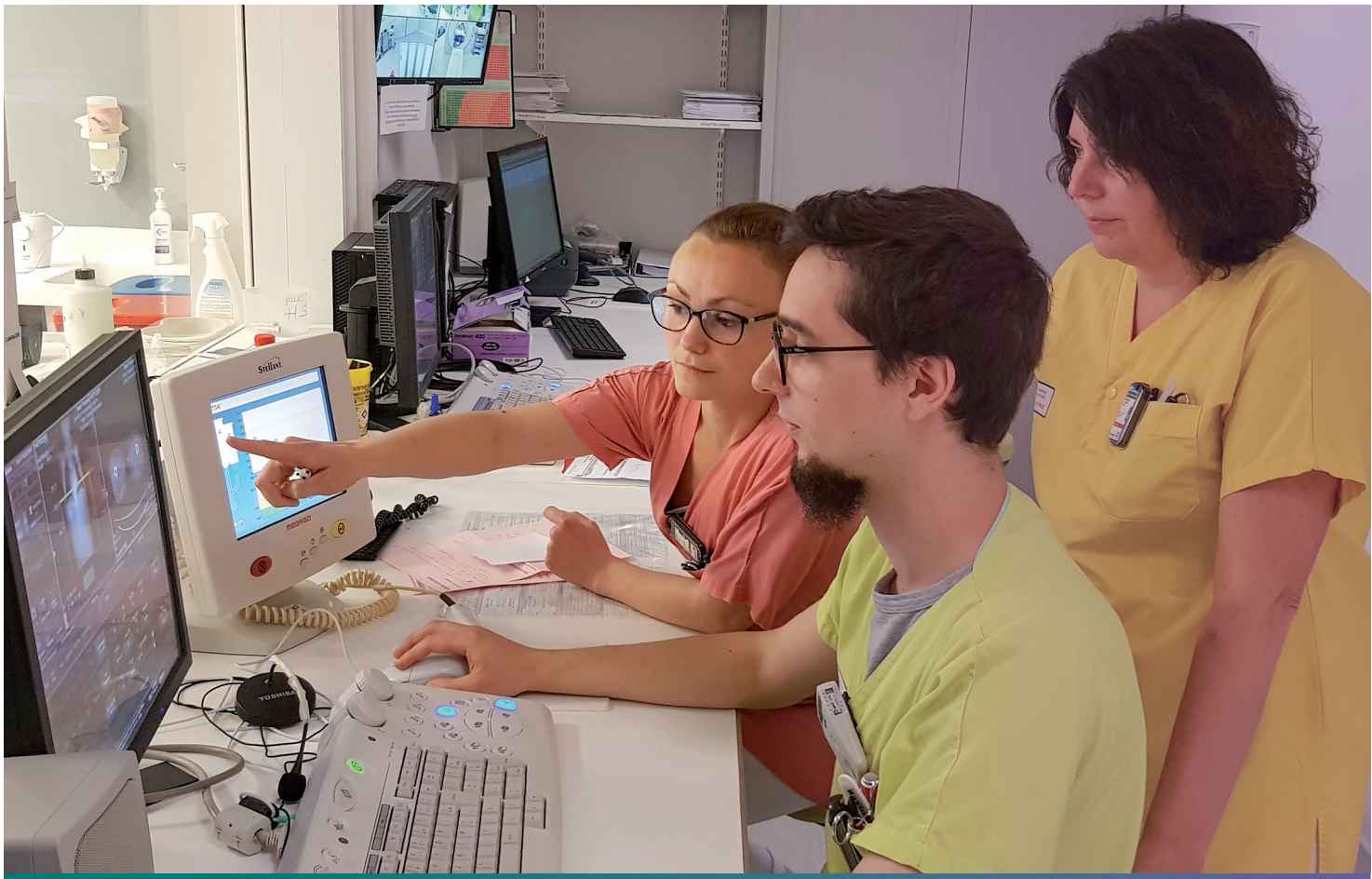
PATIENT SAFETY

PAVING THE WAY FOR PROGRESS

#

July 2019



IMPROVING USE OF CT SCANNER FUNCTIONS

Newsletter for medical imaging and radiotherapy professionals

EDITORIAL

Identifying risks, analysing malfunctions, implementing corrective action and informing the professional community...
Eleven years after taking the step for radiotherapy, medical imaging has been brought into the virtuous circle of quality by ASN resolution 2019-DC-0660 of 15 January 2019.

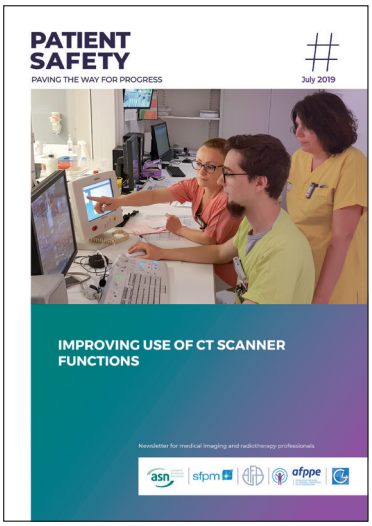
Since March 2011, the Patient Safety Bulletin has been keeping you informed of the experience feedbacks from significant radiation exposure events occurring in radiotherapy.
It will now alternate between subjects devoted to radiotherapy, diagnostic medical imaging (conventional, computed tomography (CT) scanning and nuclear medicine) and fluoroscopy-guided interventional practices.

Produced by multidisciplinary working groups coordinated by ASN, the bulletin offers a thematic presentation of the good practices of medical departments and the recommendations developed by the professional organisations of the disciplines concerned and the health and radiation protection institutions.
This issue devoted to the correct use of CT scanner functions cuts across all the medical specialities, since CT scanners are now available in the majority of nuclear medicine and radiotherapy departments.

In March 2018, the exposure of a pregnant woman undergoing a diagnostic CT scanner revealed the serious dosimetric consequences of inappropriate use of the multiple acquisitions functions.
The working group gives you the results of its in-depth analysis of the organisational deficiencies that led to this event.

Wishing 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 dedicated to reporting experience feedback and lessons learned to medical imaging and radiotherapy professionals.

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- **With the participation of:** ANSM (French Health Products Safety Agency), the DGS (General Directorate for Health in the French Ministry of Health), the HAS (French National Authority for Health) and IRSN (French Institute for Radiation Protection and Nuclear Safety).
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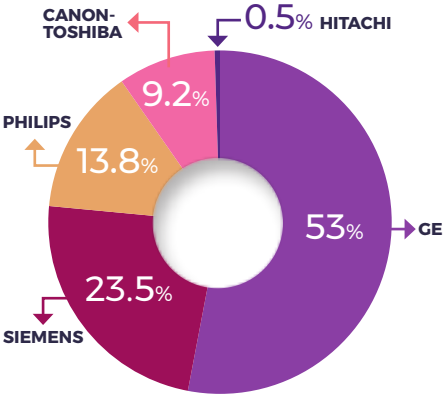
Key figures

■ CT SCANNERS INSTALLED IN FRANCE

Nearly 1,200 CT scanners are installed in more than 800 centres and covered by ASN licenses.
The majority of the scanners are of the GE (General Electric) brand.

SCANNER DISTRIBUTION BY SUPPLIER AS AT 15 SEPTEMBER 2017

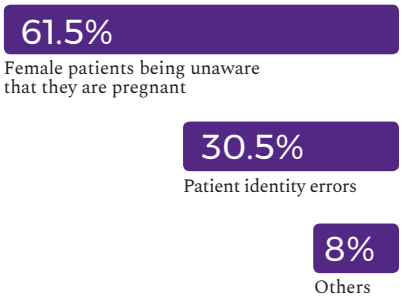


The majority of the GE scanners currently installed feature the "1 more" function, including those in nuclear medicine departments.

■ ESRS IN COMPUTED TOMOGRAPHY

Out of the 11 million CT scanner procedures performed in France in 2018, (about 10,000 procedures per device), 171 significant radiation exposure events were reported to ASN. They result primarily from female patients being unaware that they are pregnant (105 accidental exposures of fœtuses) and patient identity errors leading to the performance of examinations on a different anatomical region to the one requested (52).

DISTRIBUTION OF CT-RELATED EVENTS BY CAUSE



■ MAPPING OF FUNCTIONS THAT ARE "SENSITIVE" WITH REGARD TO RADIATION PROTECTION

In 2018, inappropriate use of the "1 more" function of a CT scanner of the General Electric (GE) Healthcare make led to highly significant overexposure (> 1 Gy) of a woman who was known to be pregnant.
The working group devoted to determining the lessons to learn from this ESR has established a map of the CT scanner utilisation modes that induce multiple acquisitions on a given anatomical area of the patient and can therefore potentially lead to high doses to the skin and the subjacent organs if used inappropriately
With regard to the GE "1 more" function, the analysis shows that it would be worthwhile making it safer by having a default parameter setting at 10 or 20 slices depending on the area to diagnose, rather than the current default parameter setting of 1 slice each time the key is pressed.

Decoding the "1 more" event

A diagnostic CT scanner of the lumbar spine was performed at night on a pregnant woman who was suffering severe pain. Faced with an unexpected interruption of acquisition, the radiographer decided to use the "1 more" function to cover the missing vertebra (32 mm).

The radiographer pressed the button 51 times, thinking that exposure was limited to very small successive areas. In actual fact, each acquisition covers virtually the same anatomical area, leading to an exceptional level of overexposure for this type of procedure.

Analysis of the causes and contributory factors (ALARM method)

1. PATIENT
> Patient pregnant, in pain and with poor understanding of French.

2. TASKS TO ACCOMPLISH
> No CT scanner utilisation memo sheet.

3. PERSON (professional)
> Training on CT scanner relatively dated;
> No specific training on the type of CT scanner used;
> No knowledge of the recommendations for use of the "1 more" function;
> Non-questioning attitude;
> Night duty.

4. TEAM
> Three radiographers present at the same time in the control room;
> No medical professional capable of confirming the method of using the function.

5. WORKING ENVIRONMENT
> Interruption of acquisition (2 vertebrae/3) for an undetermined reason;
> No defence barrier: default parameter setting at one slice, alarm not activated;
> Poor equipment ergonomics: non-intuitive procedure for changing the number of slices, total dose not displayed in real time on the control screen.

6. ORGANISATION AND MANAGEMENT
> Insufficient training of the personnel;
> No qualification on the new CT scanner;
> No mentoring of radiographers when first assigned to a CT scanner;
> Medical physicist not involved in the machine commissioning.

7. INSTITUTIONAL CONTEXT
> Centre with particularly intense emergency department activity;
> CT scanner technical platform renewed in 2015 with change of supplier.

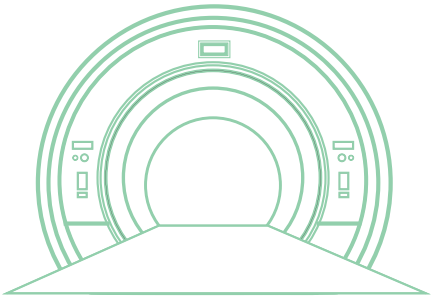
Steps for progress

1. Good practices

Reflect upon a complete organisational strategy to guarantee the presence of personnel fully trained in the use of the CT scanner

■ WHEN BUYING THE SCANNER

Work together to match the choice of device, the maintenance options and the personnel training (volume and content) to the staff numbers and activity of the department. This multidisciplinary work involves the Head of Department, the expert radiologist, the biomedical engineer, the medical physicist, the department administrative manager, the expert radiographer(s) and the radiation protection expert-officer.



■ AT THE TIME OF INSTALLATION

Set the parameters for the local protocols and the alarm dosimetric thresholds with the application engineer (presence on site for 2 to 3 weeks), the medical physicist responsible for monitoring the machine, the expert radiographer(s) and/or the expert radiologist.

***Produce a "reference memo" document** on the various functions of the scanner, based on the manufacturer's information and kept to hand near the control station.

***Train** all the personnel concerned, paying particular attention to the acquisition functions (supplier's responsibility): the application engineer trains the expert radiographers who in turn train the team of radiographers over a period of at least one week on a one-to-one basis. The schedules must be adapted accordingly.

Plan for specific training of the medical physicist in charge of monitoring the CT scanner.

***Organise formal qualification of the professionals** in the use of the CT scanner (responsibility of the Head of the Centre).

Plan for a gradual build-up in the utilisation of the new scanner.

■ IN ROUTINE USE

***Periodically assess and optimise the protocols** set (1st assessment after 3 months), according to the doses registered by the medical physicist for the principal examinations and the feedback on image quality from the expert radiographers or radiologist.

Review the training support material as required if there are recurrent questions or new functions.

Always inform the medical physicist if a pregnant woman is exposed in any way, whether her pregnancy was known or not (this is what allowed detection of the event associated with the "1 more" button).

Ensure that the operators know the procedure to follow in the event of alarm triggering.

* *In accordance with articles 7 and 9 of ASN resolution 2019-0660 of 15 January 2019 setting the quality assurance obligations in medical imaging*

RECOMMENDATIONS FROM ASN AND THE PROFESSIONALS RELATIVE TO TRAINING IN THE USE OF MEDICAL DEVICES EMITTING IONISING RADIATION (13 JUNE 2016)

This consensual framework for training users of medical devices emitting ionising radiation is the result of a joint reflection by ASN, representatives of the french professional societies (G4, SFPM, AFPPE, AFIB) and medical device manufacturers (SNITEM) with the participation of the French Health Products Safety Agency (ANSM).

Based on good practices, it forms part of a health care quality and safety improvement process aiming to avoid incorrect utilisation and to minimise the risks for the patients and medical staff alike.
It aims to guarantee full command of the available optimisation functions, of the ability to identify the warning or error messages and the corresponding action to take.

www.asn.fr/Professionnels/Activites-medicales/Radiologie-et-scanographie

2. Innovative initiative

Back in November 2013, the GHU PARIS EST–TROUSSEAU Hospital set up a formal procedure for checking radiographers' proficiency in the use of the CT scanner. What does it involve?

The procedure aims to identify all the skills and protocols that need to be mastered when working on the CT scanner so that radiographers can receive full and comprehensive training.

The training, provided by the expert radiographer, takes place in two stages:

- one week of mentoring in the preparation of patients (children),
- followed by two weeks at the work station with the two radiographers assigned to the scanner.

It ends with a day's assessment of the command of the various points on the scanner skills assessment matrix.

- If any points have not been fully grasped, either they are re-explained or the course is extended by one week.
- If the acquired skills are confirmed, the radiographer remains on the scanner for at least two weeks before joining the team of 22 radiographers.

> *"Radiographers are authorised to work on CT scanners by virtue of their diploma, but their competences must be validated before they can use them"*
>
> ***Nadège NICON***
> **Health executive at the imaging centre**
> GHU PARIS EST
> TROUSSEAU Hospital

Application

HOW IS THE ASSESSMENT MATRIX CONSTRUCTED?

The assessment matrix covers the various stages of taking up duty. It is based on the manufacturer's documentation and the protocols which are written by the expert radiographers when the scanner is installed, tested by the other radiographers, validated by the head of department and reviewed at least once per year.

WHAT ARE THE LIMITS AND CONSTRAINTS OF THIS TRAINING PROCEDURE?

The procedure requires one of the three expert radiographers to be available to work on the scanner for three weeks, or their mutual replacement if not available.

The skills are tested at the end of the assessment, but up to two months can go by between assignments to the scanner, which raises the question of re-assessment.

WHAT DO THE RADIOGRAPHERS THINK ABOUT THE PROCEDURE?

The assessment is well accepted because it validates the skills necessary to progress from relative autonomy to total autonomy on the CT scanner.

The experience of the centres

"The multidisciplinary investment is a key point when buying a CT scanner"

Sébastien PONS
Biomedical engineer
GHU PARIS Psychiatry & Neurosciences

How is the process for purchasing a new CT scanner organised in your centre?

The biomedical department manages the multi-year investment plan, determines the needs and plans the purchases of new equipment. **The choice of a CT scanner is made collegially** within a group of professionals of the department concerned, in consultation with the radiation protection unit which comprises the medical imaging executive, the occupational physician, the expert radiologist, the radiation protection expert-officer, the expert radiographer and the medical physicist.

The aim is to detail the need with the requesting department in order to establish suitable specifications and define selection criteria.

Important note: placing a contract via a central purchasing body does not obviate the need to renegotiate the specifications on the basis of the requirements and functions defined by the internal department. Administrative ease must never take precedence over the need.

How is the device selected?

The scanner selection matrix is defined and approved by the team. **The predominant criteria are the technical response of the device to the requesting department's needs and the maintenance and user training aspects.** With regard to radiation protection, we demand the presence of dose reduction features, which have enabled us to reduce patient doses by a factor of three.

Your centre has opted for an outsourced medical physics service. What impact does this have on the decision-making process?

The external medical physicist is not involved in all the project group meetings because he or she is not subject to the same non-disclosure constraints as the centre's employees. **The medical physicist is however consulted regarding questions of dosimetric efficiency and knowledge of the type of equipment,** because they will validate the protocols when the CT scanner is installed (additional on-site service time to be planned for).

What are the pros and cons of this organisation?

The difficulty with a multidisciplinary approach is to maintain the commitment of the members of the group over time, despite absences, vacancies or emergencies. On the positive side, **it guarantees a choice that meets the needs of the department.**

"The alert parameter settings depend on the site, the machine and the activity"

Didier DEFEZ
Medical physicist
Civil Hospices of Lyon - Lyon Sud
GH Sud Hospital Centre

Your centre has been using the alarms since 2018? What parameters have you chosen?

The event deciphered page 3 incited us in July 2018 to set the parameters for the alarms of the two CT scanners we operate in the department, one for scheduled activities (Philips) and one for emergency and interventional procedures (Siemens).

We have opted for a notification value using the computed tomography dose index volume (CTDIv) based on the diagnostic reference levels by anatomical region. The dose length product (DLP) was ruled out because it is more difficult to parameterise and to subsequently analyse. The alert value, which applies to the total examination dose, was defined after analysing our average activity. The threshold has been set to 300 mGy for scheduled activities and 400 mGy for emergencies.

What has been learned after using the alarms for 8 months?

I consult the log file of each scanner every month to feed back the information to the teams.

Ten exceedance notifications have been recorded monthly in emergency activities compared with 1 or 2 notifications in scheduled activities. The alert has only been triggered once, during an interventional procedure.

■ **In your opinion, what are the limits of the alerts?**

Setting the notification value parameters is a long and complicated task which has to be carried out protocol by protocol.

It comes up against three main difficulties:
- the lack of reference values for certain areas such as the joints (knee, elbow, etc.);
- the number of protocols - sometimes large - embedded for an anatomical region (skull);
- the fact that the number of helices is not taken into account.

The values associating the dosimetry with a clinical procedure, currently being discussed within a SFPM/G4 working group, will provide valuable national and consensual input data.

As for the alert value, it is a relatively limited safety mechanism insofar as the manufacturer's default settings are so high that they would not have prevented the overexposure, despite its significance (> 1 Gy) that occurred in the deciphered event. For this barrier to be effective, the threshold value must be personalised. The benefit of the function is governed directly by the stability of the imaging activity. It is much less obvious for interventional practices.

■ **What aspects requiring particular attention would you like to point out to our readers?**

Be attentive to the variability in the alert values between different devices. Although the maximum CTDIv value is usually 2,000 mGy, it can be as high as 9,999 mGy on certain scanners! Furthermore, each manufacturer has its own particularities (adults, paediatrics, head, body, etc.).

When setting the alert parameters, **it is important to inform the teams of the procedure to follow if the alert is triggered.**

Further reading

■ **Experience feedback concerning the "1 more" button on General Electric Healthcare scanners**.

■ **CT scanners – Mapping sensitive functions and alarms**
http://www.french-nuclear-safety.fr/Information/Publications/Publications-for-the-professionals

■ **Recommendations from ASN and the professionals relative to training in the use of medical devices emitting ionising radiation** (13 June 2016)
https://www.asn.fr/Professionnels/Activites-medicales/Radiologie-et-scanographie/Guides-de-l-ASN-dans-les-domaines-de-la-radiologie-et-de-la-scanographie/Recommandations-relatives-a-la-formation-a-l-utilisation-des-dispositifs-medicaux-emetteurs-de-rayonnements-ionisants

■ **Leaflet presenting ASN resolution 2019-DC-0660 of 15 January 2019 setting the quality assurance obligations in medical imaging**
https://www.asn.fr/Professionnels/Activites-medicales/Radiologie-et-scanographie/Guides-de-l-ASN-dans-les-domaines-de-la-radiologie-et-de-la-scanographie/Assurance-de-la-qualite-en-imagerie-medicale-mettant-en-oeuvre-des-rayonnements-ionisants

RETROSPECTIVE RISK ANALYSIS METHODS

These methods are based on two reference models: analysis of the root causes (cause tree analysis), or an overall «systemic» analysis of events (ALARM analysis).

Whatever the method used, the analysis of significant radiation protection events must identify:
- all the causes, including indirect causes, that contributed to the occurrence of the event;
- all the contributory factors, including the organisational and human factors.

■ **"How do you analyse your significant radiation protection events?"** - Comparative presentation of the 5 main risk analysis methods (ALARM, Cause tree, Ishikawa diagram, Orion and 5 Whys?)

"Patient safety - Paving the way for progress" bulletin of July 2012
http://www.french-nuclear-safety.fr/Information/Publications/Publications-for-the-professionals

■ **Human organizational factors in-depth event analysis**
Industrial safety booklets (*Les cahiers de la sécurité industrielle,* IFCI, April 2014)
https://www.icsi-eu.org/documents/281/csi1404_analyse_evenement.pdf

PATIENT SAFETY

MARCH 2011 - PATIENT IDENTIFICATION

NOVEMBER 2011 - THE FIRST VERIFICATION SESSION

JULY 2012 - HOW DO YOU ANALYSE YOUR SIGNIFICANT RADIATION PROTECTION EVENTS?

APRIL 2013 - WHAT EVENTS MUST BE NOTIFIED TO ASN?

DECEMBER 2013 - IN-VIVO DOSIMETRY

MAY 2014 - LATERALITY ERRORS

MARCH 2015 - RECORD AND VERIFY: RECORDING ERRORS!

JUNE 2015 - PULSED DOSE-RATE AND HIGH DOSE-RATE BRACHYTHERAPY

MAY 2016 - HIGH-PRECISION HYPOFRACTIONATED IRRADIATION

DECEMBER 2016 - PROTRACTION / FRACTIONATION

SEPTEMBER 2017 - MAKING THE PATIENT A PARTNER IN TREATMENT SAFETY

JUNE 2018 - PATIENT REPOSITIONING IMAGING: VERTEBRA IDENTIFICATION

MARCH 2019 - EXPERIENCE FEEDBACK IN OTHER COUNTRIES

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