

Radiotherapy safety and quality management system

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In the framework of the French national measure program for radiotherapy, the Ministry of Health has entrusted the French Nuclear Safety Authority (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 (no 4) and the other with radiotherapy care safety and quality management (no 5).

Obligations and tools for radiotherapy safety and quality

1 regulatory decision

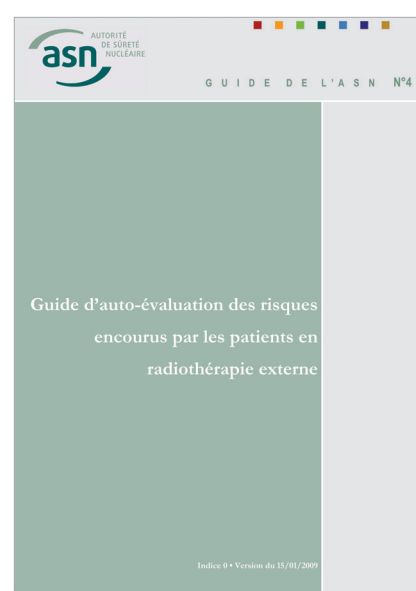


Approved on 22 January 2009, ASN decision N° 2008-DC-0103 imposes stricter regulations on the quality assurance in radiotherapy. The obligations gradually took effect over a period of 30 months and have been fully in effect since the end of 2011.

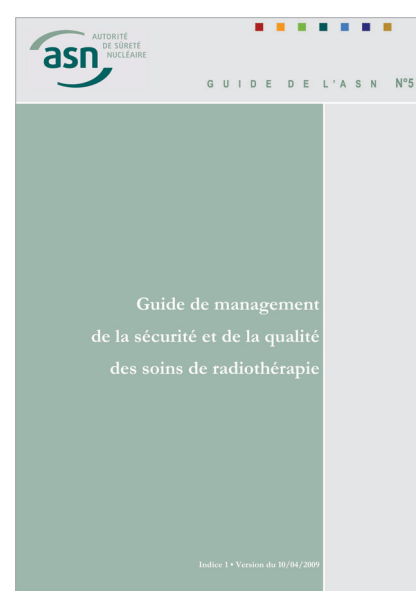
In order to guarantee the continuous improvement in the safety and quality of radiotherapy, efforts must be made in the following crucial areas:

- defining the responsibilities of personnel with regard to patients' care,
- setting out the management's commitment,
- appointing a person responsible for management system performance,
- training personnel in internal reporting of malfunctions,
- recording and resolving malfunctions according to formal organisational procedures,
- planning and keeping track of improvement actions,
- setting up a clearly defined and regularly updated documentation system,
- carrying out prior analysis of the risks to which patients are exposed during treatment,
- performing a quality and safety assessment of the management system and monitoring processes.

2 technical guides



Guide ASN n°4



Guide ASN n°5

The management system

System environment

The safety and quality management system includes:

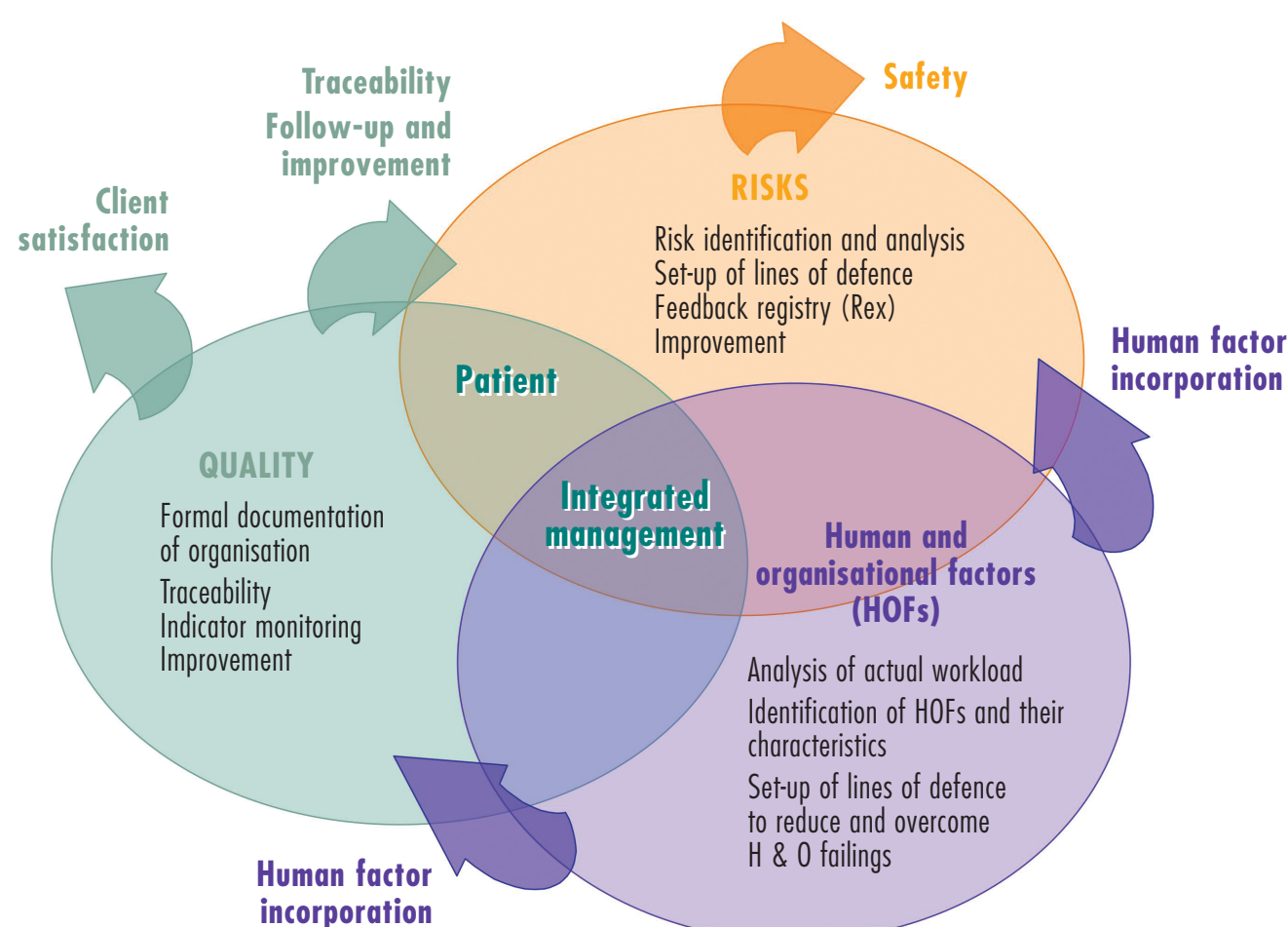
- certification requirements by the French National Authority for Health (HAS), thus making it possible to fulfil the obligation to continuously improve healthcare quality (article L. 6113-3 of the French Public Health Code),
- the main INCa (French cancer national institute) accreditation criteria for 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.
- Stabilise working practices and treatment methods.
- Improve control and calibration of measurement systems and installations.
- Better taking into account risks.
- Enhance practices for feedback on dysfunction analysis.
- Improve 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.



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.