CONTRIBUTION BY THE FRENCH NUCLEAR SAFETY AUTHORITY (ASN) TO THE MINISTRY OF HEALTH’S NATIONAL ACTION PLAN FOR RADIOTHERAPY ESTABLISHED IN 2007

Assessment of actions, may 2012
Overview

Background

1. Publish a set of ISO 9000-type radiotherapy quality assurance requirements
   1.1 The radiotherapy safety and quality of care management requirements
   1.2 The strengthening of the regulations
   1.3 Review of the progress of the implementation of Decision No. 2008-DC-103

2. Distribute a handbook for professionals on the notification of significant radiation protection events
   2.1 The ASN's No. 11 and No. 16 notification guides
   2.2 The “Vigie-radiotherapie” notification help website
   2.3 Review of notifications and operating experience feedback

3. Create an incident classification scale for the purposes of communicating to the public
   3.1 Background
   3.2 Presentation of the scale and its evolution
   3.3 Use of the ASN-SFRO scale

4. Strengthen the inspection programme
   4.1 Background
   4.2 The ASN radiotherapy inspections
   4.3 The ASN radiotherapy inspection reports
Background

In 2005 and 2006, some serious radiotherapy accidents were notified to the ASN by various hospitals in France (Grenoble, Lyon), in accordance with Article L. 1333-3 of the French Public Health Code.

Beginning in 2005, following the Grenoble accident, the ASN reminded radiation-oncologists of the regulatory principles whose observance contributes to the safety of the facility. In 2006, following the Lyon accident, the ASN sent radiotherapy professionals a new circular to raise awareness of the means of preventing radiotherapy accidents by taking into account organisational and human factors.

In July 2006, ASN was informed of the overexposure of 23 patients treated between May 2004 and May 2005 for prostate cancer at the Epinal hospital. The Minister of Health then commissioned the IGAS\(^1\) and the ASN to compile a report and in particular to draw useful conclusions locally and nationally about the safety of radiotherapy in its technical, organisational and human aspects. Its final conclusions were presented in February 2007. The mission in particular highlighted a lack of quality assurance in the practice of radiotherapy centres and a lack of organisation of radiation protection measures and the gathering of data on iatrogenic complications due to radiotherapy.

These accidents led the Ministry responsible for health, in 2007, to establish an action plan regarding the safety of patients undergoing radiotherapy, initially comprising 33 national measures spread across seven fields of action:

- the quality and safety of the practices;
- vigilance in radiotherapy;
- human resources and training;
- the safety of facilities;
- the relationship with patients and the public;
- the strengthening of inspections;
- monitoring and knowledge of the discipline.

New measures were taken in 2009 in respect of radiotherapy which were included in the Cancer Plan 2009-2013\(^2\).

The ASN has led 4 national radiotherapy measures initially included in the November 2007 roadmap. The implementation of these actions is described below. They include:

- The publication of a set of radiotherapy quality requirements and a strengthening of the regulations specifying the quality assurance obligations;
- The distribution of a handbook for professionals on the notification of significant radiation protection events;
- The creation of an incident scale rating for the purposes of communicating to the public;
- The strengthening of the radiotherapy programme of inspections.

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1 General Inspectorate of Social Affairs (http://www.igas.gouv.fr/)
2 For more information: http://www.e-cancer.fr
1 Publish a set of ISO 9000-type radiotherapy quality assurance requirements

Quality assurance in the services that use ionising radiations has been mandatory since 2003 (Article R.1333-59 of the CSP). However, its contents were left to the discretion of the health professionals. Control of the quality of the medical devices alone was set out in the regulations and subject to the control of the Afssaps in practice, except for those promoted by the national mission for hospital assessments and audits (Meah), quality assurance procedures were rare in 2007 although some of the issues related to human and organisational factors could be taken into account in this context.

1.1 The radiotherapy safety and quality of care management requirements

The ASN thus organised, between April 2007 and April 2008, the work for drawing up a set of radiotherapy quality assurance requirements, based on the international standard NF EN ISO 9001: 2000.

This work was done in collaboration with the INCa (French National Cancer Institute), the HAS (French National Authority for Health), the Meah and in consultation with health professionals. It was published on 27 March 2009 in the form of guide No. 5 by the ASN about radiotherapy safety and quality of care management requirements. It places the radiotherapy care activities within formalised and controlled processes with a concern for the continuous improvement of safety and quality. It reflects the requirements of the certification standard developed by the HAS, allowing healthcare facilities to meet their ongoing obligations of the quality of care, as specified in Article L. 6113-3 of the French Public Health Code. It also takes into account the international work of the WHO, the PAHO (Pan American Health Organization) and more especially the European Society for Radiotherapy and Oncology (ESTRO) and the IAEA.

The application of this standard, recommended by the ASN, is however, left to the discretion of each radiotherapy centre.

3 http://ansm.sante.fr/
1.2 The strengthening of the regulations

On this basis, the ASN strengthened the regulations specifying the requirements for the quality assurance of radiotherapy centres in respect of the incidents and accidents that were notified to it. It thus published on 1 July 2008, the technical decision No. 2008-DC-103 setting out the obligations of quality assurance in radiotherapy which was approved by the Minister of Health by the decree of 22 January 2009 and published in the Official Journal of the French Republic of 25 March 2009.

The requirements focus on the following:

- A management commitment as part of a QMS;
- A documentation system;
- The responsibility of the personnel;
- An analysis of the risks incurred by patients during the radiotherapy process;
- The gathering and processing of undesirable situations or malfunctions at the organisational, human or technical levels.

The obligations of this decision that came into effect gradually over a period of 2 and a half years, have been since 25 September 2011 all of a binding nature.
To support the regulatory changes, in addition to guide No. 5, the ASN has published a self-assessment guide of the risks to patients undergoing external radiotherapy, Guide No. 4. This voluntary guide aims to help centres to formalise the proactive risk assessment to patients during the clinical process of the radiotherapy. This guide was developed from September 2006 to December 2007, by a working group, led by the ASN, in consultation with various professionals (radiation-oncologists, medical physicists, personnel responsible for dosimetry, radiographers, etc.). The group identified potential failures that could lead to incidents and accidents for patients and calculated their criticality based on a risk analysis method used in industrial and medical fields. Each centre is able to use this guide to compile a customised mapping of the risks and prioritise measures to be implemented to improve the safety of the treatments.

Similar work is under way for brachytherapy and a self-assessment guide for brachytherapy risks should be distributed in 2012.

1.3 Review of the progress of the implementation of Decision No. 2008-DC-103

Based on the inspections it conducts each year in the radiotherapy centres, the ASN considers that the findings prepared in late 2010, confirmed by the initial findings of the 2011 audit, are encouraging, although efforts must be continued (see 4.2 for the 4 radiotherapy inspection reports for years 2007 to 2010).

With regard to the gradual establishment of a system of radiotherapy safety and quality of care management, the ASN has noted an improvement in the situation and widespread use of these measures. However, it believes that the supervision of radiotherapy safety and quality of care management is insufficiently advanced. The appointment of a person qualified to act as the operational manager of the external radiotherapy quality of care management system had been effected in under half the centres inspected in 2010.

In respect of the control of the process of preparing and carrying out treatments, the situation has been evolving in the right direction since 2008. However, the ASN considers that the effort to formalise the practices and skills should be continued in particular with regard to delegations by radiation-oncologists to radiographers to enable them to validate patient positioning control images during treatments.

The situation in the centres regarding risk management and dealing with malfunctions continues to improve. Over 90% of centres inspected have established a process for collecting information about malfunctions and have formed a multidisciplinary team to
analyse them. Training in developing a risk analysis is not sufficiently provided. Few centres had conducted a study of proactive risk assessment by the end of 2010 which had to be completed before 26 March 2011.

2 Distribute a handbook for professionals on the notification of significant radiation protection events

The obligations to which those in charge of a radiological activity are subject, in particular with respect to the information provided to the administrative authority for incidents or accidents in the field of radiation protection are set out in the French Public Health Code. According to the provisions of Article L. 1333-3 of this code "the individual responsible for one of the activities referred to in article L.1333-3 must immediately notify to the French Nuclear Safety Authority and to the State representative of the department any incident or accident likely to affect the health of individuals through exposure to ionising radiations".

The implementation of a system for notifying serious events is included in the measures undertaken since 2005 by the ASN in the field of radiation protection, the date when notification became mandatory.

Article L. 1333-3 was amended (by law n° 2009-879 of 21 July 2009 on hospital reform relating to patients, health and territories) and published on 22 July 2009 in n°167 of the Official Journal of the French Republic (Journal Officiel de la République Française – JORF) to extend the obligation to submit a notification to include "health professionals who are involved in the treatment or follow-up of patients exposed to ionising radiations for medical purposes, and who have knowledge of an incident or accident associated with this exposure".

Article R. 1333-109 was also subsequently amended (implementing decree published in the JORF of 4 May 2010) in order to integrate these new obligations.

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4 Administrative region headed by a préfet (in a department, representative of the State appointed by the President).
To structure the notification system in a concrete way, the ASN implemented on a trial basis from 1 July 2007, a system for notifying significant radiation protection events based on criteria. Guide No. 11 by the ASN sets out the criteria and notification arrangements. It includes, moreover, a template form for notifying and reporting significant radiation protection events. Among these criteria, criterion 2.1 relates specifically to events affecting one or more patients undergoing therapeutic exposure.

An evaluation of the system for notifying significant radiation protection events was carried out with the radiotherapy professionals concerned. This evaluation led to the revision of notification criterion 2.1, which was communicated to all radiotherapy centres in September 2009.

**Criterion 2.1**

A significant event is deemed to be one affecting one or more patients undergoing therapeutic exposure:

- any undesirable situation or malfunction at an organisational, human or technical level occurring during the care given to a patient undergoing radiotherapy having resulted in treatment non-compliant with the prescription in respect of the dose delivered(*);
- or any undesirable situation or malfunction at the organisational, human or technical level occurring during the care given to a patient resulting in the emergence of unpredictable deterministic effects given the therapeutic strategy chosen in consultation with the patient.

(*) The compliance of the dose delivered includes:

- radiotherapy and brachytherapy, compliance, with a tolerance of +/- 5%, of the total dose prescribed and compliance with the planned schedule and/or fractionation, taking into account any clinical or technical constraints for a patient's treatment; for targeted radiotherapy, compliance of the radio-pharmaceutical activity administered with a tolerance of + 10% of the prescribed activity,
- the absence of a systematic error of dose for several patients, regardless of the value of this error of dose.
To help the professionals in their notification obligations, the ASN has created in consultation with the professionals a specific guide on events affecting one or more patients undergoing therapeutic exposure (Guide No. 16).

This guide includes all the tools allowing the notifier to deal with a Significant Radiation Protection Event (SRPE) affecting a patient (criterion 2.1). For this purpose, it includes the notification form, the template for the report of SRPE and the ASN-SFRO scale (see 3.2) for rating events. It gives many SRPE examples.

2.2 The 'Vigie-radiotherapie' notification help website

On 7 July 2011, ASN and Afssaps made available to professionals an online service, "www.vigie-radiotherapie.fr", to assist them in preparing the notification of significant radiation protection events and materiovigilance notifications.


Since the website was launched, most SRPE notifications have been made using this notification portal.

Vigie-radiotherapie's purpose is to facilitate notifications and to capitalise on the operating experience feedback to continually improve the effectiveness and safety of radiotherapy treatments. It brings together all the documents from operating experience feedback such as the ASN-Afssaps reports and newsletters regarding the safety of patients undergoing radiotherapy (see paragraph 2.3).
2.3 Review of notifications and operating experience feedback

A report of the SRPE and materiovigilance notifications in respect of radiotherapy is regularly prepared by the ASN and Afssaps. Two reports have been published to date, dealing respectively with the periods, July 2007/June 2008 firstly and secondly for the years 2008 and 2009.

Over the 2007 – 2011 period, 426 incidents or risks of incidents involving radiotherapy medical devices were notified to the Afssaps regarding materiovigilance. These notifications mainly concern radiotherapy treatment planning software, control systems, the recording of the settings and linear accelerators.

Since the establishment of the notification system in July 2007, 1052 significant radiation protection events affecting patients undergoing therapeutic exposure were notified to the ASN. The vast majority of significant radiation protection events had no effect on the treatment delivered and the health of the patients and were rated at less than or equal to 1 on the ASN-SFRO scale. 26 events were rated at level 2 on the ASN-SFRO scale.

The proportion of radiotherapy departments notifying at least one SRPE to the ASN since the notification system was set up in 2007 is high (86%). In the last three years, about half of the services notified at least one SRPE per year.
The collection of a growing number of notifications and analyses carried out by the centres allow operating experience feedback to be capitalised on. For this purpose, a newsletter about the safety of patients undergoing radiotherapy is compiled by the ASN in collaboration with radiotherapy professionals. Two issues came out in 2011, one about the identification of patients and the second about the first session of radiotherapy treatment.

3 Create an incident scale rating for the purposes of communicating to the public

3.1 Background

In the nuclear safety field, in 1987 France set up a severity scale, which has been used internationally since 1991, the INES (International Nuclear Event Scale), published by the International Atomic Energy Agency (IAEA). It aims to facilitate the perception by the media and the public of the seriousness of nuclear events and accidents. It was extended in 2005 to events related to radiation protection. However, this scale does not cover events for individuals exposed intentionally as part of medical procedures (in particular external radiotherapy).

The occurrence of radiotherapy accidents from 2005 onwards and the gradual increase in notifications of events affecting patients treated by radiotherapy at various levels of severity, very quickly highlighted the need to define how the public should be informed about the occurrence of such events.

It is against this background that the ASN and the French Society of Radiotherapy and Oncology (SFRO) implemented, initially on an experimental basis, a scale for rating radiation protection events affecting patients treated by radiotherapy.
3.2 Presentation of the scale and its evolution

The experimental scale was published on 5 July 2007. It was evaluated after one year of use, in consultation with the French Society of Radiotherapy and Oncology (SFRO) and the French Society of Medical Physics (SFPM). It entered into force in its final version by Deliberation No. 2008-DL-0008 of 24 July 2008 of the French Nuclear Safety Authority. The evaluation showed that the scale was a useful information tool facilitating the perception of the severity of an event by all non-specialists.

The scale is used to rate the events in question that takes into account unexpected or unpredictable effects of radiotherapy as well as actual or potential effects, due to inappropriate doses or irradiated volumes. It also takes into account the number of patients involved. This scale, which has eight levels, is compatible with the existing INES radiation protection scale as well as the rating tables already used by practitioners (CTCAE5).

3.3 Use of the ASN-SFRO scale

One of ASN's missions is to help educate the public in the area of nuclear safety and radiation protection (law n° 2006-686 of 13 June 2006, article 4). The way in which the event is communicated to the public mainly depends on its ASN-SFRO scale rating. SRPEs are therefore brought to the public's attention in the following ways:

- All events are recorded in the ASN's annual report;
- events rated 1, with the exception of those relating to a cohort of patients (serial events), are compiled in a quarterly report which does not mention the names of the notifying establishments and is published on the www.asn.fr website;
- serial level 1 events (single cause in a cohort of patients) and those rated 2 or above are communicated via an ‘incident notice’ stating the place where the

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incident took place, in the section for the notification of incidents in the medical field. If necessary, serial level 1 events or level 2 events may be dealt with in a memo (link to the incident notice on the first page of the ASN website);

- level 3 events are systematically dealt with in a memo. They may, where appropriate, be communicated in a press release (the press informed by the ASN);
- from level 4 upwards, events are communicated via press releases.

4 Strengthen the ASN inspection programme

4.1 Background

The French Nuclear Safety Authority (ASN)\(^6\) has been responsible for the control of radiation protection in medical environments since February 2002. From 2002 to 2005, the ASN worked on the publication of a new regulatory framework for the radiation protection of patients, in particular to transform the Euratom 97/43 Directive. Simultaneously with the work of drafting the regulations and the investigation of administrative procedures, the ASN set up a radiation protection inspection system for the medical and industrial fields. Originally focused on radiation protection for professionals, inspections by the ASN were extended to patients' radiation protection only in 2005. The increase in the number of inspections in radiotherapy departments has gradually increased since 2002. From 2004 to 2006, a hundred inspections were carried out by the ASN for 182 radiotherapy centres. These inspections focused mainly on radiation protection for health professionals, the technical compliance of the facilities with the requirements of the authorisation and the rules for managing radioactive sources.

4.2 The ASN radiotherapy inspections

Incidents and serious accidents involving the medical field of radiotherapy notified to the ASN in 2005 and 2006 led in 2007 and subsequent years, to the inspection of all radiotherapy centres with checks being concentrated on organisational and human factors.

Patient radiation protection controls cover the following aspects:

- the organisation of medical physics;
- the commitment of the management to radiotherapy safety and quality of care management and in setting out responsibilities;
- control of the planning process and the implementation of the treatments;
- risk management and dealing with malfunctions (notification, analysis of causes, the implementation and monitoring of corrective actions);
- the control of equipment.

In addition, inspections are conducted, if necessary, following the notification of a significant radiation protection event.

All inspection follow-up letters are published on the ASN website.

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\(^6\) From 2002 to 2006, the ASN comprised the Department of Nuclear Facility Safety and Radiation Protection (DGSNR), under the authority of the Ministers responsible for industry, environment and health, and Division of Nuclear Safety and Radiation Protection (DSNR) of the Regional Agencies for Industry, Research and the Environment (DRIRE). In 2006 (law No. 2006-686 of 13 June 2006 on transparency and safety in the nuclear and radiological field, codified in Article L. 592-20 of the environmental code), the ASN became a independent administrative body merging the former DGSNR and DSNRs (called territorial divisions of the ASN).
4.3 The ASN radiotherapy inspection reports

Four radiotherapy inspection reports have been published and cover the years 2007, 2008, 2009 and 2010.

The latest report of the inspections conducted in 2010 by the ASN, backed up by initial data for 2011 confirms the increase in human resources devoted to medical physics begun in 2008.

The ASN notes that progress has been made in the implementation and widespread use of safety and quality of care management. However, it believes that the involvement of hospital management in safety and quality of care management remains inadequate. Some centres need to strengthen their safety culture and quality of care further, in particular, formalising the practices of care for patients and training the teams in risk analysis methods. In many centres, the drive to formalise practices and skills should be continued in respect of delegation arrangements within teams to validate patient positioning control images during treatments.

Although the internal notifications of malfunctions have been widespread, the analysis of the causes and follow-up of improvement actions in the medium and long term need to progress further.

The inspection of radiotherapy centres remains a priority for the ASN with special attention paid to those centres that still show weaknesses in terms of human resources in medical physics or in deploying a system of management for safety and quality of care.
Bilan national des inspections réalisées dans les services de radiothérapie externe sur le thème de la radioprotection des patients par une approche sur les facteurs organisationnels et humains
(Campagne 2007)

(Octobre 2009)

ASN Inspection Reports
5 Possible Future Actions

From 2 to 4 December 2009 the ASN organised in Versailles, with support from the World Health Organization (WHO), the International Atomic Energy Agency (IAEA) and the European Commission as well as the participation of many organisations, professional associations and patient associations, the first international conference on radiation protection for patients in the radiotherapy field. This conference resulted in a number of recommendations being made (Appendix 1), which were discussed nationally in 2010 with all stakeholders.

Although the national plan for radiotherapy already includes many of the recommendations made at the Versailles Conference, new actions were also identified:

- a study on the conditions of deploying new equipment and associated new practices and user needs in terms of specific skills, training and good practice guides;
- a review of individual radio sensitivity tests tried out in France and internationally, a prerequisite for developing a test for subsequently using routinely;
- a legal study to clarify the issue of the manufacturers' responsibility in the event of anomalies detected by users, leading the manufacturers to updating their application;
- a feasibility study for establishing an audit procedure of the radiotherapy centres' practices. This action, organised by the HAS, was launched in November 2011.

The international conference of 3 to 7 December 2012 in Bonn, on radiation protection in medicine, organised by the International Atomic Energy Agency (IAEA) with the support of the World Health Organization (WHO) will be the occasion for France to present operating experience feedback about the national radiotherapy plan.

In the field of medical physics, the ASN will prepare recommendations in 2012 for the health authorities to ensure that the regulations governing medical radiation physics is consolidated both in the way it is organised and how it operates as regards the involvement in medical physics tasks of professionals who are not medical physicists.

Finally, the ASN will implement a series of inspections every two years for radiotherapy centres in line with the progress made in the centres since 2007 in respect of the safety of the treatments. However, annual inspections will be maintained for centres showing weaknesses in terms of human resources, organisation or implementing a system of management for safety and quality of care.

The checks will verify the adequacy of the procedures (formalisation of practices) and their implementation. Moreover, regarding the care process, checks will be targeted on the implementation stage of treatments for 2012 and 2013.

Short unannounced inspections may be conducted on limited aspects such as how well staffing corresponds with the times the departments are open for patient treatment. Finally, inspections will continue to be conducted, if necessary, after the notification of a significant event.
Appendix 1

The conclusions of the Versailles conference

The Versailles conference resulted in the following conclusions being identified:

- the pre-eminence of radiotherapy in the treatment and cure of cancer was reaffirmed;
- the technical developments in this area, although bringing with them new benefits, also create new risks. Operator training needs to be strengthened and the initial uses of these new techniques should be subject to an independent evaluation by professionals according to methods established internationally;
- efforts made locally and internationally should be intensified in the field of the recording and analysis of the undesirable side effects and complications of treatment. Systems for notifying significant events must be developed for the purpose of analysis and feedback;
- the safety culture in radiotherapy centres should continue to move forward through the implementation of quality assurance and risk analysis by professionals trained in sufficient numbers;
- greater involvement of the authorities is needed to promote actions in the areas of quality assurance, risk analysis, good clinical practice and clinical audits;
- coordination of research programmes is essential to be able eventually to have available radio sensitivity tests that are both simple and fast;
- involvement of patients and their associations is desirable in the areas of the evaluation of the quality and safety of treatments as well as in risk management and communication.