4 ASN REGULATION OF THE RADIOTHERAPY SECTOR

Since 2005, the medical inspections carried out by ASN have included patient radiation protection aspects. From 2002 to 2005, ASN devoted considerable effort to publishing the new regulatory framework necessary for transposition of Directive 97/43/ Euratom[1], while at the same time carrying out inspection visits, primarily to look at radiation protection of health professionals, the technical conformity of the installations with the requirements of the license and the rules concerning management of radioactive sources.

The accidents which occurred in Epinal Hospital (2004-2005) and Rangueil Hospital in Toulouse (2006-2007) as well as the other radiotherapy events notified to ASN after 2005, revealed the important role of human and organisational factors in the occurrence of incidents, in certain cases compounded by poor practices, such as the lack of verification phases or inadequate operator training.

With a healing success rate of about 80% of the patients treated, radiotherapy is a fully justified method for cancer treatment. However, in the light of the organisational weaknesses detected during inspection of a number of radiotherapy centres, inspection of all external radiotherapy centres, focusing on human and organisational factors, remained a top priority for ASN in 2008, as was the case in 2007.

At the same time, ASN continued to reinforce the regulatory framework and provided information to the public concerning the inspections conducted and the radiation protection events notified to it. These actions form part of the national programme to increase radiotherapy treatment safety, placed under the responsibility of the Minister for Health.

RESULTS OF THE 2007 INSPECTIONS

In April 2008, ASN published the results of the inspections carried out in the radiotherapy centres in 2007, covering human and organisational factors. These results in particular revealed:

- that the personnel seemed to be fully in control of the treatment preparation and treatment steps, even though they were rarely formally defined;
- that post-treatment medical follow-up of the individual patients is generally well-organised;
- that it is necessary to boost the numbers of the radiation physics staff working in radiotherapy, in particular the radiation physicists, as well as the numbers of radiation oncologists and medical radiology operators;
- that internal inspections, in particular accelerator quality controls and checks concerning treatment preparation and performance, are indeed carried out by the centres, but in most case are inadequately laid out in written procedures;
- that an analysis of the hazards involved in radiotherapy, based on compilation and analysis of undesirable events, is performed in too few of the centres.

These results brought to light a contrasting picture among the radiotherapy centres: in some centres, steps are under way to make treatment safer, while in a smaller number of centres, there is a build-up of organisational weaknesses that need to be corrected as a priority.

THE INSPECTIONS CARRIED OUT IN 2008

All the radiotherapy centres inspected in 2007 were revisited in 2008. ASN was thus able to monitor the steps taken by the radiotherapy centres following the 2007 inspections. Priority was given to examining the situation in those centres which demonstrated inadequacy in terms of human resources and organisation. On this occasion, ASN noted the positive nature of the proactive approaches supported by the national mission for hospital appraisal and audit (MeaH), with a view to improving treatment safety, in particular by implementing procedures to analyse the functional problems identified by the centre.

The conclusions of this second wave of inspections were transmitted to the regional hospitalisation agencies (ARH) and forwarded to the support unit created by the national cancer institute (INCa) at the request of the Minister for Health. The work done by this unit, with participation by ASN, identified nine centres for which the Minister for Health then requested immediate action, to remedy the shortage of personnel specialising in medical radiation physics.

Inspection of the radiotherapy department in the Henri Mondor University Hospital in Créteil on 6 August 2008

1. Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure.

For ASN, the situation in these nine centres should not however mask the fact that in others, the available numbers of physicians and medical radiation physicists specialists, or indeed the technical environment, means that all the regulations in force (order of 19 November 2004) and the future approval criteria published on 16 June 2008 by INCa, cannot at present be met.

In 2009, ASN will focus its inspections on particular topics such as the organisation of medical radiophysics, the management of problems detected by the centres and the internal inspection procedures.

Strengthening the regulations

Quality assurance in departments using ionising radiation for medical purposes has been mandatory since 2003 (Article R.1333-59 of the Public Health Code). However, its content is left entirely up to the professionals themselves. Only quality control of medical equipment is regulated and subject to inspection by organisations approved by AFSSAPS.

In July 2008, ASN adopted a technical decision making it mandatory to set up quality assurance based on specific requirements produced jointly with the profession. Publication of this decision, which is currently being approved, will be accompanied by the publication of the quality assurance requirements and a methodology document on the analysis of the risks involved in external radiotherapy, also produced in cooperation with the profession.

Implementation of this decision will be gradual and will be coordinated with the action of INCa concerning compliance with quality criteria for radiotherapy care licences.

Notification of events to ASN

In order to encourage the transmission and sharing of operating feedback, ASN devoted efforts to setting up a system of notification of medical events, some of which are liable to lead to serious incidents. The main purpose of prior registration of these events within the radiotherapy department and analysis of the causes by the physician responsible for the activity, along with the members of his or her team, is to improve treatment safety, through implementation of corrective action. The mandatory notification to ASN may then lead to an immediate inspection followed, if necessary, by information of other professionals in order to improve safety in all the departments concerned. The inspection is carried out by an ASN regional division, with the possible cooperation of representatives from other departments and, if necessary, support from the Institute for Radiation Protection and Nuclear Safety (IRSN).

In July 2007, ASN therefore published an experimental guide for notification of radiotherapy events, including those for which no health consequences are anticipated.

ASN/SFRO scale for rating radiation protection events affecting patients undergoing a radiotherapy procedure

Application of this guide will be made mandatory in 2009 by means of an ASN technical decision submitted to the Minister for Health for approval.

In 2008, with regard to external radiotherapy, the number of radiotherapy centres which actually implemented the event notification system increased, although the level is still insufficient (30% of centres notified at least 1 event). In total, 204 of the 208 events notified were rated at level 1 or less, while 4 events were rated level 2 on the ASN-SFRO scale, indicating an event leading to or liable to lead to a moderate impairment of an organ or function, and were the subject of an incident notice on the ASN website.

Public information

The ASN-SFRO severity scale, applied experimentally from July 2007 to July 2008, is designed to provide the public with comprehensible and explicit information about radiation protection events affecting patients undergoing an external medical radiotherapy procedure. After the one-year trial period, this scale was updated and published in July 2008 (www.asn.fr).

In 2008, 4 events were rated level 2 and 204 events level 1 or lower. Most of these events only concerned one patient and had no health consequences. In some of them (8), the

Examples of follow-up letters sent to radiotherapy centres and available on the ASN website www.asn.fr

cause was found to be an anomaly in the equipment used, including the software associated with particle accelerators.

In the event of an incident, ASN recommends that, with the agreement of the head of the establishment, the radiotherapy centre concerned handle communications at the local level. The physician must first of all have informed the patients within fifteen days, as stipulated in Article L.1142-4 of the Public Health Code.

Communication by ASN is distinct from that of the establishment. The information is tailored to the seriousness of the confirmed or potential event, and the number of patients concerned. This information is focused primarily on the action taken by ASN to assess the situation and draw the necessary safety conclusions. Information of a medical nature may be given, provided that the source is mentioned, although the privacy of the patients involved must be protected at all times.

Since July 2008, ASN has been issuing a quarterly review of level-1 events notified to it and is continuing to publish incident notices for events rated level 2 or higher.

Publication of the ASN inspection follow-up letters

Since 1 July 2008, ASN has published the follow-up letters for the inspections carried out in the radiotherapy centres. This publication is part of ASN's public information duty as defined in the 13 June 2006 Nuclear Transparency and Security Act. This publication process, which has been applicable to basic nuclear installations since 2002, should in 2009 be extended to include all small-scale nuclear facilities.

The follow-up letters for the inspections performed in 2008 and published on the ASN website, present the deviations from the regulations and the potential organisational inadequacies that could contribute to the occurrence of undesirable events. They in no way judge the medical quality of the radiotherapy treatment and its results for the patient. They indicate the progress made by the centres inspected and the extent to which ASN requests for corrective action have been taken into account in the organisation of the radiotherapy centres.

On 31 December 2008, ASN had published 110 inspection follow-up letters.

Drafting of interim criteria to deal in particular with the shortage of radiation physicists

The national radiotherapy measures oversight committee was set up by Mrs Roselyne Bachelot, the Minister for Health, on 15 December 2008. This was an opportunity for ASN to restate the urgent need for interim operating criteria to be defined for radiotherapy centres, to enable them to achieve an acceptable level of safety in the light of the shortage of medical radiation physicists in many of these centres. An appropriate legal framework, incorporating these interim criteria, will have to be defined under the responsibility of the Minister for Health, given that a transitional period is

inevitable before the numbers of radiation physicists and dosimetry specialists have reached satisfactory levels and the quality assurance system is fully implemented.

ASN thus believes that from 5 to 10 years will be needed before sufficient medical radiation physicists are available. The new approval criteria published by INCa will in fact not be applicable until 2012. Given this context, ASN is closely monitoring the situation of those centres which only have a single radiation physicist: in the event of this person's departure without replacement and in the absence of any immediate cooperative solution, ASN may be required to suspend the radiation protection authorisation previously granted to the physician in charge of the radiotherapy centre.

ASN would nonetheless like to point out that, together with the other stakeholders taking part in the national radiotherapy measures oversight committee, it is ready to help define interim criteria within a regulatory framework under the competence of the Minister for Health.