A S N G U I D E S

MEDICAL

Significant radiation protection events affecting patients in radiotherapy (criterion 2.1): notification and ASN-SFRO scale rating

GUIDE N° 16

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Preamble

The collection of ASN guides contains documents for those professionals affected by regulations relating to nuclear safety and radiation protection (operators, users and transporters of sources of ionising radiations, health professionals).
These guides can also be distributed to the various stakeholders such as local information committees.

Each guide provides recommendations with the following aims:
- to explain the regulations and the rights and obligations of the individuals affected by those regulations;
- to clarify regulatory objectives and, if necessary, to describe the practices deemed satisfactory by ASN;
- to provide practical and useful information on nuclear safety and radiation protection.

Table of contents

1. INTRODUCTION

1.1 Context and regulatory references

Implementation in July 2007 of the system for the notification of significant radiation protection events (SRPE) affecting a patient

The obligations of the individuals in charge of nuclear activity, particularly in terms of informing the French Nuclear Safety Authority (*Autorité de Sûreté Nucléaire* - ASN) about incidents or accidents in the field of radiation protection, are stipulated in the French public health code (*Code de la Santé Publique* - CSP). According to the provisions of article L.1333-3 of this code, "the individual responsible for one of the activities referred to in article L.1333-3 must immediately notify to the nuclear regulatory body and to the State representative of the *département*[1] any incident or accident likely to affect the health of individuals through exposure to ionising radiations".

Article L. 1333-3 was amended (by law n° 2009-879 of 21 July 2009 on hospital reform relating to patients, health and territories) and published on 22 July 2009 in n°167 of the Official Journal of the French Republic (*Journal Officiel de la République Française – JORF)* to extend the obligation to submit a notification to include "health professionals who are involved in the treatment or follow-up of patients exposed to ionising radiations for medical purposes, and who have knowledge of an incident or accident associated with this exposure".

Article R. 1333-109 was also subsequently amended (implementing decree published in the JORF of 4 May 2010) in order to integrate these new obligations. In addition, it stipulates in paragraph III that "the individual responsible for a nuclear activity initiates the analysis of significant events in order to prevent future events, incidents or accidents". It is for these reasons that the present guide proposes a template for the reporting of significant events in radiation protection.

In order to implement the notification system in practical terms, ASN set up an experimental system in 2007 for notifying SRPEs, based on a set of criteria as well as a communication policy for events affecting a patient undergoing a radiotherapy procedure. This communication policy is based on a scale for rating events, known as the ASN-SFRO scale, which was developed jointly by ASN and the French Society of Radiation Oncology (*Société Française de Radiothérapie Oncologique* - SFRO).

Evaluation of the effectiveness of the system implemented alongside professionals in July 2008

ASN works with other safety-related health professionals on the follow-up of the national programme of action launched by the French Minister for Health and Sport in an attempt to improve the safety of radiotherapy treatments. As such, ASN was called upon to carry out an assessment of SRPEs in radiotherapy (action 7.4 of the roadmap of national measures for radiotherapy[2]).

An evaluation of the system for notifying SRPEs and of the ASN-SFRO scale was performed with the respective professionals. This assessment highlighted certain difficulties, particularly concerning the adoption of the notification procedure by professionals (confusion between the notification criteria and rating methods for the ASN-SFRO scale), the understanding of criterion 2.1 (event affecting one or several patients subjected to therapeutic exposure), and ASN policies for communicating events.

This evaluation led to:

- an amended definition of criterion 2.1, which was communicated to all radiotherapy centres in September 2009,
- an updated ASN-SFRO scale,
- an adjusted ASN communication policy for events rated 1 on the ASN-SFRO scale,

[1] Administrative region headed by a *prefect*

[2] 12 November 2007 version of the roadmap of national measures for radiotherapy can be viewed at http://www.sante-jeunesse-sports.gouv.fr/IMG/pdf/Sommaire_-_Feuille_de_route_des_mesures_nationales_pour_la _Radiotherapieadiotherapie-nov2007.pdf

- an amended notification form and a modified form for reporting SRPEs so as to include the elements required for the validation of the ratings by the ASN and SFRO, and to encourage operating experience feedback.

In order to facilitate the process of notifying SRPEs, the present guide sets out the procedures for notifying a SRPE, for writing up the Significant Event Report (SER) and, lastly, for rating events on the ASN-SFRO scale.

1.2 Field of application

The present guide applies to the notification and analysis of SRPEs affecting patients in the field of radiotherapy (external radiotherapy and brachytherapy).

It does not deal with the notification requirements laid down in the French labour code or environmental code, nor does it address provisions for the protection of the worker or the public, or in relation to vigilance (materiovigilance, treatment-related serious adverse events, etc.)[3].

Finally, it does not aim to explain the internal management procedures for adverse situations or malfunctions, which have been mandatory since 25/03/2010 under ASN technical ruling n° 2008-DC-0103. Nevertheless, it clarifies the link between the management procedures for these adverse situations or malfunctions and the SRPEs affecting patients that must be declared to the authorities.

In order to enable radiotherapy professionals to simultaneously fulfill their notification obligations relating to radiation protection and materiovigilance (L. 5212-2 and R. 5212-14 of the CSP) ASN and the French Health Products Safety Agency (*Agence Française de Sécurité Sanitaire des Produits de Santé* - AFSSAPS) will soon be providing a website to help them to notify these events. This tool, which was part of the ministerial roadmap measures for radiotherapy and was developed in collaboration with professionals, aims to facilitate the notification process and to capitalise on operating experience feedback for the continuous improvement of the safety and efficacy of radiotherapy treatments, which play a major role in the fight against cancer.

1.3 Aim of the guide

This guide brings together all the tools that enable the declarer to manage a SRPE affecting a patient (criterion 2.1 of guide ASN/DEU/03). For this purpose, it includes the notification form, the SER template and the ASN-SFRO scale for rating events. It therefore constitutes a freestanding document for handling SRPEs occurring in radiotherapy and affecting a patient. All other notification criteria can be found in guide ASN/DEU/03, which can be downloaded from the ASN website.

1.4 Status of the document

The present guide stems from the collaborative work undertaken with radiotherapy professionals from the SFRO, the French Society of Medical Physics (*Société Française de Physique Médicale* – SFPM) and the French Association of Paramedical Radiology Personnel (*Association Française du Personnel Paramédical d'Electroradiologie* - AFPPE). It is based on ASN guide n°11. It includes the amendments made following the evaluation of the experimental notification system for events in radiotherapy, which was carried out in July 2008.

[3] See Appendix 1 of the present guide

2. NOTIFYING A SIGNIFICANT RADIATION PROTECTION EVENT RELATED TO PATIENT EXPOSURE

2.1 General principles

In order to define the requirements in terms of quality assurance in radiotherapy, ASN issued ruling n° 2008-DC-0103 of 1st July, published in the JORF on 25 March 2009.

As part of the continuous improvement of procedures, this ruling enforces the internal declaration of adverse situations or malfunctions, and the setting up of a body responsible for analysing them and defining improvement actions. These measures must be implemented no later than one year after the publication of the decree of approval of the ruling, i.e. by 25 March 2010. Thus, the individual in charge of the activity must keep a record of all adverse situations or malfunctions declared internally. As per article L. 1333-3 of the CSP, this individual provides the radiation protection inspectors from the nuclear regulatory body with the documents and records relating to radiation protection.

Amongst all the events that may occur in a facility or during an activity, some must be declared to the competent administrative body depending on the nature of the event (see appendix 1). Malfunctions must be handled in such a way as to enable the distinction to be made between those arising from an internal process and that must be submitted for notification, as shown in the flowchart in appendix 2.

Events categorised as "significant radiation protection events" affecting patients must be declared to both ASN and the Director of the regional health agency. Notification criteria have been defined by ASN in order to identify these events. These criteria take into account:

- the real or potential consequences for workers, the public, patients or the environment, of events that may occur relating to radiation protection;
- the main technical, human or organisational factors that may lead to such an event.

The notification criteria for significant events in the field of radiation protection are laid out in ASN guide ASN/DEU/03. Amongst them, criterion 2.1 relates to events concerning one or several patients subjected to therapeutic exposure. The present guide only deals with events affecting patients.

2.2 Definition of criterion 2.1: event affecting one or several patients subjected to therapeutic exposure.

Criterion 2.1 is therefore worded as follows: Patients subjected to therapeutic exposure.

The following are considered significant events:

- any adverse situation or any malfunction on an organisational, material or human level arising during the treatment of a patient in radiotherapy, having led to the realization of treatment that does not comply with the prescription in terms of the delivered dose(*);
- or any adverse situation or any malfunction on an organisational, material or human level arising during the treatment of a patient, having led to deterministic effects which were unforeseeable in view of the therapeutic strategy agreed upon with the patient.

(*)Conforming to the delivered dose implies:

- in radiotherapy and brachytherapy: compliance with the total prescribed dose with a tolerance margin of +/-5%, and compliance with the planned overall treatment time and/or fractionation, taking into account the potential clinical or technical constraints involved in the treatment of a patient; in internal radiation therapy: compliance with the administered radiopharmaceutical activity with a tolerance margin of +10% of the prescribed activity;
- the absence of systematic dose errors for several patients, regardless of the value of this dose error.

2.3 Examples

In order to facilitate the identification of events that must be notified to ASN, a series of examples from external radiotherapy and brachytherapy are provided below:

2.3.1 Events that must be notified to ASN

- **Event having led to a patient being administered a physical dose that is different to the total prescribed dose and outside the tolerance margin of +/-5% of the planned volumes:**
  - Distance error (confusion between SSD and SAD etc.);
  - Poor assessment of beam-modifying elements (motorised or dynamic fixed wedge filter, bolus, etc.);
  - Monitor unit errors (data transmission error, error when inputting settings, etc.);
  - Etc.

- **Event relating to volume error:**

  Dose errors can involve volume errors. The radiation oncologist is responsible for judging the extent to which this type of error can be categorised as "non compliant with the prescription" in terms of the delivered dose.
  - Isocentre error (incorrect patient positioning, wrong side);
  - Beam shaping error (dimension, cover, positioning of collimator leaves);
  - Ballistics error (angulation of arm of machine, rotation of collimator);
  - Etc.

- **Event relating to patient/data identification error:**
  - Patient identification error (including cases in which both treatments relate to the same localisation and similar volumes);
  - Selection of data that does not correspond to the patient being treated (including cases in which both treatments relate to the same localisation and similar volumes);
  - Etc.

- **Event relating to a systematic error having led to several patients being administered a physical dose that is different to the total prescribed dose, regardless of the value of the dosing error.**

  Any systematic dosing error, even if minimal and within the tolerance margin of +/-5% in relation to the prescribed dose, must be declared.
  - Incorrect accelerator settings (calibration error linked to the use of a wrong correction coefficient, use of an unsuitable detector, etc.);
  - Monitor unit error linked to a data transmission problem or poor software configuration, etc.;
  - Incorrect source position in pulsed brachytherapy linked to wrong interpretation of the position of the dummy source;
  - Etc.

NB: These systematic malfunctions must be notified even if, at the time of detection, they have only affected one patient in a single session.

- **Other**
  - Any uncorrected fractionation and/or overall treatment time error (not linked to the clinical or technical constraints of the treatment).

2.3.2 Events falling outside of the notification criteria

- Dose error for one patient within the tolerance margin of +/-5% of the total physical dose;
- Non compliance with the dose in one or several sessions but corrected before the end of the treatment;
- Change in fractionation due to unavailability of machine or department opening hours;
- Treatment modification due to clinical state of patient;
- Doubts relating to dose measurement;
- Complications observed following radiotherapy that are not caused by a malfunction identified during the treatment process. This type of event may be declared under article L. 1413-14 of the CSP if it meets the criteria defined by the regulations for such purposes.

In summary, the following must be notifed for radiotherapy events affecting a patient:

- Deterministic effects that could not have been foreseen given the therapeutic strategy;
- Dose deviations over ±5%;
- Volume errors that do not comply with the prescription;
- Uncorrected overall treatment time and fractionation errors;
- Patient identification errors;
- Systematic malfunctions, even if at the time of detection, they have only affected one patient in a single session, regardless of the value of the dosing error.

2.4 Time frame and notification procedures

The term "timely notification" in the CSP requires clarification in order to bring consistency to the procedures and time frame for submitting a notification.

The individual responsible for the nuclear activity evaluates the urgency of the notification based on the confirmed or potential seriousness of the event, the number of patients affected and the greater or lesser generic nature of the event.

However, the notification must be submitted within 2 working days of the detection of the event.

A significant event notification should be addressed to the recipients identified below, even in the absence of the initial results of the investigations carried out to determine the circumstances surrounding the detection of the event.

The information that must be included in the notification as well as the notification form itself are shown in appendix 3, and are also available on the ASN website (http://www.asn.fr). This form quickly provides ASN with a minimum amount of information in order to carry out its tasks of analysis, evaluation and communication. In this case, it specifies the criterion or criteria relevant to the notification (several criteria are possible for a single event).

2.5 Recipients of a SRPE notification relating to criterion 2.1

The notification and SER should be sent independently of any notification obligations that may result from the application of other regulatory provisions, to the territorially-competent ASN Division in the region where the event occurred (see geographical distribution in appendix 6). For incidents or accidents in radiotherapy with a particularly serious confirmed or potential impact on individuals, especially in the case of patient cohorts, ASN headquarters (health and ionising radiations department) informs the competent national body responsible for the management of these types of incidents or accidents (French Ministry of Health, AFSSAPS, the French Institute for Public Health Surveillance [*Institut de Veille Sanitaire* – InVS], the French Institute for Radiological Protection and Nuclear Safety [*Institut de Radioprotection et de Sûreté Nucléaire* – IRSN]).

By application of law n° 2009-879 of 21 July 2009 on hospital reform relating to patients, health and territories and published in n°167 of the JORF on 22 July 2009, the SER notification must also be submitted to the Director of the regional health agency, who then informs the territorially-competent State representative as stipulated in article L. 1435-1 of the CSP.

In all cases, the SER is jointly signed by the individual responsible for the nuclear activity and by the head(s) of establishment concerned or their designated representative.

3. THE SIGNIFICANT EVENT REPORT (SER)

3.1 General principles

A SER must be sent to ASN so that the initial analysis of the notification can be carried out. The quality of the analysis and of the SER will determine the relevance of the operating experience feedback passed on to professionals. It is therefore essential that the information contained in this document clearly identifies the

causes and factors contributing to the onset of the event including human and organisational elements. The form has therefore been customised so as to contain the necessary information for the implementation of operating experience feedback.

The SER together with its explanatory notes can be found in appendix 4 of the present document.

3.2 Time frame and procedures for sending the significant event report

The SER should be written up and sent to the same recipients as the notification form no later than 2 months after submission of the notification. The purpose of this time frame is to enable the necessary analyses to be carried out in order to be able to complete the SER. In fact, the SER must include an update of the notification, a detailed analysis of the causes of the event and a description of the planned or implemented corrective action. A report template together with the explanatory notes needed for its completion can be found in appendix 4 and are also available on the ASN website.

In all cases, the SER is jointly signed by the individual responsible for the nuclear activity and by the head(s) of establishment concerned or their designated representative.

4. ASN-SFRO SCALE RATINGS

4.1 General principles

One of ASN's missions is to help educate the public in the area of nuclear safety and radiation protection (law n° 2006-686 of 13 June 2006, article 4).

The classification of events on the ASN-SFRO scale aims to enable events to be rated according to their seriousness and to provide appropriate information to the public.

The application of the scale was jointly evaluated in June 2008 by ASN, SFRO and SFPM. It proved to be a useful communication tool that aids media and public understanding of the significance of an event.

In order to facilitate the classification of events, the notification form has been modified so as to include the information required for a rating and its validation. This information can be found on pages 3 and 4 of the form and should only be included if the event if likely to be rated 2 or above on the ASN-SFRO scale, or in the event of uncertainty over the rating.

4.2 ASN-SFRO Scale

The different levels are shown in appendix 5.

Events are rated on eight levels on the ASN-SFRO scale:
- levels 0 and 1 are used to rate events with no clinical consequences for the patient(s) concerned;
- levels 2 and 3 correspond to events categorised as "incidents";
- levels 4 and 7 correspond to events categorised as "accidents".

The seriousness of the effects should be assessed by referring to the international clinical classification (CTCAE grades[4]), which are already used by practitioners.

The effects taken into account in the notification submitted to ASN are the unexpected or unforeseeable effects due to inappropriate irradiated doses or volumes. Not included however, are any side-effects, regardless of their grade, that result from the treatment strategy agreed upon by the practitioner with the patient, and that occur outside of any irradiated-volume or delivered-dose error (accepted risk).

For patients affected by a SRPE, the onset of effects or complications may not be immediate and may vary over time. An event may therefore be provisionally rated and later modified according to the changing status of

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

the patient.

Unlike the INES scale[5], the defence-in-depth criterion (assessment of the level of safety of the radiotherapy activity) is not incorporated into this rating, in order to avoid any confusion between medical severity and technical or organisational breakdowns.

4.2.1 Rating criteria

In the same way as the INES scale, the criteria for rating an event on the ASN-SFRO scale concern not only the confirmed consequences, but also the potential effects of the event. If several patients are affected by the same event, the rating corresponds to the most serious observed or anticipated effects. For confirmed consequences, the number of patients exposed is also taken into account.

4.2.2 Criteria for confirmed consequences

When the effects are confirmed, the rating is carried out with reference to the various clinical classification grades on the CTCAE scale as follows:

- level 1, corresponding to grade 1, includes mild effects but also events for which no effect is expected;
- level 2, corresponds to grade 2, includes acute or late-onset moderate effects such as moderate post-radiation stenosis, relatively unproblematic tissue impairment (skin fibrosis), or minimal or no disablement;
- level 3, corresponding to grade 3, includes acute or late-onset severe effects such as non-life-threatening manageable tissue necrosis with moderate disablement (severe proctitis, severe cystitis, etc.);
- level 4, corresponding to grade 4, includes acute or late-onset serious effects such as post-radiation myelitis, extensive unmanageable life-threatening tissue necrosis with serious or major disablement (serious proctitis, serious cystitis, etc.);
- levels 5, 6 and 7, corresponding to grade 5 of the clinical classification, refer to one or more deaths.

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 rating. The difference between the received dose and the intended dose is evaluated on the basis of accepted or tolerated deviations, in the light of existing practices or available references.

Similarly, the difference between the volume actually irradiated and the volume that should have been used to treat is analysed, taking into account the presence or otherwise of any organs particularly sensitive to radiation.

For any significant or extremely significant deviation, the event is rated level 2, 3 or possibly 4.

If there is a high degree of uncertainty over the potential onset of other events, the event is rated 1 or 2 (depending on the conditions of the event).

4.2.4 Criteria for the number of patients exposed

For confirmed effects at level 2, 3 or 4, the rating is assigned a "+" sign if more than 1 patient is affected.

For events having led to the death of several patients, a level 5 rating may be increased as follows:

- +1 if the number of patients affected is more than 1 and less than 10;
- + 2 if more than 10 patients are affected.

In order to avoid any confusion over the severity of the effects, the over-rating criterion for the number of cases is not applied to potential effects, except when the information concerning the delivered dose and/or irradiated volume already allows a prognosis to be made in terms of death, serious or severe effects.

[5] International Nuclear and Radiological Event Scale

4.3 Rating process

For every significant event notified to ASN, the rating proposed by the individual responsible for the activity is written on the notification form. This rating is then validated by ASN after consulting the SFRO. This consultation is systematic when the event is initially rated level 2 or above, and in the event of uncertainty for all other levels of classification.

In order to enable an event to be rated and validated, certain essential pieces of information must be recorded on the notification form. These are:

- type of tumour treated (primary tumour, single or multiple metastases, histology);
- accurate description of 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 affected;
- dosimetry:
  - difference in absolute value and percentage between the prescribed dose and the dose delivered to the target volumes;
  - dose delivered to critical organs;
- qualitative (anatomical region, organ) and quantitative (dose, volume) description of the irradiated areas outside of the target volume due to non compliance with the initial treatment plan;
- confirmed consequences (description of observed effects/clinical observations);
- potential consequences;
- number of patients affected with confirmed consequences;
- number of patients affected with potential consequences.

This information must include the data relating to the treatment actually administered after detection of the event.

5. INFORMING THE PUBLIC

Firstly, it should be emphasised that the physician is responsible for informing the patient. This must be done within 15 days of the discovery of treatment-related damage in accordance with article L. 1142-4 of the CSP. The French National Authority for Health (*Haute Autorité de Santé* – HAS) will soon publish a guide pertaining to the announcement of treatment-related damage, in order to assist health professionals in their obligation to inform the patient.

The subsequent statement issued to the public by ASN following a SRPE always takes place once the patient(s) concerned has/have been informed in accordance with article L. 1142-4 of the CSP.

This statement is issued as soon as possible, within a maximum of 2 months after the SRPE notification, and after finalisation of the SER and communication with the establishment concerned. According to the nature of the SRPE (high severity, cohorts, generic nature), this statement may be issued sooner after the notification in coordination with the establishment concerned.

The statement issued by ASN is different from that issued by the establishment. It is adapted to the seriousness of the event, whether it is confirmed or potential, and the number of patients affected. This statement essentially focuses on the actions taken by ASN and the establishment concerned to evaluate the situation and draw lessons from it in terms of treatment safety.

Each radiotherapy centre is responsible for defining its own communication policy. A statement from a radiotherapy centre on a local level and prior to the ASN statement is intended to facilitate management of the information and media relations.

The way in which the event is communicated to the public mainly depends on its ASN-SFRO scale rating. SRPEs are therefore brought to the attention of the public in the following ways:

- events rated 0 on the ASN-SFRO scale are listed in the ASN annual report;

- events rated 1, with the exception of those relating to a cohort of patients (serial events), are compiled in a quarterly report which does not mention the names of the notifying establishments and is published on the website www.asn.fr;
- serial level 1 events (single cause in a cohort of patients) and those rated 2 or above are communicated via an 'incident notice' stating the place where the incident took place, in the section for the notification of incidents in the medical field (http://www.asn.fr/index.php/Les-activites-controlees-par-l-ASN/Utilisations-medicales/Avis-d-incidents-dans-le-domaine-medical). If necessary, serial level 1 events or level 2 events may be dealt with in a memo (link to incident notice on first page of ASN website);
- level 3 events are systematically dealt with in a memo. They may, where appropriate, be communicated in a press release (press informed by ASN);
- from level 4 upwards, the events are communicated via press releases.

APPENDIX 1: Reminder of the main notification obligations regarding events affecting a patient

The notification of a significant event in the field of radiation protection does not exempt the individual or body producing or using the ionising radiations from the obligations enforced by other regulations. The reader may find it useful to refer to the 2009 edition of the regulations drawn up by the French Ministry of Health pertaining to health-related safety in health establishments (*"Sécurité sanitaire dans les établissements de santé : réglementation applicable").*

The following list is provided for reference only. It by no means constitutes an exhaustive panorama of the notification systems enforced by current regulations.

1. Provisions for external notifications

⇒ *Provisions for vigilance (health products)*

A notification must be submitted to AFSSAPS concerning:

- materiovigilance for the surveillance of incidents or risk of incidents resulting from the use of medical devices (article L. 5212-2 of the CSP);
- ionising-radiation-emitting in vitro diagnostic medical devices (article L. 5222-3 of the CSP);
- AFSSAPS notification of serious and unexpected adverse effects likely to be due to a radiopharmaceutical drug (pharmacovigilance) (article R. 5121-170 and R. 5121-171 of the CSP);
- adverse effects occurring during biomedical research on a radiopharmaceutical drug, medical device or ionising-radiation-emitting diagnostic in vitro medical device (article L. 1123-10 of the CSP, notification of AFSSAPS and competent ethics committee).

⇨ *Nosocomial infections or any other serious adverse event linked to the care administered during investigations, treatment or preventive actions, and provided for under article L. 1413-14 of the CSP, must be declared to the director of the regional health agency.*

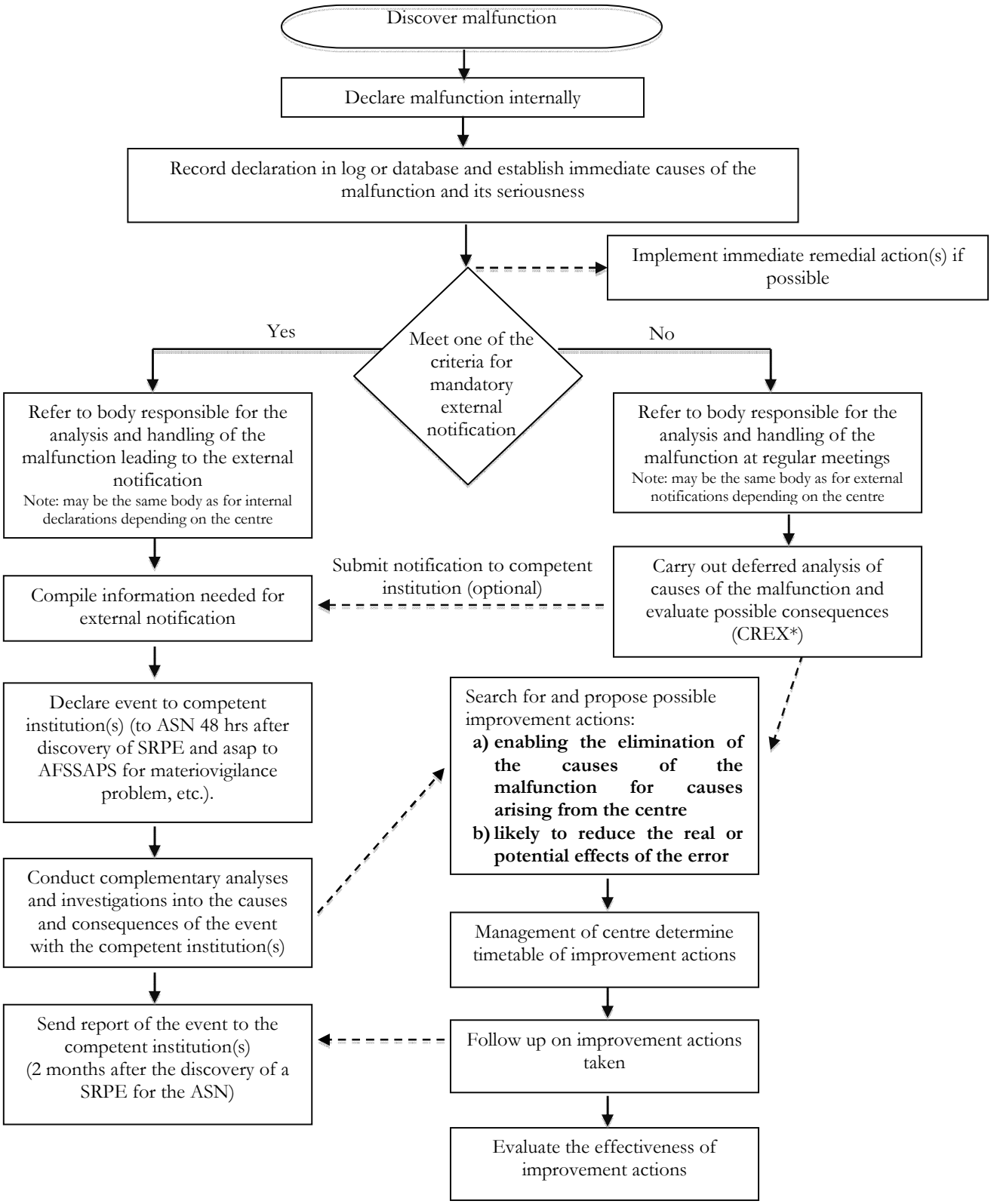
2. Provisions for the internal declaration of adverse situations or malfunctions

The internal declaration and recording of adverse situations or malfunctions became mandatory on 25 March 2010 under ASN ruling n° 2008-DC-0103 of 1st July 2008, establishing the quality assurance requirements in radiotherapy.

All staff directly involved in the therapeutic management of radiotherapy patients must declare any adverse situation or malfunction on an organisational, material or human level to the organisation cited in article 11 of the ruling.

As such, as an absolute minimum, all declarers must record the date of the declaration, a description of the event, the circumstances in which it occurred and its consequences.

APPENDIX 2: Flowchart for dealing with malfunctions



*CREX = *Comité de Retour d'Expérience* (Operating experience feedback committee)

APPENDIX 3: Form for the notification of significant radiation protection events

The notification includes the following information as a minimum:

- information concerning the individual responsible for the activity;
- information relating to the declarer (insofar as he or she may not be the individual responsible for the activity, as provided for under article L. 1333-3 of the CSP amended by law n° 2009-879 of 21 July 2009 on hospital reform relating to patients, health and territories). This section should only be completed if the individual submitting the notification is not the individual responsible for the activity;
- information relating to the significant event, in particular:
  - the date and place where the event occurred;
  - the stage of the clinical process during which the event occurred;
  - the ASN-SFRO scale rating proposed by the individual responsible for the activity;
  - information relating to the detection of the event: When? At what clinical stage? How was it detected? By whom?
  - the number of patients affected in the case of cohorts;
  - a description of the event: circumstances and description of facts, presumed causes, real consequences and immediate protective measures;
- complementary information to be completed for any event likely to be rated 2 or above:
  - pathology treated;
  - accurate description of treatment plan and treatment actually administered;
  - planned/actual dosimetry

This section of the form is essential for the validation of events rated 2 or above. It does not need to be completed for events rated lower than 2.

NOTIFICATION OF A SIGNIFICANT EVENT RELATING TO THE RADIATION PROTECTION OF PATIENTS
CRITERION 2.1: RADIOTHERAPY

Date notification sent: ……

Box for ASN use   **Reference: …… Date: …… Index: ……**
Individual in charge of the activity
Name: ……   Professional address: ……   SIRET number of the establishment: ……   Telephone: ……   Fax: ……   Email: ……
Contact details for additional information: Name: ……   Position: ……   Telephone: ……   Fax: ……   Email: ……
Declarant (if different from individual in charge of the activity)
Name: ……   Professional address: ……   SIRET number of the establishment: ……   Telephone: ……   Fax: ……   Email: ……

Significant event		
Title of the event: ……...		
Date and time of onset:	**Stage of clinical radiotherapy process during which significant event occurred:**	**Proposed ASN-SFRO scale rating (external radiotherapy and brachytherapy)**
…….	…….	…….
…….	…….	…….
…….	…….	…….
…….	…….	…….
…….	…….	…….
…….	…….	…….

Detection:

Date and time of detection:	Stage of clinical radiotherapy process permitting detection:	Method of detection:	Position of the individual who detected the event:
…….	…….	…….	…….
…….	…….	…….	…….
…….	…….	…….	…….
…….	…….	…….	…….
…….	…….	…….	…….

For cases involving cohorts: ……

Number of patients affected by confirmed effects: ……

Number of patients affected by potential effects: ……

Event:

Surrounding circumstances/description of events:

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……

Presumed cause(s) of the event

☐ material ☐ software ☐ organisational

☐ human

☐ other (specify): …….

Several causes possible

Real consequences for the patient (effects observed, dated clinical observations):

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……
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……
……

Remedial measures and immediate corrective action taken:

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……
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……
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……
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APPROVAL by the declarant

Date:

Signature:

Additional information which must be completed for all events likely to be rated 2 or above on the ASN-SFRO scale

Pathology treated

Localisation of the tumour: ……..

TNM[6] classification of the tumour: ……..……..……..……..……

Associated treatments: ……..……..……

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Treatment plan: accurate description of treatment plan (total dose, dose per session, number of sessions per week, number of beams per session, beam intensity, contribution of each beam to the dose, field size, use of filters, covers, etc.).

Validated treatment plan in compliance with the prescription:	Treatment actually administered (if necessary including modifications made to treatment after detection of the event):
1st phase: ……	1st phase: ……
……	……
……	……
……	……
……	……
……	……
2nd phase: ……...	2nd phase: ……...
……	……
……	……
……	……
……	……
……	……
……	……

Number of beams affected by the malfunction(s): …….

Number of sessions affected by the malfunction(s): ……...

Qualitative (anatomical region, organ(s)) and quantitative (dose, volume) description of the areas irradiated outside of the target volume, and of the non-prescribed volumes, following non compliance with the treatment plan:

……..……..……

……..……..……

……..……..……

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……..……..……

[6] The TNM classification was developed by the International Union Against Cancer (*Union Internationale Contre le Cancer* – UICC). It standardises the description of the anatomical extent of cancer and is based on the extent of the tumour (T), whether cancer cells have spread to nearby (regional) lymph nodes (N) and whether distance metastasis (M) has occurred.

Dosimetry: Difference between the total prescribed dose and the dose delivered:			
TARGET VOLUMES			
% volume	Planned	Delivered	
	Dose (Gy)	Dose (Gy)	% difference

CRITICAL ORGANS				
Organ affected	% volume	Planned	Delivered	
		Dose (Gy)	Dose (Gy)	% difference

APPROVAL by individual in charge of the activity
Date: **Signature:**

APPENDIX 4: Report for significant events in radiation protection - Methodological guidelines

The following instructions specify the information expected in the Significant Event Report (SER) for radiation protection. The information required in the template can be submitted to ASN in a different format.

1. Summary

The information contained in the "Summary sheet" section allows the SER to be linked to the corresponding notification. The status of the analysis of the event is also specified in this section.

2. Methods for analysing the event

The objective of the information given in this section is to describe the methods used to perform the analysis. This section should state the date(s) on which the analysis was performed, the position of the analysis leader and other individuals involved, and the method used to carry out the analysis: causality tree[7], ALARM[8]

3. Analysis of the event

⇒ *DETAILED ACCOUNT OF THE ORDER OF EVENTS:*

In this section, the identified events should be relayed in the order in which they occurred so as to recreate the scenario leading up to the occurrence of the event in question.

This description should not include any value judgements or interpretations, nor should it include any "not done's" (e.g. absence of procedure). It should describe what actually happened.

The chronology should systematically mention the dates and times of the different events mentioned and should be illustrated, if necessary, using drawings and diagrams to aid understanding.

⇒ *ANALYSIS OF THE CAUSES:*

The analysis of the causes aims to identify the causal relationships between errors/failures, contextual factors and influential factors.

The use of a method of analysis like the causality tree concept provides a simple graphic representation of the scenario. Each event prompts the following questions: "What was needed for it to happen?"; "Is this necessary?"; "Is it sufficient?".

Other methods such as the ALARM method may also be used, particularly to deal with the root causes.

✓ Human errors

The voluntary or involuntary nature of human errors should be identified according to the following definition:

- Involuntary error: unconscious at the time of performing the action or resulting from the inability to perform the activity (exceeding the physical, physiological and/or psychological capacities of the operators).

For this type of error, the stage of the process during which the error occurred needs to be identified:

- during the perception and/or interpretation of the situation: in this case, the main influential

[7] Causality tree: method of a posteriori analysis developed by the French Research and Safety Institute (*Institut National de Recherche et de Sécurité* – INRS): http://www.cram-bfc.fr/prevention/PDF_prevention/arbre_des_causes.pdf

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

factors will be the presentation of the information and the improvement of the ability to detect situations.

- during the action of the operator: in this case, the main influential factors will relate to the actions of the operator (availability, accessibility of technical devices, documentation, prioritisation of actions, etc.).

- voluntary error ("violation" according to Reason [9]) made when the operator considers that the aspects of the work situation (work organisation, workforce and skills, technical devices and work environment) and the applicable guidelines do not meet the criteria for carrying out the activity. This violation differs from malevolence in the sense that the objective was to carry out the activity and not to damage the system.

These elements enable the local components of the work situation that led to the human error(s) to be identified.

✓ Technical failures:

Equipment failures involved in the event scenario should be described in terms of the type and purpose of the equipment, working order, faults, checks carried out during the period preceding the event, etc.

✓ Influencing factors:

The influencing factors considered here refer to the concept defined in the ALARM method. They relate to the inherent characteristics of the system and/or its organisation in normal conditions that led to the onset of the event.

There are two different levels:

- a local level corresponding to the characteristics of the different components of the work situation(s) (technical devices, work environment, workforce and skills, work organisation) having led to the human error(s) in question. Examples would be a clearly inadequate work plan, software with poor fault tolerance, unclear task allocation, etc.

- a global level characterising the way in which the components of work situations (technical devices, work environment, workforce and skills, work organisation) are set up and modified, and the cultural factors specific to the sector or activity that led to the onset of the local influencing factors in the work situation(s) in question. Examples would be inadequate assessment of the conditions for executing the activity when developing new work situations, modifying work situations without factoring in the available workforce, inadequate estimation of the different modes of access and patient accessibility when designing the premises, etc.

N.B: in the case of the medical sector, elements relating to the patient (in terms of normal functioning for influencing factors) should also be taken into consideration.

✓ Contextual factors:

The contextual elements that contributed to the onset of the event should be identified. These relate to:

- recent changes in work situation (new accelerator, relocation, new work organisation, changes to opening hours, new treatment techniques, new protocols etc.);

[9] Reason model: James Reason developed a model based on the Swiss cheese metaphor, which suggests that multiple contributing factors (the holes in the slices of cheese) must be aligned for an accident to occur. The barriers, represented by the lined up slices of cheese, are intended to prevent the errors that result from an adverse event. This model identifies several types of failure: latent failures and active or patent ones. The third version of this model proposed by J. Reason in "Managing the Risks of Organizational Accidents (1997) introduces 2 subtypes of active failures: violations and errors, terms which are conserved in subsequent versions of the model (Revisiting the 'Swiss Cheese' model of accident, EEC Note No. 13/06., J. Reason, E. Hollnagel, J. Pariès, 2006).

- management of downgraded situations: unavailable equipment or staff, unusual situation in terms of patient management, emergency treatment associated with the clinical state of the patient, etc.

4. Identification of deviations:

Amongst the causes identified in the preceding analysis, those that relate to a deviation from regulations (e.g. treatment not validated by practitioner and radiotherapist, non compliance with periodic quality control, etc.), should be differentiated from those corresponding to deviations from internal quality standards, good practice or industry guidelines when the internal standard is not, for example, comprehensive.

Deviations are the subject of a causal analysis aimed at establishing the relevance of the proposed corrective measures.

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

On the basis of the reconstructed scenario, this section aims to determine the robustness of the existing lines of defence, and therefore ascertain whether or not they worked. Undetected errors in the preliminary risk analysis should also be identified, and actions for implementing lines of defence should be defined. The discovery through a SRPE that it is not possible to put in place a double control may lead to the re-evaluation of the effectiveness of this line of defence, its replacement or the introduction of an additional line of defence, for example.

This section should also detail any unplanned actions that enabled the event or certain failures to be detected and the consequences limited, but which had not been previously identified as lines of defence (particularly in the preliminary risk analysis). The adaptive or resilient nature of the human activity should be highlighted by describing the influencing factors leading to the ability to rectify these failures, and which could as a result be incorporated into the preliminary risk analysis.

6. Consequences (on the installation, the patient, the staff, the environment)

⇒ *REAL CONSEQUENCES*

These relate to:

- unavailable resources following the event: duration and type of main unavailable installation or unit functions. Examples include accelerator shortages or lack of available machine for patient transfer.

- radiologic effects on staff, patients or the public: the sources or radionuclides involved, exposure conditions and estimated internal and external doses received by the individuals concerned.

⇒ *CONSEQUENCES IN THE EVENT OF A WORSENING SCENARIO (OR POTENTIAL CONSEQUENCES)*

A worsening scenario should be posited in order to determine the precursory nature of the event in question vis-à-vis a more serious event. The following methods may be applied here:

- eliminate unplanned actions from the real scenario. Example: imagine that the absence of field reduction that occurred in 2 sessions and was then detected will recur in all the planned sessions;

- imagine the complete modification to a line of defence that enabled the real event to be limited;

- hypothesise that the same failures occur in different circumstances or higher-risk activities, provided that they are comparable. Example: imagine that the absence of field reduction with limited consequences in one area recurs in an area with more significant consequences; or imagine that the use of an energy of 6 MeV instead of 18 MeV in an event is carried out in reverse: use of energy of 18 MeV instead of 6 MeV.

These scenarios must, however, remain realistic.

The worsening factors should be specified, followed by the worsening scenarios and their projected consequences.

Finally, a conclusion must be given as to whether the real scenario constitutes a precursor to a worsening scenario(s). If this is the case, additional lines of defence for the detection and limitation of the consequences of the real scenario must be defined in order to ensure that such an event does not lead to a worsening scenario.

7. Improvement actions:

⇒ *IMMEDIATE IMPROVEMENT ACTIONS*

This section should contain the improvement actions implemented immediately after discovery of the event and the date on which they were implemented. These actions are generally included in the notification form.

⇒ *IMPROVEMENT ACTIONS AIMED AT AVOIDING THE RECURRENCE OF THIS EVENT OR SIMILAR EVENTS*

This section should include the implemented or planned improvement actions with regard to the different causes identified and their date (provisional if necessary) of implementation. These improvement actions are identified during the event analysis. Actions should also be prioritised based on the risk analysis and implementation options.

8. Lessons learned, operating experience feedback

Distinguish between:

⇒ *INTERNAL OPERATING EXPERIENCE FEEDBACK*

Identification of recurrent causes (already identified during previous events). This analysis enables the relevance of the implemented corrective measures to be re-assessed if necessary and the priority levels to be re-adjusted.
Identification of elements likely to lead to a change in the risk management system: change in the frequency of corrective action follow-up, revision of preliminary risk analysis, change in the type of events recorded, etc.

⇒ *EXTERNAL OPERATING EXPERIENCE FEEDBACK*

This section should indicate the aspects of the analysis that could be shared with other professionals who use similar practices or equipment: if applicable, this should include experience-sharing actions that have been planned or implemented with other operators or sites with installations, units or systems that could be affected.

REPORT FOR SIGNIFICANT EVENTS
IN THE FIELD OF RADIATION PROTECTION

Box for ASN use		
Reference: ……	Date:……	Index: ……

Summary sheet	
Name of establishment: …… …… …… **Authorisation number**: …… **Title of the event**: …… **Date and time of onset of the event**: …… …… **Location of the event**: …… …… **Date of notification**: ……	
Is this the final report [810]? ☐ yes ☐ no	If no: deadline for final report: ……
Methods for analysing the event	
Date(s) of the analysis: …… Role of the analysis leader: …… Role of individuals involved in the analysis: …… …… …… …… …… Method used for the analysis: ……	

[10] The definitive nature of the report does not mean that the improvement actions have all been implemented, but only that the analysis has been finalised, the improvement actions have been defined and their implementation has been planned.

Analysis of the event
Detailed account of the order of events: …… …… …… …… …… …… …… …… ……
Analysis of the causes (attach analysis identifying causal links) Human errors: …… …… …… …… Technical failures: …… …… …… …… Influencing factors (characteristics inherent to the system in normal circumstances and/or to the organisation having contributed to the onset of the event): …… …… …… …… Contextual factors (recent and permanent changes to working conditions[11] and other specific adverse situation[12]): …… …… …… ……
Identification of deviations from regulations: …… …… …… from internal quality standards (non compliance): …… …… …… from industry rules (good practice): …… …… ……

[11] E.g.: new equipment, new work organisation, relocation, changes to opening hours, treatment techniques, technology, etc.
[12] E.g.: staff or equipment shortages, unusual situations in terms of patient management, etc.

Identification and analysis of the robustness of the lines of defence: ……

	Planned		Unplanned	
	Title	Robustness	Title	Robustness
Preventive actions [13]				
Detective actions [14]				
Consequence-limiting actions [15]				

……

Real consequences	Description of consequences on installation:	Unavailable resources following the event: ....
	Radiologic/dosimetric consequences (population, patient, worker, environment): .... Description of possible methods of specific medical follow-up:	
Consequences in the event of worsening scenario (radiation protection, environment)	Identification of potential deteriorations following the event (breakdowns in lines of defence that probably enabled the prevention, detection or limitation of the consequences of the event, elimination of favourable unplanned actions, and conditions etc.):	
	Possible worsening scenario(s):	
Consequences in the event of worsening scenario (radiation protection, environment), continued	Consequences of identified scenarios (worsening of radiologic consequences, increase in number of individuals or size of area affected, etc.):	
	Conclusion (possible precursory factor in terms of worsening scenarios identified):	

[13] Preventive line of defence: aims to prevent the onset of a failure.
[14] Detective line of defence: aims to detect the failure when it occurs.
[15] Consequence-limiting line of defence: aims to limit the consequences of the failure detected.

Improvement actions

Immediate improvement actions

Description of the action	Date implemented

Improvement actions aimed at avoiding the recurrence of this event or similar events

Causes	Improvement actions	Description of actions	Date of implementation
Causes 1: …… …… ……	Preventive		
	Detective		
	Consequence-limiting		
Causes 2: …… …… ……	Preventive		
	Detective		
	Consequence-limiting		
Causes X: …… …… ……	Preventive		
	Detective		
	Consequence-limiting		

Lessons learned, operating experience feedback
Internal operating experience feedback Existence of recurrent causes (already identified during previous events) and adjustments to corrective actions that did not work: .... Identification of elements likely to lead to a modification of the risk management system (change in the frequency of corrective follow-up actions, revision of preliminary risk analysis, change in the type of events recorded): ....
External operating experience feedback Useful operating experience feedback for other operators: ....

APPENDIX 5: ASN-SFRO scale for radiation protection events affecting patients undergoing a medical procedure in radiotherapy

Events (unforeseen, unexpected)	**Causes**	**Consequences (CTCAE V3.0 grade)**	**Level**
Death	Dose (or irradiated volume) far higher than normal leading to fatal complications or sequelae	Death	**5 to 7**[16]
Serious life-threatening event, disabling complications or sequelae	Dose or irradiated volume far higher than tolerable doses or volumes	Acute or late-onset serious effect, either unexpected or unforeseeable, grade 4	**4**[17]
Event leading to **severe** impairment of one or more organs or functions	Dose or irradiated volume higher than tolerable doses or volumes	Acute or late-onset severe effect, either unexpected or unforeseeable, grade 3	**3**[17]
Event leading to or likely to lead to **moderate** impairment of one organ or function	Dose higher than the recommended doses, or irradiation volume leading to unexpected but moderate complications	Acute or late-onset moderate effect, either unexpected or unforeseeable, grade 2, minimal or no disablement	**2**[17]
Event **with dosimetric consequences but no expected clinical consequences**	Dose or volume error (e.g. dose or target error in one session uncorrected throughout entire treatment)	No expected symptoms	**1**
Event **with no consequences** for the patient	Dose error (number of monitor units, filter, etc.) corrected throughout entire treatment Identification error of patient treated for the same pathology (correctable)		**0**

[16] In the event of the death of several patients:
- the minimum level 5 increases to 6 if the number of patients is more than 1 but less than or equal to 10;
- the minimum level 5 increases to 7 if the number of patients is more than 10.

[17] If the number of patients is above 1, a "+" sign is added to the chosen level (e.g. 3 becomes 3+).

APPENDIX 6: Geographical distribution of the territorial divisions of the French Nuclear Safety Authority

List drawn up on 1st October 2010 (1)

Division	Competent territory	Address	Telephone/Fax	Email
Bordeaux	Aquitaine, Midi-Pyrénées, Poitou-Charentes	42 rue du Général de Larminat – BP 55 - 33035 Bordeaux Cedex	Tel: +33 (0)5 56 00 04 46 Fax: +33 (0)5 56 00 04 94	bordeaux.asn@asn.fr
Caen	Basse-Normandie, Haute-Normandie	10 Boulevard du Général Vanier - BP 60040 - 14006 CAEN Cedex	Tel: +33 (0)2 31 46 50 42 Fax: +33 (0)2 31 46 50 43	caen.asn@asn.fr
Châlons-en-Champagne	Champagne- Ardenne, Picardie	2, rue Grenet-Tellier BP 80556 - 51022 Châlons-en-Champagne	Tel: +33 (0)3 26 69 33 05 Fax: +33 (0)3 26 69 33 22	chalons.asn@asn.fr
Dijon	Bourgogne, Franche-Comte	15-17 Avenue Jean Bertin - BP 16610 21066 Dijon Cedex	Tel: +33 (0)3 80 29 40 30 Fax: +33 (0)3 80 29 40 88	dijon.asn@asn.fr
Douai	Nord-Pas-de-Calais	941, rue Charles Bourseul - BP 750 - 59507 Douai Cedex	Tel: +33 (0)3 27 71 20 20 Fax: +33 (0)3 27 87 27 73	douai.asn@asn.fr
Lyon	Rhône-Alpes, Auvergne	2, rue Antoine Charial 69426 Lyon Cedex 03	Tel: +33 (0)4 37 91 44 44 Fax: +33 (0)4 37 91 28 04	lyon.asn@asn.fr
Marseille	Provence-Alpes- Côte-d'Azur, Languedoc-Roussillon, Corse	67-69 avenue du Prado - 13286 Marseille Cedex 06	Tel: +33 (0)4 91 83 63 02 Fax: +33 (0)4 91 83 64 10	marseille.asn@asn.fr
Nantes	Bretagne, Pays de Loire	2, rue Alfred Kastler - La Chantrerie - BP 30723 - 44037 Nantes Cedex 3	Tel: +33 (0)2 51 85 86 55 Fax: +33 (0)2 51 85 86 37	nantes.asn@asn.fr
Orléans	Centre, Limousin	6, rue Charles de Coulomb - 45077 Orleans Cedex 2	Tel: +33 (0)2 36 17 43 90 Fax: +33 (0)2 38 66 95 45	orleans.asn@asn.fr
Paris	Ile-de-France, Martinique, Guadeloupe, Guyane, La Réunion	10, rue Crillon – 75194 Paris Cedex 4	Tel: +33 (0)1 44 59 47 98 Fax: +33 (0)1 44 59 47 84	paris.asn@asn.fr
Strasbourg	Alsace, Lorraine	2 route d'Oberhausbergen BP 81005 67070 Strasbourg		strasbourg.asn@asn.fr

(1) These contact details are regularly updated on the ASN website **(www.asn.fr)**

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