AUTORITÉ DE SÛRETÉ NUCLÉAIRE

ASN GUIDES

Guide 16

ALL FIELDS

Significant patient radiation protection events in radiotherapy (criterion 2.1): notification and classification on the ASN-SFRO scale

Version of 17/07/2015

Preamble

The ASN collection of guides is intended for professionals concerned by the nuclear safety and radiation protection regulations (licensees, users or transporters of ionising radiation sources, general public, etc.).

The guides set out recommendations with the aim of:

- explaining the regulations and the rights and obligations of the persons concerned by the regulations;
- explaining the regulatory objectives and, as applicable, describing the practices considered by ASN to be satisfactory;
- giving practical tips and information concerning nuclear safety and radiation protection.

Application of these guides does not in any way reduce the responsibility of a Basic Nuclear Installation licensee with regard to the safety of its installation.

ASN Guide no. 16 was edited on 17 July 2015.

Contents

1. INTRODUCTION

1.1. Background and regulatory references

The system for notifying significant radiation protection events (ESR) affecting patients was put in place in July 2007 The obligations incumbent on those responsible for a nuclear activity, particularly with regard to informing ASN (Autorité de Sûreté Nucléaire), the French nuclear regulator, about the incidents or accidents in the field of radiation protection, are specified in the Public Health Code. In effect, the Public Health Code stipulates in its Article L. 1333-3 that the "person/entity responsible for one of the activities mentioned in Article L. 1333-1 is obliged to notify ASN and the State representative in the *département* without delay of any incident or accident that could jeopardise the health of persons through exposure to ionising radiation."

Article L. 1333-3 was amended (by Act 2009-879 of 21 July 2009 reforming the hospital and relative to patients, health and the regions) published in the Official Journal of the French Republic (JORF) No. 167 of 22 July 2009 to extend the notification obligation to health professionals participating in the treatment or monitoring of patients exposed to ionising radiation for medical purposes and having knowledge of an incident or accident linked to this exposure."

Article R. 1333-109 was also amended (the implementation decree was published in the JORF of 4 May 2010) accordingly to integrate these new requirements. Furthermore, it stipulates in paragraph III that "the person/entity responsible for a nuclear activity has the significant events analysed in order to prevent future events, incidents or accidents." It is to these ends that this guide proposes a Significant Radiation Protection Report template.

In the course of 2007, in order to apply the notification system in practice, ASN set up, as an experiment, a system for notifying significant radiation protection events based on criteria, along with a communication policy for events affecting patients in the course of medical radiotherapy procedures. This communication policy is based on an events classification scale developed jointly by ASN and the French Society for Radiation Oncology (SFRO), namely the ASN-SFRO scale.

Evaluation of the effectiveness of the system put in place with the medical professionals in July 2008

ASN participates, with the other health safety players, in following the national actions programme launched by the Minister of Health and Sports, with the aim of improving the safety of radiotherapy treatments. On this account, ASN was called upon to carry out an assessment of the significant radiation protection events in radiotherapy (action 7.4 of the roadmap of national measures for radiotherapy[1]).

An assessment of the significant radiation protection events notification system and of the ASN-SFRO scale was carried out with the medical professionals concerned. This assessment revealed difficulties, particularly regarding the assimilation of the notification procedure by the medical professionals (confusion between the notification criteria on the one hand, and the methods of classification on the ASN-SFRO scale), the

[1] *The version of 12 November 2007 of the roadmap of national measures for radiotherapy can be consulted at https://sante.gouv.fr/IMG/pdf/Sommaire_-_Feuille_de_route_des_mesures_nationales_pour_la_Radiotherapieadiotherapie-nov2007.pdf*

understanding of criterion 2.1 (event concerning one or more patients subjected to exposure for therapeutic purposes) and ASN's communication on the events, on the other hand.

This assessment led to:

- a change in the definition of criterion 2.1, which was disseminated to all the radiotherapy centres in 2009,
- updating of the ASN-SFRO scale,
- an adjustment in ASN's communication policy for events rated level 1 on the ASN-SFRO scale,
- a change of the notification form and the significant radiation protection event report to incorporate the information necessary for validation of the classification by ASN and SFRO and promote learning from experience.

To facilitate the significant radiation protection event notification process, the guide presents the procedures for notifying a Significant Radiation Protection Event (ESR), for drawing up the Significant Event Report (CRES) and lastly for classifying the event on the ASN-SFRO scale.

1.2. Scope of application

This guide is applicable for the notification and analysis of significant patient radiation protection events in the field of radiotherapy (external-beam radiotherapy and brachytherapy).

It does not address the notification obligations imposed in application of the Labour Code and the Environment Code. Nor does it address the measures to take for the protection of workers or the public, or with regard to vigilance (medical devices vigilance, serious adverse event linked to treatment, etc.)[2].

Lastly, it is not intended to set out the methods of internal management of adverse situations or malfunctions which have been obligatory since 25/03/2010 in application of ASN Technical Resolution 2008-DC-0103. It nevertheless details the relationship between the methods of managing these situations or malfunctions and the significant radiation protection events concerning patients that are required to be notified to the authorities.

To enable the radiotherapy professionals to fulfil their notification obligations concerning both radiation protection and medical devices vigilance (L. 5212-2 and R. 5212-14 of the Public Health Code), ASN and the ANSM created an on-line portal in July 2011 for notifying these events (www.vigieradiotherapie.fr). This tool, which is part of the measures of the ministerial roadmap for radiotherapy, produced in collaboration with the medical professionals, is intended to facilitate notifications and foster capitalising on lessons learned to continuously improve the effectiveness and safety of radiotherapy treatments, which occupy a major position in the fight against cancer

1.3. Purpose of the guide

The guide provides the tools and the methodological references enabling the notifier to manage a significant radiation protection event (ESR) concerning a patient (criterion 2.1 of ASN Guide No. 11). It effectively presents the procedures for notifying significant events and drawing up the significant event report, and the ASN-SFRO scale used to classify the event. It thus constitutes a stand-alone document for addressing significant radiation

[2] *See appendix 1 of this guide*.

protection events occurring in radiotherapy and concerning a patient. For the other notification criteria, refer to Guide No. 11 which can be downloaded from ***https://teleservices.asn.fr***.

1.4. Document status

This guide results from the collaborative work of the radiotherapy professionals, the SFRO, the French Society of Medical Physics (SFPM) and the French Association of Radiographers (AFPPE). It stems from ASN Guide No. 11 "Significant radiation protection events (excluding Basic Nuclear Installations and the transport of radioactive materials): notification and codification of the criteria" for events concerning patients occurring in the field of radiotherapy (external-beam radiotherapy and brachytherapy).

2. NOTIFYING A SIGNIFICANT RADIATION PROTECTION EVENT CONCERNING THE EXPOSURE OF A PATIENT

2.1. General principles

In order to define the quality assurance requirements in radiotherapy, ASN Resolution 2008-DC-0103 of 1 July 2008 was published in the Official Journal on 25 March 2009.

As part of the continuous improvement of processes, this resolution imposes the internal notification of malfunctions or adverse situations, the setting up of a specific organisation for analysing them and the defining of improvement actions. These measures are to be put in place no later than one year after publication of the resolution approval order, that is to say 25 March 2010. Consequently, the person/entity responsible for the activity must record all the internally-notified malfunctions or adverse situations. It keeps the documents and records relating to radiation protection at the disposal of the ASN radiation protection inspectors referred to in Article L. 1333-17 of the Public Health Code.

Among the events that can occur in a facility or during an activity, it is obligatory to notify some of them to the competent administrative authority, depending on the nature of the event (see Appendix 1). The process for addressing malfunctions must enable those that can be addressed internally to be distinguished from those that are subject to notification.

As for the events qualified as "significant radiation protection events" concerning patients, they must be notified to ASN and to the Director General of the Regional Health Agency (ARS). Notification criteria have been defined by ASN in order to identify these events. These criteria take account of:

- the consequences, whether real or potential, for the workers, the general public, patients or the environment, of the radiation protection events that can occur;
- the main technical, human or organisational causes that can lead to the occurrence of such an event.

The notification criteria for significant radiation protection events are set out in Guide No. 11. Among these, criterion 2.1 applies to events concerning one or more patients subjected to exposure for therapeutic purposes. This guide only addresses the events concerning patients.

2.2. Definition of criterion 2.1: event concerning one or more patients subjected to exposure for therapeutic purposes

The following are considered to be significant events:

- any undesirable situation or any malfunction concerning organizational, material or human aspects occurring during the radiotherapy treatment of a patient resulting in the delivery a dose that does not conform to the prescription(*);
- any undesirable situation or any malfunction relating to organizational, material or human aspects occurring during the treatment of a patient having caused the appearance of unforeseeable deterministic effects given the therapeutic strategy adopted in consultation with the patient.

(*) The conformity of the delivered dose includes:

- o in radiotherapy and brachytherapy, compliance with the total prescribed dose to within a tolerance of +/-5%, and compliance with the planned dose protraction and/or fractionation, taking into account any clinical or technical constraints in the treatment of a patient; in targeted internal radiotherapy, compliance of the activity of the administered radiopharmaceutical with a tolerance of +10% of the prescribed activity;
- o the absence of systematic dose errors for several patients, whatever the value of that dose error.

2.3. Examples

To facilitate the identification of events that must be notified to ASN, a series of examples in external-beam radiotherapy and brachytherapy is provided below.

The reader can refer to the newsletter *Patient safety – Paving the way for progress* No.4, published in April 2013 entitled "Which events are to be notified to ASN ?" available on ***https://teleservices.asn.fr***.

2.3.1. Events that must be notified to ASN

- Event having led to the delivery of a physical dose to a patient that differs from the total prescribed dose outside a tolerance of +/- 5 % in the planned volumes:
  - Distance error (mixing up source-tumour distance/source-skin distance (STD/SSD), etc.); ;
  - Error in taking into account beam modifying devices (manual, motorised or dynamic wedge filter, bolus, etc.);
  - Error in the monitor units (data transmission error, parameter entry error, etc.); ; o etc.
- Event associated with a volume error; Dose errors can include volume errors. It is up to the radiation oncologist to assess to what extent this volume error can be qualified as "not conforming to the prescription" as regards the delivered dose.
  - Isocentre error (patient positioning error, wrong side, etc.);
  - Beam shaping error (dimension, cover, positioning of collimator leaves, etc.);
- Ballistic error (gantry angle, rotation of the collimator, etc.);

- Event associated with patient or data identification error
  - Patient identification error (including cases in which the two treatments involved concern the same location and similar volumes);
  - Selection of data that do not correspond to the patient undergoing treatment (including cases in which the two treatments involved concern the same location and similar volumes);
- Event associated with a systematic error resulting in the delivery to several patients of a physical dose different to the total prescribed dose, whatever the value of the dose error; thus a systematic dose error, even minimal within the tolerance margin of ±5% with respect to the prescribed dose, must be notified.
  - Error in setting the accelerator parameters (calibration error due to using the wrong correction factor or an inappropriate detector, etc.);
  - Error in the monitor units associated with a data transmission problem, incorrect software parameter setting, etc.);
  - Source positioning error in pulsed dose rate brachytherapy due to a misinterpretation of the identification of the fictitious source used;

    NB: These systematic malfunctions must be notified, even if at the time of detection they have only affected a single patient in a single session.
- Other: Any non-compensated protraction and/or fractionation error (not associated with the clinical or technical constraints of the treatment).

2.3.2. Events not falling within the notification criteria

- Dose error for a patient within the +/-5% tolerance margin with respect to the total physical dose;
- Nonconformity of the dose for one or more treatment sessions, compensated for before the end of the treatment;
- Change in the fractionation due to unavailability of the machine or restricted opening days of the service;
- Change in treatment due to the clinical condition of the patient;
- Uncertainties in the measurement of doses;
- Complications observed further to a radiotherapy treatment and not caused by a malfunction identified during the treatment process. They can form the subject of a notification under Article L. 1413-14 of the Public Health Code if they meet the regulatory criteria for making the notification.

To summarise, the following radiotherapy events concerning a patient must be notified:

- Deterministic effects that were unforeseeable given the therapeutic strategy;
- Dose errors exceeding ±5%;
- Volume errors;
- Non-compensated protraction and fractionation errors;
- Patient identity errors;
- Systematic malfunctions, even if at the time of detection, they have only affected a singled patient in a single session, whatever the value of the dose error.

2.4. Notification deadlines and procedures

The expression "notification without delay" figuring in the Public Health Code requires clarification in order to harmonise the notification procedures and deadlines.

The person/entity responsible for the nuclear activity assesses the urgency of notification in view of the confirmed or potential seriousness of the event, the number of patients affected and how generic the event is. Nevertheless, this notification deadline shall not exceed 2 working days following detection of the event.

A "significant event notification" is sent to the addressees referred to below, even if the initial results of the investigations to determine the circumstances of the event have not yet been obtained.

The elements to include in the notification are set out in Appendix 2, as is the notification form. This form enables ASN to rapidly obtain a minimum amount of information enabling it to fulfil its analysis, evaluation and information duties.

The on-line notification website ***https://teleservices.asn.fr*** enables radiotherapy professionals to give the competent authorities notification of:

- a significant radiation protection event (ESR) concerning any incident or accident that could jeopardise the health of persons through exposure to ionising radiation;
- a medical devices vigilance incident: any incident or accident incriminating a device which has led or could lead to the death or severe deterioration of the health of a patient, an operator or a third party,
- an event concerning both medical device vigilance and radiation protection (a combined event).

Complications observed further to a radiotherapy treatment and not caused by a malfunction identified during the treatment process are not to be notified via this portal.

2.5. Addressees of an ESR notification under criterion 2.1

Independently of the obligations to inform that may stem from the application of other regulations, the notifications are sent to the competent ASN regional division in the region in which the event occurred (contact details of the ASN regional divisions on www.asn.fr /Contact). With radiotherapy incidents or accidents whose confirmed or potential impact is of a particularly serious nature, and notably if a cohort of patients is involved, the ASN head office departments (department of ionising radiation and health) inform the competent national authorities as required for the management of these incidents and accidents (Ministry of Health, ANSM, InVS and IRSN).

In application of Act 2009-879 of 21 July 2009 reforming the hospital and concerning patients, health and the regions, published in the JORF No. 167 of 22 July 2009, the ESR notification is also made to the Director General of the Regional Health Agency (ARS) who will inform the regionally competent State representative under the conditions provided for in Article L. 1435-1 of the Public Health Code.

3. THE SIGNIFICANT EVENT REPORT (CRES)

3.1. General principles

To supplement the initial analysis of the notification, a significant event report is to be sent to ASN. The quality of the analysis and of the significant event report will determine the relevance of the experience feedback to the medical professionals. It is therefore essential for the content of this document to clearly identify the causes and factors contributing to the occurrence of the event by integrating the human and organisational aspects. It is in this sense that the *CRES/MED/RT* template proposed on ***https://teleservices.asn.fr*** has been adapted in order to integrate the information necessary for experience feedback.

3.2. Deadlines and procedures for sending the significant event report

The "significant event report is drawn up and sent to the same addressees as the notification form within 2 months following notification. This time frame is intended to allow performance of the analyses necessary in order to fill out the significant event report form. The report must effectively integrate an update of the notification and a detailed analysis of the causes of the event and a description of the corrective measures implemented or planned. The explanations necessary for drawing up the CRES are provided in Appendix 3. A template of the *CRES/MED/RT* report is provided on ***https://teleservices.asn.fr***.

Whatever the case, the significant event report is co-signed by the person responsible for the nuclear activity and by the head(s) of the establishment(s) concerned or by their designated representatives.

4. CLASSIFICATION ON THE ASN-SFRO SCALE

4.1. General principles

One of the duties of ASN is to take part in informing the public in the fields of nuclear safety and radiation protection (Environment Code, Article L. 125-13).
The aim of classifying the events on the ASN-SFRO scale is to rate them according to their seriousness and define an appropriate means of communication to the public.

Application of this scale was jointly evaluated in June 2008 by ASN, the SFRO and the SFPM. It proved to be a good information aid, facilitating the perception of the seriousness of an event by the media and the public.

To facilitate events classification, the notification form includes the information necessary for classification and validation of the classification. This information figures on pages 3 and 4 of the form and is only to be filled out if the event is likely to be classified at level 2 or higher on the ASN-SFRO scale or if in doubt about the classification.

4.2. ASN-SFRO scale

The different levels are presented in appendix 4.

The events are classified on the ASN-SFRO scale into eight levels.

- Levels 0 and 1 are used to classify events that have no clinical consequences for the patient(s) concerned;
- levels 2 and 3 correspond to events qualified as "incidents";
- levels 4 to 7 correspond to events qualified as "accidents".

The severity of the effects is assessed by referring to the international clinical classification (CTCAE[3] grades), already used by practitioners.

The effects taken into consideration in the notification to ASN are the unexpected or unforeseeable effects due to inappropriate doses or irradiated volumes; any secondary effects, whatever their grade, resulting from the treatment strategy chosen by the practitioner in consultation with the patient, and which appeared in the absence of any error in the irradiated volumes or dose delivered (accepted risk) are not taken into consideration.

For patients affected by an ESR, the resulting effects or complications may be latent or vary in time. An event can thus be provisionally classified at one level, which may be modified according to the development of the patient's state of health.

Unlike the INES scale, the defence in depth criterion (assessment of the level of safety of the radiotherapy activity) is not used in this classification, to avoid confusion between medical seriousness and a failure in the system or the organisation of the department.

4.2.1. Classification criteria

Like the INES scale, the criteria for classifying an event on the ASN-SFRO scale concern not only the confirmed consequences but also the potential effects of the events. When several patients are concerned by the same event, the chosen classification level corresponds to the most serious observed or expected effects. In the case of confirmed effects, the number of patients exposed is also taken into account.

The radiotherapy events notified to ASN under criterion 2.1 are classified on the ASN-SFRO scale, with the exception of events giving rise to underdosing of the target volume (see newsletter *Patient safety – Paving the way for progress* No.4, published in April 2013 entitled "Which events are to be notified to ASN?" available on *https://teleservices.asn.fr* .

4.2.2. Criteria concerning the confirmed consequences

When the effects are confirmed, classification is carried out referring to the different clinical classification grades of the CTCAE scale. Therefore:

- level 1, corresponding to grade 1, covers benign effects as well as events for which no effects are expected;
- level 2, corresponding to grade 2, covers acute effects or moderate latent effects such as moderate radiation-induced stenosis, tissue damage causing little inconvenience (cutaneous fibrosis), or minimal or zero deterioration in quality of life;

[3] *Common Terminology Criteria for Adverse Event, Cancer Therapy Evaluation Program, August 2006, http://ctep.cancer.gov*

- level 3, corresponding to grade 3, covers acute effects or severe latent effects such as manageable and non-life-threatening tissue necrosis, with moderate deterioration in quality of life (severe proctitis, severe cystitis, etc.);
- level 4, corresponding to grade 4, covers acute effects or severe latent effects such as tissue necrosis that are manageable and not life-threatening, with moderate deterioration in quality of life (e.g. severe proctitis, severe cystitis);
- levels 5, 6 and 7, corresponding to grade 5 of the clinical classification, make reference to one or more cases of death.

4.2.3. Dosimetric criteria and potential effects

When the effects are not yet confirmed, dose or irradiated volume criteria are used for a provisional classification. The difference between the dose received and the planned dose is evaluated on the basis of permissible or tolerated deviations, in view of existing practices or available references.

Likewise, the difference between the volume actually irradiated and the volume that should have been treated is analysed taking into account whether or not organs particularly sensitive to radiation are present in the area.

In the case of significant, perhaps even very significant differences, the event will be rated level 2 or 3, or perhaps even 4.

If there is great uncertainty about the possible appearance of potential effects, the event is rated level 1 or level 2 (depending on the conditions of the event).

4.2.4. Criteria concerning the number of patients exposed

For confirmed effects of level 2, 3 or 4, the rating is assigned a + sign when the number of patients concerned is greater than 1.

In the case of an event having resulted in the death of several patients, the level 5 rating is increased by:

- + 1 if the number of patients concerned is greater than 1 and less than or equal to 10;
- + 2 if the number of patients concerned is greater than 10.

In order to avoid any confusion about the severity of the effects, the upgrading criterion concerning the number of cases is not applied in the case of potential effects unless the information concerning the delivered dose and/or the irradiated volume already enable(s) a prognosis to be made in terms of death, serious or severe effects.

4.3. Classification (rating) process

For each significant event notified to ASN, the rating is proposed by the person responsible for the activity on the notification form. This rating is then validated by ASN after consulting the SFRO. The SFRO is always consulted if the prospective rating of the event corresponds to level 2 or higher, and in case of doubt for all the other rating levels.

To enable this event to be classified and validated, some essential information must be recorded in the significant event notification form. This information is listed below:

- type of tumour treated (primitive tumour, metastatis whether single or not, histology);
- precise description of the treatment plan (total prescribed dose, dose fractionation, number of beams and contribution of each beam to the dose);
- number of sessions during which the error occurred and number of beams concerned; ▪ dosimetry: ○ difference in absolute value and as a percentage between the prescribed dose and the dose delivered to the target volumes;
- ○ dose delivered to the critical organs;
- qualitative description (anatomical region, organ) and quantitative description (dose, volume) of the irradiated regions outside the target volume further to noncompliance with the initial treatment plan;
- confirmed consequences (description of the observed effects / clinical observations);
- potential consequences;
- number of patients concerned with confirmed effects; number of patients concerned with potential effects.

The above information must include the data concerning the continuation of the treatment effectively carried out after detection of the event.

5. INFORMING THE PUBLIC

By way of introduction, it must be underlined that the physician is responsible for informing the patient. The patient must be informed within 15 days after discovering a harmful treatment outcome, in accordance with Article L. 1142-4 of the Public Health Code. The French National Authority for Health (HAS) has published a guide entitled "*Annonce d'un dommage associé aux soins* " (Disclosing harmful treatment outcomes to patients) to help the medical professionals in their obligation to inform the patient.

If ASN informs the public following a significant radiation protection event, this is done obligatorily after the patient(s) concerned by this event has/have been informed, in accordance with Article L. 1142-4 of the Public Health Code.

The information is communicated as early as possible after finalising the significant event report (CRES) and dialoguing with the medical centre concerned. If the nature of the ESR so necessitates (very serious, involving cohorts, generic), it can be communicated more promptly after notification, in consultation with the medical centre concerned.

ASN's communication is separate from that of the medical centre. The information is adapted to the seriousness of the event, whether confirmed or potential, and the number of patients concerned. The information provided focuses essentially on the actions taken by ASN and the medical centre concerned to assess the situation and learn the lessons from it in terms of treatment safety.

The radiotherapy centre is responsible for defining its communication policy. Information communicated locally by the radiotherapy centre and prior to ASN's communication is likely to facilitate information management and relations with the media.

The methods of informing the public depend essentially on the event's rating on the ASN-SFRO scale. The ESRs are thus made known to the public as follows:

- events rated level 0 on the ASN/SFRO scale are listed in the ASN annual report;
- events rated level 1, other than events concerning a cohort of patients (serial events), are summarised in a quarterly report that does not mention the names of the notifying medical centres, published on the website ***www.asn.fr***;
- serial events rated level 1 (single cause in a cohort of patients), and those rated level 2 or higher form the subject of an incident notice mentioning the place of occurrence in the section devoted to incident notices concerning the medical field (***https://www.asn.fr/espace-professionnels/activites-medicales/evenements-significatifs-dans-le-domaine-medical***). Where applicable, level-1 serial events or level-2 events may be covered by an information notice (teaser on first page of the ASN website with a link to the incident notice);
- events rated level 3 are always covered by an information notice. They may, where appropriate, be covered by a press release (ASN informs the media);
- as of level 4, the events are covered by a press release.

For reasons of ethics, some events rated level 2 are not covered by an incident notice.

Appendix 1

REMINDER OF THE MAIN REPORTING OR NOTIFICATION OBLIGATIONS FOR EVENTS AFFECTING A PATIENT

The notification of a significant radiation protection event does not exempt the person or organisation producing or using the ionising radiation from the obligations imposed by other regulations. A useful reference document is the 2009 issue of "*Sécurité sanitaire dans les établissements de santé - réglementation applicable*" (Health safety in health care facilities – Applicable regulations), a frame of reference produced by the Ministry of Health (DGOS).

The list proposed below is for information only. It does not in any way constitute an exhaustive overview of the reporting systems imposed by the regulations in effect.

1. Applicable provisions regarding external notifications

Applicable provisions regarding vigilance (health products)

Notifications to the ANSM are mandatory with regard more specifically to:

- medical devices vigilance, for the purpose of monitoring incidents or risks of incidents resulting from the use of medical devices (Article L. 5212-2 of the Public Health Code);
- in vitro medical diagnostic devices emitting ionising radiation (Article L. 5222-3 of the Public Health Code);
- reporting to the ANSM of the serious and unexpected adverse effects that could be caused by a radiopharmaceutical drug (drug safety monitoring) (Articles R. 5121-170 and R. 5121-171 of the Public Health Code);
- adverse effects occurring during biomedical research concerning a radiopharmaceutical drug, a medical device or an in vitro medical diagnostic device emitting ionising radiation (Article L. 1123-10 of the Public Health Code, notification to ANSM and the competent research ethics committee).

Notification to the Director of the Regional Health Agency (ARS) of nosocomial infections or any other serious adverse event associated with the health care delivered during investigations, treatments or prevention actions, provided for in Article L. 1413-14 of the Public Health Code.

2. Applicable provisions regarding internal notification of adverse situations or malfunctions

The notification and internal recording of adverse situations or malfunctions was rendered mandatory as of 25 March 2010 by ASN Resolution 2008-DC-0103 of 1 July 2008 setting the quality assurance obligations in radiotherapy.

All personnel directly involved in the therapeutic treatment of radiotherapy patients must thus notify each adverse situation and each malfunction, whether of organisational, material or human origin, to the organisation described in Article 11 of the resolution. On this account, all notifiers must record at least the date of notification, a description of the event, the circumstances under which it occurred and its consequences.

Appendix 2

SIGNIFICANT RADIATION PROTECTION EVENT NOTIFICATION FORM

The notification contains the following information at least:

- the information concerning the person responsible for the activity;
- the information concerning the notifier (insofar as this may not be the person responsible for the activity, in application of Article L. 1333-3 of the Public Health Code amended by Act 2009-879 of 21 July 2009 reforming the hospital and concerning patients, health and the regions). This part is only to be filled out if the notifier is not the person responsible for the activity;
- the information concerning the significant event, including more specifically:
    - the date and place of occurrence of the event;
    - the stage of the clinical process at which the event occurred;
    - the proposed classification (rating) on the ASN-SFRO scale, which must be decided by the person responsible for the activity;
    - the information concerning detection of the event: When? At which stage of the clinical process? What were the means of detection? By whom?
    - the number of patients concerned in the case of cohorts;
    - a description of the event: circumstances of occurrence and description of the facts, presumed cause, actual consequences and immediate precautionary measures;
- additional information to be provided for any event that could be classified level 2 or higher:
    - pathology treated;
    - precise description of the treatment plan and the treatment effectively delivered;
    - planned dosimetry / effective dosimetry.

This part of the form is vital for validation of the classification of events rated level 2 or higher. Below this level there is no need to fill it out.

It is recommended to use the notification website *https://teleservices.asn.fr* for the notification of ESRs.

NOTIFICATION OF SIGNIFICANT EVENTS IN PATIENT RADIATION PROTECTION
CRITERION 2.1: RADIOTHERAPY

It is preferable to enter the information in the file you can download from www.asn.fr

Date of sending the notification: ……

Space reserved for ASN

Reference: …… **Date: ……** **Revision: ……**

Person responsible for the activity

Surname, first name: ……
Professional address: ……
……
SIRET (company registration No.): ……
Telephone: ……
Fax: ……
E-mail: ……

Person to contact for further information:

Surname: …… first name: ……
Function: ……
Telephone: ……
Fax: ……
E-mail: ……

Notifier (if other than the person responsible for the activity)

Surname, first name: ……
Professional address: ……
……
SIRET (company registration No.): ……
Telephone: ……
Fax: ……
E-mail: ……

Space reserved for ASN

Reference: ..... **Date:** ..... **Revision:** .....

Person responsible for the activity

Surname, first name: .....
Professional address: .....
.....
SIRET (company registration No.): .....
Telephone: .....
Fax: .....
E-mail: .....

Person to contact for further information:

Surname: ..... first name: .....
Function: .....
Telephone: .....
Fax: .....
E-mail: .....

Notifier (if other than the person responsible for the activity)

Surname, first name: .....
Professional address: .....
.....
SIRET (company registration No.): .....
Telephone: .....
Fax: .....
E-mail: .....

The significant event:

Description of the event:

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Date and time of occurrence:	**Stage of the clinical radiotherapy process at which the significant event occurred:**	**Proposed classification on the ASN/SFRO scale (external-beam radiotherapy and brachytherapy):**
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Detection:			
Date and time of detection:	Stage in the clinical radiotherapy process that allowed detection:	Means of detection:	Function of the person who detected the event:
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.....	.....	.....	.....
.....	.....	.....	.....
.....	.....	.....	.....
.....	.....	.....	.....

In the case of cohorts: .....

Number of patients concerned with confirmed effects: .....

Number of patients concerned with potential effects: .....

Event:

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Presumed cause(s) of the event

☐ equipment ☐ software ☐ organisational

☐ human others (specify): .....

Several possible causes

Actual consequences on the patient (observed effects, dated clinical observations):

.....

.....

.....

.....

Immediate precautionary measures and corrective actions:

.....

.....

.....

.....

.....

.....

Signature of notifier

Date:

Signature:

Completion of this section is mandatory for any event that could be classified level 2 or higher on the ASN-SFRO scale.

Pathology treated

Location of the tumour: .....

TNM classification (staging) [4] of the tumour:

.....

Associated treatments:

.....

.....

.....

Treatment plan precise description of the treatment plan (total dose, dose per session, number of sessions per week, number of beams per session, beam energy level, contribution of each beam to the dose, size of fields, presence of filters, covers, etc.)

Treatment plan validated and in conformity with the prescription:	Treatment effectively delivered (including, where applicable, the treatment modifications introduced further to detection of the event):
1st phase:	1st phase: .....
.....	.....
.....	.....
.....	.....
2nd phase:	2nd phase: .....
.....	.....
.....	.....
.....	.....
.....	.....

Number of beams concerned by the malfunction(s): .....

Number of sessions concerned by the malfunction(s): .....

Qualitative description (anatomical region, organ(s)) and quantitative description (dose, volume) of the irradiated regions outside the target volume and volumes not specified in the prescription, further to noncompliance with the treatment plan: .....

.....

.....

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.....

.....

[4] TNM Classification of the Union for International Cancer Control standardises the description of the anatomical extent of the cancer, where T refers to the size of the main tumour, N to the number of nearby lymph nodes that have cancer, and M refers to whether the cancer has metastasized or not.

Dosimetry: Difference between the prescribed total dose and the dose delivered

TO THE TARGET VOLUMES

% volume	Planned	Delivered	
	Dose (Gy)	Dose (Gy)	Difference in %

TO THE CRITICAL ORGANS

Organ concerned	% volume	Planned	
		Dose (Gy)	Dose (Gy)

Signature of person responsible for the activity

Date:

Signature:

Appendix 3

REPORT OF A SIGNIFICANT PATIENT RADIATION PROTECTION EVENT IN RADIOTHERAPY (CRITERION 2.1) - METHODOLOGICAL REFERENCES

The information expected in the Significant Radiation Protection Event Report (CRES) is indicated below. **A template of the CRES/MED/RT report (criterion 2.1) is provided on *https://teleservices.asn.fr*.** The required information can nevertheless be communicated to ASN in another form.

1. Event synthesis

The information contained in the section "Event synthesis" enables the Significant Event Report to be linked to the notification. The state of progress of the event analysis is also indicated in this section.

2. Methods of event analysis

The aim of the information provided in this section is to characterise the methods and means used for the analysis. The following are specified: the date(s) of the analysis, the functions of the analysis supervisor and the other people involved, and the method used to perform the analysis: cause tree[5], ALARM [6]...

3. Analysis of the event

DETAILED RECONSTRUCTION OF THE CHRONOLOGY OF FACTS:

What is required here is to set out the identified fact in their chronological order in order to reconstruct the event scenario until the feared event occurred.

The description shall not contain any judgement of value or interpretation. It shall not contain any "non-facts" either (e.g.: absence of procedure) but shall describe what effectively happened.

The chronology shall always indicate the dates and times of the various events mentioned and shall be illustrated by drawings and diagrams to facilitate understanding where necessary.

[5] *Cause tree: Retrospective events analysis method developed by INRS: http://www.intefp-sstfp.travail.gouv.fr/datas/files/SSTFP/1999%20Arbre%20des%20causes%20CRAM%20Bourgogne.pdf*

[6] *ALARM method: analysis method developed by Charles Vincent and his team, published in 1998 (Vincent, Taylor-Adams and Stanhope, BMJ 1998 316:1154-1157).*

ANALYSIS OF THE CAUSES:

The analysis of the causes aims to identify the causal concatenations between the shortcomings, the context factors and the influencing factors.

The use of a "cause tree" analysis method provides for an easily accessible graphic representation of the scenario. For each fact mentioned, the following questions must be asked: "what mistakes had to be made for this to happen?"; "Is it necessary?" "Is it sufficient?"

Other methods can also be used, notably to address the root causes, such as the ALARM method.

Human failings

The unintentional or intentional nature of the human failings shall be specified, in accordance with the following definition:

- Unintentional failing: unaware of the act at the time it was carried out, or displaying an incapacity to perform the activity (exceeding of the physical, physiological and/or psychological capacities of the operators).

With this type of failing, the question is to identify in which phase of the process the failing occurred:

  - during the perception and/or interpretation of the situation: in this case, the influencing factors will focus primarily on the presentation of the information and improving the ability to detect situations.
  - during the action of the operator: in this case the influencing factors will focus primarily on the conditions of action of the operator (availability, accessibility of the technical devices, of the documentation, prioritisation of the actions, etc.).

- the intentional failing ("violation" according to Reason[7]) when the operator considers that the work situation components (work organisation, staffing levels and skills, technical devices and work environment) and the prescribed frame of reference do not meet the criteria necessary for performance of the activity. This violation differs from a malicious act in that it is committed with the aim of performing the activity and not to harm the system.

These elements will serve to identify the components of the local work situations that fostered the onset of the human failing(s).

[7] ***Reason model: James Reason has developed a model based on the metaphor of Swiss cheese which suggests that numerous contributors (the holes in the slices of cheese) must be aligned for a feared event to occur. The barriers, symbolised by the aligned cheese slices, are provided to prevent the errors that result from a feared event. This model identifies several types of failings: latent failings and active or patent failings mentioned in the ANAES (French National Agency for Health Accreditation and Evaluation) document: Methodological principles for managing risks in health care facilities. The third version of the model proposed by J. Reason in Managing the Risks of Organizational Accidents (1997) introduces 2 types failings in the active failings: violations and errors, terms that are maintained in the subsequent versions of the model (Revisiting the "Swiss Cheese" model of accident, EEC Note No. 13/06., J. Reason, E. Hollnagel, J. Pariès, 2006).***

Technical failings:

The aim here is to characterise the equipment failings involved in the event scenario: nature and role of the equipment items, operating status, failed statuses, verifications performed during the period preceding the event, etc.;

Influencing factors:

The influencing factors considered here make reference to the notion defined in the ALARM method. They concern the characteristics inherent to the system and/or its organisation in the normal situation that fostered occurrence of the event.

Two levels can be identified:

- a local level, corresponding to the characteristics of the components of the work situation(s) (technical devices, work environment, staffing levels and skills, work organisation) that fostered the human failing(s) concerned: Examples of components that shall be identified include insufficient illumination of the work surface, software with low error-tolerance, lack of clarity in task allocation, etc.
- ○ an overall level, characterising the methods of design and modification of the work situation components (technical devices, work environment, staffing levels and skills, work organisation) and the cultural factors specific to the sector or to the activity which fostered the appearance of the local influencing factors in the work situation(s) considered. Examples of components that shall be identified include insufficient consideration of the conditions of performing the activity in the design of new work situations, a change in work situations that does not take into account the staff actually available, insufficient consideration of the different modes of access and accessibility of the patient in the design of the premises, etc.

NB: in the case of the medical sector, the elements characterising the patient (in the normal operating context for the influencing factors) are also to be taken into account.

Context factors:

The aim is to identify the contextual elements that contributed to occurrence of the event. These concern the following elements:

- recent changes in the work situation (commissioning of a new accelerator, relocation, putting in place a new work organisation, changes in opening hours, implementation of new treatment techniques, new protocols, etc.);
- the management of one-off degraded situations: equipment not available, personnel not available, unusual situation in terms of patient management, emergency treatment due to the clinical condition of the patient, etc.

4. Identification of deviations:

The aim here is to distinguish, among the causes identified in the previous analysis, those that constitute deviations from the regulations (e.g.: treatment not validated by the physicist and radiation oncologist, non-compliance with quality control frequency, etc.), deviations from the internal quality baseline requirements or from good practices or rules of the trade if, for example, the internal baseline requirements are incomplete.

The deviations are subject to a causal analysis to determine the appropriateness of the proposed corrective actions.

5. Identification and analysis of the robustness of the lines of defence:

Based on the reconstructed scenario, this section aims to characterise the robustness of the existing lines of defence, and therefore to determine whether or not they functioned. The failings not detected in the prospective risk analysis shall also be identified, and for which the aim will be to determine measures for setting up lines of defence. The discovery, through a significant radiation protection event, that it is impossible to apply a double check may lead the department to reassess the effectiveness of this line of defence, to replace it or to introduce a supplementary line of defence, for example.

Also, to be indicated here are the incidental actions that led to the detection of the event or certain failings or enabled the consequences to be mitigated, but which were not previously identified as a line of defence (notably in the prospective risk analysis). The aim here will be to put forward the adaptive and resilient nature of the human activity by characteristising the influencing factors that contribute to this ability to recover from failings and which may subsequently be transcribed in the prospective risk analysis.

6. Consequences (on the facility, the patient, the personnel, the environment)

THE ACTUAL CONSEQUENCES

They concern:

- Unavailability further to the event: duration and characterisation of the unavailability of the main functions of the facility or unit; accelerator downtimes, patient transfers to another machine, for example, shall be indicated here.
- the radiological consequences on the personnel, the patients or the public: here must be indicated the sources or radionuclides involved, the conditions of exposure and the estimated internal and external doses received by the persons concerned.

THE CONSEQUENCES (OR POTENTIAL CONSEQUENCES) ON THE ASSUMPTION OF AN AGGRAVATING SCENARIO

The aim here is to postulate an aggravating scenario in order to decide whether the event in question foreshadows a more serious event. The following methods can be applied for this:

- remove the incidental actions from the actual scenario. Example: postulate that the absence of field reductions which occurred on 2 sessions and was then detected, is reproduced on all the planned sessions;
- make the assumption that a complete line of defence that enabled the actual event to be contained, has been degraded;
- postulate that the same failings occur under different circumstances or on higher-risk activities, provided that the conditions are comparable. Example: postulate that an absence of field reduction which occurred on a zone for which the consequences were minor, occurs on a zone where this omission has more serious consequences; postulate that the use of an energy level of 6 MeV instead of 18 MeV in an event takes place the opposite way round: use of 18 MeV energy instead of 6 MeV.

The scenarios thus identified must nevertheless remain realistic.

The aggravating factors must first be detailed, followed by the aggravating scenarios and their estimated consequences.

Lastly, the summary must indicate whether the actual scenario foreshadows the aggravating scenario(s). If such is the case, additional lines of defence for detecting and mitigating the consequences of the actual scenario must be defined in order to prevent such an event from drifting towards the aggravating scenario.

7. Improvement actions:

IMMEDIATE IMPROVEMENT ACTIONS

The aim here is to detail the improvement actions put in place immediately after discovering the event, and their date of implementation. These actions usually figure in the notification form.

IMPROVEMENT ACTIONS AIMING TO PREVENT RECURRENCE OF THIS EVENT AND SIMILAR EVENTS

The aim here is to detail the improvement measures put in place or planned with regard to the different causes identified and their date (or forecast date, if applicable) of implementation. These improvement actions are identified in the analysis of the event. The actions shall also be prioritised in view of the risks analysis and the implementation possibilities.

8. Lessons learned, experience feedback

The following shall be distinguished:

INTERNAL EXPERIENCE FEEDBACK:

- Identification of recurrent causes (already identified from previous events). This analysis provides the opportunity to review, if necessary, the appropriateness of the corrective measures put in place or to readjust their prioritisation.
- Identification of factors that could lead to a modification of the risk management system: modification of the corrective action monitoring frequency, revision of the prospective risk analysis, modification of the typology of the events to collect, etc.

EXTERNAL EXPERIENCE FEEDBACK:

The aim here is to indicate the elements stemming from the analysis that should lead to exchanges of experience with other medical professionals using similar practices or equipment: where applicable, past or planned exchanges of experience with other licensees or sites having facilities, units or systems that are potentially concerned.

Appendix 4

ASN-SFRO SCALE FOR CLASSIFYING RADIATION PROTECTION EVENTS AFFECTING PATIENTS UNDERGOING MEDICAL RADIOTHERAPY PROCEDURES

ASN-SFRO SCALE APPLICATION	EVENTS (UNPREDICTED, UNEXPECTED)	CAUSES	CONSEQUENCES (CTCAE V3.0 GRADE)
5 to 7* ACCIDENT	Death	Dose (or irradiated volume) much greater than normal resulting in complications or sequelae incompatible with life	Death
4** ACCIDENT	Serious life-threatening event, disabling complication or sequela	Dose or irradiated volume much greater than the tolerable doses or volumes	Serious unexpected or unpredictable acute or delayed effect, grade 4
3** INCIDENT	Event resulting in severe alteration of one or more organs or functions	Dose or irradiated volume greater than the tolerable doses or volumes	Severe unexpedted or unpredictable acute or delayed effect, grade 3
2** INCIDENT	Event resulting in or likely to result in moderate alteration of an organ or function	Dose greater than the recommended doses, or irradiation of a volume that may lead to unexpected but moderate complications	Moderate unexpedted or unpredictable acute or delayed effect, grade 2, minimal or absence of alteration of quality of life
1 EVENT	Event with dosimetric consequences but no expected clinical consequences	Dose or volume error (e.g. dose error or target error in a session not compensable over the treatment as a whole)	No symptoms expected
0 EVENT	Event with no consequences for the patient	Dose error (number of monitor units, filter, etc.) compensated over the treatment as a whole. Error of identification of a patient treated for the same pathology (compensable)	

** In the case of deaths of several patients:*
- *the minimum level 5 is raised to 6 if the number of patients is greater than 1 but less than or equal to 10;*
- *the minimum level 5 is raised to 7 if the number of patients is greater than 10.*

*** If the number of patients is greater than 1, a + sign is added to the assigned level (example: 3 become 3+).*

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