AUTORITÉ DE SÛRETÉ NUCLÉAIRE

RÉPUBLIQUE FRANÇAISE

IONISING RADIATION AND HEALTH DEPARTMENT

Montrouge, July 26th 2016

CODEP-DIS-2016-027942

Addressees at end,

Subject: ASN recommendations concerning the handling[1] of radiopharmaceuticals (MRP) and the administration of MRP to patients following an ergonomic study performed by IRSN within an *in vivo* nuclear medicine unit

Dear Sir or Madam,

Since July 2007, when the system for notification of significant radiation protection events was put into place, ASN has registered about 800 events notified by nuclear medicine departments. Of these, 50% concern patients. These events, most of which were of no consequence for the patients, involved errors in the activity or the MRP administered, as well as a lack of verification of the identity of the patients.

In a circular of 22nd May 20132, I informed you of the lessons learned from feedback from the ESR of which ASN was notified concerning certain MRP handling errors.

ASN is still regularly notified of similar events, at a rate of about fifty per year and certain departments are faced with the recurrence of MRP administration errors3 despite the corrective measures taken following the assessments they carried out.

In order to understand the reasons for this recurrence of events, even though there were no clinical consequences for the patients, and the lack of effectiveness of the corrective measures taken, ASN made a proposal to a nuclear medicine department with a good culture of notification, yet still faced with these difficulties, to run an assessment of organisational and human factors.

The organisational and human factors approach to safety consists in identifying and implementing the conditions conducive to a positive contribution to safety by professionals and groups. It allows a clearer understanding of what determines human activity and makes it possible to influence the design of

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1 Definition of the appendix to ASN Resolution 2014-DC-0463 of 23rd October 2014 concerning minimum design, operation and maintenance rules to be met by in vivo nuclear medicine facilities: "operation consisting in handling radionuclides with a view to administering them to patients, such as placing an MRP in a syringe, reconstitution, preparation, etc."

2 Circular CODEP-DIS-2013-n°026709 concerning ASN recommendations regarding the radiation protection of patients receiving an administration of radiopharmaceuticals (MRP) prepared by automated systems

3 Lessons learned from events notified to the French nuclear Safety Authority during 2007-2013 in the medical field Radiation protection Dosimetry (.2014 : 61-67)

working situations and the organisation adopted, in order to make the activity safer[4]. It is then becomes clear that achieving safety necessarily involves taking account of technical, human and organisational aspects.

The ergonomic study carried out by IRSN in a nuclear medicine department analysed about a dozen events concerning the MRP preparation phase (error in preparation or selection of a vial, error in calibrating the automatic dose preparation system), the patient appointment phase (patients with same name), receipt of the MRP (erroneous input into the software), provision of the correct syringe and finally injection. About half of the ESR are related to PET scan activity.

Even when the events occur in a different context, the lessons to be learned usually concern generic issues relating to the organisation of work or the management of safety. Even though the situation studied is unique, I consider that the lessons learned from this study enable me to issue recommendations for *in vivo* nuclear medicine departments with regard to the handling of MRP and their administration to patients, as well as with regard to the deployment of risk management approaches.

This study identified the technical and organisational conditions which increase the risk of error and of which I feel that it is essential you be aware, so that you can incorporate them into your risk assessments. The situations described are given as examples and should enable nuclear medicine departments to examine comparable situations.
It is up to you to examine these conditions and whether they can be transposed to your own organisation and, if so, to implement appropriate lines of defence.

As regularly observed by ASN in the event reports transmitted to it, the study also identifies limits linked to the implementation of risk management approaches, which could have contributed to the lack of effectiveness of the corrective measures and draws conclusions for improved prevention of the events. It is up to you to examine your experience feedback practices on the basis of the recommendations made in this letter.

These recommendations were made following consultation with the professional societies[i] concerned.

1. Identifying and addressing the conditions conducive to the occurrence of errors

The ergonomic study identified conditions conducive to the occurrence of errors. If these conditions are transposable to their own situation, the departments must examine the risk management measures that have been implemented to deal with these malfunctions.

1.1. Speaking the same professional language

The results of the ergonomic study revealed the use of a professional language which differs in the formal working documents, depending on whether they are aimed at the team handling the MRP or the team dealing with the other activities. The differences concern the name of the radiopharmaceuticals, the abbreviations used to encode them in the software used by the radiopharmacy and the corresponding scintigraphy examination abbreviations in the camera schedule. Nor is this professional language harmonised with that in the MRP management software.
Harmonisation of the professional language and practices is all the more necessary when there are large numbers of health professionals, of different categories and not permanently assigned to the nuclear medicine department.

[4] Cahiers de la sécurité industrielle 2010-02, Foundation for an industrial safety culture

1.2. Mitigating the risk of administration error through the packaging and presentation of the MRP vials

The study highlighted situations which increase the risk of error owing to the packaging and presentation of the radiopharmaceuticals. Although the departments have little influence upstream, as these modifications are the responsibility of the manufacturers, they must be aware of these situations and once again set up appropriate lines of defence to minimise the occurrence of errors.
This risk must be taken into account in the various steps from MRP storage in the specific MRP handling area to use in the radiation protected chamber[5] or in the automated system up until administration to the patient. It will have to be reassessed in the event of any change to the packaging by the manufacturers.

I also drew your attention in May 2013[2] to the need to define and systematically implement the checkpoints necessary for ensuring correct administration of the right MRP, to the right patient, with the right activity level, prior to any administration. The adoption of self-checks or a double-check by two different people (when no error recovery measures are possible before injection to the patient) at the various steps in the process, is one means of mitigating the risks.

Organisational measures also help to make the process safer. One could for example mention the steps taken by certain nuclear medicine departments:

- the scheduling of appointments per type of examination, thus limiting the variety of examinations carried out in any given day or half-day (thereby limiting the variety of MRP used),
- classification and marking of the MRP within the radiation protected chamber such as to limit the risk of confusion between the MRP used,
- clear labelling of the MRP vials and syringes, as soon as they have been prepared.

1.3. Identifying working situations for which task interruptions should be limited

In the case studied, the observation of the work done by the MERM showed that those allocated to PET cameras carried out a large number of related activities at the same time as dealing with the patients. They carry out other procedures in addition to injection and imaging (glycaemia measurement, fitting a drip, monitoring the patient after injection) as well as secondary tasks such as dealing with appointments (receipt of requests by fax, transmission to the physician, input into an appointments software), or restocking of boxes.

This situation specific to the department examined illustrates the fact that the departments must identify work situations entailing risks, for which the secondary tasks (unrelated to dealing with the patient) and task interruptions must be limited. The nuclear medicine departments could benefit from using the HAS guide on task interruptions when administering drugs[6].

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[5] Definition of the appendix to ASN Resolution 2014-DC-0463 of 23rd October 2014, concerning minimum technical rules for the design, operation and maintenance of in vivo nuclear medicine facilities: *"chamber, with shielded walls and a specific ventilation system, designed to provide protection against external and internal exposure and to contain the radionuclides and unsealed sources handled inside it"*

[6] http://www.has-sante.fr/portail/jcms/c_2618396/fr/interruptions-de-tache-lors-de-l-administration-des-medicaments

1.4. Promoting measures to improve synchronisation between the radiopharmacy and the MRP administration locations

- **Consideration given to communication at the interfaces as of the premises design phase**

In the department which underwent this study, the MRP – once in the syringe – are made available to the health professionals through 3 hatches. Two of these hatches communicate directly with an administration room. Each administration room is dedicated to certain types of examinations. The 3rd hatch is specifically for transmitting syringes to the other administration locations, which means that the person who then transfers them to the injection location must be defined (radiographer who comes to collect their MRP, or preparer who takes them to the injection room). In most cases, the ready-to-use syringes in their sealed case are placed in each of the hatches and transmitted with no oral communication between the professionals who prepare the syringes and those who will be administering them to the patients.

Here again - and going beyond this particular situation - which illustrates the extent to which communication within a group is a decisive factor in safety - I would ask you to examine the working organisation to be implemented so that conditions conducive to good communication between professionals required to work together in dealing with a particular patient are created, more specifically at the interfaces (preparation/administration). In the situation studied, the configuration of the premises penalised communication between the radiopharmacy and the injection locations, thus creating constraints on the work of the operators. The design phase is an important one and the interactions between professionals must be taken into account as of this phase. Once constraints have been identified and, in terms of communication and premises (oral communication impossible, existing premises constraints) it is difficult to eliminate them, steps must be taken to reduce communication errors.

Synchronisation between the professionals, in particular between the radiopharmacy and the injection locations, could also be improved by real-time sharing of knowledge of the patient's history and the respective constraints of the various players. Provided that they integrate the needs of the operators for the performance of their tasks, information systems are also tools that can facilitate communication at the interfaces.

- **Addressing and improving the human-machine interface**

The study highlighted the difficulties encountered by the professionals owing to the lack of interfacing and interoperability between the various information systems.
In addition, the software and equipment used do not have any means for avoiding or making up for errors.

In the case studied, two IT applications and two software are used, one for scheduling examinations and the other for preparation of the MRP. Apart from the fact that the examinations scheduling software does not take account of the variability and complexity of the examinations, which entails numerous readjustments in the schedules, multiple inputs into the various applications are necessary and are a source of transcription errors.

The nuclear medicine departments must thus examine ways of limiting operator constraints by improving their own human-machine interfaces. All measures to limit re-entry of data, all IT solutions comprising locking and alert functions and blocking steps contribute to making the health care process safer.

2. Improving the risk management approaches

2.1. In-depth analysis going beyond the actual event scenario itself

The purpose of the analysis of significant radiation protection events (ESR) carried out by an experience feedback committee (CREX) comprising various professionals directly involved in the care of patients is to identify the underlying causes[7] leading to the ESR, in order to take appropriate corrective measures to prevent the ESR from happening again.

ASN regularly observes that the event analyses are not conducted in sufficient depth. They stop with the immediate causes, thus hampering the identification and implementation of effective lines of defence[2,3].

As was also observed in the study carried out by IRSN, the event analyses comprise "methodological" bias, which could explain the lack of effectiveness of the corrective steps taken:

- a lack of depth in the analysis, notably organisational failures and/or potential impacts of organisational and technical changes. These failures or changes impact daily working practices. Taking account of these failures or constraints generated by the changes is a means of reducing errors in the activity. For example, an increase in activity led to significant variability in the MRP to be prepared the same day, which more specifically affected the conditions of use of the shielded chambers.

- a consequence of the previous point, an event analysis method leading to a lack of an overview of the error propagation scenario which led to the event, by focusing solely on the immediate causes of this error. This results in difficulty with effectively identifying the nature and possible locations of prevention "barriers", but above all with remedying these errors before they lead to unacceptable consequences. An overview of error propagation in the preparation of a vial of MRP would have highlighted the inability to remedy this error (with the current system) before injecting the patient and would have made the activity safe, notably through the clear definition and implementation of double checks (who? how? when?).

- an analysis limited to the processing of the detected malfunctions, without transposition by analogy to other types of problems which could occur and which could have led to similar consequences. For example, an error in loading the automatic picking machine could have been identified by analysis with the observed error in preparation of an MRP vial in the shielded chamber.

Furthermore, the analysis reveals the fact that the experience feedback committees tasked with analysing the events are essential forums for dialogue between disciplines and that cross-cutting exchanges on practices dealing with organisational matters are to be encouraged within them.

Finally, this ergonomic study proves to be of interest because it complements the more usual experience feedback methods (ORION®, ALARM, causes tree, etc...). This working situation based approach queries the working organisation, the working environment, the material and human resources used to perform the work, as well as relations and communication in the workplace. Direct observations of working situations within a department, supplemented by interviews with the professionals concerned, make it possible to more easily identify the actual working constraints and requirements in the handling and administration of MRP to the patients and to identify weak points in the organisation which can lead to conditions conducive to the occurrence of events.

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[7] HOSF: in-depth event analysis. Les cahiers de la sécurité: n° 2014-04. Institute for an Industrial Safety Culture (ICSI). "Improving the incidents assessment process" Working group.

The deployment of this type of study requires time and skill and can only be performed with the involvement of all those concerned by the activity. Even if not a first-choice tool for drawing up experience feedback about malfunctions and incidents, the repeated occurrence of events should lead the departments to consider the benefits of resorting to this type of study. Finally, the departments could benefit from examining their experience feedback system with the help of the experience feedback practices review guide published by the FONCSI[8].

2.2. Assessing the impact of an organisational or technical change on the work of the operators prior to its implementation

The analysis of the events revealed that most of them occur against a backdrop of reorganisation of the MRP handling work. In the case studied, this reorganisation on several occasions concerned the creation of the pairing of health care professionals responsible for the MRP and for administration to the patients. The latest modification consisted in entrusting the MRP handling and patient administration activity to two separate categories of health care professionals working with different hierarchical and functional links. As these two activities are carried out in separate areas, this led to the creation of two distinct working units within the same department. The result was a breakdown in communication with problems in synchronisation and coordination between the teams handling the MRP and those in charge of caring for the patients with regard to all the other activities in the nuclear medicine department (administration of MRP to the patient, performance of scintigraphy examination with gamma camera or PET scan).

In fact, most of the events analysed by IRSN concerned the preparation of MRP. The professionals were faced with human-machine interface problems, an increase in the rate of PET scintigraphy examinations, with increasingly diverse and complex examinations being performed (increase in the number of MRP used, faster preparation of these products, complex examinations such as myocardium and search for sentinel node), without any assessment of whether the radiopharmacy was capable of handling this increased number of MRP preparation procedures and the diversity of associated protocols.
ASN had already drawn the attention of the departments to the fact that any introduction of a new technique modified the working processes and to the need to run a risk assessment before any deployment2.

The ergonomic study illustrated how an organisational change, an increase in activity and the introduction of a new technique affects the work of the first-line operators (paramedic professionals). ASN made similar findings on several occasions in other fields, such as radiotherapy or interventional radiology.

A study carried out ahead of a technical or organisational change, targeting the working activity, should be able to identify the organisational strengths and weaknesses and allow an upstream identification of the lines of defence that could mitigate the risks, by taking account of all aspects of the work (workers concerned by the activity, environment, working organisation and workspaces, relations and communication between players, tools, equipment and working documents).

The conclusions of the report from the Working Group of the Advisory Committee for medical radiation protection[9] stresses the importance – when introducing a new technique (for example an automated MRP preparation or injection system, a new camera, etc.) – of reviewing the organisation and of managing any reorganisation of work in project mode, involving all the professional categories

[8] Cahiers de la sécurité industrielle n°2014-01 "some pertinent questions to be asked about one's OEF system", Foundation for an industrial safety culture
[9] Recommendations of the working group concerning the conditions of implementation of "new techniques and practices" in radiotherapy

concerned. The project to commission new equipment should take account of the gradual increase in the number of patients, the complexity of the examinations and the means of acquiring and maintaining professional skills in the workplace.

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Experience feedback from events notified to ASN[2, 3] and this study in particular, reveal the need to regularly examine the patient care process and more specifically on the occasion of any technical or organisational change.

The study performed – based on direct observations of working situations, supplemented by interviews with the professionals concerned – can prove to be particularly useful, notably when deployed ahead of any change. It is able to identify the actual working constraints and requirements, to identify weak points in the organisation which can lead to conditions conducive to the occurrence of events, in order to set up lines of defence.
Whatever the lines of defence you consider would be usefully implemented, I would remind you of the need to assess them regularly, as this is the only means of evaluating their effectiveness.

The notifications submitted by the nuclear medicine departments underline the responsible attitude of the professionals in the performance of their duties, ensuring that collective progress is made in the radiation protection of patients.

Yours sincerely,

The deputy Director of
the French Nuclear Safety Authority

SIGNED by

Jean-Luc LACHAUME

Addressees:
The Heads of nuclear medicine departments
The President of the Nuclear Medicine National Professional Council (CNP MN)
The President of the French Nuclear Medicine and Molecular Imaging Society (SFMN)
The President of the French Radiopharmacy Society (SoFRA)
AFPPE: French Association of Radiographers (Association Française du Personnel Paramédical d'Electroradiologie)
The President of the French Association of Nuclear Medicine Technicians (AFTMN)
The President of the National Association of Hospital Pharmacy Preparation Personnel (ANPPH)
The President of the French Society of Medical Physics (SFPM)

[i] AFPPE, AFTMN, ANPPH, CNP de médecine nucléaire, SFPM, SOFRA