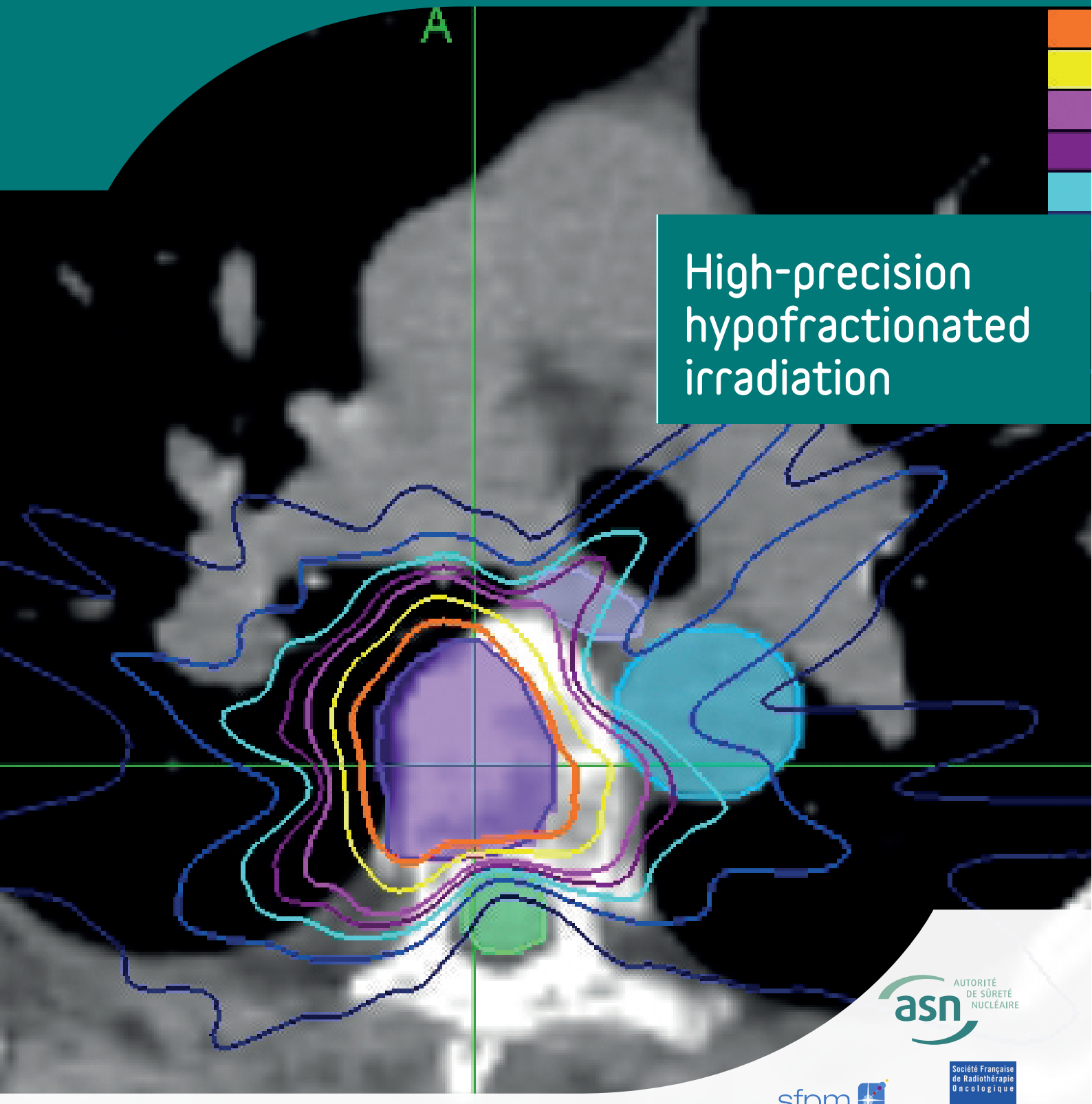
Patient safety

Paving the way for progress

N°9

September 2016



High-precision hypofractionated irradiation

Newsletter for radiotherapy professionnals

> Editorial

Nearly 2/3 of the events occurring during high-precision hypofractionated stereotactic radiation treatment[1] and notified to ASN have had or are likely to have clinical consequences for the patient.
In the light of these figures, in 2016, ASN will increase its oversight of this type of treatment, which delivers high doses in a small number of sessions.
Hypofractionated radiation treatment is indicated primarily for the treatment of small tumours that are poorly accessible to surgery, sometimes inoperable, such as intracranial lesions and tumours in the lungs, the liver or the vertebrae.
The treatments necessitate highly precise targeting of the volumes to irradiate, made possible by the development of sophisticated devices for repositioning the patient, taking into account and limiting possible movements of the target volume within the patient during the session, and delivering the dose.
The corollary of the medical progress resulting from these cutting-edge technologies is that the implications for patient radiation protection are potentially more serious. In bulletin No.9, the testimonials of the Antoine Lacassagne Centre in Nice and the Oscar Lambret Centre in Lille urge that the utmost vigilance be exercised. Errors such as misidentification of vertebrae or laterality errors, which can have potentially serious consequences, cannot be ruled out.
The good practices resulting from the reflections of the editorial committee and the recommendations of the GPMED[2] on the new techniques in radiotherapy provide ways of optimising treatment safety.

We wish you enjoyable reading.

The Editorial Team

> Sommaire

[1] Bulletin No.9 addresses hypofractionated treatments using photon beams, excluding pain-relief treatments.

[2] Advisory committee of experts in radiation protection for medical and forensic applications of ionising radiation

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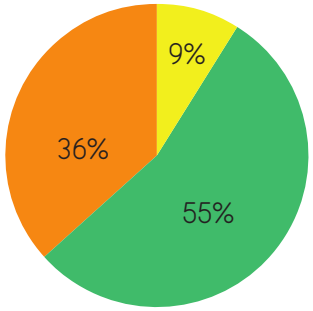
> Key figures

Rating on the ASN/SFRO scale of significant radiation protection events (ESR) concerning hypofractionated stereotactic treatments

11 ESRs between June 2013 and August 2015.

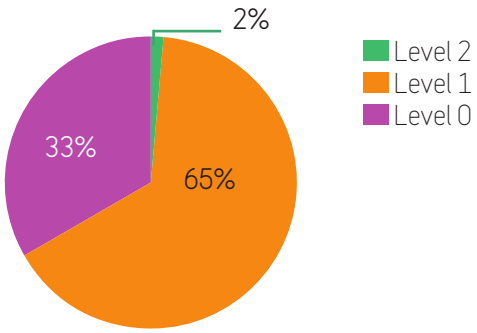
- Level 1: 4
- Level 2: 6
- Level 2+: 1



The impact of an error in a hypofractionated radiation treatment can be potentially much more significant than with other treatment methods. This is due in particular to the high doses delivered with each fraction or to high dose gradients between the tumour volume and organs at risk (OAR).

Nearly 2/3 of the significant events occurring during high-precision hypofractionated radiation treatments notified to ASN between June 2013 and August 2015 were rated level 2 or higher on the ASN/SFRO scale, which means that they have had or are likely to have clinical consequences for the patient.

For the purpose of comparison, ASN/SFRO scale rating of ESRs concerning the other types of treatment between 2013 and 2015



Unlike hypofractionated radiation treatments, events having occurred during other types of radiation treatment are virtually all rated level 0 or 1 and therefore have no clinical consequences for the patient.

> Decoding

1. Description of the events notified to ASN

Type of error

- Patient positioning : 4
  - Misidentification between vertebrae T8 and T9
  - Treatment performed without rotation of table
  - Reversal of respiratory gating parameters (between inspiration and expiration phases)
- Volume : 5
  - Treatment delivered to the target of a preceding treatment: 4
  - Laterality (wrong side) error: 1
- Interchanging of 2 patients: 1
- Field size: 1

Types of devices used to deliver the hypofractionated treatments on which the ESR's in question occurred:
Cyberknife : 5 ESRs
Gammaknife : 3 ESRs
Non-dedicated linear accelerator: 3 ESRs

Number of treatment sessions concerned:
1 incomplete session (1 beam): 1
1 complete session (with dose > 10 Gy): 5
2 sessions: 1
Total: 4 (including 3 single-session treatments)

Who detected the error?
Radiographer: 5
Radiation oncologist: 2
Medical physicist: 3
Patient: 1

Location of target volume:
Pulmonary (lungs): 4
Cerebral lesion: 6
Hepatic (liver): 1

2. Contributory causes and factors identified by the centres

The causes of the events occurring during hypofractionated stereotactic radiation treatments are similar to those identified during more common treatments.
The specific errors tend to be linked to successive irradiations (irradiation in a previously irradiated area, 2nd - 3rd location in the same organ, etc.), which are more frequent in high-precision hypofractionated radiation treatments than in more common treatments.

The immediate causes are associated with errors in patient positioning, target volume or patient identification (interchanging of 2 patients).

The causes of wrong-patient and wrong-side treatment errors presented in bulletins No. 1 and No. 6 can be transposed to hypofractionated radiation treatments.
Typical examples include misidentification of vertebrae (T8 and T9), errors associated with multiple locations or re-irradiations, inadequate image quality or use of the wrong image, a poorly visible target volume, clip tracking using the wrong clip, a patient suffering pain and having to be repositioned several times.

The **more deeply-rooted causes** include problems with skills management (including the training of radiographers at the treatment workstation), work organisation (interruption of tasks, lack of rigour in the order in which patients are taken, incomplete medical files, inadequate defining of validation checks to carry out, insufficient consideration of the impact of increases in activity on operators' work), communication (numerous people involved in the treatment of the same given patient) and lastly, the ergonomics of the software (for example: accidental unchecking of the MLC box when modifying a field in the treatment file).
Moreover, poor interoperability between the different treatment planning systems (TPS) penalise the operators who do not have access to all the information, particularly that concerning previous treatments. Here again, difficulties in keeping to schedules foster the occurrence of errors.

It is to be noted that some technical safety barriers, such as position verification imaging, are not available for hypofractionated radiation treatments performed by Gammaknife (older devices).

The multifactorial nature of the causes of event occurrence is illustrated in the following analysis of the accidental interchanging of 2 patients receiving a single-session treatment (classification inspired by the ALARM grid)

Factors associated with the task	
Defining tasks, scheduling, planning	- Patient identity verification procedure not clear (distribution of roles); - The patients are taken in tacit order, based on the order of the files on the table and the position of the beds. Regulation of activity lost from sight if it is decided to change the order in which patients are taken (bed position and order of files not changed); - Grouping together of the development/validation phases of treatment plans (always the case with a physician on account of his availability) resulting in patients waiting in the same place at the same time and a 1st late start of treatment; - Regular overtime hours (impact on job attractiveness).
Factors associated with the individual	
Physical or psychological stress factors	- Poor physical/mental disposition due to high work load with numerous interruptions in tasks (imaging/treatment unit interface, etc.) contributing to the failure to make a final patient identity verification.
Factors associated with the team	
Communication	- Communication deficiency within the team (change of programme, identity check).
Factors associated with the work environment	
Premises	- Cramped facilities (difficult to move beds)
Supplies and equipment	- Paediatric perfusions regularly used for adults (proximity of paediatrics department); - Sharing of equipment (stereotactic frame between treatment unit and operating theatre) and difficulty of access to the accident and emergency MRI device delaying start of treatment; - Ageing of cobalt-60 sources increasing treatment duration.
Factors associated with management	
Management of treatment quality and safety	- Quality assurance system failing to take into account changes in practices since the start of the activity.
Factors associated with the context	
Health policy	- Increase in the number of treatments (development of the indications); - Increase in cerebral metastases (longer treatment times).
Reporting culture	- Failure to notify the use of inappropriate perfusion equipment.

> Steps for progress

1. Good practices

In the case of high-precision hypofractionated treatments, the requirements must be adapted to the potential risks associated with the high doses delivered and the small number of treatment sessions (therefore the consequences of an error are potentially more serious).

Patient identification:

Define a patient identity verification procedure that involves the patient and a specific procedure for patients who are sedated or unable to respond to the standard procedure.

Treatment preparation:

- Define an explicit designation for the target volumes. Avoid using the terms PTV (planning target volume), GTV (gross tumour volume) with no other indications. The year can be specified if it is discriminating. E.g.: PTV Temporal R 2015-09.
- Verify the laterality (side to treat).
- In the case of successive treatments:
  - Reinforce the traceability of the preceding treatment history of a patient as soon as the planned new treatment is prescribed;
  - Define a methodology for importing images (CT scans, MRI, structures, etc.) into the TPS to guarantee that the files of the new envisaged treatment are used for the planning and not those of a preceding treatment;
  - Have tools for summing the dose distributions of the different treatments to estimate the doses delivered to the organs at risk and to healthy tissues, and visualise - if applicable - dose overlapping causing exceeding of permissible doses.

Patient positioning:

- Trying to be extremely precise (millimetre-scale adjustments) can lead to big mistakes:
  - Avoid the placement of a single clip to limit the risk of performing the treatment on a clip corresponding to a preceding treatment;
  - Avoid basing positioning on a single numerical indicator;
  - Before starting the treatment, zoom-out the images, identify a few singular points on the actual images and verify that they project to the right place on the reference image and vice versa.
- Carry out a "verification session";
- Organise double validation of the repositioning images on the treatment station;
- Carry out a systematic medical verification of patient set-up:
  - All the beams/arcs at the first session;
  - The first beam/arc for the subsequent sessions.

Verification of dose by in vivo dosimetry (if feasible):

If the results are out of tolerance, immediately look for the cause of the measurement nonconformity, and do not authorise the next session until the cause has been identified.

Training:

- Provide assistance to radiographers when starting work on complex and specific techniques;
- Ensure that radiographers remain at a given treatment work station to consolidate their training.

Organisation :

- Harmonise practises within a given team. Failing this, assess the practises in order to validate or invalidate them;
- Ensure compliance with internal procedures;
- When implementing a new technique, re-assess the organisation and verification procedures after the start-up phase, when number of patients treated increases;
- Take into account the good practices defined by the French Society of Medical Physics (SFPM) for the quality controls.

Risk of misidentification of vertebrae with Cyberknife

Event (Oscar Lambert Centre):
Positioning error further to misidentification of vertebrae during a treatment using Cyberknife with the Xsight Spine algorithm.

The Xsight Spine algorithm is designed for treating targets in the spine (vertebral column) or correlated with the spine. The image repositioning method is based on the contrast created by the bones. A grid of points of interest is defined on the segmented DRRs (digitally reconstructed radiographs) produced from the planning scan and the definition of a region of interest around the vertebrae.
A similarity measurement is taken in the region of interest (% of false nodes). It depends on the size of the grid and is specific to each patient. In the event in question, the misidentification concerned vertebrae T8 and T9. As these two vertebrae are very similar, it is particularly difficult to distinguish them on the 2 oblique views. The Xsight Spine algorithm similarity measure was not sufficient to ensure correct positioning.

Measures applied since the error was detected:
- After positioning on the targeted vertebra, the superjacent and subjacent vertebrae are tested with the same Xsight Spine image and calculation parameters. If the similarity measure gives a better result, the initial positioning must be called into question;
- The centre tested the measurement of the difference between the longitudinal coordinates of the suprasternal notch and the treatment position which seemed to be a reliable anatomical reference. However, the test turned out to be only partially conclusive and finally was not retained.

2. Recommendations of the GPMED (Advisory Committee of Experts in Radiation Protection for Medical Applications of Ionising Radiation)

In 2015, the GPMED issued 12 recommendations on the implementation of "new techniques and practices" in radiotherapy, of which the benefits and risks had been widely discussed 5 years earlier at the international radiotherapy conference organised by ASN with the support of the WHO (World Health Organisation) and the IAEA (International Atomic Energy Agency).

The GPMED's recommendations address both organisational and technical questions and aspects relating to human resources. They inform the centres of the conditions to be satisfied before purchasing new equipment or implementing new practices.

Eric Lartigau and Albert Lisbona, *coordinators of the working group (WG) mandated by the GPMED*

1. In what ways does work on the new radiotherapy techniques and practices seem important to you?

The implementation of a "project methodology" when deploying new techniques and practices in radiotherapy is essential for the quality and safety of treatments for patients and medical staff alike. It involves all the actors, from the manufacturers to the hospital administrators, the physicians, physicists and radiographers who use the equipment, as well as the patients in feeding back experience and therapeutic results. This work has confirmed the importance of adopting a project approach as soon as the use of a new technique or practice is envisaged in radiotherapy.

2. What are the main messages you would like to pass on to new users, to the institutions and to equipment manufacturers?

Radiotherapy benefits and will continue to benefit from technical changes, advanced practices and new therapeutic schemes in the direct interest of the patient and society. The future of our radiotherapy practices is dependent on close collaboration within the teams. This collaboration must be recognised and encouraged by hospital administrators by providing the necessary human resources. Appropriate regulatory support from ASN, ARS (Regional Health Agencies) and HAS (French National Authority for Health) remains vital, aided by the manufacturers and, above all, the peers: the notion of auditing good clinical practices and medical physics is a key factor in our document.

3. What follow-ups have been given to these recommendations?

The recommendations were examined by the National Radiotherapy Committee at the end of 2015. ASN referred the matter to the Ministry responsible for health (DGOS - General Directorate for Treatment Offering, and DGS - General Health Directorate) and the health agencies concerned, namely INCa (French National Cancer Institute), ANSM (French Health Products Safety Agency) and HAS, in order to define the actions deemed necessary, including with regard to regulations. The conclusions of the GPMED were also transmitted to the European Commission, the IAEA and the WHO.

> Medical centre experience

« In the cases of re-irradiation, the risk is maximal: no questions must remain unanswered»

Interview with Dr PY Bondiau, *radiation oncologist at the Antoine Lacassagne Centre in Nice.*

Event:

During the hypofractionated stereotactic treatment of a second target volume, the first fraction of the new treatment was delivered to the target volume treated one year earlier. The 2 target volumes were situated 10 cm from each other in the same pulmonary lobe.

What share do hypofractionated stereotactic treatments represent in the activity of your department?

More than 500 patients per year receive hypofractionated stereotactic treatment on Cyberknife, that is to say more than 20% of our centre's radiotherapy treatments. And this number will increase in the coming years, given the very good clinical results.

Are these treatments subject to particular vigilance?

A procedure has been developed internally concerning the "medical control points for validating treatments on the Cyberknife console" for each repositioning method used (6D skull tracking, Xsight Spine, etc.). To reduce the risk of confusion, we have set a clip movement threshold at 1.5 cm beyond which it cannot result from respiratory movements alone and questions must be asked. Furthermore, each week the physics team spends half a day specifically checking the Cyberknife.

At the treatment station, an expert radiographer is responsible for keeping the quality documents up to date and for training new radiographers on the station (usually for 4 to 5 months).
Two secretaries are necessary due to the high proportion of new patients and the time required to constitute the medical file and gather the various elements.
The team is particularly attentive to cases of re-irradiation. In these cases, which are relatively frequent (1 patient in 5), the risk is maximal: the medical file must be perfectly clear; there must be no unanswered questions.

What reasons can explain the failure to detect the location error on the Cyberknife control imaging?

The position of the clips on the image varies depending on the respiratory phase. The 2 sites, one treated and the other to be treated, were situated in the same pulmonary lobe and projected close to each other. Furthermore, the images displayed on the treatment console are small in size.
However, two factors were chiefly to blame: firstly the Cyberknife was prepositioned on the wrong clip, and secondly excessive confidence was placed in the system for automatically identifying the pulmonary clip on the images. Clip identification was announced with a confidence level of 100%, except that it was the wrong clip...

Have you identified other risks associated with use of the Cyberknife?

We detected in good time a repositioning problem linked to a vertebrae identification error on the kV imaging. Following this precursory event, we instituted systematic verification of the 2 positioning control images for treatments necessitating identification of vertebrae. We click on identical structures on the actual image and on the simulation image with a screen shot to keep a record of it. A few months ago we extended this protective barrier to the treatments with clips.

The 12 recommendations of the GPMED on the conditions of implementation of new techniques in radiotherapy and the associated practices - June 2015:

1. Create an Advisory Committee of Experts comprising professionals having contact with representatives of the health and radiation protection authorities concerned
2. Organise clinical audits by peers
3. Verify the prerequisites of a centre before starting to implement the new technique or practice
4. Ensure rigorous and robust project management, including the medical-economic aspect
5. Human resources: adapt the human resources when setting up and using innovative or special techniques
6. Integrate the changes in techniques and practices into the initial and continuous training as soon as they arise, and reinforce the role of the manufacturer
7. Improve the testing of the technical and dosimetric performance of new equipment or techniques at acceptance testing, and periodically thereafter (quality control)
8. Supervise external services in medical physics
9. Develop the prospective collection and analysis of data concerning radiotherapy patients for the new techniques
10. Enhance the informing and involvement of patients
11. Revise the INCa approval criteria for the practice of radiotherapy
12. Improve the dissemination of information relative to medical devices vigilance and experience feedback

To consult the complete report:
http://www.asn.fr/Informer/Actualites/Nouvelles-techniques-en-radiotherapie-et-pratiques-associees

> Further reading

On-line notification of events at www.vigie-radiotherapie.fr !
Since 15th July 2015, the event notifications made by the centres are automatically transmitted to the authorities concerned.

Hypofractionated radiotherapy

Hypofractionated radiotherapy: what rules are to be followed?
Supiot S. D. et al. p. 421-425, Cancer Radiothérapie 19 (2015)

Hypofractionation in radiotherapy: an endless cycle.
Cosset JM et al. p.355-362, Cancer Radiothérapie 17 (2013)

Radiation safety oversight and experience feedback

SAFRON newsletter on Patient Safety in Radiotherapy
• *June 2015* "Limiting Distractions and Interruptions"
https://rpop.iaea.org/RPOP/RPoP/Content/Documents/White-papers/2015_02Newsletter.pdf
• *March 2016* "Learning from Near Misses"
https://rpop.iaea.org/RPOP/RPoP/Content/Documents/White-papers/SAFRON_March2016.pdf

RO.ILS-Radiation Oncology incident learning system-quarterly report Q1 2015
https://www.astro.org/uploadedFiles/Main_Site/Clinical_Practice/Patient_Safety/Radiation_Oncology_Incident_Learning_System/Q1_2015_Report.pdf

> 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)
N°8 Pulsed dose-rate and high dose-rate brachytherapy (June 2015)

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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