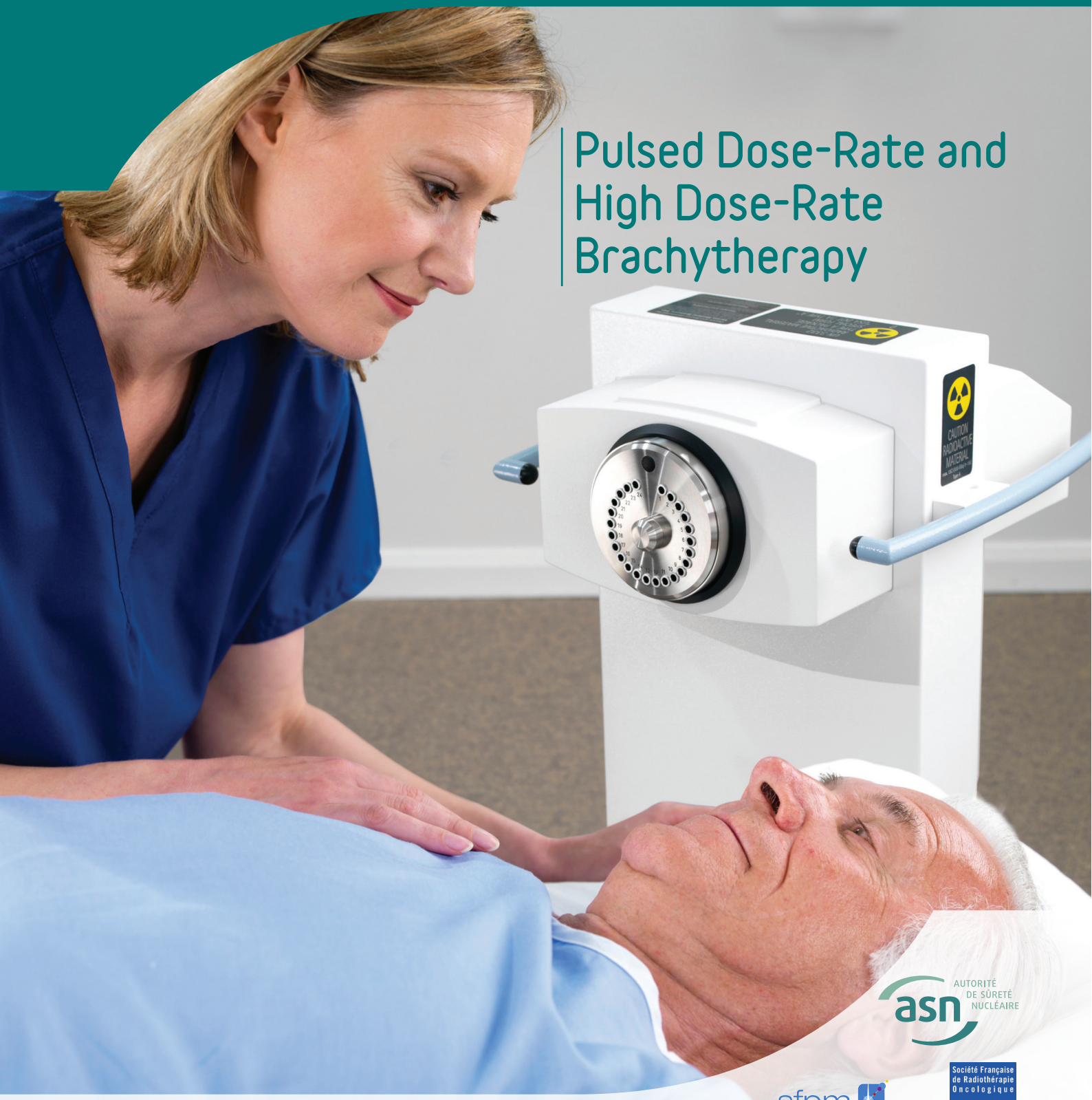
Patient safety

Paving the way for progress

N°8

June 2015



Pulsed Dose-Rate and High Dose-Rate Brachytherapy

Newsletter for
radiotherapy professionnals

> Editorial

Brachytherapy, which is particularly recommended for certain medical indications, has the advantage of delivering a very closely-targeted treatment with few secondary effects. However, it represents only 4% of radiotherapy treatments in France.

The relatively low number of brachytherapy treatments induces specific treatment safety issues. This is the subject of this bulletin No.8, devoted to the two main brachytherapy techniques that use an afterloader: pulsed dose-rate (PDR) and high dose-rate (HDR) brachytherapy.

The various sections of this bulletin address the major issues of brachytherapy: the training and organisation of teams, the traceability of the technical elements of the patient's file given that the afterloaders are not connected to a Record & Verify system, and oversight of the treatment, particularly at night in the case of PDR brachytherapy.

Lastly, we would like to take this opportunity to welcome the AFQSR (French Association for Quality and Safety in Radiotherapy) onto our editorial committee. Created in September 2013, the AFQSR groups the radiotherapy operational quality managers of public and private centres. It will provide the bulletin with the viewpoints and recommendations of the quality specialist.

We wish you enjoyable reading!

The Editorial Team

> Contents

Patient safety – Paving the way for progress is published 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 / **Author:** Aurélie Isambert / **Editorial Committee:** French Radiation Oncology Society (SFRO), French Society of Medical Physics (SFPM), French Association of Radiographers (AFPPE), French Association of Quality and Safety in Radiotherapy (AFQSR).
With the participation of: IRSN (French Institute for Radiation Protection and Nuclear Safety), ANSM (French Health Products Safety Agency) and HAS (French National Authority for Health) / **Photo credits:** Varian
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> Key figures

Brachytherapy in France

According to the SFRO's contributory report to the cancer plan of December 2011, brachytherapy represents 4% of radiotherapy treatments (i.e. 7527 treatments per year).

Two techniques are no longer, or virtually no longer, used today, namely low dose-rate brachytherapy using iridium-192 wires (the commercialisation of iridium wires stopped in 2014), and caesium source afterloaders (159 in 1995 versus 10 in 2012*).

Conversely, three techniques have been progressing strongly since 2000: high dose-rate (HDR) brachytherapy which today accounts for 52% of brachytherapy treatments, followed by iodine-125 seed implants (17%) and pulsed dose-rate (PDR) brachytherapy (15%).

Notifications received by ASN

During the years 2013-2014, ASN was notified of 23 significant radiation protection events (ESR) concerning patients in brachytherapy (criterion 2.1). Over that same period, 403 events involving external-beam radiotherapy patients were notified.

This bulletin concerns the events notified in 2013 and 2014 involving brachytherapy delivered using a PDR or HDR afterloader.
During these two years, 19 events concerning this type of treatment were notified.

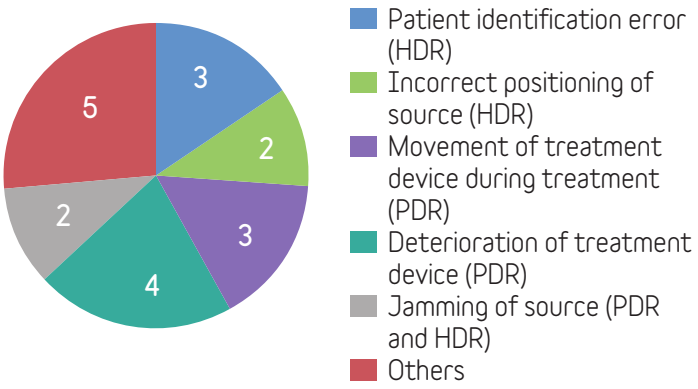
15 ESRs were rated level 1 on the ASN-SFRO scale, while the other 4 were rated level 0 or out of scale.

> Decoding

1. Description of the events notified to ASN

The notified events were caused by malfunctions that occurred at different stages of the treatment.

Distribution by cause of the 19 notified ESRs in brachytherapy



When starting the treatment:

1. Patient identification error (HDR):
   Three female patients in different centres received an HDR session with the treatment data of another patient. Two situations were encountered::
   - patient A is installed in the room and patient B's file is selected for delivery of the treatment,
   - patient A is called for her session. Patient B responds to the call and receives the HDR session.
2. Incorrect positioning of source (HDR) during 2 bronchial treatments:
   - incorrect positioning of the radiopaque markers during a session,
   - incorrect defining of the origin of the treatment channel (distal end) in the 2nd case.
3. Incorrect entry of the number of positions during manual programming of the afterloader (HDR).
4. Reversal of the 2 treatment channels (HDR) with respect to the planned treatment when connecting the catheters.
5. Omission of bolus material in a skin HDR brachytherapy.
6. Deformation of a catheter over time (elongation by a few millimetres) (HDR).

During treatment:

7. Movement of treatment device (PDR):
   Partial withdrawal (by slipping or pulling out) of the vaginal applicator in several cases, and movement of a needle during interstitial brachytherapy.
   On several occasions when the event occurred at night, the nursing staff on the oncology ward, not qualified for this type of act, tried to reposition the applicator without calling a doctor.

** Voir Peiffert et al, CanRad 18 (2014).*

8. Deterioration of treatment device (PDR):
   - separation of the probe and cylinder constituting the vaginal applicator, unhooking of the fasteners connecting the catheters to the plastic tubes of the customised gynaecological applicator, and catheter slippage,
   - breaking of probe at the cylinder connection caused by falling of the patient (applicator consisting of a vaginal cylinder stitched to the skin, and a probe),
   - probe found to be twisted due to the sitting position of the patient.

9. Jamming of source (PDR and HDR):
   This problem occurred at the end of an HDR treatment session and during a PDR session as a result of the patient falling.

Jammed source in high-dose-rate brachytherapy.

When carrying out high-dose-rate brachytherapy using a source afterloader, the source should retract automatically at the end of treatment to return to the storage position. In November 2014, an experience feedback sheet was published in collaboration with a centre that had to cope with the source jammed at the end of a high-dose-rate brachytherapy session. The centre shares its analysis and its tips to avoid this type of incident.

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

2. Contributory causes and factors identified by the centres

The analyses conducted by the centres do not always allow the identification of the root causes of the events notified to ASN. It should be noted that a lack of regular practise in certain treatment techniques is undoubtedly a contributing factor, even if has not been identified by the centres.

When starting the treatment:

1. patient identification error: same name, no identity photo in the file, no patient identification tag and verbal communication of patient identity, "oriented" questioning of patient, problem of punctuality of the patient (patient 1 late and patient 2 early for appointment) or of the radiographers;
2. incorrect positioning of the source (HDR): first bronchus treatment carried out with an afterloader newly installed in the department and with insufficient personnel training, start of treatment using new device during the annual vacation period.

When delivering the treatment:

3. Equipment problem:
   - no alarm to indicate separation should this occur,
   - design defect or deterioration over time.
4. Utilisation of the equipment:
   - surveillance camera (PDR room) directed towards the ceiling and not connected (monitor unplugged, photocopying machine plugged into the power socket),
   - poor attachment of the devices (PDR): problem when designing the customised applicator or poor retightening during patient care.
5. Patient behaviour:
   - movement or falling of the patient (PDR): patient suffering from nausea (abdominal contractions), patient suffering from agitation or anxiety, probable noncompliance with a low-residue diet resulting in more frequent visits to the toilet, which increased the risk of falling,
   - subconscious withdrawal of the device while sleeping (PDR).

> Steps for progress

Good practices - Recommendations

HDR and PDR :
- Carry out an a priori risk analysis when putting in place new equipment or a new treatment technique;
- Cross-check patient identities and treatment parameters;
- Limit treatment preparation and delivery to a small number of staff (radiation oncologists, physicists and radiographers) having received specific training in order to maintain and consolidate their mastery of the technique;
- Formalise in writing the tasks assigned to each professional involved in the management and treatment of the patients;
- Implement periodic inspection of the source transfer guide tubes, the applicators and the catheters (distal length, deformation, etc.).

R&V and brachytherapy

Given that the brachytherapy afterloaders are not connected to a Record and Verify (R&V) system which enhances treatment safety, as is the case in external-beam radiotherapy, additional safety barriers must be provided. Users must identify the steps involving risks and set up check points for both patient identity and treatment session recording. The tasks to perform and the persons capable of performing them must be formalised in writing. **The implementation of R&V systems in brachytherapy would enhance treatment safety: system manufacturers, the ball is in your court!**

PDR :

The patient :

- Give PDR brachytherapy patients a prior paramedical consultation to inform them of what the treatment involves and the importance of complying with the medical personnel's instructions to ensure the treatment runs smoothly;
- Analyse the patient's compliance with a PDR treatment beforehand (ability to understand and comply with the constraints associated with the treatment);
- In case of doubt about a patient's compliance, implement tightened monitoring during the treatment.

Monitoring during hospitalisation:

Unlike external-beam radiotherapy, there are no imaging devices available for verifying the position of the treatment device in brachytherapy.

Monitoring must therefore be based on other visual means (colour-codes, etc.).

- Enclose in the file an individual photograph of the treatment device to verify the position of the guides with respect to the applicator with markers on the sheaths or catheters to facilitate checking of the position of the applicator;
- Systematically check the treatment device at each visit by the nurses: it is suggested that a check be made every 2 pulses with signed confirmation;
- Restrict the monitoring of patients receiving PDR treatment to a limited number of staff members (nurses, nursing assistants) who have received specific training;
- Provide periodic training for the staff. This training can be ensured by the physicists and carried out in the brachytherapy room to consolidate the practical aspects;
- Define the conditions of patient care, particularly during the night (monitoring, conditions of intervention, responsibilities and authority delegation between nurses and doctors);
- Train the nursing staff on the ward in the rules concerning the actions to take in the event of abnormal situations involving the equipment (primarily the afterloader) or the patients (excessive agitation, fall).

> Medical centre experience

« Closer identity monitoring to enhance the safety of high dose-rate brachytherapy treatments »

Bergonié Centre, Bordeaux.

Dr Laurence Thomas, *radiation oncologist, head of the brachytherapy unit*

Sarah Belhomme, *medical physicist, medical physics department coordinator*

Event concerned: Patient identity error for an HDR brachytherapy session

Unlike external-beam radiotherapy, current HDR brachytherapy systems do not provide for a connection between the R&V system and the afterloader control console. You have been confronted with a patient identity error, what have you done to limit this type of error?

Further to this event, we thought of applying a bar code to the patients' administrative file. However, this system did not enable the treatment technical file to be opened on the afterloader console, therefore it only brought a small improvement in identification security. Consequently we have opted for tightened cross-checks. At each HDR treatment session the patient must present an "administrative passport" which they receive on the day the treatment planning scan is carried out.

After installing the patient in the treatment room, the physician and the radiographer place the treatment protocol on the treatment console. Then they each communicate the patient's identity to the physicist who loads the treatment plan onto the console (double information input).

In spite of everything, identity monitoring remains highly dependent on the involvement of the staff during the treatment...

Absolutely, we consider that having a small and experienced team limits identification errors: 2 radiation oncologists, 3 physicists and one expert radiographer are involved, mainly for HDR brachytherapy treatments.

Furthermore, at the Bergonié centre, the HDR brachytherapy sessions are all carried out on one day per week (10 to 12 patients/day). This organisation enables the on-duty physicist to manage all the HDR treatments of the day. In the majority of cases, it is the same physicist who prepares the dosimetries beforehand. Always out of concern for enhancing treatment safety, the radiographer who greets the patient at the first treatment session is usually the one who performed the planning scan with the applicator in place.

« In PDR brachytherapy, organise hospitalisation around a committed and trained team »

Lorraine Institute of Oncology, Vandoeuvre Les Nancy

Lydie Lemoine, health manager, brachytherapy department technical platform
Catherine Mayer, health manager
Sophie Renard-Oldrini, brachytherapy radiation-oncologist, head of the brachytherapy unit technical platform
Christelle Cuisinier, brachytherapy radiographer
Isabelle Buchheit, brachytherapy medical physicist, head of the medical radiation physics unit.

Event concerned: partial applicator withdrawal during a gynaecological PDR brachytherapy

PDR brachytherapy requires several days of hospitalisation with extremely limited mobility. Is the patient's ability of to accept these severe constraints on mobility assessed before confirming the choice of the PDR treatment?

In a number of indications there is no alternative to brachytherapy in terms of effectiveness. The principle of PDR treatment and the hospitalisation room are presented to the patients during a prior appointment, but it is not always easy to identify the patients who might be unable to put up with the treatment constraints. Calm patients sometimes react badly to prolonged immobilisation in a hospital room.
In extreme cases (patients with mental disorders, for example), we sometimes administer medication or attach the mould to the vaginal mucous membrane with stitches.

How do you promote the transmission of information between the technical platform and the nursing staff on the ward?

The brachytherapy and oncology wards are situated next to each other, which facilitates communication between the staff.
When connecting the afterloader to the patient, the transmission of the treatment data takes place at the foot of the patient's bed, with the viewing of the equipment in place between the radiographer who helped place the applicator in the operating theatre and the nurse, then between the nurses at each change of shift.

You have had to deal with a case of partial withdrawal of a vaginal applicator. What changes were made in treatment monitoring following this event?

A folder containing photos of the typical indications has been created, with images corresponding to what the nurses see when they perform their visual checks and the 3 or 4 points to be checked. The folder is available in the nurses' office. If a treatment presents a particularity (implantation of unusual equipment or vectors, another location being treated), an individual photo of the application is taken and enclosed in the patient's file. In order to detect any rotation of the mould, self-adhesive tapes with a colour code are placed on the customised applicator to identify the right-hand and left-hand probes. Coloured adhesive tapes put in place in the operating theatre on the sheaths next to the vulva enable movement of the applicator to be detected. In the case of treatment of the anal canal, the stitches are checked regularly.

When the event occurred, the team in charge of the hospitalisation had a doubt about the position of the applicator during the evening but the duty doctor was not called. What have you done to prevent this situation from occurring in the future?

Since the event, 2 or 3 in-house theory and practical training sessions have been held for the nursing staff on the oncology ward (about 3 hours) and will be repeated each year. The practical part is carried out in a PDR room with use of the afterloader and the applicators.
These are supplemented by more closely-targeted one-off training sessions to answer the individual questions of the nurses. Some of the nurses moreover went to the operating theatre to observe the placement of applicators. The personnel numbers (nurses and nursing assistants) working in brachytherapy was reduced at the same time.
The quality requirements baseline has been updated regarding the need to call the duty radiation oncologist if there is the slightest doubt or problem during the night, including when near the end of treatment: movement of a vector device, irradiation time, number of pulses remaining, etc. The brachytherapy teachers, including when training new interns, insist on this point and underline that it is more dangerous to continue a treatment in the wrong position than to stop it and resume it the following morning.
As a result, telephone calls to the night-duty radiation oncologist are much more frequent, and all the more so since this instruction has also been conveyed to the duty doctors.

> Further reading

Brachytherapy

ASN recommendations concerning radiation protection of patients and professionals in brachytherapy.
Letter addressed to the heads of radiotherapy - brachytherapy departments, January 2013 [in French].
http://professionnels.asn.fr/Activites-medicales/Curietherapie/Lettres-circulaires-en-curietherapie/Recommandations-adressees-aux-professionnels-de-radiotherapie-curietherapie

Expert appraisal report on brachytherapy
SFRO contributory report to measure 22.3 of the Cancer Plan 2009-2013, December 2011 [in French].
http://www.siriade.org/lettreSFRO/curietherapie.pdf

Stopping of the sale of iridium-192 wires in France: proposal from the brachytherapy group of the French Society for Radiation Oncology.
Peiffert D. et al. p. 441-446, Cancer Radiothérapie 18 (2014) [in French]

Implementation of the global risk analysis in pulsed-dose rate brachytherapy: Methods and results.
Mazeron R et al. p.89-97, Cancer Radiothérapie 19 (2015)

INRS sheets on brachytherapy [in French]
http://www.inrs.fr/

Prevention of High-dose-rate Brachytherapy Accidents.
ICRP Publication 97. Ann. ICRP 35 (2005).

Comprehensive brachytherapy. Physical and clinical aspects.
Venselaar J. et al. CRC Press, 2012.

Events analysis and risk analysis

Patient safety - Ensure the management of risks associated with treatments in healthcare centres.
HAS Guide, 2012 [in French]
http://www.has-sante.fr/portail/upload/docs/application/pdf/2012-04/okbat_guide_gdr_03_04_12.pdf

«HOSF: in-depth analysis of events.»
Document of the ICSI (Institute for an Industrial Safety Culture), 2014 [in French]
http://www.icsi-eu.org/docsi/fr/fhos-l-analyse-approfondie-d-evenement-f285?id_cible=1

Identity monitoring

Bulletin No.1 "Patient safety" - Patient identification
March 2011
http://www.french-nuclear-safety.fr/Information/Publications/Publications-for-the-professionals

> Previously published bulletins

- **N°1** Patient identification (March 2011)
- **N°2** The verification session (Nov. 2011)
- **N°3** How to analyse your significant radiation protection events? (July 2012)
- **N°4** Which events are to be declared to ASN? [Available in French only] (April 2013)
- **N°5** In-vivo dosimetry (December 2013)
- **N°6** Laterality errors (May 2014)
- **N°7** Record and Verify: recording errors! (March 2015)

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

TO BE NOTED

Forthcoming changes at www.vigie-radiotherapie.fr

Before summer 2015, www.vigie-radiotherapie.fr will become a true on-line events notification portal. This will have little impact on the way the form is used, but will be more practical for users: the notifications filled out by the centres will be sent automatically to the appropriate authorities.

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ASN, June 2015