

Making radiotherapy safe

In the framework of the French national radiotherapy plan, the French Nuclear Safety Authority (*Autorité de sûreté nucléaire - ASN*) has set up a radiotherapy management system to ensure control of both radiotherapy safety and quality.

In support of the regulatory evolutions, ASN has published two guides*:

- Risk self assessment in radiotherapy (Guide n°4).
- Radiotherapy care safety and quality management (Guide n°5).

**English translation in progress.*



In the framework of the French national measure program for radiotherapy, the Ministry of Health has entrusted the French Nuclear Safety Authority (*Autorité de sûreté nucléaire - ASN*) with the development of a ISO 9001 quality management system. The principles and methods set up jointly with healthcare professionals aim to ensure control of both radiotherapy safety and quality. The system crucial requirements are made mandatory pursuant to ASN decision no. 2008-DC-103 dated July 1, 2008. In support of the regulatory evolutions, ASN has published two guides: one dealing with the risk self-assessment (n° 4) and the other with radiotherapy care safety and quality management (n° 5).

Obligations and tools for radiotherapy safety and quality

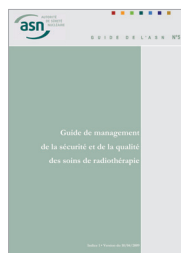
1 regulatory decision



2 technical guides



Guide ASN n°4



Guide ASN n°5

Regulatory obligations

The technical decision no. 2008-DC-0103 issued by ASN on July 1, 2008, the ASN strengthens regulations by specifying the quality assurance obligations incumbent on radiotherapy centres. The decision, ratified on January 22, 2009, was published in the French official journal on March 25, 2009. The obligations stipulated by the decision shall gradually take effect based on the following schedule:



The management system

System environment

The safety and quality management system includes:

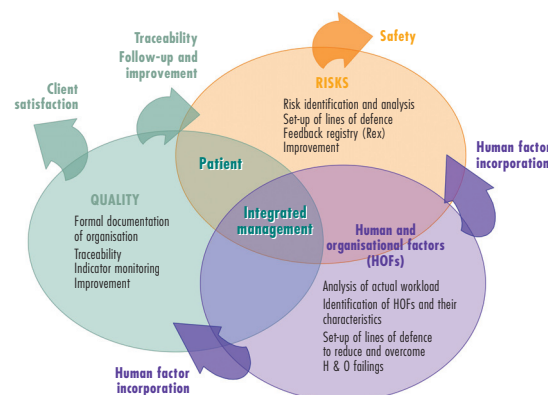
- certification requirements by the French National Authority for Health (*Haute Autorité de Santé - HAS*), thus making it possible to fulfil the obligation to continuously improve healthcare quality (article L. 6113-3 of the French Public Health Code),
- the main INCa (French cancer national institute) accreditation criteria for the practice of radiotherapy,
- the measures taken by the MeaH since 2006 in order to enhance the organisation and safety of radiotherapy departments,
- the international work of the World Health Organisation (WHO), Pan American Health Organisation (PAHO), and, more particularly, the European Society for Therapeutic Radiology and Oncology (ESTRO) and the International Atomic Energy Agency (IAEA).

System objectives

- Better define each contributor's responsibilities.
- Stabilising working practices and treatment methods.
- Improving control and calibration of measurement systems and installations.
- Better taking into account risks.
- Enhancing practices for feedback on dysfunction analysis.
- Improving follow-up of statistical indicators for safety and quality (deadlines, non-compliance, etc.).

An overall organisational approach

The ASN suggests that radiotherapy centres adopt an overall approach to care organisation, in which the safety, organisational, human and quality dimensions are the integrated management system mainstays.



Conclusion

Inadequate radiotherapy management may have serious health impacts. Improving radiotherapy safety and quality is contingent on a formally documented and controlled process of the entire healthcare chain, from the initial consultation through post-treatment follow-up.

The more quality and safety culture in treatment centres will develop, the more patients' confidence in their radiotherapy will be enhanced.

The purpose of the guide “radiotherapy risk self-assessment” is to help centres to fulfil their regulatory obligations with respect to risk assessment.

The guide offers a methodology for the assessment of the risks incurred by patients during the clinical process of radiotherapy and a formal basis for this analysis. The guide is available on the ASN website: www.asn.fr.

Description of the clinical process for external-beam radiotherapy



A guide compiled with and for healthcare professionals

The guide for risk self-assessment results from the joint work of ASN's Nantes Division and the radiotherapy professionals of Brittany and the “Pays de la Loire” region, supported by the French society of radiation oncology (SFRO) and the French society of medical physic (SFPM).

Scope

Radiotherapy-related risks, whose effects are generally deferred, may have several causes:

Adverse effects resulting from a concerted strategy implemented by the medical practitioner and patient during treatment.

Unexpected effects that may be:

- either related to intangible factors (individual sensitivity to ionising radiation, unforeseeable change in the patient's condition, etc.),
- or derive from abnormalities occurring during the radiation therapy clinical process.

The guide focuses on analysis of the risks associated with the latter effects.

Methodology

The working group relied on several risk analysis methods widely used in industrial settings:

- (1) Failure Mode Effect Analysis (FMEA),
- (2) Hazard Analysis and Critical Control Points (HACCP),
- (3) Ishikawa diagram (cause-and-effect diagram).

The guide is mainly based on implementation of the FMEA.

Working approach

The group structured its failure mode analysis on three mainlines:

- the patient itinerary ;
- the equipment, i.e. technical devices used throughout treatment ;
- the human and organisational factors, i.e. components related to organisation, information circulation and contributor training.

Risk characterisation: the severity and frequency concepts

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

However, the table differs in two respects:

- the severity level is generic for all organs,
- 4 levels (*versus* 5 in the CTCAE) were selected in order to prevent median effects.

The working group selected the following scoring for severity and probability scales:

Event severity scale (S)

Level	Criterion	Score	Level	Criterion
Not very critical	Temporary discomfort, malaise, unpleasantness	1	Very rare	Once every 5 years
Critical	Prolonged discomfort Reversible lesion or impairment Medical treatment required Temporary handicap	2	Rare	Once per year
Very critical	Delayed consequences but marked for the patient Irreversible lesion or impairment Permanent handicap Not life threatening	3	Frequent	Once per month
Serious	Short-term fatal outcome for the patient Life threatening	4	Very frequent	Once per session

Event probability scale (P)

Table synthesis example

Patient circuit	Failure mode	Potential effects	Causes	S	P	RPN*	Possible corrective effects	S	P	RPN*	Optimisation
3 - morphological data acquisition	CP-8 - error in the acquisition of patient parameters (for each imaging system (CT scanner, MRI, PET scanner))	Patient integrity is significantly jeopardised (treatment error)	Coding, direction, magnification of images differ (emitter vs. receptor) (particularly if external images) Error in laser movement direction (reverse direction) Inconsistency between the laser system indication and the actual position of the slice plane	4	3	12	Check the standards for coding and transmission between the emitter and receptor Conduct the quality controls New imaging system / new software: - Check that slice orientation has not changed - Check laser and scanner zero concordance Train the personnel on new equipment and software	4	2	8	Check the direction and precision of laser movement. Conduct validation imaging of the position of the selected isocentre

* Risk priority number

Conclusion

The guide to the self-assessment of radiotherapy risks naturally supplements event analysis and is designed to be used by all members of the medical teams (radiation oncologists, medical physicists, dosimetrists, radiation therapists, technicians, health-

care managers, secretaries, etc.).

The guide also aims to promote discussion on potential improvements in radiotherapy safety and thus further enhance patients' confidence on external-beam radiotherapy.

Lessons learned from significant events in radiotherapy

As part of the French national radiotherapy plan, the French Nuclear Safety Authority (*Autorité de sûreté nucléaire - ASN*) has established a radiotherapy safety monitoring system. The initial lessons drawn from significant radiation protection events have confirmed the need to structure risk management, improve traceability and tasks formalism. These three recommendations have been documented in ASN decision no. 2008-DC-0103 dated July 1, 2008, relating to the regulatory quality assurance obligations.

Characteristics of the events reported to the ASN in 2008

Number of reports

208 events reported, all level ≤ 2 , of which:

- 98% classified level ≤ 1 on the ASN-SFRO scale,
- 1 cohort (level 1).

→ Essentially events of level ≤ 1 .

Event occurrence

92% affected a single patient.
59% occurred during a single radiotherapy session.

Origin of significant radiation protection events

94% from human and organisational failures.
6% of purely technical origin, mainly due to software malfunctions.

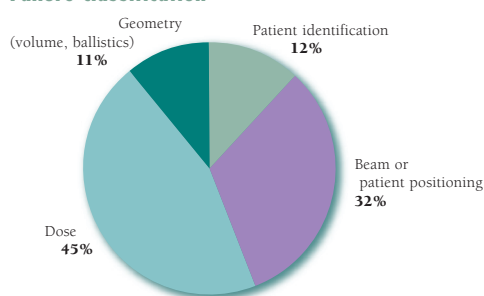
→ Human failures promoted by inadequate device ergonomics highlighting shortcomings in device design.

Representativeness of reporters

33% reporting centres versus 20% during the experimental period (July 2007 to July 2008).

→ Increase in the number of reporting centres but under-representation of the private sector.

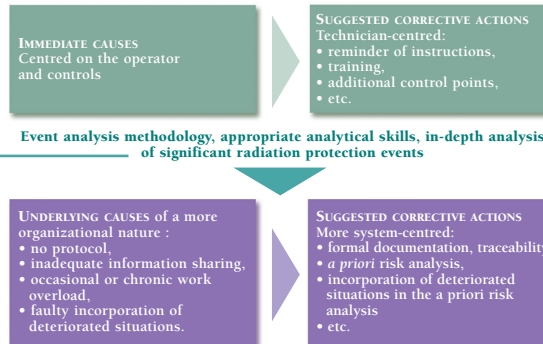
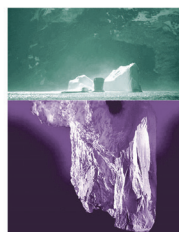
Failure classification



Lessons learned from the analyses of significant radiation protection events

While the immediate causes are generally identified, the underlying causes remain insufficiently understood.

Methodological shortcomings and lack of time for the analysis limits appropriate identification of effective corrective actions.



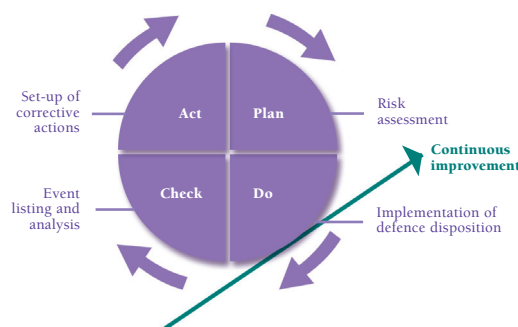
Quality assurance for risk management

ASN technical decision no. 2008-DC-0103 specifies quality assurance obligations being incumbent on radiotherapy centres. It aims to set up a rigorous risk management system incorporating risk assessment and event experience feedback as part of a continuous-improvement approach.

The methodology for the analysis of significant radiation protection events (ALARM, causal tree, ORION, etc.) is designed to make it possible to:

- 1- accurately reconstitute event chronology,
- 2- identify both immediate and underlying causes,
- 3- setup suitable corrective actions.

This approach shall be mentioned in the Significant Radiation Protection Event Report (*Compte-rendu d'Evènement Significatif de Radioprotection*) for inclusion in the national feedback registry (Rex).



Perspectives

Without underestimating the current difficulties related to the shortage of medical physicists, the ASN-supported approach consisting in reporting significant events and analysing risks

should eventually make it possible for the French radiotherapy to become an international reference.