Patient safety

Paving the way for progress

N°2

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The verification session

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Société Française de Radiothérapie Oncologique SFRO

>Editorial

The first radiotherapy session, or verification session, is an essential component of risk control in radiotherapy. This appointement under the treatment machine provides an opportunity for all of the treatment parameters and patient positioning to be checked before treatment begins.

The second issue of the patient safety bulletin discusses the importance of this verification session.
The good practices presented are derived from current discussions by the three French learned bodies in the field of radiotherapy: AFPPE, SFRO, and SFPM. They are intended to prevent the errors that can cause events which are often repeated over the course of several sessions.

The Editor

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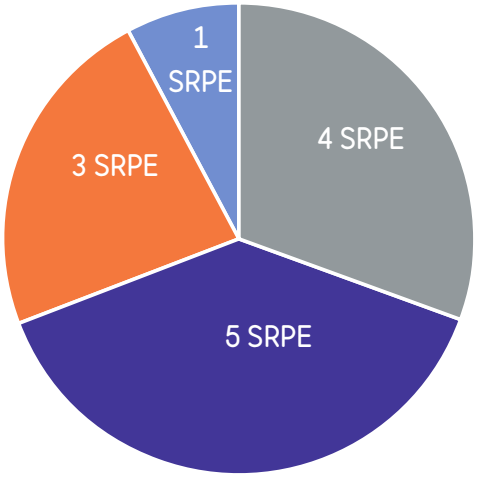
Patient safety - Paving the way for progress is edited by the French Nuclear Safety Authority (ASN) in the framework of the multidisciplinary working group dedicated to experience feedback to radiotherapy professionals.
Executive editor: Jean-Christophe Niel, Director General of ASN **/ Chief Editor:** Nathalie Clipet **/ Editorial committee:** French Society of Radiation Oncology (SFRO), French Society of Medical Physics (SFPM) and French Association of Radiographers (AFFPE) **/ Design:** Margoland®

>Key figures

In 2010, approximately 180,000 patients received radiotherapy treatment in France.
In 2010, ASN received 254 reports concerning a radiotherapy event.

The analysis presented here is based on 13 representative events that occurred in 2010 or 2011.

Of these 13 events:
- Four occurred in public healthcare facilities, five in regional cancer centres (CLCC), and four in private healthcare facilities,
- Nine were categorised as level 1 events, and four were categorised as level 2.



Sessions concerned

- 1 session
- 2 to 5 sessions
- 10 to 15 sessions
- All of the sessions

>Decoding

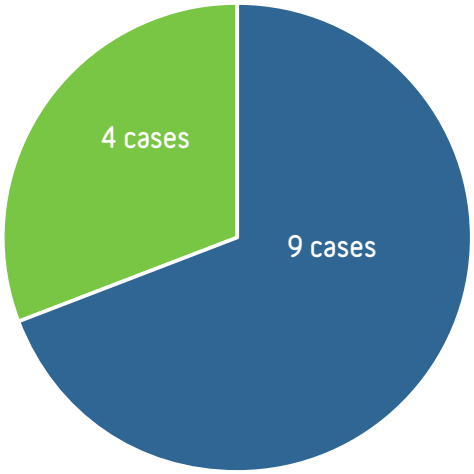
1. 1. Description of the events chosen and analysed

• Number of sessions concerned
One session: 4 significant radiation protection events (SRPE)
Two to five sessions: 5 SRPE
10 to 15 sessions: 3 SRPE
All of the sessions: 1 SRPE

• Location
Events related to the verification session are likely to concern all locations.

• Treatment technique
Of the 13 events declared, 12 involved patients treated by conventional external radiotherapy using photon or electron beams, and one involved extracranial stereotactic radiotherapy.

• Detection of the error
When?
The errors were detected at different stages of the treatment: when reading the images for the repositioning check (portal images), during or after the treatment session, during a treatment appointment, or during a post-treatment appointment.
By whom?
The radiographer, in 9 cases out of 13
The physician, in 4 cases out of 13



Detection of the error

- The radiographer
- The physician

2. Known consequences

The verification session is the last stage at which an error or inaccuracy committed in the preceding stages can be detected. Fractionated radiotherapy is based on the perfect repeatability of patient positioning, which requires great care and unfailing precision. Any error or inaccuracy at that stage is liable to be repeated during all or part of the treatment, and might then not be detected until unusual side effects appear or inadequate coverage of the target volume is detected at the time of a check during the treatment.
Incorrect positioning of the patient during the treatment preparation session can therefore have serious, acute, or long term side effects with regard to both the tolerance of healthy tissues and the control of the disease.

3. Main causes identified

Positioning checks
• **Insufficient technical quality** (lack of anatomical references) or radiological quality (EPID quality) **of the portal images**. In six SRPE out of 13, they did not allow the radiation -oncologist to detect a non-compliance with respect to the treatment plan,
• **Failure to check the treatment fields,** their junctions, shape, and positioning **by light projection** on the patient's skin,
• **Use of an incorrect reference image** (DRR).

Organisation of work
• **Verification session** not performed or incomplete,
• **Radiation oncologist** absent from the verification session,
• **Portal images checked by the radiographer** and approved after the start of treatment by the radiation oncologist,
• **Treatment parameter modification rights in the Record & Verify (R&V)** software inappropriately allocated to radiographers,
• **Use of several redundant information sources** (R&V and hard copy of treatment sheet),
• **Beams not masked and active** in the R&V despite being intended for a second phase of treatment,
• **Electron beams not programmed** in the R&V.

Technical tools and devices
• **No final patient positioning check imposed by the software,** in particular for treatments with several isocentres requiring the patient to be moved during a session,
• **R&V which does not allow to completely eliminate the hard-copy treatment sheet** from the process,
• **No possibility of automatic computerised transfer of certain treatment parameters** (particularly shifts) between the treatment planning system (TPS) and the R&V, which makes it necessary to copy them manually,
• **Problem with the transfer of irradiation parameters** between the TPS and the R&V.

>Steps for progress

1. Good practices

Systematically perform a verification session; this is essential before any radiotherapy.

• **Dissociate the check from the actual treatment,** whether or not it is performed in a dedicated session,
• **Hold internal discussions in each department to anticipate situations** in which the radiation oncologist and/or the medical physicist must be present (field junctions, breast, stereotactic radiotherapy, etc.). The radiographer must not end up in a situation where he/she needs to make a choice whilst treating the patient,
• **Consider implementing a checklist** specific to the practice in each centre,
• **Notify the medical physics department of any need to change a treatment plan** so that they can analyse and review the planned dose calculation.

Carefully check the positioning
• **Check the treatment fields by light projection on the patient's skin,** when the radiation method allows, especially in the presence of field junctions, electron beams, or for breast treatments,
• **Analyse in detail any patient positioning shifts outside the tolerance defined by the department,** even for apparently «simple» reasons (patient morphology, etc.).
• **Use the best available imaging equipment** in terms of performance,
• **Make double exposure portal images** with a wide enough field to include anatomical references, and have them approved by a physician before the start of treatment.

Avoid patient repositioning errors
• **Clearly identify** the isocentre,
• **Limit the number** of reference points,
• **Minimise shifts** with respect to the reference points,
• **Systematically mention any shifts,** even in the event of zero displacement,
• **Transmit important information** using simple visual indications (colour code, drawing, etc.), particularly for beams that cannot be viewed by portal imaging,
• **Set appropriate user rights** in the R&V software according to each user's level of responsibility.

2. Innovative techniques

Image-Guided Radiation Therapy

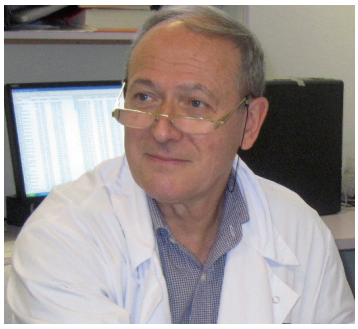
The high-performance radiation techniques developed in recent years require high precision to locate and define the volumes of interest (areas to be irradiated and organs at risk).

IGRT (image-guided radiation therapy) techniques satisfy this need, using various technologies:

- 2D imaging performed using a low-energy photon beam, such as systems including an x-ray tube and an associated detector built into linear accelerators or placed as a fixed installation in the treatment room,
- Cone beam computed tomography using a low-energy (kV-CBCT) or high-energy (MV-CBCT) photon beam.

>The experiences of the centres

Céline BRAMOULLE,
medical physicist at the Tours university hospital.



Jean-Michel ARDIET,
radiation-oncologist at the Bayard radiation therapy centre (Villeurbanne), with Valérie Caudrelier, medical physicist and quality manager for the radiation therapy department.

Anne DEMOUCHY,
radiographer at Centre Henri-Becquerel (Rouen).

What is the importance of the verification session?

JM. ARDIET : Precise positioning with a dual goal: local control of the tumour, and protection of organs at risk.
Since 2011, the Bayard radiation therapy centre has been using volumetric modulated arc therapy for prostate cancer and head and neck cancer. By modulating the intensity, the margins around the volumes of interest are reduced. Imaging is therefore very important for the quality of the treatment.

C. BRAMOULLE : For medical physicists, it is more important always to carry out a verification session without the patient. This stage is currently performed for IMRT only. It lets us check all the parameters at the treatment station and compare the calculated doses to the delivered doses.

A. DEMOUCHY : It is the starting point of the treatment and is essential in ensuring successful treatment. It requires us to be very careful and extremely alert.

What part do you play in this?

JM. ARDIET : The radiation-oncologist is like the conductor of an orchestra. His or her presence at the first session is programmed for potentially complex cases: unusual patient morphology, doubt concerning the treatment field angles with respect to the mechanical constraints, new irradiation in the region of a previously irradiated area, etc.

C. BRAMOULLE : The medical physicist guarantees the dose that can be delivered to the patient.

(...) The experiences of the centres •

At the Tours university hospital, he/she is not directly involved in the treatment verification session. He/she checks the planned dose calculation (dosimetry) in advance, as well as the technical file, fractionation, correct transmission of the treatment parameters via the R&V, and carries out the double calculation of monitor units.

A. DEMOUCHY : Before the treatment verification appointment, the team of radiographers spends half an hour checking all the data in the file (on paper and computerised). During the appointment, they greet the patient, check the patient's identity, and collect any information to supplement that given during the pre-radiation therapy appointment.
For breast cancer treatments, the radiographers draw the treatment fields on the patient's skin, and keep a photograph in the file. Finally, they check all the fields by light simulation and portal imaging or kilovoltage imaging.

The keys to success?

JM. ARDIET : Maximum preparation and anticipating the difficulties during the simulation CT scan acquisition session.

C. BRAMOULLE : Respecting the organisation of the department and the expected deadlines, as well as mutual trust within the team. Each professional has his or her own set of responsibilities and must apply some critical scrutiny whilst carrying them out, because each person participates in the joint effort to make the treatment run smoothly.

A. DEMOUCHY : Working in pairs is essential, because everything can be cross-checked: one radiographer confirms the opening of the patient file, the other confirms the closing, one announces the treatment parameters, and the other checks them.

Do you encounter any particular problems?

JM. ARDIET : Breast treatments are the trickiest because oblique and juxtaposed beams are used.

C. BRAMOULLE : Technical validation of the treatment plan that needs to be performed urgently, without the necessary perspective.

A. DEMOUCHY : The most complex set-ups involve the less common treatments (ventral decubitus, lateral decubitus, personalised immobilisation for limbs, etc.) and patients who are obese, in pain, or agitated.

Agnès Puyal Breszynski,
received treatment for breast cancer
at the Institut Curie from September 2010
to March 2011.

How did your treatment preparation appointment go?

I was calm. I had received information about the purpose of this verification session on the linac from my radiation oncologist, from explanatory leaflets, and during an appointment prior to the CT scan.
That was my opportunity to 'get to know' the machine and some of the patient care team. The radiographers took the time to explain how the treatment would happen, the importance of the markings applied to the breast, and the need for accurate positioning. They also answered my questions.
Above and beyond the obvious technical reasons for this appointment, it also gives the patient a reassuring first contact with a world that could otherwise be very frightening.

>Methodological references

'a posteriori' event analysis method rely on two reference models :

1. **The 'Root cause analysis' model** (cause tree),
2. **The global event analysis model** (such as ALARM, Association of Litigation and Risk Management, based on the Reason model).

Certain methods combine the two models, such as the ORION method developed from work carried out in the field of aviation safety. This is the method applied by review committees (CREx) to analyse precursor events in radiation therapy departments. The guide 'Review of Mortality and Morbidity' (RMM) drawn up by HAS (French health authority), published in November 2009, also suggests a methodology for the analysis of such cases (see 'Further reading', below).

Whichever method is used, the analysis of significant radiation protection events must allow the following to be identified:
• All causes, including indirect ones, that contributed to the occurrence of the event,
• All contributory factors, including organisational and human factors.

An exact reconstruction of the chronology of events and the causal links is essential. This must be accompanied by an identification of the failures that occurred and a ranking of the causes to define corrective actions. This approach assumes the prior existence of a clear, shared frame of reference which is integrated in the quality assurance approach.

www.vigie-radiotherapie.fr

The 'vigie radiotherapie' (radiation therapy watch) internet portal was launched in July 2011 as a joint project by ASN and the French Agency for the Security of Medicines and Health Products (ANSM). It allows radiation therapy professionals to satisfy all of their declaratory obligations concerning radiation protection and medical device vigilance:
• Regulatory references and declaration criteria
• Single declaration form
• Identification of recipients of the declaration according to the criteria indicated

(1) http://www.inrs.fr/accueil/demarche/savoir-faire/suivi/arbre-cause.html
(2) James Reason, **Human Error**, PUF, 1993

>Further reading

ORION© Method

Improving safety in healthcare organisations; Using experience feedback.
Report by MEAH, February 2008
http://www.anap.fr/uploads/tx_sabasedocu/SECURITE_RADIO.pdf
(Tool n°9)

Documents drawn up by HAS:

• Review of Mortality and Morbidity (RMM)
Guide 2009
http://www.has-sante.fr/portail/jcms/c_837036/revue-de-mortalite-et-de-morbidite-rmm-guide-2009

• Patient safety in interventional radiology' checklist
in cooperation with SFR (the French Radiology Society) and the interventional radiology federation
http://www.has-sante.fr/portail/jcms/c_1068103/check-list-securite-du-patient-en-radiologie-interventionnelle

• 'Patient safety in the operating theatre' checklist
http://www.has-sante.fr/portail/upload/docs/application/pdf/2011-01/checklist_secu_bloc_v2011_01.pdf

• Guide to announcing treatment-related damage
March 2011
http://www.has-sante.fr/portail/upload/docs/application/pdf/2011-01/checklist_secu_bloc_v2011_01.pdf

National and international publications

• Patient safety in External Beam Radiation Therapy.
E. Yorke, D. Gelblum, E Ford. AJR 196, April 2011

• Can and should the patient participate in radiation therapy risk management?
V Mollo et al. Cancer / Radiother 15 (2011) 176-181

• Radiation Oncology Safety Information System (ROSIS) – Profiles of participants and the first 1074 incident reports.
J Cunningham et al. Radiother Oncol. 97 (2010) 601-607

• Preventing Accidental Exposures from New External Beam Radiation Therapy Technologies
ICRP publication 112, vol 39 n°4, 2009

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ASN, November 2011