



How to improve radioprotection for patients and workers during interventional procedures

Experience feedback from notified events

Carole ROUSSE, Marc VALERO, Sandrine MOUGNIOT, Aurélie ISAMBERT, Paul CILLARD, Jean-Luc GODET^a

^a Ionising radiation and health department, French Nuclear Safety Authority (ASN)

Abstract. Among events occurring during interventional procedures notified to ASN, 16 of them involved patients, including in one case a group of patients, and some led to severe radiation injuries. The doses received were in some cases up to 60 Gy to the skin or 15 Gy to the brain. Sixteen events concerned operators: in five of them doses exceeded the annual dose limits, either for effective dose (up to 27 mSv/year), or for equivalent dose to extremities, (up to 875 mSv/year to one hand).

Lessons learned from these events reveal several failures: a misunderstanding in the use of the X-ray equipment and incomplete application of the optimisation procedure; inconsistency between the devices used and the acts performed; an inadequate management of equipment settings with insufficient reference to manufacturers' maintenance and adjustments; a poor knowledge of the dose delivered; and the possibility of induced radiation deterministic effects leading to a lack in patient follow-up. In terms of operators, there is evidence of poor (or wrong) practices from a radioprotection point of view, and poor use of personal or collective protective equipment.

The roles of the qualified experts and medical physicists are essential to improve the radiation protection of staff and patients in interventional radiology, particularly for professionals who are regularly exposed due to their expertise and for long-duration interventional radiology procedures. User training, dose monitoring for patients and workers, particularly for the extremities, also represent a major avenue for progress.

1. Introduction

The requirements for those in charge of a radiological activity to notify incidents or accidents in the field of radiation protection to the administrative authority, are set out in the French Public Health Code. According to the provisions of Article L. 1333-3 of this code "the individual responsible ... must immediately notify to the nuclear regulatory body and to the State representative in the department¹ any incident or accident likely to affect the health of individuals through exposure to ionising radiations". This obligation includes health professionals who are involved in the treatment or follow-up of patients exposed to ionising radiation for medical purposes, and who have knowledge of an incident or accident associated with this exposure.

The objective of this paper is to present an assessment of events that had been notified to ASN since 2007 and the lessons learned in order to improve radioprotection for patients and workers during interventional procedures.

After presenting the number of notified events, we will describe the main notified events, the failures that occurred and the main causes. Afterwards, we will discuss actions and recommendations that could be given in order to improve radioprotection of patients and workers.

2. Method

To formally structure the notification system, ASN implemented on a trial basis from July 2007, a system for notifying significant radiation protection events based on certain criteria. Guide No. 11 by ASN sets out the criteria and notification arrangements. It includes a template form for notifying and reporting significant radiation protection events. Among these criteria, criterion 2 relates specifically to events affecting one or more patients undergoing diagnostic or therapeutic exposure and criteria 1 to events affecting occupational exposure of operators.

3. Results

3.1. Number of notified events

The number of events notified each year is shown in the table 1. Table 2 shows the distribution of events according to the consequences (patient, workers,

¹ Administrative region headed by a prefect (in a department, representative of the State appointed by the President).

public or environmental). A serious patient event, notified at the beginning of 2012, is also included.

Year	2007	2008	2009	2010	2011
Number of events	1	3	9	10	13

Table 1: Number of events notified each year

Radiological consequences	Patient	Worker	Public or environmental
Number of events	16	16	4

Table 2: Number of events according to the criteria

3.2. Events dealing with patients

Among the 16 patient-related events, five of them had consequences for the patient's health. Radiation-induced skin damage is a well-known complication of interventional radiology [1]. On rare occasions, severe injuries can be unavoidable due to life-saving necessity (Events n°2 in Table 3).

The procedures involved in the notified events are: cardiology (fitting of cardiac defibrillator, Chronic Total Obstruction procedure), interventional neurology (embolisation for intracerebral arteriovenous malformations), vascular radiology (embolisation of the coeliac trunk), and uterine embolisation. Except for the fitting of cardiac defibrillators, skin damage appeared after several fluoroscopically-guided interventional procedures.

The high doses delivered led to deterministic effects (erythema, dry or moist desquamation, temporary alopecia, necrosis), which prompted the notifications. The dosimetric evaluations carried out by IRSN (see table 3) show that these procedures contribute to the delivery of very high dose level, particularly, to the skin or the brain.

Event		Skin dose Gray	Lung dose Gray	Brain Dose Gray	Heart dose Gray
N°1	Fitting of defibrillator	16,2	8		
N°2	Uterine embolisation	15			
N°3	Intracerebral arteriovenous malformations	17		[11-15]	
N°4	Embolisation of the coeliac trunk	[17-13]			
N°5	Angioplasty (Total chronic obstruction)	[35-60]	[1-3]		2

Table 3 : Dosimetric reconstruction of events notified to ASN

Concerning event n°2, for which a group of patients were involved, a report on the experience feedback was published on the ASN website in March 2010 [2]. In this event, the follow-up did not reveal any neurological, meningeal or subcutaneaous abnormalities, and the cases of alopecia observed have fully regressed. ASN reiterated the regulatory requirements, in a memorandum dated December 11, 2009 and sent a number of recommendations to the heads of interventional vascular neurology departments together with the general managers of hospitals.

The main root causes of these events are:

- Inadequate operator training, both in patient radiation protection and in the use of the radiological devices. Concerning event n°1, the physician was confused between the footswitch rfor radiography with the one for fluoroscopy.
- Imperfect understanding of the doses delivered during the procedures and a lack of detection and follow-up of patients liable to present radiation-induced deterministic effects; dosimetric data are very often not available and not detailed enough to produce a reliable estimate of doses.
- Almost non-existent application of the optimisation procedure and evaluation procedures for dosimetry.
- Use of inappropriate devices for long and complex procedures (device unable to offer optimised protocol conditions and no dose indicator device available).
- Inadequate management and follow-up of maintenance and adjustments performed by the manufacturer
- Failures in the management of the medical referral and its traceability.

The feedback reveals that incomplete application of dose optimisation is due to a lack of medical physicist input.

3.3. Events dealing with workers

Among events concerning medical staff, in five of them workers exceeded one of the annual dose limits (effective dose or dose to extremities). Table n°4 summarizes the maximal dose received by the operators

	Event	Effective dose mSv	Doses to extremities mSv
N°1	Nurse of operating theatre	21 / a quarter	
N°2	Digestive radiologist		523 / year
N°3	Orthopaedic surgeon	27 / year	
N°4	Digestive radiologist	3.5 / year	571 right hand / year 875 left hand / year
N°5	Radiologist (intra-articular injections)		525/ four months 677 /four months

Table n°4 : Doses received by operators

The procedures involved in these events are: digestive procedures (Biliary drainage, chemoembolisation, embolisation of digestive arteries); and orthopaedic procedures (vertebroplasty, kyphoplasty, infiltration). In these procedures, the physicians work in the immediate vicinity of the patient and are exposed to higher levels of dose than during other radiological practices.

The main root causes of these events are:

- Inadequate operator training, both in occupational radiation protection and in the use of the radiological devices.
- Failure to wear individual protective equipment.
- Inadequate optimisation of procedures.

The feedback reveals that there is a lack of a radiation protection officer in operating theatres. The availability of the RP officers and the resources allotted to them must be increased to improve the radiation protection of workers. There is also a misunderstanding of doses likely to be received by the operators and a lack of radiation protection culture.

3. Conclusions

Since 2009, the monitoring and regulation of radiation protection in interventional radiology has become a national priority for ASN. ASN considers that urgent steps must be taken to improve the radiation protection of patients and workers in interventional radiology, particularly for fluoroscopy-guided interventional procedures in operating theatres. ASN issued a position statement on 14 June 2011 concerning the improvements to radiation protection in interventional radiology.

Together with the departments concerned at the Ministry for Labour, Employment and Health, ASN sent out a letter to the regional health agency Director Generals in November 2011, describing the current radiation protection situation in the medical field. This letter highlights the necessary improvements concerning the radiation protection of patients and healthcare staff, especially in terms of human resources.

ASN also asked the learned societies and professional organisations representing the radiologists and non-radiologist practitioners (interventional cardiologists, vascular surgeons, neurosurgeons, orthopaedists, etc.) who perform interventional radiology procedures, to step up their efforts with regard to training and the drafting of guides on good practice.

Finally, ASN is anxious to underline the major role of the medical physicist and the radiation protection officer in the radiation protection of patients and workers..

Owing to the inadequacies observed in radiation protection in the interventional radiology field, ASN is maintaining the national priority status it accords to the control of interventional radiology in its inspection programme.

REFERENCES

- [1] Stephen Balter et al. Fluoroscopically guided interventional procedure, a review of radiation effects on patients' skin and hair. RSNA, 2010.
- [2] Experience feedback from the report of an interventional radiology event at the Strasbourg Academic Hospitals.