Patient safety

Paving the way for progress

N°7

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ansm
Agence nationale de sécurité du médicament et des produits de santé

Record and verify: Recording Errors

Newsletter for radiotherapy professionnals

asn Autorité de sûreté nucléaire

afppe

sfpm Société Française de Physique Médicale

Société Française de Radiothérapie Oncologique SFRO

> Editorial

During a survey conducted at the end of 2013 by the SFPM (French Society of Medical Physics), 52 radiotherapy centres - that is to say 98% of the respondents - declared that they had experienced recording errors in the Record and Verify (R&V) system. Even if no clinical consequences have been reported to date, there is a risk of exceeding the prescribed dose, which can be critical in the case of hypofractionated radiotherapy treatment.

The R&V system is designed to reduce the risk of errors in the treatment parameters. Bulletin No.7 addresses errors in the recording of treatment parameters, but excluding problems in transfer from the treatment planning system (TPS) to the R&V system, and manual data entry errors.

The subject falls within the scope of medical devices vigilance, which is why this bulletin has been produced in close collaboration with the ANSM (French Health Products Safety Agency).
It contains the results of the investigations conducted with users and manufacturers, the testimonials of the Le Raincy-Montfermeil hospital and the St Vincent Centre in Saint Malo, and an analysis of the possible consequences of these malfunctions put forward by the AFQSR (French Association of Quality and Safety in Radiotherapy).

We wish you enjoyable reading!

The Editorial Team

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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)
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> Background: medical devices vigilance in radiotherapy

The aim of medical devices vigilance is to prevent the occurrence or recurrence of incidents and risks of serious incidents involving medical devices by taking appropriate preventive and/or corrective measures. It is defined in Articles L. 5212-2 and R. 5212-1 of the French Public Health Code and applies to all medical devices once they have been put on the market, and to medical radiotherapy devices in particular.

The ANSM is responsible for medical devices vigilance. In this capacity it has set up a system for centralising reports and alerts from patients, health professionals and manufacturers. The ANSM analyses and assesses the transmitted reports and, if need be, takes the necessary measures to improve the safety of the medical devices concerned.

Two types of actions contribute to medical devices vigilance:

Reporting incidents to the ANSM

The health professionals, the local medical devices vigilance representatives, patients and third parties report incidents using a CERFA form that includes a notification aid flow diagram.
The manufacturers are also required to report incidents or risks of incidents.

For medical radiotherapy devices that are subject to medical devices vigilance rules, the joint ASN/ANSM portal at www.vigie-radiotherapie.fr facilitates reporting.

Field safety corrective actions

These are the actions taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health of patients, users or third parties associated with the use of a medical device which has already been placed on the market. A Field Safety Corrective Action (FSCA) is notified to the customers and/or users by means of a Field Safety Notice (FSN).

An FSCA can consist in a modification, an exchange, a recall of the medical devices concerned, or the updating of the equipment pool, of utilisation recommendations, of patient monitoring recommendations, etc.

Assessment of the incidents

After recording and sorting the incident reports, the ANSM assesses them on the basis of 3 factors: frequency, seriousness and detectability. The Agency bases its assessment on the users' declarations and the manufacturers' analyses.
The ANSM has the possibility of organising any studies or work deemed necessary concerning the safety of use of medical devices (Article L. 5212-2 of the French Public Health Code).

> Key figures

The events associated with recording errors in the R&V system have been notified either jointly to ASN (on account of radiation protection) and to ANSM (on account of medical devices vigilance), or only to ANSM if the incident had no consequences for the patient.

Notifications received by ASN

Between 2011 and 2014, ASN received 869 notifications of events in external-beam radiotherapy involving a patient.

14 of these signification radiation protection events (ESR) concerned R&V system recording errors:

- 3 ESRs were rated level 0 on the ASN-SFRO scale,
- 3 ESRs were rated level 1 on the ASN-SFRO scale,
- 8 of the notified events did not enter into the ASN notification criterion 2.1 and are therefore listed as "out of scale" events.

The R&V system recording errors do not always enter into the ASN notification criteria because the dose errors are often less than 5% of the prescribed dose. The number of notifications made to ASN is therefore not representative of the scale of the malfunctions.

Reports received by the ANSM

Between 2011 and 2013, the ANSM received 319 medical devices vigilance reports relating to external beam radiotherapy, of which 15 concerned a recording error in the R&V system.

These incidents were detectable and had no clinical consequences for the patients.

The incidents do not always enter into the mandatory reporting criteria (see the ANSM notification aid flow diagram link in the "Further reading" section). It is therefore likely that the number of incidents concerning R&V system recording errors inventoried at the ANSM is less than the number of events that actually occurred (see Decoding - SFPM survey).

> Decoding

1. Description of the events

The problems associated with the recording of radiotherapy sessions in the R&V system chiefly concern complete or partial non-recordings of treatment sessions and sometimes non-stored imagery for the control of patient positioning.
Further to unscheduled interruption of the treatment (electrical power failure, computer malfunction, emergency stop, etc.):

1. the delivered beam or session is not recorded and can be processed again. An alert message may or may not be displayed, depending on the type and version of the R&V system,
2. the numbers of MUs (monitor units) recorded and delivered are inconsistent.

Who detected the error?

In the very large majority of cases it is the radiographer who detects the error. In the case of one notification received by ASN it was the patient who alerted the radiation oncologist during a consultation in the course of the treatment.

Possible origins/causes identified or suspected by the notifying establishments

The recording problems have multiple causes, and occurred in particular further to:

- electrical power failures,
- intentional interruption of the beam,
- blocking of the R&V system.

The suspected causes include:

- a problem with the computing network,
- conflict between the R&V system and treatment console (communication failure).

The solutions are highly dependent on the centres concerned. Few appear to be able to be generalized.

2. SFPM survey conducted in 2013

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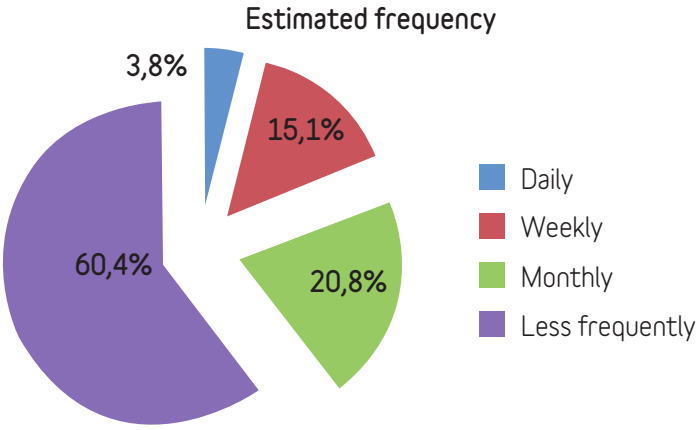
At the end of 2013, within the framework of a joint reflection by the learned radiotherapy societies[1] and ANSM, ASN and IRSN, the SFPM addressed a questionnaire to the radiotherapy departments on the occurrence of problems associated with the recording of radiotherapy sessions in the R&V system.
The aim of this survey was to assess the scale of malfunctions of this type in order to envisage the possibility of action at national level.
53 centres responded (i.e. about 1/4 of the French centres).
98% of the respondent centres had encountered a problem of recording in the R&V system. There is nevertheless a possible bias in these responses given that the respondent centres are undoubtedly those that had experienced a problem.

Frequency and conditions of occurrence

40% of the respondent centres encounter the problem at least once a month.



The treatment technique does not seem to influence the frequency of problem occurrence.
The occurrence of these malfunctions concerns all the manufacturers (in proportions that tally closely with the number of machines installed), independently of the type and version of R&V system, and all the "machine manufacturer/R&V system manufacturer" configurations.

3. Possible consequences of these malfunctions

Essentially three cases can lead to treatment errors:

- Case 1: conformal radiotherapy, with conventional fractionation of 2 Gy/ session, 5 days/week, for a total dose of between 46 and 60 Gy,
- Case 2: modulated volumetric arc therapy, with fractionation of 2 Gy/ session, 5 days/week.

In these 2 cases, forgetting to manually re-enter data (following an automatic recording error) can have the consequence of re-administering the session, that is to say the delivery of an additional 2 Gy for the overall treatment.
Barring particular situations, the criticality of these 2 cases can be considered to be low.

- Case 3: hypofractionated radiotherapy, for example in 4 sessions of 6 Gy each.

The potential consequences for this type of treatment are greater. An error or manual data entry omission for 1 session can result in a dose error that can represent up to 20% of the total prescribed dose.
The case can be considered as critical to very critical. Risk management must play an important role in the prevention of this type of event.

1. French Radiation Oncology Society (SFRO), French Society of Medical Physics (SFPM) and French Association of Radiographers (AFPPE)

> ANSM survey involving 3 Record & Verify system manufacturers

Given the high frequency of recording errors evidenced by the SFPM survey, in July 2014 the ANSM asked the manufacturers to review the reports concerning this problem. The aim of this is to identify any common causes of the various incidents and determine the prospects for improvement.
The ANSM has moreover questioned the manufacturers on their procedure for integrating these reports in the risks analysis of the CE marking of their systems.

Review by the manufacturers

In France since 01/01/2011:

For the first manufacturer, 5 incidents involving the R&V system have been reported. 4 incidents related to a beam or session recording problem, and only one constituted a risk for the patients.

For the second manufacturer, 64 incidents involving the R&V system have been reported. 52 incidents related to a beam or session recording problem. No incident had clinical consequences.

For the third manufacturer, 35 incidents relating to an R&V system beam or session recording problem have been reported. Among these incidents, 1 led to the administration of an additional treatment session and 3 led to the administration of an additional beam. In 3 cases, no error message was displayed.

The causes

The survey reveals 2 main causes of the incidents:

- problems with the configuration of the R&V system or the computer network of the hospitals concerned,
- incompatibility between the R&V system and the treatment console.

The other identified causes relate to:

- utilisation errors,
- sudden shutdown of the R&V system or the accelerator,
- electrical power failure,
- R&V system configuration problems,
- design problems,
- problems with the management of the random access memory (RAM) of the computer on which the R&V software is installed,
- hard disk failure.

In 10% of the cases the cause of the malfunction could not be identified.

How the reported problems are taken into account by the manufacturers

When a beam or session recording problem occurs, the manufacturers review the risk analysis. If the risk is already identified, the risk assessment is likely to be modified according to the incident that has occurred. If the risk has changed, or had not been identified previously, a new risk analysis is carried out.

The beam or session recording problems are taken into account in system design modifications as and when new versions are introduced, in particular through the display of alerts on the screen. Technical and/or information bulletins may be sent to the users.
The data recovery procedure is described in the users' manuals provided by the manufacturers.

The survey shows that R&V recording incidents are taken into account by the manufacturers in their risk analysis and their software upgrades. The ANSM nevertheless remains extremely attentive to the evolution of incident reports in this area.

> Steps for progress

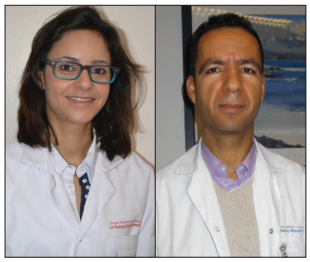
Good practices - Recommendations

Recommendations of the working group with the contribution of Pierre Fau - Medical Physicist, Head of the Medical Physics Department, Paoli Calmettes Institute, Marseille

- Conduct a quality appraisal of the local network and of the operating software used,
- Take the recording errors into consideration in the risk analysis, and all the more so if dematerialisation of the patient's medical file is envisaged,
- Plan a procedure for recovering the data from an interrupted session before restarting the medical devices concerned (MUs delivered, position of the accelerator gantry for arc therapy beams, etc.). This procedure must include a double verification of the manual re-entry of parameters not recorded automatically (between radiographers or by calling a physicist),
- Draw up an operating procedure to validate resumption of an interrupted treatment session in the information system and make it available at the treatment stations. This operating procedure must take into consideration the recommendations of the information system supplier,
- Ensure the traceability of such events in the patients' medical files and in the R&V system logbook.

Report equipment malfunctions that present a potential or confirmed risk for the patient or the user on www.vigie-radiotherapie.fr. This enables ANSM to consolidate its action with the manufacturers.

> Medical centre experience



Radiotherapy Department of Le Raincy-Montfermeil CHI (Intercommunal Hospital Centre)
Dr Besma M'BAREK
Radiation oncologist, Head of Department
Kamel MHAMDI
Medical physicist

SCM St Vincent Oncology and Radiotherapy Centre, Saint Malo site
Dr Jérôme CHAMOIS
Radiation oncologist, Quality Supervisor
Jérôme LACHICHE
Medical physicist

The Radiotherapy Department of Le Raincy-Monfermeil Intercommunal Hospital Centre (CHI) and the St Vincent Oncology and Radiotherapy Centre (SCM) - Saint Malo site, were faced with recording errors in the R&V system.

What malfunctions were encountered?

SCM - Saint Malo
7 cases of non-recording of partially or fully delivered beams or arcs in the R&V system have been inventoried since the beginning of 2014, that is to say 1.5 per month on average.
They result from network communication failures, given that our centre's server is located on the other site of the Saint Vincent centre.
Le Raincy-Montfermeil CHI
Between July 2013 and April 2014, we listed 77 cases of non-recording of the delivered beams in the R&V system. A problem of compatibility between the R&V system and the accelerator was suspected because they come from 2 different manufacturers. The problem disappeared at the end of April 2014 after changing the R&V system "treatment module".

What measures have you taken?

SCM - Saint Malo
As soon as a network problem causes an unwanted interruption of the treatment delivery, the team of radiographers checks the correspondence between the delivered MUs (displayed on the accelerator computing tower) and the MUs announced by the R&V system.
In the case of disagreement, the physics team is immediately called upon to restore the patient's computerized medical file.
Le Raincy-Montfermeil CHI
We have set up a daily verification of the list of beams delivered and a consistency check between R&V and paper record sheets of the weekly dose delivered.
A procedure has been drawn up for the radiographers to apply in the event of non-recording. It provides for a physicist to carry out retrospective manual recording in all such cases.

What action has the manufacturer taken?

SCM - Saint Malo
The R&V system manufacturer takes control remotely each time there is a beam interruption problem in order to analyse the beam in question. On one occasion the manufacturer sent a technician to the site. Despite these numerous exchanges, the root cause of the malfunction has never been identified.
Le Raincy-Montfermeil CHI
The R&V manufacturer has provided us with an operating procedure to manually record the beams, but we have never obtained an answer regarding the origin of the problem.
During the months with frequent recording problems, we were "shunted back and forth" between 3 entities, namely the R&V system manufacturer, the accelerator manufacturer and the hospital computing department, each claiming that the other parties were responsible for the problems.
In future the department will acquire the equipment from a single manufacturer to avoid the finding itself in such a situation again.

What are the consequences for the patients?

SCM - Saint Malo
There is a risk of patient being treated twice with the same beam or the same arc...
Le Raincy-Montfermeil CHI
...which could be harmful for the patient if the tolerances adopted in the treatment planning are too close to the recommended dose limits.
This is why the team maintains a safety margin by ensuring that the planned doses for the organs at risk remain below the upper tolerated dose limits.
This precaution ensures that the exceeding of a dose by a few centigrays due to non-detection of an unrecorded beam will have no adverse effects for the patient.

Has the functioning of the service been affected?

SCM - Saint Malo
These malfunctions have an impact on our project for the dematerialisation of the technical file.
They must be included in the a priori risk analysis.
Le Raincy-Montfermeil CHI
The department also had a project to "computerise" everything. Given this situation of recurrent computing malfunctions, the department finally abandoned this project and now is more dependent than ever on paper data records.
Even if the problem seems to be solved, the radiographers must remain particularly vigilant with regard to all the data managed by the R&V system.

> Further reading

White Paper on Radiotherapy in France

Twelve objectives to improve one of the major treatments of cancer (2013)
http://www.sfro.org/client/gfx/utilisateur/File/Livre_blanc_SFRO_2013(1).pdf

R&V Systems

IAEA Human Health Reports 7 (2013): "Record and Verify Systems for Radiation Treatment of Cancer: Acceptance Testing, Commissioning and Quality Control"
http://www-pub.iaea.org/books/IAEABooks/8941/Record-and-Verify-Systems-for-Radiation-Treatment-of-Cancer-Acceptance-Testing-Commissioning-and-Quality-Control

Medical devices vigilance

Article L 5212-2 : The manufacturer, the users of a device and the third parties aware of an incident or risk of an incident involving a device which led to or is liable to lead to death or serious deterioration of the health of a patient, a user or a third party, must immediately notify the ANSM (French Health Products Safety Agency).

Article R.5212-1 : Medical devices vigilance aims to monitor the incidents or risks of incidents resulting from the use resulting from the use of the medical devices that are defined in Article L. 5211 and come under the present title by virtue of Articles R. 5211-1 to R. 5211-3.

Reporting incidents or incident risks – CERFA form
https://www.formulaires.modernisation.gouv.fr/gf/cerfa_10246.do

European Commission recommendations (MEDDEV) MEDDEV 2.12-1 rev 6 -Guidelines on a medical devices vigilance system
http://ec.europa.eu/health/medical-devices/files/meddev/2_12_1-rev_6-12-2009_en.pdf

Radiation safety oversight and experience feedback

Reducing errors in radiation therapy through electronic safety checklists.
Greenwalt Julie, and al. Applied Radiation Oncology. July 2014
http://appliedradiationoncology.com/reducing-errors-radiation-therapy-electronic-safety-checklists/

Safer Radiotherapy
Radiotherapy Newsletter of Public Health England
https://www.gov.uk/government/publications/safer-radiotherapy-error-data-analysis-report

Radiation Oncology Incident Learning System™
Ford E. C. et al. Consensus recommendations for incident learning database structures in radiation oncology Med. Phys. 39, 7272 (2012)
http://scitation.aip.org/content/aapm/journal/medphys/39/12/10.1118/1.4764914

> 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)

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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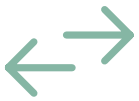

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