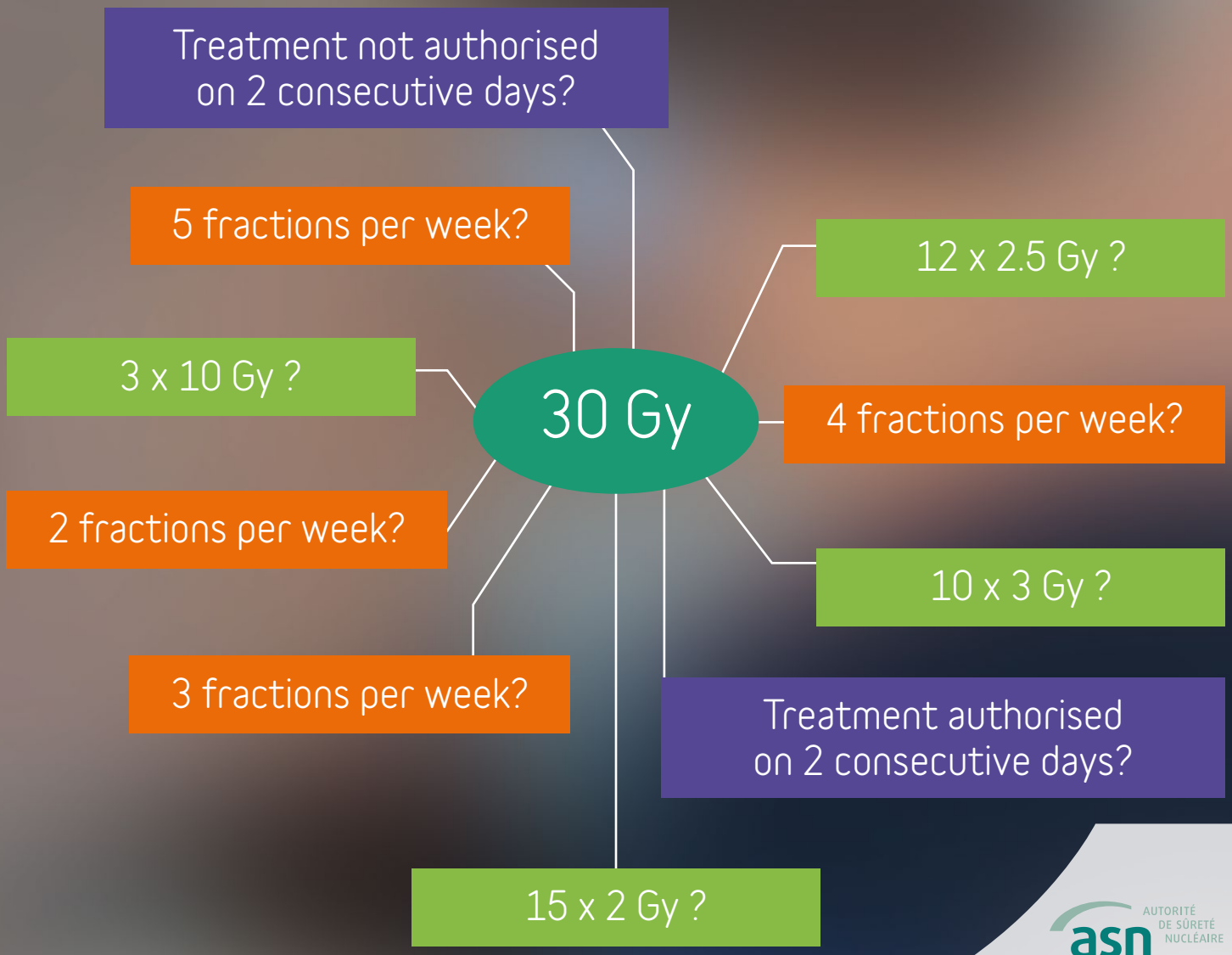
Patient safety

Paving the way for progress

N°10

January 2017

Protraction / Fractionation



Newsletter for radiotherapy professionnals

> Editorial

This issue is devoted to two key parameters in radiotherapy protocols and which must be included in any radiotherapy prescription, namely "fractionation", i.e. the total number of fractions and the dose per fraction, and "protraction", i.e. the total duration of the treatment.

Between January 2013 and June 2015, ASN was notified of 17 significant radiation protection events (ESRs) linked to a problem of fractionation or protraction of the dose to deliver.
The importance of ensuring the exactness of these data in the record and verify systems is all the greater given that the number of hypofractionated stereotactic treatments is going to increase in the coming years (see newsletter No. 9).

This is why in July 2015 ASN mandated IRSN to carry out a technical, organisational and human analysis of the causes of these malfunctions. This issue presents the main conclusions of these analyses along with the good practices and recommendations resulting from the reflections of the multidisciplinary working group dedicated to providing the radiotherapy professionals with experience feedback.

We extend our thanks to the 17 institutions and the companies Varian and Eleckta who contributed to IRSN's work. The results of this study enabled the subject to be brought to the attention of the manufacturers at a meeting held on 4th July 2016.

We wish you enjoyable reading.

The Editorial Team

> Summary

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.
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> Benchmarks

Background

Today in France there are only 2 record and verify (R&V) systems designed for use with non-dedicated accelerators of different makes: ARIA (from Varian Medical Systems, Inc., USA) and MOSAIQ (from Elekta, Sweden), which the manufacturers have upgraded to transform them into radiotherapy information systems (RIS).

Definitions

Fractionation: the total dose to deliver is divided between several sessions (fractions). It is characterised by the dose per session and the number of sessions.
Protraction: total duration of the treatment (number of days between the 1st and last session).

ASN notification criterion 2.1

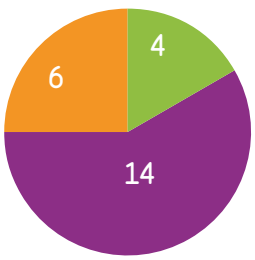
Any protraction and/or fractionation error which is not compensated for and is not associated with the clinical or technical constraints of the treatment must be notified (via the www.vigie-radiotherapie.fr portal for example).

> Key figures

Between January 2013 and June 2015, ASN was notified of 17 significant radiation protection events (ESRs) linked to a problem of fractionation (11) or protraction (6) of the dose to deliver during external-beam radiotherapy treatments.

Between June 2015 and August 2016, ASN received 7 further notifications.

These 24 events were rated as follows on the ASN-SFRO scale:



Level 0 : 4
Level 1 : 14
Level 2 : 6

The majority of the events were rated level 1 on the ASN-SFRO scale, but the proportion of events rated level 2 (25%) is not negligible.

In nearly 2/3 of the cases, the error was detected by the radiographers.

> Decoding: IRSN analysis of the technical, organisational and human causes

At the request of ASN, the 17 events notified between January 2013 and June 2015 were analysed by IRSN (see IRSN opinion in "Further reading"):

- regarding the technical aspects (software): 2 questionnaires were sent to the notifying centres, interviews were held with the two RIS/R&V system manufacturers and one user centre for each system;
- regarding the organisation and human factors (OHF) a questionnaire was sent to the notifying centres and IRSN conducted an in-depth analysis in 4 centres.

a. Occurrence of the events

Context of event occurrence:
- modification of the initial prescription,
- multiplicity of treatment protocols in a service,
- application of unusual / non-standard treatment protocols.

Fractionation (11 ESRs analysed):
In 8 of the 11 ESRs, the error occurred during manual entry of the medical prescription into the treatment planning system (TPS); for these 8 ESRs, a prescribed treatment of 30 Gy in 15 fractions (2Gy/f) was finally delivered in 10 fractions (3Gy/f).

Protraction (6 ESRs analysed):
For the majority of these ESRs, the error occurred when programming the projected treatment dates: incorrect manual entry or failure to revise the entry following a change in the prescription. The treatments planned in 2f or 3f or 4f per week were finally delivered in accordance with the conventional scheme of 5f per week.

b. Identified contributory causes and factors

Main factors contributing to the errors and failure to detect and correct them:

- manual retranscription of the data due to the use of several non-interfaced media containing the information concerning the fractionation and protraction: RIS/R&V, TPS, paper patient records;

- lack of an automatic check of consistency or an alert if the fractionation or protraction is modified; the computerised systems (RIS/R&V, TPS) do not consider these data to be reference information;

- loss of references (number of monitor units (MUs) delivered), particularly by the dosimetrists and radiographers after a change of treatment technique (change from 3-dimensional conformal radiotherapy (3D CRT) to intensity modulated radiotherapy (IMRT) or volumetric modulated arc therapy (VMAT) for example);

- frequent interruptions in dosimetry tasks;

- inadequate management of the streams of medical files in dosimetry (files arrive in dosimetry in packets to be processed in a short length of time, lateness in medical validation of the treatment plans, with validation sometimes arriving on the day of the 1st treatment session);

- increased workload due to an increase in the activity over time (longer treatment preparation times, deployment of new techniques, increased in the number of patients), accentuated in pre-holiday periods.

> Steps for progress

Good practices - Recommendations

The defence barriers should preferably be of a technical nature because they are more robust and allow the automation of transfers and verifications.
In radiotherapy, the solutions are based on parameter settings and better interfacing of the computer systems. **It is vital for the manufacturers to know the users' needs so that the systems can be optimally configured for the operating practices** so as to limit human interventions and render them safer. The manufacturers have a vital role, particularly during the equipment installation and the inherent user training. Consequently, several recommendations will require close collaboration between the users and the machine manufacturers.

The good practices and recommendations presented in this section result from the reflections of the working group based on the conclusions of IRSN. They comprise three lines:

use of computer aids and work organisation (users),

design and development of computerised systems (manufacturers),

training in system use and parameter settings (users and manufacturers).

The recommendations for the manufacturers were discussed in the presence of representatives of 2 RIS /R&V system manufacturers (Varian and Elekta) and of AFQSR, AFPPE, SFPM, ANSM and IRSN.

Limit manual data entry steps and, when these are unavoidable, analyse the robustness of the defence barriers against these risks.

Good user practices:

Whenever it is technically possible, use:
- the prescription models/templates,
- automatic insertion of the fractions into the treatment schedule from the prescription and with a treatment start date.

Recommendations to the manufacturers:

- In the R&V system, plan for the **parameter setting of standard prescription models/templates** by clinical location (restricted access rights). In the event of a deviation from the prescription entered in the R&V system, mandatory confirmation should generate an automatic signal at the subsequent stages.
- Introduce a notion of **prescription intent** for the dosimetric planning stage (automatic retrieval of the total dose and the fractionation to the TPS). This intent will be transformed into a treatment prescription after viewing the dose distributions and dose-volume histograms and validation by the physician. A message will be displayed if the dose is changed.
- If the TPS is not integrated in the RIS/R&V, provide for automatic transfer of the data from the prescription intent (total dose, dose by fraction and/or number of fractions) to the TPS.
- Introduce **automatic and dynamic programming of the dates** of patient appointments as from a treatment start date and the medical prescription entered into the RIS/R&V. This programming should be automatically updated (both in the patient's appointments diary and the provisional treatment schedule)

when the treatment dates have to be changed due for example to failure of the treatment machine, suspension of the treatment for medical reasons, patient missing one or more sessions, a change in the prescription and any treatments carried out on public holidays.
- Allow the exporting from the TPS to the RIS/R&V of the calculated dose per beam **at the place of the prescription** (so as to avoid manual modifications, particularly where techniques with intensity modulation are involved).

Favour technical barriers and automatic user alert systems that require human action in order to be overridden.

Recommendations to the manufacturers:

- When a prescription is modified after the treatment has been approved or in the course of treatment, provide for the **automatic triggering:**
  - of invalidation of the "approved" status of the treatment plan and the associated beams in order to block administration of the treatment pending verification of the concordance/consistency of the data and revalidation;
  - of signalling to the users concerned by the management of the patient's treatment schedule and appointments.
- Put in place an **automatic check of consistency** between the dose reached (including cases of under-dosing) and the programmed dose by the R&V module at the treatment station at the start of each session. If there is a significant difference (taking into account the dose due to the positioning imagery if applicable), display an alert with compulsory validation by a member of the radiotherapy team (to be defined) in order to start the treatment.
- When the beam data from the TPS are automatically retrieved in the RIS/R&V, integrate an automatic verification of consistency between the total dose and the dose per fraction on the one hand, and the prescription entered in the RIS/R&V system on the other hand. If a deviation is observed, the dosimetry transfer should be blocked.
- Add the possibility of setting the parameters of the compulsory **computerised check lists** to validate a crucial step in the process before starting the treatment.

Explain and formalise the checks relating to compliance with the prescription, especially those relative to fractionating and protraction.

Users and manufacturers:

During the training courses provided by the manufacturers, present the system functions that are most relevant for the practices of the radiotherapy service in order to **make the most of the possibilities offered by the installed system**, particularly in terms of verification.
Define more specifically:
- The points checked, particularly during the medical validations;
- The reference document for the checks, including the list of check, the professionals involved in the checks and the steps of the process concerned;
- The checks which, if incomplete, prevent continuation to the next step.

Supplement the process of continuous improvement in work organisation practices.

Good user practices:

- **Formalise the prescription** and any modification to it in a comprehensive manner (with dose per fraction, number of fractions per week and distribution of the fractions over the week), ideally through computer entry into the RIS/R&V system by the radiation oncologist so that a treatment plan can be validated (anticipate the possible occurrence of an error during initial data entry).
- When a prescription is modified after approval of the treatment or during treatment, check the appropriateness of the beams associated with the new prescription and adapt the treatment schedule and the patient's appointments.
- Favour **calm work conditions**, in particular by identifying the work situations in which task interruptions must be minimized to avoid disturbing the activity.
- Conduct **audits of the file channels in dosimetry** to check the correct functioning of the organisation, better control the streams of files and ultimately the operator workload (e.g. setting up dosimetric time slots for medical validations, intervals between medical validation and the 1st treatment session, defining file prioritisation criteria, etc.).
- **Re-examine the risk analysis** on the basis of feedback from the ESRs relative to fractionation and protraction errors by widening the reflection to all the errors associated with non-compliance with the prescription (contouring, laterality error, etc.), taking care to explain what the validations cover. This reflection should lead to an evaluation of the robustness of the lines of defence and, if necessary, to their modification, favouring simplification of the operators' tasks whenever possible.

> What's news with the manufacturers ?

Interview with Nia van Baalen, PhD,
Director Global Risk Management
at Varian Medical Systems

« The DICOM standard must evolve to take into account progress in treatment planning »

At the beginning of summer 2016, ASN organised a multidisciplinary meeting on the problems of dose fractionation and protraction in external-beam radiotherapy treatments. How did you react to this invitation?

As a manufacturer, Varian Medical Systems is committed to designing and producing medical equipment that enables patients to receive safe and effective treatments and integrates the latest technological advances. This is why we considered it very worthwhile to be actively involved in this important issue.

Some of the notified ESRs occurred in centres with environments sourced from several suppliers. How do you at Varian approach such situations?

Given the fact that customers are free to choose to source their radiotherapy equipment from different manufacturers, the interoperability of the machines is an important design requirement for Varian. The RT objects of the DICOM standard, introduced in the 1990's, facilitate the interoperability of radiotherapy equipment from different suppliers. Varian was one of the first manufacturers to adopt this standard. Given the significant recent advances in radiotherapy, the DICOM standard must now be updated to better take them into account. Varian is an important actor in these developments.

What changes are necessary?

Today there are essential aspects in radiotherapy that the current DICOM objects do not manage well, or even not at all, such as the ability to correctly define an RT prescription and transfer it without ambiguity from one system to another. While a given supplier such as Varian can manage dose fractionation and protraction within its own system, the current standard does not support the transfer of a detailed prescription between systems from different suppliers. The standard must also evolve to integrate the major advances in treatment planning, such as complex 3D objects and adaptive planning.

What actions are currently in progress to meet these needs?

A Working Group (DICOM WG-07) comprising manufacturers and clinicians from the radiotherapy industry and clinical sites has been set up to work on the required restructuring of the radiotherapy objects in DICOM-RT. A series of complements to the DICOM standard has been planned for with the aim of defining the second-generation DICOM radiotherapy objects that will support all radiotherapy technologies and practices, whether old or new. These new objects will also better support the workflows, and the architecture resulting from this 2nd-generation DICOM-RT will provide the necessary flexibility to integrate future technologies.

The tests, open to those who develop the software using DICOM RT (suppliers and institutions) and coordinated by the working group WG-07, should begin during the first half of 2017 and will focus on the exchanges of the "Physician's Intent" object (prescription) between the different applications.

> Further reading

IRSN opinion on the events associated with a problem of fractionation or protraction of the dose to deliver during external-beam radiotherapy treatments (July 2016)
http://www.irsn.fr/FR/expertise/avis/2016/Pages/Avis-IRSN-Juillet-2016.aspx#.V-4aBHp8F68

Current activities and future directions of the DICOM standard
International work group WG-07 radiotherapy
http://dicom.nema.org/dicom/geninfo/strategy.pdf

Vers un retour d'expérience prenant en compte les facteurs organisationnels et humains (Promoting experience feedback taking organisational and human factors into account)
Institut pour la maitrise des risques (Institute for the control of risks) - September 2016
http://www.imdr.eu/upload/client/document_site/gtr/Brochure_REX_FOH_30-08-2016.pdf

Guide HAS : Interruptions de tâche lors de l'administration des médicaments (French Authority for Health - Task interruptions during the administration of medication)
Outils de sécurisation et d'auto-évaluation de l'administration des médicaments (Aids for increasing safety and self-assessing the administration of medication) - (January 2016)
http://www.has-sante.fr/portail/jcms/c_2618396/fr/interruptions-de-tache-lors-de-l-administration-des-medicaments

Safer radiotherapy: the radiotherapy newsletter of PHE
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/525711/Safer_RT_No19_StdQ.pdf
(May 2016, issue 19)

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/558593/Safer_radiotheraphy_20th_Newsletter.pdf
(September 2016, issue 20)

> 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)
N°9 High-precision hypofractionated irradiation (September 2016)

These publications are also available in English:
http://www.french-nuclear-safety.fr/Information/Publications/Publications-for-the-professionals

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ASN, January 2017