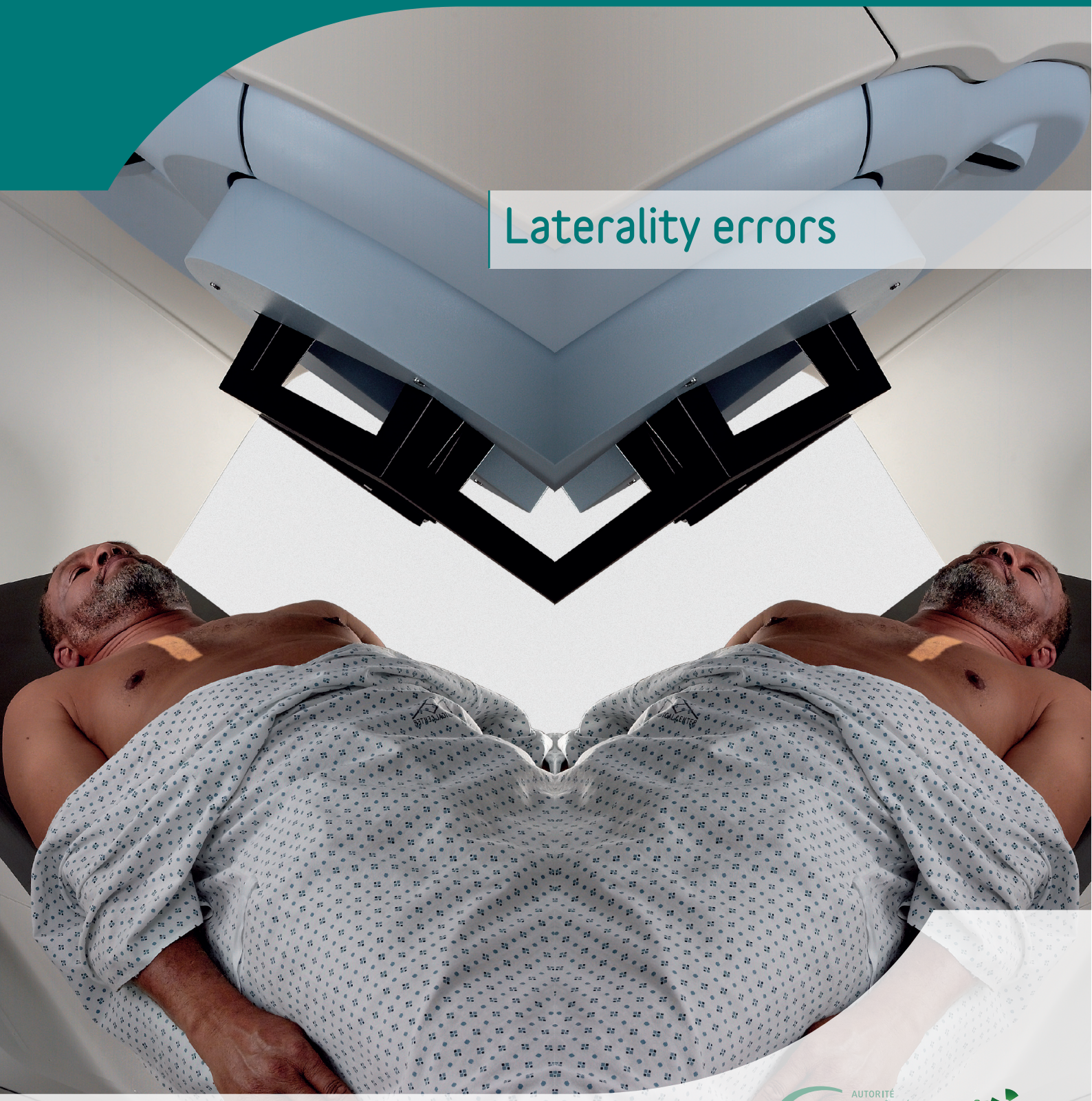
Patient safety

Paving the way for progress

N°6

May 2014



Laterality errors

Newsletter for radiotherapy professionnals

asn Autorité de sûreté nucléaire
afppe
sfpm Société Française de Physique Médicale
Société Française de Radiothérapie Oncologique SFRO

> Editorial

Getting the patient's side wrong during treatment? The error seems unlikely and yet, in 2013, 6 significant radiation protection events of this type were reported to ASN.

What are the risk situations? What preventive and effective detection measures exist? Newsletter no.6 provides some keys to prevent laterality errors.
Here you will find recommendations from two centres that have conducted an in-depth analysis of an event regarding the treated side, as well as evidence from the Brittany regional health agency about its joint preventive action with the Eugène Marquis centre (Rennes).

Laterality errors are not restricted to radiotherapy; the newsletter brings you news of an international initiative in surgery to prevent operative site errors. An interesting opening to add to lessons drawn from radiotherapy.

Enjoy reading it !

The editors

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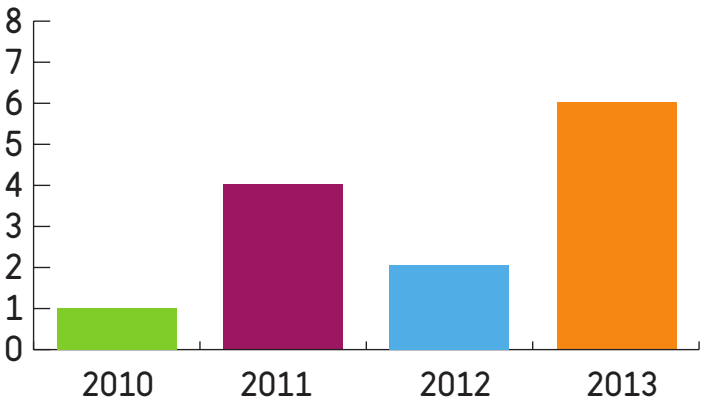
Patient safety - Paving the way for progress is edited by the French Nuclear Safety Authority (ASN) as part of the work of the multidisciplinary working group specially created to provide radiotherapy professionals with feedback.
Executive Editor: Jean-Christophe Niel, ASN Director General / **Chief Editor:** Nathalie Clipet / **Editorial Committee:** French Radiation Oncology Society (SFRO), French Society of Medical Physics (SFPM), French Association of Radiographers (AFPPE) / **With the participation of:** IRSN, the French Institute for Radiological Protection and Nuclear Safety / HAS, the French National Authority for Health / , ANSM, the French Health Products Safety Agency / **Photo credits:** Siemens (front cover) **Design and realisation:** Margoland®

> Key figures

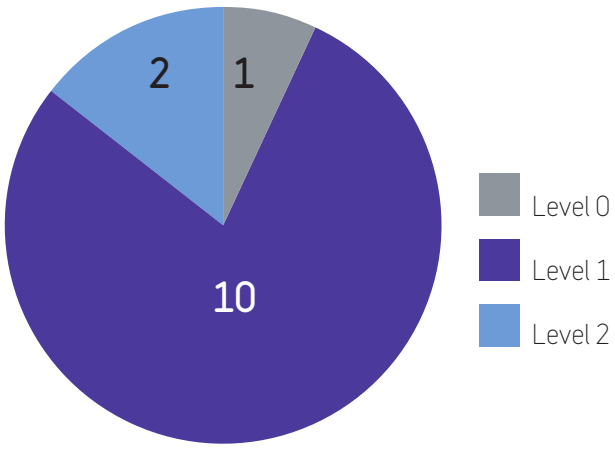
During the 4 years 2010 to 2013, ASN has received 936 notifications of events (SRPE - Significant Radiation Protection Events) in external beam radiotherapy involving a patient.

Among these SRPE, **this newsletter decodes 13 laterality errors when delivering treatment**. The laterality errors considered do not include organ or level (vertebral) errors. Patient errors having led to a side error arise from an identity monitoring issue covered in newsletter no.1 (March 2011).

Distribution of 13 laterality error notifications since 2010



Classification of 13 laterality error notifications on the ASN-SFRO scale.



> Decoding

1. Description of events leading to a laterality error

Treatment technique

- conformational radiotherapy for the majority,
- 2 tomotherapies,
- one treatment by neuroradiosurgery.

Number of sessions involved

1 session: 4 SRPE including one single-session treatment (therefore all treatment involved),
Between 3 and 5 sessions: 5 SRPE,
10 sessions and more: 4 SRPE, including one involving almost the entire course of treatment (38/39 sessions).

Who detected the error?

The radiographer detected the error in more than half of cases. The patient was also able to highlight the error on several occasions, as well as the spouse (once). The error was detected by a radiation oncologist on 2 occasions.

Which stage of the clinical radiotherapy process caused the significant event?

Errors leading to the event occurred at:
- prescription: 2,
- delineation: 9 (including one error associated with a protocol error),
- treatment planning (dosimetry): 1,
- treatment: 1.

Identified risk situations

- file incomplete at first appointment,
- prescription made without stating the side or by indicating the laterality,
- target volume not visible or poorly visible on imaging (e.g. after a surgical procedure or for prophylactic treatment),
- patient positioning (head to feet - which disturbs the usual positioning markers),
- changing the treatment machine (with possible change of patient's head to feet orientation),
- files handled by a large number of different people (transmission problem).

2. Main causes identified

Organisation of work

Effect of context on the organisation:
- the summer period affects the availability of resources (only one physicist present),
- change of machine: changing the patient's head to feet orientation.

Organisation of side check:
- no rules for checking the side to be treated,
- inconsistent practices,
- non-systematic verification of the side (restricted to certain locations),
- sectorisation of responsibilities (medical vs medical physics),
- confidence at each stage in the previous stage,
- numerous manual inputs into different documents,
- attention given to clinical accuracy (technical data) to the detriment of more general information (side not specified).

Technical tools and devices

- **inadequate opening of the field** to carry out imaging,
- **impossible to project a light field** and display rotation of an arm (tomotherapy),
- **impossible to record the side to be treated in the software** so that it shows up on the treatment console,
- **no possibility of positioning imaging** (Gamma Knife ®),
- **no encoding of the table in the R&V to check positioning** of the patient,
- **merging MRI and CT images not available** at the time of delineation.

Patient

- **radiotherapy treatment deadlines restricted** by the pathological context,
- **grouping certain treatment stages on the same day** to reduce journeys for patients living a long way from the centre (treatment performed at day 0).

3. Barriers that functioned

- **new radiographer** who takes up a file in progress,
- **seeing healing on the right** side to be treated,
- **questioning the patient or their spouse** about the side to be treated,
- **radiation oncologist present** at the treatment station during the first session.

4. Improvement actions implemented by the centres involved

- **obligation to indicate the side** to be treated in the prescription for side-specific irradiation,
- **modification of the software** to show the side to be treated on the console,
- **radiographers question the patient** at all treatment stages,
- **addition of the side parameter to the checklist** for parameters before starting treatment (in dosimetry and treatment),
- **check by the physicist** of the side of the dosimetry using a checklist,
- **check by the radiographer using a checklist,** comparing the side treated versus the side prescribed,
- **check of the side** during weekly staff meeting by reviewing clinical history.

> Centre experience

« Anyone can make a mistake! »

Interview with Dr Christine BRUNET*, doctor and public health inspector for the ARS- Brittany Regional Health Agency and* Dr Elisabeth LE PRISÉ*, manager of the radiotherapy department at the Eugène Marquis centre (Rennes)*

What actions have been taken by the Regional Health Agencies?

The role of the ARS is to ensure the quality and safety of healthcare in the region for which it is responsible. Notification of serious adverse events (SAE) is one of the main tools of the accident prevention policy used by the ARS. In as much as any person/centre can make a mistake, SAE notifications are used to share lessons drawn from errors that have occurred in other centres.

The roles, objectives and skills of the ARS complement those of the French Nuclear Safety Authority (ASN) on the question of improving the safety of patient care.

Could you illustrate your action with the event that occurred in 2013 at the Eugène Marquis Centre (Rennes)?

The Brittany ARS met teams from the radiotherapy department following a laterality error for a patient suffering from a rare eye condition.

Excellent discussions identified preventive action for the managers of Brittany's radiotherapy centres and managers of multidisciplinary team meetings. Two letters were circulated by the ARS to draw their attention to 'laterality' errors in radiotherapy.

Dr Elisabeth Le Prisé, you are manager of the radiotherapy department at the Eugène Marquis Centre. What lessons would you like to share with our readers?

Patients' file absolutely must include the surgical report to avoid errors, which requires coordination with other hospital departments. We now postpone the appointment with the radiation oncologist if the surgical report could not be obtained in time.

« Simplify practices for better management of increasingly complex techniques! »

Interview with Dr Philippe LAGARDE, radiation oncologist and manager of the Radiotherapy experience feedback multidisciplinary team at the Bergonié Institute in Bordeaux

What type of laterality error have you encountered?
In 2013 we discovered a laterality error in the treatment of an iliac pelvic ganglion recurrence. After being questioned by the patient, the radiographers performed a 'cross-check' that revealed the error in the side treated.

You led the analysis of the event with the medical manager, radiotherapy department quality manager and your hospital's quality department manager. What causes for the error were identified?
The radiation oncologist delineated the laterality under the effect of two influencing factors:
- *The change of treatment equipment: in fact, at the time the incident was notified, irradiation of the pelvis was carried out on a 'head-first' linac and on the other linac in 'feet-first'; the dosimetry scan is performed in the treatment position. The change of treatment equipment after the dosimetry scan therefore led to presenting this scan to the radiation oncologist for delineation with head and feet the wrong way round.*
- *Absence of radiological target (operative site without clip)*

What measures have you implemented to avoid laterality errors occurring?
We have systematised performing the 'head-first' scan to reduce the risk of a laterality error during delineation. The treatment table of our tomotherapy equipment, which dates from 2007, has been upgraded to modify the 'head-first' treatment position as in IMRT on the multi-purpose linac (Rapidarc technique).

In addition to this standardisation of practices, we have worked on procedures to increase vigilance over the side to be treated:
- *the computerised prescription, set up with templates, specifies the side.*
- *the radiotherapy preview is rechecked when performing the dosimetry scan (dose, volume, treatment equipment, etc.) and any change in this preview leads to a new radiotherapy preview (traceability) to replace the previous one.*

Do you have any recommendations for readers of the newsletter?
Simplify practices for better management of increasingly complex techniques! And avoid introducing multiple delineation tools, particularly in a university department receiving large numbers of junior doctors undergoing training, to reduce the risks of error.

> Steps for progress

1. Good practices

Prevention measures:

- take all necessary measures so that a radiotherapy cannot begin without first having the patient's complete medical file, including the surgical report, the pathological report and the imaging file,
- ensure, for paired organs, that the information from these different documents is consistent with that supplied by the patient or their family and the multidisciplinary team meeting report,
- meet deadlines for the different preparation stages for the treatment,
- avoid treatment on day 0,
- always question the patient at all stages of treatment, including a question about the side to be treated,
- medical staff present on day 0 to confirm positioning and validate images,
- inform the patient (and their family) about the treatment to be carried out and get the patient involved in their care.

Detection measures (radiation oncologist):

- review the file in detail during the first follow-up appointment (particularly for files identified as at risk – cf. Decoding),
- review the positioning images regularly.

Note: certain recommendations arise from coordination between departments (e.g. with the surgical department to obtain the surgical report sufficiently early).

2. Innovative initiatives

In surgery, the WHO Marking Guide

In October 2012, HAS and CEPPRAL* jointly published the surgical site marking guide, as part of the international High 5s project.

This is a WHO project to improve the safety of treatment for major patient safety problems, and particularly preventing site and procedural errors in surgery.

The guide presents detailed procedures regarding sequence, place, method and other aspects of marking the surgical site as well as recommendations about managing certain special situations.

This guide offers an overall approach for a team activity, with special attention given to the role of the patient and their family in the process. Specific examples show correct and incorrect marking of sites, and there are patient photos explaining procedures.

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> Methodological references

This section clarifies the terms and concepts used in the 'good practices' section

Prevention measures:
measures taken in normal operation of an installation to prevent errors, incidents and accidents;

Detection measures:
measures enabling detection of deviations or a worsening situation to restore the installation to normal operation;

Mitigating measures (limitation of consequences):
measures used to control an accident and to avoid making the situation worse.
These three levels of measures are derived from the concept of in-depth defence in nuclear safety.

The concept of in-depth defence consists of a set of actions, equipment or procedures grouped into levels, each of which is intended to prevent deteriorations likely to lead to the next level and to limit the consequences of failure at the previous level.

** CEPPRAL (Coordination for Evaluation of Professional Practices in healthcare in Rhône-Alpes)*

> Further reading

Radiotherapy

AAPM Safety Profile Assessment (SPA)
http://spa.aapm.org/default.aspx

The purpose of the SPA is to provide a practical means of assessing and improving the safety and quality of clinical radio-oncology. The tools comprises 92 questions and answers designed to evaluate clinical performance in key aspects of safety and quality.

Surgery

WHO High 5s initiative
http://www.has-sante.fr/portail/jcms/r_1498429/fr/linitiative-oms-high-5s?xtmc=&xtcr=1
Guide to marking the surgical site - High 5s
http://www.has-sante.fr/portail/jcms/c_1517677/fr/guide-de-marquage-du-site-chirurgical-high5s
Key points from the Guide to marking the surgical site
http://www.has-sante.fr/portail/jcms/c_1561432/fr/points-cles-du-guide-de-marquage-du-site-chirurgical

Pennsylvania Patient Safety Authority
http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Pages/home.aspx

Patient relationship

Guide to notification of treatment-linked damage
HAS Guide 2011
http://www.has-sante.fr/portail/jcms/c_1051851/fr/annonce-dun-dommage-associe-aux-soins-ameliorer-la-relation-soignant-patient

Experience feedback

Provide experience feedback today: Why? How?
IRSN PSN-SRDS report 2014-00019, March 2014 (in French)
http://www.irsn.fr/FR/expertise/rapports_expertise/surete/Pages/surete-retour-experience_PSN-SRDS-2014-00019.aspx#topPage

A few good questions to consider about your experience feedback system
Compendium review guide from FonCSI, no. 2014-01, February 2014 (in French)
http://www.foncsi.org/fr/publications/collections/cahiers-securite-industrielle/bonnes-questions-REX/CSI-REX-bonnes-questions.pdf

> Previously published bulletins

N°1 Identification du patient [Patient identification] (March 2011),
N°2 La première séance "à blanc" [The verification session] (November 2011),
N°3 Comment analyser vos événements significatifs de radioprotection ? [How to analyse your significant radiation protection events?] (July 2012)
N°4 Quels événements déclarer à l'ASN ? [Available in French only] (April 2013)
N°5 La dosimétrie in-vivo [In-vivo dosimetry] (December 2013)

french-nuclear-safety.fr > information > publications for the professionals
http://www.french-nuclear-safety.fr/Information/Publications/Publications-for-the-professionals

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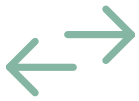

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