Lessons learned from significant events in radiotherapy

Carole Rousse, Paul Cillard, Aurélie Isambert, Jean-Luc Godet (ASN)

AUTORITÉ DE SÛRETÉ NUCLÉAIRE
www.asn.fr

As part of the French national radiotherapy plan, the French Nuclear Safety Authority (ASN) has set up 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 set working procedures. The three recommendations have been documented in ASN decision no. 2008-DC-0103 dated July 1, 2008, setting radiotherapy regulatory quality assurance obligations.

Characteristics of the events reported to ASN since July 2007

ASN SFRO scale

	EVENTS CAUSES (UNPREDICTED, UNEXPECTED)
5 to 7* ACCIDENT	Death
4** ACCIDENT	Serious life-threatening event, disabling complication or sequela
3** INCIDENT	Event resulting in severe alteration of one or more organs or functions
2** INCIDENT	Event resulting in or likely to result in moderate alteration of an organ or fuction
1 EVENT	Event with dosimetric consequences but no expected clinical consequence
0 EVENT	Event with no consequence for the patient

ASN developed a scale in collaboration with SFRO (French Society of Radiation Oncology) to inform the public about radiation protection events affecting patients undergoing radiotherapy procedures. The final version of the scale was published in July 2008.

Number of reports

1 053 events reported (about 250 a year):
- 1 event rated level 4+ on the ASN-SFRO scale,
- 26 events rated level 2 on the ASN-SFRO scale,
- 1 026 events rated level ⩽ 1 (of which 52% are level 1) on the ASN-SFRO scale.

→ Mainly events of level ⩽ 1 i.e without clinical consequences expected by the patient

Event occurrence

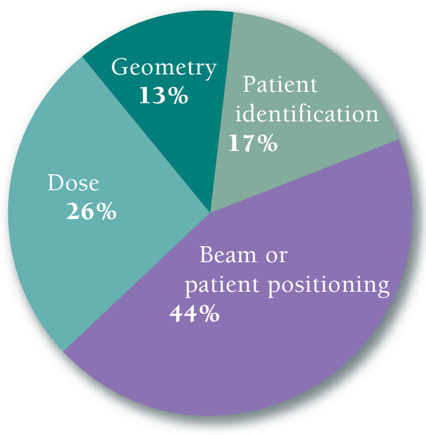
99% affected a single patient.
Nearly 4/5 occurred during a single radiotherapy session.

Origin of significant radiation protection events

96% from human and organizational failures.
4% of purely technical origin, mainly due to software malfunctions.

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

Failure classification



The majority of events occurred during treatment sessions. They involved incorrect positioning, treatment parameter settings (incorrect dose to the planned volume) or beam shaping (geometry). Most were detected by the radiation therapy technician.

Representativeness of reporters

At the end of 2011, 87% of radiotherapy centers had reported at least one significant radiation protection event since the notification system was set up. For 3 years, half of the centers have reported at least one event a year.
Since July 2011, *www.vigie-radiotherapie.fr* facilitates reporting of significant radiation protection event or medical device failure.

→ The reporting culture is taking place gradually since 2007

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.

Immediate causes
Centred on the operator and controls

Suggested corrective actions
Technician-centred:
- reminder of instructions,
- training,
- additional control points,
- etc.

Event analysis methodology, appropriate analytical skills, in-depth analysis of significant radiation protection events

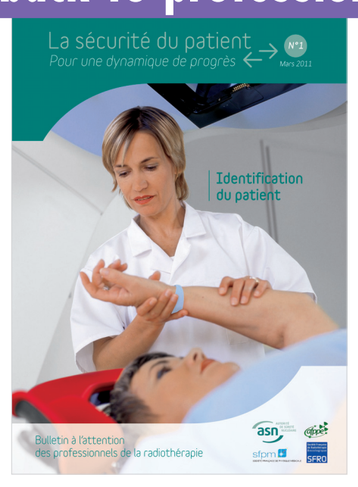
Underlying causes of a more organizational nature :
- no protocol,
- inadequate information sharing,
- occasional or chronic work overload,
- faulty incorporation of deteriorated situations.

Suggested corrective actions
More system-centred:
- formal documentation, traceability,
- *a priori* risk analysis,
- incorporation of deteriorated situations in the *a priori* risk analysis
- etc.

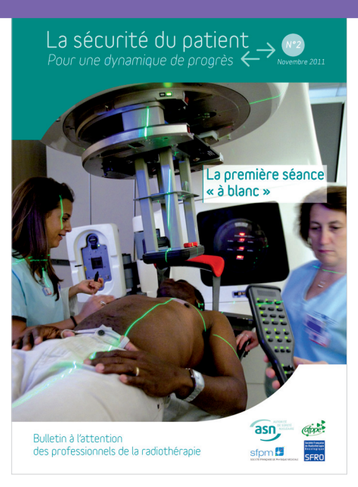
Communication and feedback to professionals

Every quarter, ASN publishes on its website information notice about radiotherapy events, rated level 1 on the ASN-SFRO scale.

After 4 years collecting notifications, ASN publishes twice a year, with the collaboration of radiotherapy professional societies (radiation oncologists, medical physicists and radiation therapy technologists), a feedback newsletters about patient safety.



N° 1, patient identification



N° 2, first treatment session

The experience feedback on the events is going to feed the reflection on French clinical audit. Besides, the French experience on notification system will substantiate the reflections of a European working group (ACCIRAD project, funded by the European Commission) to develop guidelines on a risk analysis of accidental and unintended exposures in radiotherapy.

Main author: Carole Rousse (French Nuclear Safety Authority) - carole.rousse@asn.fr - www.asn.fr - March 2012