes within the jurisdiction of the structure responsible for analysing the internal reports and for planning the improvement actions as part of its everyday activities, covered under section 2 chapter 5. Implementing actions such as this also helps to improve the quality and safety of radiotherapy treatment.

Evaluating actions for improvement

Documented procedures should formalise the measures taken in planning and implementing actions for improvement by enabling evaluation of the impact of these actions on the functioning of the processes and on the activities in order to prevent the transfer of risks.

Annexes

Annex 1 Definition of terms

S

T

V

ADVERSE EVENT:

Event which does not conform to the desired, normal or usual function of the healthcare facility; [CEN/TS 15224: 2005 3.3.1].

NOTE 1: Initiation of a report and a registry within the facility of any adverse event for the purpose of analysis, constitutes an ideal means to acquire a culture of reporting and implementation of feedback conducive to the improvement of care.

NOTE 2: The adverse events may be many in nature, when they are features of radioprotection they are called "significant radioprotection events"* .

NOTE 3: The adverse events may be of different levels of seriousness; it is appropriate to identify the level of seriousness in order to implement an appropriate corrective * action* or improvement *. This can range from having no impact on the patient, the personnel or a third party, to their accidental death, errors in medication (delays, incorrect dosage, wrong medication); a treatment or a procedure with unexpected results; a material error to the person; malfunction/or incorrect use of medical devices, with harm or not to the patient, personnel, etc

ADVERSE SITUATION:

Situation not conforming to the desired, normal, or usual function of the healthcare facility [CEN/TS 15224: 2005 3.3.1].

AFPPE:

Association française du personnel paramédical d'électroradiologie (French Association for Electroradiology Paramedic Personnel).

AFSSAPS:

Agence française de sécurité sanitaire des produits de santé (French Agency for the Safety of Health Products, public administrative facility under the auspices of the health ministry).
This agency participates in the application of laws and regulations and takes decisions on the evaluation, the trials, manufacture, preparation, import, export, bulk distribution, packaging, storage, operation, marketing, publicity, entry into service or use of the healthcare products for use in man and products for cosmetic use, in cases provided for by specific provisions.

AIEA:

Agence internationale de l'énergie atomique (International Atomic Energy Agency)
Created in 1957 by the United Nations in response to the profound fear resulting from the discovery of nuclear energy. The agency works with the member states and multiple partners globally to promote the certain and peaceful safety of nuclear technologies.

ARH:

Agence régionale de l'hospitalisation (Regional hospitalization agency - institution created by the statute of April 24, 1996 reforming public and private hospitals). The ARH is particularly charged with defining and implementing regional policy by offering care through a regional plan for care organizations and pluri-annual contracts with healthcare facilities of objectives and means, analyzing and co-ordinating the activity of these latter, determining their resources through budgets and monitoring their function.

ASN:

Nuclear safety authority (independent French administrative authority, created by the law of June 13 2006 relating to transparency and safety with nuclear material, responsible for engaging in monitoring nuclear safety and radiation protection, and in providing public information in these areas).

AUDIT:

Methodological, independent and documented process enabling results of important facts or data to be obtained and the objective evaluation of these facts/data to determine to what extent the policies, procedures or expressed needs or expectations, usually implicit or imposed, used as reference, are satisfied. [EN ISO 9000: 2005 3.9.1]

NOTE 1: It is known as internal when it is carried out by the healthcare facility* itself or on its behalf by a third party for internal reasons, and can constitute the basis of a self-declaration of satisfaction with respect to the expressed needs or expectations, usually implicit or imposed (self-declaration of conformance). It is known as external when it is carried out by a second party (parties with an interest in the healthcare facility, such as patients, other health service providers, or even if necessary, health or mutual insurance companies requiring the services of the healthcare facility* or by other people on their behalf) or by a third party (independent external organization).

NOTE 2: External audits must be included as they must be carried out solely by a third party completely independent of the healthcare facility.

CLIENT/CUSTOMER:

The patient/person receiving care (he is the key client and beneficiary of healthcare service provision). The other health service providers or the healthcare facility* department/service receiving the products/ services provided, may be considered as clients.
The health insurance or mutual insurance companies requiring the services of the healthcare organization*, etc may also be considered clients. As far as family/parents/very close relatives, are concerned, refer to stakeholder * [CEN/TS 15224: 2005 3.4].

NOTE 1: In order to facilitate the reader's understanding, this term has been replaced by the terms "patients, other health service providers*, also if necessary, the health insurance or the mutual insurance companies requiring the services of the healthcare facility".

COMMON/ INDIVIDUAL RISK:

In this document the idea of common risk applies to all persons and is opposite to the idea of individual risk, specific to one person.

CONFIDENTIALITY:

All information about patients is confidential and should be protected by professional secrecy/ confidentiality. The clinical data relating to the radiotherapy may only be communicated to the patients themselves, to a third person duly elected by the patient, to a prescribing practitioner and to any other practitioner designated by the patient, except if there are exemptions or specific rules provided for by the law and current regulations.

CONTINUOUS IMPROVEMENT IN QUALITY:

Part of the coordinated activities enabling regular direction and control of a healthcare facility* as regards quality centred on the increase in capacity to satisfy expressed needs or expectations, usually implicit or imposed, for quality [EN ISO 9000: 2005 3.2.12 and 13].

CONTRACT REVIEW:

Systematic actions carried out in order to make sure that the active unit (enterprise, organization, association or part of same) has understood and recorded all the needs expressed by the client* or user, and that it can fulfil them [Christian HERSAN; Vade-mecum assurance qualité (p. 45); 3rd edition; Lavoisier Technique et Documentation; Paris 1995]

CONTROL:

Evaluation of the fulfilment of a requirement by observation and judgement, accompanied if necessary by measurements, tests or calibrations [EN ISO 9000: 2005 3.8.2].

CORRECTIVE ACTION:

Action aimed at eliminating the cause or causes of a non-conformance*, adverse situation* or malfunction* [EN ISO 9000: 2005 3.6.5].

NOTE 1: There may be many causes of a non-conformance.

NOTE 2: Curative* and corrective actions should be distinguished.

CRITICALITY:

Rating factor allowing prioritisation of improvement efforts to be conducted on a process, a product, a system, while working by order of decreasing criticality, seeking to always keep it as low as possible. Many methods may be used to obtain this factor. The 'analyse des modes de défaillance de leurs effets et de leur criticité (AMDEC) - failure mode effects and criticality analysis' is a tool of functioning safety (SdF) which uses this factor to prioritise actions to be performed. Criticality is determined from the rating of frequency of appearance of a fault and its severity/gravity*. A third parameter can be added to take account of the non-detection of a fault. Criticality is defined by the following formula:

$$C = G . F . N$$

G : indice de gravité
F : indice de fréquence
N : Indice de non-détection

G= gravity index
F- frequency index
N= index of non-detection

It is preferable to talk of non-detection (N) rather than detection (D); because as in the case of F and G, criticality is much weaker if the non-detection is low.
Such analyses can be adapted to any interrogation in any field. They can be used as a basis, for risk analysis amongst other things.

NOTE 1: Another tool which may be used in the field of the radiotherapy is the analysis of the effects of errors on the software (AEEL) which is a tool, adapted by AMDEC, used by software developers.

CURATIVE ACTION:

Action aimed at correcting a non-conformance, adverse situation or malfunction [EN ISO 9000: 2005 3.6.6].

NOTE 1: A curative action pay be taken jointly with a corrective action

NOTE 2: A curative action may consist of modifying current radiotherapy and under certain conditions, without acting on the cause of the non-conformance or the adverse situation, to make it conform to requirements.

DANGER OR DANGEROUS PHENOMENA:

Potential sources of physical injury or damage to people's health or well-being or to the environment [ISO EN 14971: 2007 2.3].

DOCUMENTED PROCEDURE:

The term "documented procedure" signifies that the procedure is established, documented, applied and up-to-date. A single document may contain requirements relating to one or more procedures or in contrast, one requirement relating to one documented procedure may be covered by many documents.

ESTRO:

The European Society for Therapeutic Radiology and Oncology is an international learned society based in Brussels promoting oncological radiotherapy by incorporating it as a clinical specialty integrated with the other methods of cancer treatment. It especially develops European recommendations as regards quality assurance, in medical radiological physics, for new technologies of irradiation and in radiobiology then supports their implementation to improve the treatment practices for cancer. It also supports the international exchange of scientific information and co-operation with societies and international and national authorities in the field of oncological radiotherapy.

EXTERNAL RADIOTHERAPY PROCEDURE GUIDE

Guide coordinated by the SFRO, by application of article R.1333-71 of the French Public Health Code enabling optimisation of procedures for carrying out radiotherapy.

HAS:

Haute autorité de santé (French National Authority for Health) , (independent public scientific authority equipped with corporate status created by law n° 2004-810 of 13 August 2004 relating to health insurance, with responsibility for maintaining a supportive healthcare system and strengthening quality of care for the benefit of patients).

HEALTHCARE FACILITY:

A healthcare facility is public or private including private practices for the purposes of the guide. The definition selected is that based on article L. 6111-2 of the French Public Health Code, as interpreted by the Administrative Court of Appeal of Lyon in its ruling of Nov 19 2002 [Brun et al: J.Cl.Adm.2003 n°20062, obs. M.Cormier.]
Healthcare facilities, public or private, aim to dispense:

1° with or without board:
   a) care which is short-term or concerns serious disorders during their acute phase, in medicine, surgery, obstetrics, odontology or psychiatry;
   b) follow-on care or rehabilitation during treatment or medical surveillance for illness requiring on-going care, with the aim of re-integration;

2° long-term care, including board, for people who do not live independently and whose condition requires constant medical surveillance and maintenance treatment.

NOTE 1: In the case of radiotherapy, a healthcare facility can thus be a hospital, a cancer treatment centre, a private hospital or a private clinic which may or may not give public service, a company of independent professionals or a company of professional partners, a person working in an individual capacity, an economic or public interest group or health co-operative group, an inter-hospital union, a private practice etc.

NOTE 2: In order to facilitate the understanding of the reader, the term "Organization", used extensively in the ISO 9000 standards, has been replaced by the term "healthcare facility" by superficially modifying the definition given [EN ISO 9000: 2005 3.3.1] to make it more comprehensible because this term had been defined as being a collection of installations and people with mutual responsibilities, authority and relationship.

HEALTHCARE ORGANISATION:

Organisation directly involved in the provision of healthcare services. The groups or subdivisions of a healthcare facility*, for example the centre or departments, may also be considered as organisations, if it is necessary to identify them. A healthcare organisation may therefore be considered to be like an independent healthcare facility or a superstructure consisting of centres and departments, that is, lower level entities [CEN/TS 15224: 2005 3.6.1].

HEALTHCARE PROFESSIONAL:

Person directly involved in the provision of care services [CEN/TS 15224: 2005 3.6.3].

IMPROVEMENT ACTION:

All actions designed to:

a) Correct a malfunction or adverse situation or non-conformance (curative action) or authorise their acceptance by exemption,

b) Eliminate the cause of causes of the malfunction or adverse situation or non-conformance when the cause or causes is/are can be attributed to the healthcare facility (corrective action),

c) Carry out actions aimed at eliminating the cause or causes of a potential non-conformance or potential adverse situation or potential malfunction when the cause or causes is/are can be attributed to the healthcare facility* (preventative action),

d) Carry out actions in order to lessen the effects, actual or potential, of malfunctions or adverse situations or non-conformances, or even to eliminate them, when the causes cannot be attributed to the healthcare facility.

INCA:

French National Institute of Cancer. Created in the form of a public interest group between the State and public and private legal entities involved in the area of cancer healthcare and research, by the public health law of August 9, 2004, within the cancer Plan, it is responsible for establishing an integrated national policy for cancer control. Under the supervision of the ministries responsible for health and research, it coordinates all those involved with cancer control in France and was entrusted with coordinating the radiotherapy roadmap established by the ministry of health following the Epinal radiotherapy accidents.

INFORMATION:

Significant data. [EN ISO 9000: 2005 3.7.1].
The concept of information applies to healthcare records*, the control of documents and records* in the form of documents.
French regulation states that access to all documentation relating to the patient is made under certain conditions clearly specified by the provisions of articles L.1111-7 to 9 of the French Public Health Code and implementing regulations, taking into consideration the private nature of all this information. The healthcare record is important not only for the documentation and continuity of care of each patient, but also as a source for follow-up and scientific research in general.

INJURY

Physical injury or damage to health or well-being of individuals or environment. [ISO EN 14971: 2007 2.2].

INVS:

Public State corporation, under the auspices of the ministry of Health, the InVS (Institute of Health Surveillance) unites the remits of surveillance, vigilance and alert in all fields of public health.
Created by the law of July 1st 1998 relating to the reinforcement of health and safety monitoring of products intended for humans, the InVS saw its mission supplemented and reinforced by the law of August 9th 2004 relating to public health policy, in order to contribute to the management of healthcare crisis situations and in particular while having to propose any measure or action necessary to the public authorities. As part of its mission, the InVS participates in French European and international activity, in particular public health global area networks.

IRSN:

L'Institut de Radioprotection et de Sûreté Nucléaire (IRSN) – the French Institute for Radiation Protection and Nuclear Safety was created in February 2002 by law n° 2001 – 398 of 9th May 2001, and by the application decree of 22nd February 2002. It is a public facility of industrial and commercial nature under the joint supervision of the ministries responsible for the Environment, Health, Industry, Research and Defence. It has public expertise in research matters and expertise on nuclear and radiological risks in the following areas:
- environment and intervention
- radiation protection for people,
- prevention of major accidents,
- safety of reactors,
- safety in factories, laboratories, transport and waste (disposal)
- expertise in nuclear defence

INTERESTED PARTY:

People or groups of people with an interest in the operation or success of a healthcare facility * [IN ISO 9000: 2005 3.3.7] (for example: patients, other health service providers, or if appropriate, the State or national health insurance requiring the services of the healthcare facility, owners, people from a healthcare facility, suppliers, banks, trade unions, partners or society). Patients' families, their parents/ their closest relatives, should be considered as interested parties [CEN/TS 15224: 2005 3.5].

INTERNAL STRUCTURE:

Organization reserved for radiotherapy care within which the authorization holder exercises the use of a particle accelerator or medical device containing radio nuclides in accordance with article R. 1333-17 of the French Public Health Code. In a public healthcare facility, this internal structure is placed within an activity centre.

MALFUNCTION:

Term meaning either an event which has produced a situation which does not correspond to that which is desired, normal or usual in the organisation, or an event which does not allow a requirement to be fulfilled.

MANAGEMENT:

The director of a public healthcare facility or organisation considered to be a private healthcare facility or the secretary general of an inter-hospital union or the administrator of a co-operative health group or the legal person in a society and their delegatees by letter of assignment and delegation of a formal signature, transferring the authority necessary to enable the projects which are entrusted to them to be successfully concluded.

MANAGEMENT REVIEW:

Formal evaluation, carried out by the highest level management, of the state and adequacy of the quality system compared to the quality policy and to its objectives. [Christian HERSAN Vade-mecum assurance qualité (p. 46); 3rd edition; Lavoisier Technique et Documentation; Paris 1995]

MEAH

National mission for Hospital Expertise and Audit (this remit, created in May 2003, is one of 3 remits planned with the MainH and MT2A, to accompany under the 2007 Hospital Plan, hospital reforms, especially law n°2003-1199 of 18th December 2003 relating to financing of social security. Attached to the Ministry of Health (DHOS), it helps public and private healthcare facilities to improve their organisation voluntarily. It is financed by funds from modernization of the public and private healthcare institutions (FMESPP). Within the context of support for the radiotherapy healthcare institutions for the year 2008, it received an exceptional amount of finance from INCa.

NON-CONFORMANCE:

Non-fulfilment of a requirement [EN ISO 9000: 2005 3.6.2].

OMS:

World Health Organisation which is an agency of the United Nations.

ONCOLOGY RADIOTHERAPIST, PRESCRIBER:

All qualified persons with diplomas or necessary qualifications, required by current law to practise their speciality or to ensure management of a radiotherapy department* carrying out radiotherapy treatments.

NOTE 1: In the guide, the term "prescriber" is also employed to describe the oncology radiotherapist.

OTHER HEALTH SERVICE PROVIDERS:

Other healthcare professional or healthcare organisation directly involved in the provision of healthcare [CEN/TS 15224: 2005 3.5.3].

NOTE 1: In the case of radiotherapy the other medical specialists following the patient's pathology, the doctor treating the patient, the nurse(s), especially during home-hospitalisation, outpatients, are particularly considered as other health service providers.

OTHER HEALTHCARE PERSONNEL:

Personnel not directly involved in the provision of healthcare services [CEN/TS 15224: 2005 3.6.4] (for example: people specialised in medical radiophysics (PSRPM), engineers, technicians and other representatives especially from departments of physics, data processing, telecommunications, catering, biomedicine, cleaning and administration, etc.)

PAHO:

Pan American Health Organization. The trans-American healthcare organisation is an international agency aiming to improve public health and standards of living in the American countries. It is a specialised healthcare organisation of the inter-American system, and is also the regional office for the Americas of the World Health Organisation gaining from international knowledge as part of the United Nations.

PATIENT NOTES:

This may also be called "health record" or "patient health record" and corresponds to the file used to store information* relating to the health of an individual receiving care [CEN/TS 15224: 2005 3.4.1]. Administrative, medical and paramedical information is collected in this file*.

PERSONNEL:

All people in a healthcare organisation composed of healthcare professionals and other healthcare personnel [CEN/TS 15224: 2005 3.6.2].
The following clauses of these guide concern, more specifically, all medical persons, specialists in medical radiophysics, technicians in medical electroradiology, dosimetry technicians, healthcare manager, and senior healthcare manager, biomedical engineer, senior technician responsible for maintenance, nurse, secretary, contributing to carrying out the radiotherapy procedures in accordance with current regulations.

PRECURSOR EVENTS

Event, which when compared to that expected, may potentially lead to injury to a person (patient, professional, third party etc.)
The event is described as precursor according to the professionals concerned. The professional skills of those involved make it possible in the majority of cases to identify this deviation and to correct it in real-time to prevent the occurrence of injury*. If the event is not corrected, it can lead to an incident or an accident, which must then be reported. The precursor event thus acts as a signal whose generic analysis makes it possible to improve the organisation's risk prevention mechanisms.

PRESCRIBER:

See oncological radiotherapist.

PRÉVENTIVE ACTION

Action aimed at eliminating the cause(s) of a potential non-conformance or a potential adverse event or a potential malfunction [IN ISO 9000: 2005 3.6.5].

NOTE 1: The detection of a potential non-conformance or potential adverse event or a potential malfunction is determined by the detection of a precursor event*.

PROCEDURE:

Specified way of carrying out an activity or process being the object or not of documentation [EN ISO 9000: 2005 3.4.5].

PROCESS:

All the correlated or interactive activities which transform input factors into output factors [IN ISO 9000: 2005 3.4.1].
Process: All of the interdependent resources and activities which make it possible to transform production inputs into products*." [the World Health Organization; WHO Guide of standards relating to good manufacturing practice (GMP) - Part 1: Standardized procedures and original formulae of manufacture - Vaccines and Biological products; WHO/VSQ/97.01]

Strategic or coordinating process: All activities enabling the functioning and improvement of operational processes and support processes, ensuring their direction and their coherence. These activities are mainly generated by the management, in particular enabling the development of the facility's strategy, the management of quality, including the determination of policy, the deployment of objectives in the healthcare facility, the allocation of resources. They include the measurement and monitoring of the process system and the analysis of results for the improvement of performance.

Operational Process: All clinical and non-clinical activities directly associated with a patient or person receiving care such as:

- administrative processes such as admissions, the department of medical information.
- Clinical Process: all the medical and practical care activities are grouped here.

Help or Support Processes: they are essential to the operation of all of the processes by providing the essential resources. They include in particular activities linked with:

- human resources;
- financial resources;
- installations and their maintenance (premises, equipment, hardware, software, etc.);
- processing of information.

NOTE 1: Clinical radiotherapy process: All medical and care activities relating to patient management, from the first consultation with an oncology radiotherapist to follow-up after treatment; this process can be divided into a succession of stages.

PRODUCT:

Resulting from a process [EN ISO 9000: 2005 3.4.2].

NOTE 1: In order to aid the reader's understanding, this term has been replaced by the term "treatment"

QUALIFICATION:

Process enabling ability to meet the specified requirements to be demonstrated. It can also relate to people, results of a process, the process and the systems such as qualification by an auditor, equipment qualification or qualification of special procedures [EN ISO 9000: 2005 3.8.6].

QUALITY:

Quality is the aptitude of an outcome of a process *, a procedure or a service given to satisfy the expressed needs or desires, implicit or imposed [EN ISO 9000: 2005 3.1.1].

NOTE 1: In the field of radiotherapy, it is the adequacy of care and the methods implemented for the patient's needs and the results anticipated by the prescribing *doctor after the multi-disciplinary consultation meeting is held (having opted for treatment by irradiation)

QUALITY ASSURANCE:

Part of the coordinated activities enabling direction and control of a healthcare facility * as regards quality, aiming to give confidence concerning the expressed needs or expectations, usually implicit or imposed, for quality [EN ISO 9000: 2005 3.2.11].

NOTE 1: In the absence of a more explicit definition, the confidence in question is that of individuals having recourse to the healthcare facility * and its personnel.

QUALITY CONTROL:

Part of the co-ordinated activities enabling the direction and monitoring of a healthcare facility* in matters of quality, based on satisfying the expressed needs or expectations, usual, implicit or imposed [EN ISO 9000: 2005 3.2.10].

NOTE 1: In the area of radiotherapy, quality assurance allows control of the organization of tasks resulting in quality and covers in particular the stages of admission, management, treatment and follow-up after treatment.

QUALITY CONTROL OF A MEDICAL DEVICE:

All operations intended to evaluate the maintenance of performance claimed by the manufacturer or, if necessary, established by the director general of the AFSSPS. Quality control is said to be internal if it is carried out by the owner or under his responsibility by a service provider; it is said to be external if it is carried out by an organisation independent of the owner, the manufacturer and those who ensure maintenance of the device, as agreed by the decision of the director general of the AFSSPS published in the official Journal of the French Republic [R.°5211-5 and R.°5211-29 of the French Public Health Code].

QUALITY MANAGEMENT:

Co-ordinated activities enabling the direction and monitoring of a healthcare facility* in matters of quality [EN ISO 9000: 2005 3.2.8].
The management of quality includes, in the present guide, establishment of a quality policy* and quality objectives*, quality planning*, quality control*, quality assurance* and improvement in quality*.

QUALITY MANAGEMENT SYSTEM:

All correlating or interacting factors enabling a policy and its objectives to be established in terms of quality, in order to direct a healthcare facility* and to monitor that it achieves its goals. [EN ISO 9000: 2005 3.2.4].

QUALITY OBJECTIVES:

That which is researched or aspired to in matters of quality [EN ISO 9000: 2005 3.1.1].

QUALITY PLANNING:

Coordinated activities enabling the direction and monitoring of a healthcare facility* in matters of quality [EN ISO 9000: 2005 3.2.8] centred on the definition of quality objectives and the specification of operational processes and related resources necessary to meet the quality objectives [EN ISO 9000: 2005 3.2.9].

QUALITY POLICY:

General direction and intentions of a healthcare facility* relating to quality as officially devised by a person or group of people who direct and monitor this organisation at the highest level [EN ISO 9000: 2005 3.2.4].

RADIOTHERAPY:

Radiotherapy is a treatment method, especially for cancer, using rays (rays or irradiation). The aim of this treatment is to destroy all cancer cells and/or to block their capacity to multiply while saving peripheral healthy tissue. Radiotherapy is widely used and may be combined with other techniques (surgery, chemotherapy etc).

There are three main techniques in radiotherapy:

- external radiotherapy (tele-radiotherapy or transcutaneous radiotherapy or external radiotherapy) which uses beams of radiation produced either by particle accelerators or by a radioactive source and penetrating tissues through the skin. In this method, the radiation source is outside the patient.
- - Brachytherapy involves implanting sealed radioactive sources during a limited period (a few hours) or for life (prostate sufferer) internally in the tumour (endobrachytherapy or interstitial brachytherapy) or in the immediate vicinity, in a natural cavity (plesiobrachytherapy or endocavity brachytherapy) or in a natural channel (intraluminal brachytherapy).
- vectorized metabolic radiotherapy involves administering (injecting) non-sealed radioactive sources in liquid form which will be fixed, metabolically, on the target cells.

These techniques use radioactive elements transmitting ß, γ and even high energy α in order to destroy the cancer cells.

RADIOTHERAPY DEPARTMENT:

Place where radiotherapy care is carried out by personnel, in premises and with equipment that fulfils the legal and regulatory provisions in force.

RADIOTHERAPY TREATMENT:

All of the activities relating to the management of a patient within the context of radiotherapy, from first consultation with an oncology radiotherapist to follow-up after treatment.

RADIOVIGILANCE/RADIATION VIGILANCE [L.1333-3 OF THE FRENCH PUBLIC HEALTH CODE]:

By application of article L. 1333-3 of the French Public Health Code, the aims of radiation vigilance are to detect, report, collect, store, evaluate and analyse all significant radioprotection events * likely to affect the health of a patient, a user or a third party by exposure to the ionizing rays used for medical, dental, human biology and biomedical research purposes.

RECEIPT:

Process grouping all these activities: purchase, installation, acceptability or reception tests, use or commissioning, initial quality control, training users and exploitation of a medical device in clinical routine or accessories among the devices used in external radiotherapy.
[Afssaps 8th April 2008, Recommendations relating to receipt of external radiotherapy devices, http://afssaps.sante.fr/htm/10/dm/radio_therapie/radio_therapie_recette.pdf]

RECORD:

Document giving a report on results obtained or containing evidence of an activity which has been carried out [EN ISO 9000: 2005 3.7.6]].
Document presenting the results obtained or the evidence of an activity which has been carried out. It makes it possible to ensure that the hoped-for results were achieved or that the activities were conducted as planned: it is an essential component of traceability [HAS certification manual for health facilities p 163 V 2007]

RESOURCE:

Element of a computing system (file, memory, peripheral) likely to be allocated to many processes.[Le Petit Robert, Edition 2001]

RESULT/OUTCOME:

Effect or data (output elements) resulting from an activity or a process.[Le Petit Robert, Edition 2001].

NOTE 1: In the case of radiotherapy, the result of the clinical process of radiotherapy is the sum of the fractionated doses received by the patient at targeted places and while having protected the organs at risk. The cure of the patient is not the result of the clinical process of radiotherapy even if it is the sought-after goal. The cure must be regarded as the consequence of the treatment as well as a complication which may occur if the process of care is complied with.

REVIEW:

Examination undertaken to determine the relevance, adequacy and effectiveness of what is examined to achieve defined objectives [IN ISO 9000: 2005 3.8.7].
EXAMPLE: Review of management*, review of designs* and of development, review of contract*, review of the requirements of patients or of interested parties and review of non-conformance

REVIEW OF DESIGN:

Examination of an idea carried out in a complete and systematic way using documents, in order to evaluate its capacity to fulfil the requirements for quality, to identify problems and, if there are some, to propose the development of solutions [Christian HERSAN; Vade-mecum assurance qualité (p. 45); 3rd edition; Lavoisier Technique et Documentation; Paris 1995]

RISK:

Combination of the probability of injury* and its severity* [ISO EN 14971: 2007 2.13].

RISK ANALYSIS:

Use of available information to identify dangerous* phenomena and to estimate risk [ISO EN 14971: 2007 2.14].

RISK ASSESSMENT:

Process comprising risk analysis* and risk evaluation * [ISO EN 14971: 2007 2.15].

RISK CONTROL:

Process by which decisions are taken and protective measures introduced to reduce the risks or keep them within specified limits [ISO EN 14971: 2007 2.16].

RISK EVALUATION:

Judgement based on the analysis of risk, indicating if the level of risk achieved is acceptable under certain conditions, on the basis of values allowed by the company [ISO EN 14971: 2007 2.17].

RISK MANAGEMENT:

Systematic application of management policy, procedures and practices to tasks of analysis, of evaluation and risk control [ISO EN 14971: 2007 2.18].

SAFETY:

Absence of unacceptable risk [ISO EN 14971 2.20].

SEVERITY:

Measurement of the possible consequences of a dangerous phenomenon* [ISO EN 14971: 2007 2.21].

NOTE 1: [DREES Studies and results n°398, May 2005]. In the case of care activities, the phenomena may be considered as dangerous when they are likely to produce serious adverse events, being able to be defined as being likely:

- to lead to a prolongation of hospitalisation for at least a day
- or being the cause of a disability or incapacity at the end of the patient's hospitalisation or treatment;
- or being associated with a life-threatening event or death;

NOTE 2: It may be practical to classify the severity of an event with the help of a geometrical sequence in order to differentiate the significance of each level.

SFPM:

French society for medical physics

SFRO:

French Society for radiotherapy and oncology

SIGNIFICANT RADIOPROTECTION EVENT:

All radioprotection incidents or accidents of particular significance, especially as regards actual or potential consequences for workers, the public, patients or the environment, and fulfilling the criteria defined in an ASN resolution ratified by the ministry for health; [L. 1333-3 and R. 1333-109 to R. 1333-110 of the French Public Health Code].
From July 1st 2007, on an experimental basis, a criterion (criterion 2.1) makes it possible to consider that an event within radiotherapy is a significant radioprotection event. This criterion is defined in the ASN/DEU/03 guide relating to the methods of reporting and the coding of criteria relating to significant events in the field of radiation protection outside basic nuclear installations and transport of radioactive materials. All significant radioprotection events are considered as adverse events*, the latter covering areas other than radioprotection.

SPECIALIST IN MÉDICAL RADIOPHYSICS (PSRPM):

All people qualified with a diploma in medical radiophysics (DQPRM) or an approval provided by the ministry for health (before the decree of 19th November 2004). His role is to "guarantee that the dose of rays received by the tissues being subjected to the exposure corresponds to that prescribed by the requesting doctor". He has responsibility for physical dosimetry (the initial determination then the regular follow-up of installation performance, dosimetry in-vivo etc).
Although he takes part, in liaising with the medical team, in the clinical dosimetry and optimization of the treatment plan (ballistic, weighting of the beams, accessories), current French regulation does not recognize this professional as a healthcare professional. He is regarded as "other healthcare personnel" *.
He may be assisted in the different tasks by electroradiology technicians full-time or on a rota with the dosimetry units, or with technicians in physical or biomedical measurements.

SPECIFIC REQUIREMENTS:

All legislative and regulatory requirements, specific internal requirements which the facility wishes to fulfil voluntarily, and requirements linked to patients and other health service providers. These requirements are expressed, in writing, in quantitative or qualitative terms, with defined criteria of conformance, which are measurable or verifiable.

STAKEHOLDER:

In the healthcare services sector, the term stakeholder is often used for the idea of 'interested party"* [CEN/TS 15224: 2005 3.5.1] (for example: health insurance organisation, patient, other health service providers, or if appropriate, the State or national health insurance requiring the services of the healthcare facility, family/parents, citizens, professional organisations, healthcare administration, suppliers and society in general, etc.).

STUDY OF RISK:

See risk assessment.

THIRD PARTY CONTRIBUTING TO CARE:

Party involved in the support of health services, financially or practically [CEN/TS 15224: 2005 3.5.2].

TRACEABILITY:

Ability to trace the history, the implementation or the location of that which is being examined [EN ISO 9000: 2005 3.5.4].

NOTE 1: In the case of radiotherapy, this is linked:

- to the installation (installation of equipment and software, qualification* (ensuring the quality) of equipment and validation of the newly acquired or modified software, maintenance operations, quality control operation);
- to the personnel (recruitment, training, qualification*, skills maintenance);
- to the process (decision criteria and decision, treatment file, plans, first consultation, dosimetric scanner, centring, treatment sessions, follow-up after treatment, release, planning report, non-conformance to the specifications of treatment or error, exemption, correction made to the treatment, corrective action or preventive if necessary);
- to the patient (identification, constitution of health record).

TREATMENT REPORT:

Document written, validated and signed by an oncology radiotherapist, including qualitative and/ or quantitative results of treatment, accompanied by comments as often as is necessary or as provided for by the regulations. These results must be presented in compliance with the current regulations.

VALIDATION:

Confirmation by data demonstrating the existence or the veracity of something, that the needs or expectations, usually implicit or imposed, for a specific use or an anticipated application, were fulfilled. [EN ISO 9000: 2005 3.8.5].

NOTE 1: The conditions of use can be real or simulated.

NOTE 2: Validation consists of making a verification* for a specific use or an envisaged application.

VERIFICATION:

Confirmation by data demonstrating the existence or the veracity of something, that the expressed needs or expectations, usually implicit or imposed, were fulfilled. [EN ISO 9000: 2005 3.8.4].

NOTE 1: confirmation can cover activities such as:

- carrying out other calculations or the same calculations with another method (employed in dosimetry),
- the comparison of a document formulating the requirements of a new idea with a document formulating similar proven requirements,
- carrying out tests (determining one or more characteristics according to a procedure) and demonstrations,
- review of the documents before circulation

Annex 2 — Table mapping standard ISO 9001 to the ASN Guide n°5

Table mapping the requirements of the international standard NF EN ISO 9001: 2000 relating to systems of quality management to the ASN's management guide on safety and quality in radiotherapy.

Scope of requirements of the standard NF EN ISO 9001	NF/EN/ISO 9001:2000	ASN Guide n°5 References
Requirements of the quality management system	4	1
General requirements	4.1	1.1.
Requirements relating to documentation	4.2	1.2.1
A quality policy and objectives	4.2.1 and 5.3	1.2.1
A quality manual	4.2.2	1.2.1
Control of documentation	4.2.3	1.2.2
Control of records*	4.2.4	1.2.3
Responsibility of management	5	2
Using principles of quality management	N.A	2.1
Commitment of management	5.1	2.1
Needs and expectations of interested parties	5.2	2.2
Quality planning	5.4	2.3
Responsibility authority communication	5.5	2.4
General comments	5.5.1	2.4.1
Responsibilities of person in charge of quality assurance	5.5.2	2.4.2
Internal communication	5.5.3	2.4.3
Management review	5.6	2.5
Managing resources	6	3
General comments	6.1	3.1
Human resources	6.2	3.2
Responsibilities of management	6.2.1 and 6.2.2	3.2.1
Responsibilities of personnel	N.A.	3.2.2
Infrastructures	6.3	3.3
General comments	6.3	3.3
Control and follow-up of medical devices	N.A	3.3
Control and follow-up of control, measurement and equipment testing (ECME)	N.A	3.3
Working environment	6.4	3.3
Implementing treatment	7	N.T.
Planning implementation of treatment	7.1	N.T.
Processes relating to customers/clients*	7.2	N.T.
Determination of requirements relating to implementation of treatment	7.2.1	N.T.
Review of requirements relating to implementation of treatment	7.2.2	N.T.
Communication with patients and other interested parties	7.2.3	N.T.
Design and development	7.3	N.T.
Planning design and development	7.3.1	N.T.
Inputs of design and development	7.3.2	N.T.
Outputs of design and development	7.3.3	N.T.

Scope of requirements of the standard NF EN ISO 9001	NF/EN/ISO 9001:2000	ASN guide n°5 References
Review* and verification* of design and development	7.3.4 et 7.4.4	N.T.
Validation of design and development	7.3.6	N.T.
Control of amendments to design and development	7.3.7	N.T.
Purchases	7.4	3.3
Purchasing procedure	7.4.1	3.3
Information* relating to purchases	7.4.2	3.3
Verification* of product purchased	7.4.3	3.3
Production and preparation of the service	7.5	4
Control of the preparation for and performance of activities connected with patient management, from first consultation to follow-up after treatment	7.5.1	4.1
Validation of the preparation for and performance of activities connected with patient management from first consultation to follow-up after treatment	7.5.2	4.2
Identification and traceability	7.5.3	4.3
Ownership and safety* of the customer/client* and the personnel	7.5.4	N.T.
Storage of treatment	7.5.5	N.T.
Control of monitoring and measurement devices	7.6	N.T.
Measurement, analysis and improvement	8	5
General comments	8.1	5.1.1
Monitoring and measurement	8.2	5.1.1
Client/customer satisfaction*	8.2.1	5.1.1
Internal audit	8.2.2	5.1.2
Monitoring and measurement of the processes	8.2.3	5.1.1
Monitoring and measurement of the treatment	8.2.4	5.1.1
Control of treatment that does not comply	8.3	5.2
Analysis of data	8.4	5.3
Improvement	8.5	5.4
Continuous improvement	8.5.1	5.4
Corrective action	8.5.2	5.4
Preventive action	8.5.3	5.4

Key:

N.A: Requirement not provided for in the standard
N.T.: Requirement not covered in the ASN guide

Annex 3

Mapping tables HAS / ASN
Certification manual V 2007- ASN Guide n°5

a.

Table mapping the requirements of the ASN safety and quality management guide to the generic references of the 2007 version of the HAS certification manual **that also includes a specific reference, 33a, dedicated to the implementation of quality assurance in external radiotherapy**. This 2007 version is inevitably aimed at health facilities whose certification visit is timetabled from **1st April 2008** up until version 2010 comes into effect.

ASN GUIDE N°5 References In grey-blue and bold the requirements supported by resolution n° ASN 2008-DC-103	HAS MANUAL V2007 Criteria * * in addition to criterion 33a
1 Requirements of the quality management system	
1.1 General requirements	1b, 3a, 3b, 4a, 4b, 6, 7, 10b, 10d, 10e, 11, 18c, 28
1.2 Requirements relating to documentation	
1.2.1 General comments	6a, 10b, 10e
1.2.2 Control of documentation	10e
1.2.3 Control of records*	4b, 10e, 28, 29
2 Responsibility of management	
2.1 Commitment of management	1a, 2c, 3b, 5a, 6a, 7b
2.2 Needs and expectations of interested parties	10a, 11a, 24b
2.3 Quality planning	10b, 10d
2.4 Responsibility, authority, communication	
2.4.1 General comments	1c
2.4.2 Responsibilities of person in charge of quality assurance	1d
2.4.3 Internal communication	5a
2.5 Management review	44d
3 Managing resources	
3.1 General comments	3a, 3c, 7b, 15a
3.2 Human resources	
3.2.1 Responsibilities of management	3b, 3d, 8a, 8b, 8c, 8d, 10c
3.2.2 Responsibilities of personnel	
3.3 Equipment resources	14c, 16a, 16c, 18a, 18c
4 Preparation for and performance of activities connected with patient management, from first consultation to follow-up after treatment	
4.1 Control of the preparation for and performance of activities connected with patient management, from first consultation to follow-up after treatment	11b, 11c, 11d, 17b, 19b, 20a, 24a, 24b, 27a, 30b, 37a, 37b, 41a
4.2 Validation of the preparation for and performance of activities connected with patient management, from first consultation to follow-up after treatment	
4.3 Identification and traceability	18b, 28a, 28b, 28c, 37b

GUIDE ASN N°5 References In grey-blue and bold the requirements supported by resolution n° ASN 2008-DC-103	HAS MANUAL V2007 Criteria * * in addition to criterion 33a
5 Evaluation, analysis and improvement	
5.1 Monitoring and evaluating the performance of the management system	
5.1.1 Monitoring and measurement of the processes and their outcomes	10b, 40a, 43 a, 43b, 43c, 44c, 44d, 44e
5.1.2 Internal audit	10b
5.2 Management of the malfunctions, adverse situations or results that do not comply with those found in connection with patient management, from first consultation to follow-up after treatment	12b, 12c, 12d, 19d
5.3 Analysis of data	43a, 43c , 44e
5.4 Improvement, corrective action, preventive action	17b, 32c, 41a, 43a, 43b, 43c, 44b

Annex 3

Mapping tables HAS / ASN
Certification manual V 2010- ASN Guide n°5

Table mapping the requirements of the ASN safety and quality management guide to the generic references of the 2010 version of the HAS certification manual. This 2010 version applies to health facilities that will have their certification visit from January 2010.

ASN GUIDE N°5 References In grey-blue and bold the requirements supported by resolution n° ASN 2008-DC-103	HAS MANUAL V2010 Criteria In grey-blue and bold the priority elements (PEP)
1 Requirements of the quality management system	26b
1.1 General requirements	1a, 1e, **1f**, 1g, 2e, 8a, 18a, 28a, 28b, 28c
1.2 Requirements relating to documentation	5c, 26b
1.2.1 General comments	
1.2.2 Control of documentation	
1.2.3 Control of records*	5a, 5b, **14a**
2 Responsibilities of management	
2.1 Commitment of management	1e, 1g
2.2 Needs and expectations of interested parties	1d, 1e, 1g, 8a, 8c, 8d, **9a**, 9b, 11a, 11b, 11c
2.3 Quality planning	1e, 1g, 2a, 2b, 8a, 26b, 28a, 28c
2.4 Responsibility, authority, communication	
2.4.1 General comments	2a, 3a, 3b, 26b
2.4.2 Responsibilities of person in charge of quality management	2a, 26b
2.4.3 Internal communication	1e, 1g, 2e, 8a, 8d, **9a**, 26b, 28c
2.5 Management review	2a, 2e, 8a, 26b, 28c
3 Managing resources	
3.1 General comments	3a, 3b, 4a, 5a, 5b, 6a, 6b, 6f, **8g**, 8k, 22b, 26b
3.2 Human resources	3a, 3b
3.2.1 Responsibilities of management	**1f**, 2a, 8a, 26b
3.2.2 Responsibilities of personnel	
3.3 Equipment resources	1b, 2d, 3c, 3d, 5a, 5b, 6a, 6b, 6f, 7a, 7b, 7c, 7d, 7e, **8g**, 8k, 22b, 26b
4 Preparation for and performance of activities connected with patient management, from first consultation to follow-up after treatment	
4.1 Control of the preparation for and performance of activities connected with patient management, from first consultation to follow-up after treatment	1g, 2a, 3a, 3b, 5a, 5c,8a, **8b**, 8d, 8k, **15a**, 16a, 22a, 22b, **25a**, 26b
4.2 Validation of the preparation for and performance of activities connected with patient management, from first consultation to follow-up after treatment	**1f**, 8c, **12a**, **13a**, **14b**, 18a, 19a, 22a, 24a, 26b
4.3 Identification and traceability	**14a**, **15a**, 24a, 26b, 28a
5 Evaluation, analysis and improvement	
5.1 Monitoring and evaluating the performance of the management system	2a, 2e, 8a, 8d, 26b
5.1.1 Monitoring and measurement of the processes and their outcomes	**9a**, 9b, **14a**, 17a, 24a, 28a, 28b, 28c

ASN GUIDE N°5 References In grey-blue and bold the requirements supported by resolution n° ASN 2008-DC-103	HAS MANUAL V2010 Criteria In grey-blue and bold the priority elements (PEP)
5.1.2 Internal management	
5.2 Management of the malfunctions, adverse situations or results that do not comply with those found in connection with patient management, from first consultation to follow-up after treatment	3a, 3b, 5c, 8a, **8b**, 8d, **8f**, 8i, 11c, 26b, 28a, 28b, 28c
5.3 Analysis of data	2e, 8a, **8f**, **9a**, 9b, 26b, 28a, 28b
5.4 Improvement, corrective action, preventive action	2e, 8a, **8b**, 8d, **8f**, **9a**, 26b, 28a, 28b, 28c

Annex 4

Location in ASN guide n°5 of INCa accreditation criteria for use of external radiotherapy

ASN GUIDE N°5 References In bold the requirements supported by resolution n° ASN 2008-DC-103	RESOLUTION N° 3 OF THE ADMINISTRATION COUNCIL OF INCA OF 20/12/2007 * N° of criteria	Page of ASN guide n°5
3 Resource management		
3.2 Human resources		
3.2.1 Responsibilities of management	4, 5, 7 and 8	page 32
4 Preparation for and performance of activities connected with patient management, from first consultation to follow-up after treatment		
4.1 Control of the preparation for and performance of activities connected with patient management, from first consultation to follow-up after treatment	10, 11, 12, 13, 14, 15, 16 and 17	page 45
4.2 Validation of the preparation for and performance of activities connected with patient management, from first consultation to follow-up after treatment	11 and 18	page 52
4.3 Identification and traceability	3 and 6	pages 53 and 54
5 Evaluation, analysis and improvement		
5.1 Monitoring and evaluation of the performance of the management system		
5.1.1 Monitoring and measurement of the processes and their outcomes	9	page 55

For the purposes of articles L. 1514-2 and D. 1415-1-9 of the French Public Health Code, accreditation criteria which the health facilities practising cancerology must fulfil in compliance with the provisions of article R. 6123-88, 3° of this code have been defined by the Institut national du cancer (French National Institute of Cancer) at the meeting of the administration council on 20 December 2007. Resolution n°3 of the administration council was made public on the INCa internet site (www.e-cancer.fr) on 16 June 2008. This posting constitutes the legal publication of these criteria. It has also been adopted in the opinion of 20 June 2008 relating to the accreditation criteria of health facilities practising cancerology that appeared in the Official Bulletin n° 2008/7 of 15 August 2008, page 149.

NOTE 1: There is no direct comparison between the INCa accreditation criteria for practising external radiotherapy and the requirements of guide ASN n°5 since the criteria establish the methods and requirements of the organisational objectives. However, the INCa accreditation criteria for practising external radiotherapy enable a response to the objectives of the requirements of the present document.

NOTE 2: On the day of publication of this version of the guide, the INCa accreditation criteria for practising brachytherapy have not yet been defined.

Annex 5 — Proposed implementation timetable for SMSQ

b.

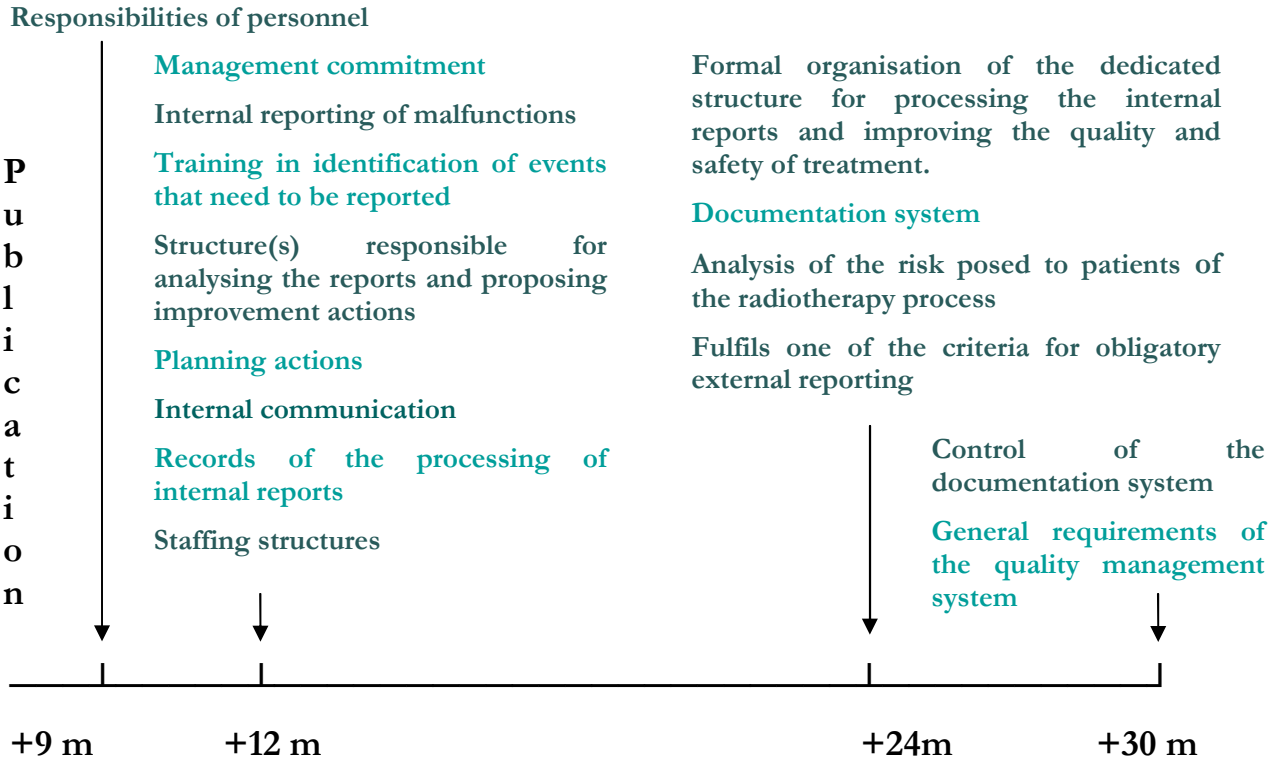
ASN GUIDE N°5 References In bold the requirements supported by resolution n° ASN 2008-DC-103	YEAR (Resolution published 25 March 2009)			
	Dec	March	March	March
1 Requirements of the quality management system	2009	2010	2011	2012
1.1 General requirements	2009	2010	2011	**Sept 2011***
1.2 Requirements relating to documentation	2009	2010	2011	**Sept 2011**
1.2.1 General comments	2009	2010	**2011**	**Sept 2011**
1.2.2 Control of documentation	2009	2010	**2011**	**Sept 2011**
1.2.3 Control of records*	2009	2010	**2011**	**Sept 2011**
2 Management responsibilities	2009	2010	2011	2012
2.1 Management commitment		**2010**	**2011**	**Sept 2011**
2.2 Needs and expectations of interested parties				2012
2.3 Quality planning	2009	**2010**	**2011**	**Sept 2011**
2.4 Responsibility, authority, communication	2009	**2010**	**2011**	**Sept 2011**
2.4.1 General comments	**2009**	**2010**	**2011**	**Sept 2011**
2.4.2 Responsibilities of person in charge of quality management	2009	**2010**	**2011**	**Sept 2011**
2.4.3 Internal communication	2009	**2010**	**2011**	**Sept 2011**
2.5 Management review			2011	2012
3 Resource management	2009	2010	2011	2012
3.1 General comments				2012
3.2 Human resources	2009	2010	2011	2012
3.2.1 Responsibilities of management		2010	2011	2012
3.2.2 Responsibilities of personnel		2010	2011	2012
3.3 Equipment resources			2011	2012
4 Preparation for and performance of activities connected with patient management, from first consultation to follow-up after treatment	2009	2010	2011	2012
4.1 Control of the preparation for and performance of activities connected with patient management, from first consultation to follow-up after treatment	2009	2010	**2011**	**Sept 2011**
4.2 Validation of the preparation for and performance of activities connected with patient management, from first consultation to follow-up after treatment	2009	2010	2011	2012
4.3 Identification and traceability	2009	2010	2011	2012
5 Evaluation, analysis and improvement	2009	2010	2011	2012
5.1 Monitoring and evaluation of the performance of the management system			2011	2012
5.1.1 Monitoring and measurement of the processes and their outcomes		2010	2011	2012
5.1.2 Internal audit			2011	2012

* In grey-blue and bold: Date the requirement of resolution ASN-DC-n°103 mentioned in the corresponding reference (Publication of ministerial decree of 25 March 2009) comes into effect

ASN GUIDE N°5 References In bold the requirements supported by resolution n° ASN 2008-DC-103		YEAR (Resolution published 25 March 2009)			
		Dec	March	March	
5.2	**Management of the malfunctions, adverse situations or results that do not comply with those found in connection with patient management, from first consultation to follow-up after treatment**	2009	**2010***	**2011**	**Sept 2011**
5.3	Analysis of data		2010	2011	March 2012
5.4	Improvement, corrective action, preventive action			2011	March 2012

* In grey-blue and bold: Date the requirement of resolution ASN-DC-n°103 mentioned in the corresponding reference (Publication of ministerial decree of 25 March 2009) comes into effect

Annex 6 — Timetable for implementation of resolution ASN 2008-DC-n°103



Annex 7

Tables mapping the requirements of resolution ASN 2008-DC-n°103 to guide ASN n°5

Resolution ASN 2008-DC n°103 ⇨ Guide ASN n°5

Resolution ASN-DC n°103 Article references	ASN Guide n°5 N° of requirements
2	1.1
3	2.1
3	2.3
4	2.4.2
5	1.2.1
6	1.2.2
6	1.2.3
7	2.4.1
8	4.1
9	5.2.B
10	5.2.A
11	5.2.C
12	5.2.C
13	2.4.3
14	5.2.A
15	5.2.E

ASN Guide n°5 ⇨ Resolution ASN 2008-DC n°103

Guide ASN n°5 N° of requirements	Resolution ASN-DC n°103 Article references
1.1	2
1.2.1	5
1.2.2	6
1.2.3	6
2.1	3
2.3	3
2.4.1	7
2.4.2	4
2.4.3	13
4.1	8
5.2.A	10
5.2.A	14
5.2.B	9
5.2.C	11
5.2.C	12
5.2.E	15

FRENCH REPUBLIC

Resolution No 2008-DC-0103 of the Autorité de Sûreté Nucléaire of 1 July 2008 establishing quality assurance obligations for radiotherapy

The Board of the Nuclear Regulator the Autorité de Sûreté Nucléaire
Having regard to Articles L.1333-3, L.1333-8, L.1333-17, L.1333-18, L.1414-3, L.5212-2, L. 6113-1–4, R. 1333-59, R. 5212-14 and 5212-15 of the *Code de la Santé Publique* (Public Health Code);
Having regard to Act No 2006-686 of 13 June 2006 on nuclear transparency and safety, in particular Articles 3, 4 and 63,
Has adopted this Resolution:

Section 1: General Provisions

Article 1
Definitions

For the purposes of this resolution, the definitions of words marked with an asterisk are given in the annex.

Article 2
Quality management system: general requirements

All healthcare establishments* carrying out external radiotherapy* or brachytherapy* treatment activities shall have in place a quality management system* designed to guarantee the quality and safety of the treatments. To this end, the top management* of these healthcare establishments shall ensure that the processes* that make up all the external radiotherapy or brachytherapy treatment activities are identified then analysed, with a view in particular to mitigating the risks inherent in their implementation.

Article 3
Management commitment to the quality management system.

The top management of a healthcare establishment carrying out external radiotherapy or brachytherapy treatment activities shall establish the quality policy*, determine the quality objectives* and set the quality management system implementation schedule.

Article 4
Staffing structure

The top management of a healthcare establishment carrying out external radiotherapy or brachytherapy treatment activities shall make available to the radiotherapy department* an operational manager for the quality management and treatment safety system. This individual must have the appropriate training, skills, experience, authority and accountability and must have the necessary time and resources for managing the system in liaison with the healthcare establishment's quality management department where applicable.

Article 5
Documentation system

The top management of a healthcare establishment carrying out external radiotherapy or brachytherapy treatment activities shall ensure that a documentation system is put in place. The system shall contain the following documents*:

1. a quality manual* comprising:
    a. the quality policy*
    b. specified requirements* which must be met
    c. the quality objectives*
    d. a description of the processes* and how they interact;
2. procedures* and work instructions*, in particular those mentioned in Articles 6, 8 and 14 below;
3. all the necessary records*, in particular those mentioned in Articles 9 and 15 below;
4. an analysis of the risks posed to patients during the clinical radiotherapy process, which must as a minimum include the risk described in Article 8 below.

Article 6
Documentation system control

The top management of a healthcare establishment carrying out external radiotherapy or brachytherapy treatment activities shall ensure that document management procedures are put in place, as well as management procedures for the records and/or information contained in patient notes*.

Top management shall ensure that the documentation system mentioned in Article 5 is implemented and continuously updated in order to continually improve the quality and safety of treatment. Top management shall also ensure that the system is reviewed at regular intervals to verify that it is fit for purpose and shall ensure that it is accessible to the radiation protection inspectors mentioned in Articles L.1333-17 and L.1333-18 of the *Code de la Santé Publique*.

Article 7
Staff accountability

The top management of a healthcare establishment carrying out external radiotherapy or brachytherapy treatment activities shall formally set out the duties, authority and delegations of authority of its staff at all levels and shall keep all members of the radiotherapy department informed of these.

Article 8
Analysis of the risk to patients of the radiotherapy process

The top management of a healthcare establishment carrying out external radiotherapy or brachytherapy treatment activities shall ensure that a risk analysis is carried out regarding the risks posed to patients. This analysis should relate as a minimum to risks which could lead to a mistake in the irradiated volume or delivered dose at each stage of the clinical radiotherapy process* and must take the use of the various medical devices into consideration. The risk analysis must include a assessment of the risks* and the steps taken to mitigate any risks considered to be unacceptable.
Risks which do not need to be taken into consideration are those relating to possible side effects, regardless of severity, resulting from a treatment strategy that has been agreed between the practitioner and the patient and accepted in the light of the expected benefits of the treatment, having taken into consideration the principles of justification and optimisation mentioned in Article L. 1333-3 of the *Code de la Santé Publique*.
Top management must also ensure that the following are drawn up on the basis of the above-mentioned risk analysis:

1. procedures designed to ensure that the delivered dose, the treated volume and the irradiated and protected organs are in compliance with those stated on the medical prescription;
2. methods designed to ensure that the equipment is used correctly.

These documents must be accessible at all times in each specific work area of the internal structure, in keeping with the activities performed and the equipment used there.

Section 2: Internal reporting of failures and adverse events

Article 9
Internal reporting of adverse events and failures

All staff directly involved in the therapeutic management of patients undergoing external radiotherapy or brachytherapy must report every organisational, physical or human adverse event* or failure* to the structure described in Article 11. This reporting is referred to hereinafter as 'internal reporting'.

All persons making a report must record as a minimum the date of the report, the description of the event, the circumstances in which it occurred and its consequences.

Article 10
Training in the identification of adverse events and failures

The top management of a healthcare establishment carrying out external radiotherapy or brachytherapy treatment activities must organise training for all staff directly involved in the therapeutic management of patients undergoing external radiotherapy or brachytherapy, which must enable them as a minimum to identify adverse events* or failures* occurring in day-to-day practice and to report these internally within the establishment.

Article 11
Dedicated structure for analysis of internal reporting and identification of improvement actions

The top management of a healthcare establishment carrying out external radiotherapy or brachytherapy treatment activities shall put in place a dedicated structure for analysing failures and adverse events and for planning the necessary actions for improving treatment safety, hereinafter referred to as improvement actions.

This structure should comprise representative skills from the different professions directly involved in the therapeutic management of patients undergoing radiotherapy.
The structure shall:

1. analyse internal reports, in particular those that have required a statutory report to be sent to the Autorité de sûreté nucléaire under the radiation vigilance* requirements and/or to the Agence française de sécurité sanitaire des produits de santé under the materials vigilance requirements;
2. suggest improvement actions* for each report analysed;
3. monitor the implementation of these actions and evaluate their effectiveness.

Article 12
Planning of improvement actions

Top management shall ensure that a schedule is drawn up for implementing the improvement actions proposed by the structure described in Article 11 and that the responsibilities associated with implementing them and evaluating their effectiveness are defined.

Article 13
Internal communication

The top management of a healthcare establishment carrying out external radiotherapy or brachytherapy treatment activities shall put in place processes designed to:

1. facilitate internal reporting of failures or adverse events and convey the importance of the reporting;
2. let staff know what improvements have been made to the quality management system;
3. stimulate staff interest and involvement in sharing feedback.

Top management must also communicate to all staff directly involved in the therapeutic management of patients undergoing external radiotherapy or brachytherapy:

4. the importance of meeting compulsory and voluntary requirements;
5. the quality policy it intends to conduct;
6. the quality objectives it has set, including the schedule for implementing the quality management system.

Article 14
Formal organisation of the dedicated structure for processing internal reporting and improving the quality and safety of radiotherapy treatment

The top management of a healthcare establishment carrying out external radiotherapy or brachytherapy treatment activities shall also ensure that the documentation system mentioned in Article 5 includes procedures that specify the organisational measures in place and associated responsibilities for:

1. handling and processing internal reporting;

2. discontinuing or cancelling treatment that does not meet the specified requirements;
3. resuming discontinued or cancelled treatments after ascertaining that the problem has been eliminated;
4. carrying out treatment that does not meet all the specified requirements after having evaluated the benefits and risks*.

Article 15
Records based on analysis of internal reporting

For each internal report analysed a record must be kept, as a minimum of: the names of all the individuals who have taken part in the evaluation, in proposing improvement actions and deciding on the action plans and in identifying the possible causes and justifying the elimination of certain causes, as well as the nature of the proposed improvement actions with their implementation dates, names of persons designated to oversee their implementation and monitoring and completion of the actions.

Section 3: Miscellaneous Provisions

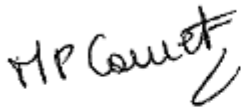
Article 16
Introduction and implementation schedule

This resolution shall come into force according to the timescale set out in the table below, once it has been approved and published in the *Journal Officiel de la République française*. It shall be published in the Nuclear Regulator's Official Bulletin (*Bulletin officiel*)

Subject of Article	*Article*	*Time to implementation after publication*
Quality management system (QMS): general requirements	Article 2	Two and a half years maximum
Management undertakings under the quality management system	Article 3	One year maximum
Staffing structure	Article 4	One year maximum
Documentation system	Article 5	Two years maximum
Documentation system control	Article 6	Two and a half years maximum
Staff accountability	Article 7	Nine months maximum
Analysis of the risk to patients of the radiotherapy process	Article 8	Two years maximum
Internal reporting of adverse events and failures	Article 9	One year maximum
Training in the identification of adverse events and failures	Article 10	One year maximum
Dedicated structure for analysis of internal reporting and identification of improvement actions	Article 11	One year maximum
Planning of improvement actions	Article 12	One year maximum
Internal communication	Article 13 Paragraphs 1–3	One year maximum
Internal communication	Article 13 Paragraphs 4–6	One year maximum
Formal organisation of the dedicated structure for processing internal reporting and improving the quality and safety of radiotherapy treatment	Article 14	Two years maximum
Records based on analysis of internal reporting	Article 15	One year maximum

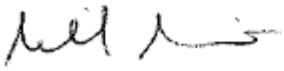
Done at Paris, 1 July 2008

The board of the Autorité de sûreté ncléaire

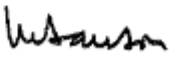


Marie-Pierre COMETS

Jean-Rémi GOUZE



Michel BOURGUIGNON



Marc SANSON

Annex
Definitions

1 Improvement action

All actions designed to:

1. correct a failure or adverse event or authorise them to be passed as an exception;
2. eliminate the cause(s) of a failure or adverse event where the cause(s) can be attributed to the healthcare establishment;
3. carry out actions aimed at eliminating the cause(s) of a potential failure or potential adverse event where the cause(s) can be attributed to the healthcare establishment;
4. carry out actions aimed at mitigating the actual or potential effects of failures or adverse events or eliminating them if possible when the cause(s) cannot be attributed to the healthcare establishment.

2 External radiotherapy or brachytherapy treatment activities

All the activities comprising management of the patient's external radiotherapy or brachytherapy treatment, as defined below, from the patient's first consultation to their post-treatment follow-up.

3 Risk assessment

Process comprising:

1. identifying risk situations on the basis of the information available and calculating the risk level;
2. the assessment based on this analysis, stating whether the risk level is acceptable in certain circumstances, on the basis of values accepted by society.

4 Brachytherapy

Method of treating cells by irradiation, used in particular for cancer and consisting of inserting sealed radioactive sources close to or actually inside the target irradiation area.
Different types of brachytherapy are distinguished according to the placement of the radioactive elements in relation to the target irradiation area:

1. Contact brachytherapy: the sources are placed in contact with the target tissue by making use of natural cavities, which act as receptacles for the radioactive material and its applicators. The two different types are intracavitary brachytherapy, the most common being utero-vaginal brachytherapy, and intraluminal brachytherapy;
2. Interstitial brachytherapy: the sources are implanted inside the tumour.

Brachytherapy can be combined with other techniques (surgery, chemotherapy, etc.).

5 Top management

The director of a public healthcare establishment, the head of a private healthcare establishment, the general secretary of a hospital union, the managing director of a joint healthcare group or the legal head of a company and their representatives appointed by a formal letter of delegation and delegation of signature assigning to them the necessary authority to carry out the tasks delegated.

6 Document

Any information media and the information it contains.

7 Patient notes

May also be referred to as 'healthcare record' or 'patient healthcare record'. The repository of administrative, medical and paramedical information regarding a subject of care.

8 Failure

Term designating either an event which has led to a situation that is not consistent with the desired, normal or usual operation of the organisation or an event which has prevented a requirement from being met.

9 Record

Document stating results achieved or providing evidence of activities performed. It provides assurance that the desired results have been achieved or that the activities have been performed as planned.

10 Healthcare establishment carrying out external radiotherapy or brachytherapy treatment activities

All legal forms of public or private healthcare establishments or companies, including private practices, in which external radiotherapy or brachytherapy treatment is carried out.

11 Specified requirement

All statutory and regulatory requirements, specific internal requirements that the healthcare establishment wishes to fulfil on a voluntary basis and requirements associated with patients and other healthcare providers. These requirements are state in writing in qualitative or quantitative terms, with defined measurable or verifiable conformity criteria.

12 Work instruction

A specified way of carrying out a series of simple actions or operations.

13 Quality manual

A document setting out an organisation's quality management system.

14 Quality objective

Something sought or aimed for, related to quality.

15 Quality policy

Overall direction and intentions of a healthcare establishment* related to quality as formally expressed by a person or group of persons who lead and control the establishment at top level.

16 Procedure

Specified way to carry out an activity or process. A procedure may or may not be documented.

17 Process

Set of interrelated or interacting activities which transforms inputs into outputs:

1. Strategic or coordinating process: set of activities which enables operational processes and support processes to function and to improve, as well as directing them and ensuring cohesion between them. These activities are primarily generated by senior and top management and are aimed in particular at devising the strategy for the establishment, quality management including formulating the quality policy, implementing its objectives within the healthcare establishment and allocating resources.
2. Operational process: set of clinical and non-clinical activities directly associated with a patient or a subject of care, for example:
    a. administrative processes such as admission and medical information;
    b. clinical processes: this covers all medical and practical care activities.

    Clinical radiotherapy process: all the medical and care activities comprising management of the patient from their first consultation with the oncology radiotherapist to their post-treatment follow-up. This process may be broken down into a series of stages.
3. Support processes: these are essential to the functioning of all the processes as they provide the necessary resources. Some of the main activities they cover are:
    a. human resources;
    b. financial resources;

c. equipment and maintenance thereof (premises, machines, hardware, software, etc.);
d. information processing.

18 External radiotherapy

A treatment method primarily for cancer which uses beams of radiation produced either by particle accelerators or by a radioactive source that penetrate tissues via the skin. In this method, the radiation source is external to the patient. The purpose of this treatment is to destroy all the cancer cells and/or to impede their capacity to multiply, whilst sparing the surrounding healthy tissues. External radiotherapy is very widely used and can be combined with other techniques (surgery, chemotherapy, etc.).

19 Radiation vigilance

The purpose of radiation vigilance, pursuant to Article L 1333-3 of the *Code de la Santé Publique*, is to detect, report, collect, store, evaluate and analyse all significant events which might affect the health of a patient, user or third party by exposure to ionising radiation used for medical, dentistry, human biology and biomedical research purposes.

20 Risk

The likelihood of harm (physical injury or damage to personal health, property or the environment) combined with its degree of severity.

21 Adverse event

Event which is not consistent with the desired, normal or usual operation of the healthcare establishment.

22 Radiotherapy department

A unit established to provide external radiotherapy and in which the holder of the licence to use a particle accelerator or a medical device containing radionuclide sources practises, pursuant to Article R. 1333-17 of the *Code de la Santé Publique.*

23 Quality management system

Set of interrelated or interacting elements that a healthcare establishment uses to direct and control how quality policies are implemented and quality objectives achieved.

History of revisions

Index	Application date	Part modified	Page	Comments
0	15/01/2009			Original edition
1	10/04/2009	Table of contents	4	Insertion of history of revisions
		Annex 5	Page 93 to 94	Addition of the date of publication (25 March 2009) of the ministerial order of 22 January 2009
		Annex 7	Page 96	Addition of comparison of 3-2.1 and 2.1-3 on tables
		History of revisions	Page 106 to 107	Update of history of revisions

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