AUTORITÉ DE SÛRETÉ NUCLÉAIRE

ASN GUIDES

Guide 11

ALL FIELDS

Significant radiation protection events (excluding BNIs and radioactive material transport operations): notification and codification of criteria

Revised version of 01/07/2015

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. 11 was edited on 07/10/2009 and revised on July 2015.

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1. PREAMBLE

"Radiation protection means protection against ionising radiation, in other words all the rules, procedures and means of prevention and surveillance aimed at preventing or mitigating the harmful effects of ionising radiation caused to people, directly or indirectly, including by their adverse environmental impact" (Act 2006-686 of 13th June 2006 on Transparency and Security in the Nuclear Field, Article 1).

Radiation protection is one of the components of nuclear security which also includes nuclear safety, the prevention and combating of malicious acts, and civil protection actions in the event of an accident;

Protection of the general public, patients and the environment against the dangers of ionising radiation is the prime responsibility of the person or organisation that holds, produces or uses the ionising radiation. Furthermore, the employer is responsible for the health and safety of workers who could be exposed to ionising radiation in the course of their professional activity. ASN ensures through its oversight actions that the persons responsible for nuclear activities and the employers concerned do indeed exercise their responsibilities in this area.

Lessons must be drawn from each event relating to radiation protection (technical anomalies, deviations from procedures, etc.) in order to reinforce the measures to prevent recurrence of the event. **Incidents or accidents of particular significance, especially in terms of actual or potential consequences on the workers, the public, the patients or the environment, are called "significant events".** Detection of these events plays a fundamental role in accident prevention in the field of radiation protection.

The notification system described in this guide is not intended for identifying or imposing sanctions on individuals. Its purpose is to analyse the significant events, thereby providing knowledge intended to facilitate the subsequent assessment of an incident or incident risk and improve practices in an establishment and/or a sector of activity[1].

The obligations incumbent on those responsible for a nuclear activity, particularly with regard to informing the administrative authority of incidents or accidents in the field of radiation protection, are specified in the Public Health Code. Article L. 1333-3 of the Public Health Code states that "*the person responsible for one of the activities mentioned in Article L. 1333-1 is obliged to notify without delay ASN and the State representative in the département*[2] *of any incident or accident that could adversely affect human health through exposure to ionising radiation*".

Furthermore, the amendment by Act 2009-879 of 21 July 2009 - Art. 106 (V) of Article L. 1333-3 obliges health professionals involved in the treatment or follow-up of patients exposed to ionising radiation for medical

[1] ***This notification system corresponds to the notion of radiation safety oversight, usually used in the medical field, which is defined by all the procedures for detecting, notifying and assessing any significant event that could jeopardise the health of a patient, an operator or a third party through exposure to ionising radiation.***

purposes, who know of an incident or accident linked to this exposure, to notify ASN and the Director General of the ARS (regional health agency) of it without delay, without prejudice to application of Article L. 5212-2.

Notification obligations are moreover provided for by Article R. 4455-7 of the Labour Code for the employer as part of the protection of workers who could be exposed to ionising radiation.

The legislative provisions relative to incident notification are applicable immediately.

Their conditions of application shall be determined by decree in State Council and specified in an ASN resolution approved by the ministers responsible for health, labour and agriculture.

ASN publishes this guide, applicable on an experimental basis as of 1st July 2007, in order to familiarise the professionals with this procedure and to take into account any difficulties they might encounter while at the same time enabling them as of now to comply with their legal obligations.

2. SCOPE OF APPLICATION

This guide details the measures applicable by those responsible for a nuclear activity with regard to the procedures for notifying significant events that concern radiation protection.

It does not under any circumstances substitute for the other obligations that may result from application of the Labour Code, the Public Health Code, the Environment Code or any other regulations. More specifically it does not substitute for the provisions set out for the protection of workers, the general public and patients, or for monitoring the safety of use of health products (safety oversight) [2].

The "nuclear activities" concerned by this guide are defined in Article 1333-1 of the Public Health Code. These are "activities involving a risk of human exposure to ionising radiation […] emitted either from an artificial source, whether a substance or a device, or a natural source, when natural radionuclides are or have been processed because of their radioactive, fissile or fertile properties, as well as the actions taken to prevent or reduce a radiological risk further to an accident or contamination of the environment".
However, this guide does not cover:

- significant events occurring in basic nuclear installations or during the transport of radioactive materials, notified under Article 54 of the Act of 13 June 2006 (these activities are covered by a specific guide dated 21/10/2005 which has been applicable since 01/01/2006);
- the procedures to be followed by the operators of landfill sites, waste incineration facilities, scrap metal collection sites and foundries in the event of activation of radiation portal monitors, as these are governed by specific provisions[3].

[2] *See Appendix 3, for information only*

Case of an accident situation in which the public authorities' resources could be called upon to mitigate the consequences: such situations are governed by the provisions concerning the emergency situation management organisation that could be activated should an incident lead to the deployment of a contingency plan (interministerial directives on the action of the public authorities in the event of an radiological emergency situation and Articles R. 1333-75 *et seq.* of the Public Health Code)[4]. Priority must be given to complying with these provisions. Nevertheless, this does not exempt the person/entity responsible for the nuclear activity from notifying ASN in accordance with the procedures recommended in this guide.

3. GENERAL PRINCIPLES

The approach that aims to avoid accidents and mitigate their effects is based on the "defence in depth" concept, the principle of which can be summarised as follows: "*Although the measures taken to prevent errors, incidents and accidents are, in principle, sufficient, it is postulated that errors do occur and means to cope with them are studied and put in place to bring their consequences to levels considered acceptable.*

Compliance with this principle obliges the implementation of a reliable and adequate system for detecting and analysing the anomalies or deviations that could occur. Notifying the administrative authority of significant events occurring in a nuclear installation or activity comes within this context.

The analysis of the events detected in a nuclear installation or during a nuclear activity and the implementation of the appropriate modifications and corrective measures evidenced by this analysis have the following main objectives:

- to learn lessons from the events by identifying their immediate and root causes, to prevent an event that has already occurred from happening again;
- to limit the risks of a more serious event occurring under similar circumstances;
- to promote good practices intended to improve the protection of persons against exposure to ionising radiation resulting from a nuclear activity;

[3] ***More specifically:***

- ***Order of 9th September 1997 amended, concerning non-hazardous waste disposal facilities and (Minister of Regional Planning and Development);***
- ***Order of 20 September 2002 concerning hazardous waste incineration and coincineration facilities (Minister of Ecology and Sustainable Development),***
- ***Order of 20 September 2002 concerning non-hazardous waste incineration and coincineration facilities and facilities incinerating potentially infectious health-care waste (Minister of Ecology and Sustainable Development), - Order of 30 September 2002 concerning hazardous waste disposal (Minister of Ecology and Sustainable Development),***

[4] ***More specifically:***

Interministerial directive of 7 April 2005 on the action of the public authorities in the case of an event leading to a radiological emergency situation;

Circular DGSNR/DHOS/DDSC No. 2005/1390 of 23 December 2005 relative to the principles of intervention in the case of an event that could lead to a radiological emergency, other than situations covered by a contingency plan or an emergency response plan.

These documents can be consulted on the ASN website (www.asn.fr).

- to build up "experience feedback", a continuous improvement approach stemming from the defence in depth concept.

The significant events notification process aims at fostering the sharing of experience feedback between the stakeholders and enabling the authorities:

- to make an independent analysis of the event or event risk;
- to assess the extent to which the person responsible for the nuclear activity has taken into account their own experience feedback and that of other licensees or users where applicable;
- to verify, during inspections, the work carried out by the person/entity responsible for a nuclear activity with regard to the detection and analysis of deviations or anomalies, the implementation and follow-up of corrective measures; to inform the general public of significant events having occurred during nuclear activities.

4. NOTIFICATION CRITERIA

The events that can occur in a nuclear installation or during a nuclear activity do not necessarily always justify notification to the administrative authority. This is why ASN defines criteria for notifying the public authorities of events considered "significant".

These criteria take account of:

- the consequences, whether real or potential, on 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 appendix 1.

Events that do not enter into the scope of these criteria are not notified to ASN, but shall nevertheless be recorded and analysed by the person/entity responsible for the activity. The reason for this is that anomalies or deviations whose immediate significance does not justify an individual analysis may be of a recurrent nature that could be the symptom of a more deeply-rooted problem, foreshadowing more serious incidents. The person/entity responsible for the activity keeps a record of all events and holds it at the disposal of the competent authorities.

5. NOTIFICATION DEADLINES

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

Apart from a confirmed emergency situation requiring action by the public authorities[5], the person/entity responsible for the nuclear activity assesses the urgency of the notification with regard to the confirmed or potential severity of the event and the required speed of reaction to avoid an aggravation of the situation or to mitigate its consequences.
Nevertheless, this deadline shall not exceed **2 working days following detection of the event**.

6. NOTIFICATION PROCEDURES

6.1. The notifier

Under Article L. 1333-3 of the Public Health Code, the person who is obliged to notify the significant event in accordance with the procedures set out in this guide, is the person responsible[6] for one of the nuclear activities defined in Article L. 1333-1 of the Public Health Code and mentioned in chapter 2 (scope of application) or the health professional involved in the treatment or follow-up of patients exposed to ionising radiation for medical purposes who is aware of an incident or accident linked to that exposure. According to the provisions of the Labour Code, the notifier of a significant event affecting a worker is the employer. When the head of a company exercising one of the activities mentioned in the preceding paragraph calls upon the services of an outside company or a non-salaried worker, the significant events concerning the salaried or non-salaried workers are notified in accordance with the prevention plans and the agreements concluded in application of the provisions of Article R. 4451-8 of the Labour Code. The notification documents provided for in section 6.2 indicate, where applicable, the corporate name and contact details of each of the establishments employing workers concerned by the notified event.

In application of the preceding paragraphs, the notification form for a significant event affecting one or more workers 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.

Any person having knowledge of a significant radiation protection event is advised to report it to the person responsible for the nuclear activity and, if applicable, to the company head(s) concerned.

[5] *Article R1333-76 of the Public Health Code states that "a radiological emergency situation exists when an event risks leading to the emission of radioactive materials or a level of radioactivity liable to prejudice public health [...]". This event can occur:*

- *during a nuclear activity, whether for medical, research or industrial purposes; for example: fire in a place where radioactive sources are stored, accident on an industrial radiator, etc.;*
- *in the event of intentional or unintentional dissemination of radioactive substances into the environment; for example:*
- *unintentional incineration of a radioactive source;*
- *if radioactive sources are discovered in places where they are not supposed to be; in the case of theft of radioactive sources;*

In such cases it is necessary to take action in order to end any risk of human exposure to ionising radiation, in accordance with the procedures provided for in the last paragraph of chapter 2 of this guide.

- *- for activities subject to licensing, the "person/entity responsible for the activity" is the person/entity that holds the license or their representative;*
- *- for activities subject to notification, the "person/entity responsible for the activity" is the person/entity that benefits from the notification, or their representative;*

6.2. The documents

It is mandatory to indicate the identity of the notifier of the significant event and the person/entity responsible for the nuclear activity, and the information concerning the establishment (or establishments if applicable) in the notification documents.

However, as the significant events notification system is based on the lessons learned from the analysis of events and not on the identifying or sanctioning of a person, the data relative to the other persons involved in the event (workers, patients, public) remain anonymous.

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. The notification form *DEC/ESR* is available at ***https://teleservices.asn.fr***. These documents enable ASN to rapidly obtain a minimum amount of information enabling it to ensure its analysis, evaluation and information duties. It indicates **the criterion or criteria** concerned by the notification (there can be several criteria for the same event).

A "**significant event report**" is also drawn up and sent to the same addressees within 2 months at the latest following notification. The report integrates an update of the notification and a detailed analysis of the event, and describes the corrective measures implemented or envisaged. The "significant event report" template (*CRES*) is available at ***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.

6.3. The addressees

1- The significant event notification and report are sent independently of the information obligations that might result from the application of other statutory provisions (see Appendix 3), to the regionally competent division of ASN in the region in which the event occurred (contact details of the ASN regional divisions can be found at www.asn.fr /Contact).

2- The significant event notifications and reports are also sent to:

For events concerning industrial, veterinary and research applications:

ASN - Director for transport and sources (DTS)
15, rue Louis Lejeune
CS70013
92541 Montrouge
Fax: 01.46.16.44.24

For events that do not concern the industrial or medical activity sectors, particularly events concerning polluted sites and ground and radioactive waste:

ASN - Waste, Research Facilities and Fuel Cycle Department (DRC)
CS70013
92541 Montrouge
Fax: 01.46.16.44.30

A copy of these documents is sent to the Institute for Radiation Protection and Nuclear Safety (IRSN).

IRSN
BP 17
92262 Fontenay-aux-Roses Cedex

7. INFORMING THE PUBLIC

One of the duties of ASN is to inform the public in the fields of nuclear safety and radiation protection (Act 2006-686 of 13 June 2006, Article 4).

The INES scale (International Nuclear Event Scale – published by the International Atomic Energy Agency - IAEA) is a communication scale intended to facilitate the perception of the significance of events by the media and the public. A description of the scale and utilisation instructions are available in French on the ASN website.

This scale, which is based partly on objective criteria and partly on subjective criteria, is not an evaluation aid and cannot under any circumstances be used as a basis for international comparisons; more specifically, there is no relation between the number of non-serious events declared and the probability of a serious accident occurring.

A scale adapted to radiation protection events affecting patients undergoing radiotherapy treatment has been established in collaboration with the professionals concerned (French Society of Radiation Oncology – SFRO – in particular). This scale, called the ASN-SFRO scale, has been in effect in its definitive version since 24 July 2008. The classification on this scale gives an appreciation of the potential or confirmed effects on the health of the patients. At present, events concerning patients undergoing medical procedures other than radiotherapy are not classified on an events communication scale. Communication on these events is left to the initiative of ASN, depending on their significance.

The notifier proposes a classification on the appropriate scale (INES or ASN-SFRO) and ASN decides on the final classification.

The aim of the significant event notification is to help improve individual and collective practices. Consequently, if an event enters into the scope of the notification criteria, it is always notified. The use of the INES scale and the ASN-SFRO scale enables ASN to select, among all the events notified, those that have sufficient significance to be the subject of specific communication action on its part.

Furthermore, ASN informs the general public on the number and nature of the significant events notified each year.

Appendix 1

NOTIFICATION CRITERIA FOR SIGNIFICANT RADIATION PROTECTION EVENTS

These criteria do not apply to basic nuclear installations or the transport of radioactive materials, for which the specific guide dated 21st October 2005 and applicable since 1st January 2006 remains the reference

*The notification of a significant radiation protection event does not relieve the person or organisation that produces or uses the ionising radiation from their **other reporting obligations** that may result from application of the Labour Code, the Public Health Code, the Environment Code or any other regulations. This notification does not substitute, for example, for the provisions set out for the protection of workers, the general public and patients, or for monitoring the safety of use of health products (see appendix 3).*

Criterion 1 (Workers)

Exposure or a poorly controlled or uncontrolled situation that has led or could lead to an exceedance of the regulatory annual individual dose limit for the worker's classification; or
Unplanned situation having led, in a single operation, to the exceeding of one quarter of an annual individual dose limit for a worker.

Details

This criterion applies:

- to all workers, salaried or non-salaried, practising their professional activity in an establishment exercising one of the activities mentioned in Article 4451-1 of the Labour Code, classified in category A or B or not classified;
- to cases of external and internal exposure (notably incidents involving contamination by radioactive substances in the exercise of nuclear activities);
- when the analysis submitted shows that exceedance of the limit dose was possible in likely and realistic conditions;
- when the loss of control of a radioactive substance or a device, notified in accordance with criterion 4, has or could have led to a worker exceeding the dose limit.

It includes, for example:

- noncompliance with the safety procedures, deficiencies in signalling or noncompliance with the technical conditions of access to or spending time in a specially regulated or prohibited area (as defined in the Order of 15 May 2006 of the Ministers responsible for labour, health, agriculture and industry, on the conditions of delimiting or signalling monitored and controlled areas and specially regulated or prohibited areas in view of the exposure to ionising radiation, and the health, safety and maintenance rules imposed in them.)
- the loss of availability, the malfunctioning or the ineffectiveness of the safety or radiation protection devices that could lead to above-normal exposure of a worker. Examples: uncoupling of a gamma radiography source from its guide tube, retraction failure of a gamma radiography source or a brachytherapy source, etc.

The term device can mean, for example:

- locking or protection devices[7];
- systems for measuring radioactivity or equivalent dose rates required in order to use the source[8];
- personal or collective radiation protection equipment.

Reminders

For workers classified in category A or B, the dose limits are as defined in Articles R. 4451-12 to R.4451-15 of the Labour Code.
Under their normal working conditions, "non-classified" workers may not receive during twelve consecutive months, an effective dose or an equivalent dose exceeding the limits given in Article R. 1333-8 of the Public Health Code.

[7] ***locking or protection devices:*** *locking in an irradiating zone or locking of a source in the safety position, beam limiter, shields, radiation protection lead glass, etc.*
[8] ***systems for measuring radioactivity or equivalent dose rates required in order to use the source:*** *this concerns the measuring systems installed on fixed-station systems and on mobile systems when required (for example, the radiation meters on industrial radiography work sites).*

Notification criterion 2.1: (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 comply with the prescription[(1)];

• 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.

[(1)] The conformity of the delivered dose includes:

- 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;
- the absence of systematic dose errors for several patients, whatever the value of that dose error.

Details

For more details on notification criterion 2.1 (significant patient radiation protection event in radiotherapy), refer to ASN Guide No. 16 on the website http://professionnels.asn.fr.

Criterion 2.2 (Exposure of patients for diagnostic purposes)

Inappropriate practice or malfunction when using radioactive sources or X-ray generators for diagnostic purposes which has resulted or could have resulted in:

- **significant exposures exceeding the diagnostic reference levels;**

or

- **errors in performing the examination.**

Details

The following can be considered as significantly higher than the diagnostic reference levels:

- in radiology, mean dose values established in application of article 2 of the order of 24 October 2011 of the Minister responsible for health, relative to the diagnostic reference levels, exceeding:
    - in conventional radiography, in the adult: 4 times the reference levels set by this order;
    - in conventional paediatric radiology: 2 times the reference levels set by this order;

- in computed tomography, in adults: 2 times the reference levels set by this order.

- In nuclear medicine: mean administered activity values exceeding the reference level of the examination specified in this order.

This criterion also includes errors relating to the performance of a diagnostic examination, such as the administration of a radiopharmaceutical to the wrong patient or the performance of a radiological examination on a non-prescribed area.

Reminder: the notification of a significant event further to the malfunctioning of a machine or the failure of safety or radiation protection devices to fulfil their function does not relieve the medical device user of his or her obligation to report an incident or potential incident on account of medical devices vigilance.

Likewise, pursuant to Act 2004-806 of 9 August 2004 concerning the public health policy, criteria and procedures for notifying events concerning patients called, depending on their level of seriousness, "serious adverse events" (order of 25 April 2006 of the Minister responsible for health relative to the conditions of experimentation of notification of serious adverse events relating to health-care) or "risk-bearing events" are defined by the Minister of Health on the basis of a proposal by the InVS (Health Monitoring Institute) and the HAS (National Authority for Health).

Criterion 3 (Public)

Poorly controlled or uncontrolled situation, loss of control of a radioactive substance or a device leading to exposure that has resulted or could result in the exceeding of a regulatory annual individual dose limit for the public.

Details

This criterion applies in the event of external exposure or internal exposure to members of the general public and workers not exercising their professional activity in an establishment governed by the provisions of Article R. 4451-11 of the Labour Code.
The dose limits are taken within the meaning of Article R. 1333-8 of the Public Health Code.

It includes, for example:

- accidental exposure of the embryo or foetus of a pregnant woman in a situation where the medical personnel were unaware of the pregnancy of the irradiated patient, and the patient's uterus was situated in the field of exposure to ionising radiation;
- events occurring on an industrial radiography work site that have resulted or could result in exposure of the public;
- loss of control of a radioactive substance or a device, notified in accordance with criterion 4, which has resulted in or could result in exposure of the public.

Appendix 2

NOTIFICATION OF A SIGNIFICANT RADIATION PROTECTION EVENT

1. ESR excluding a patient radiation protection event in radiotherapy: It contains the following information at least:

- the date and place of occurrence of the event;
- the name, the contact details and the function of the person notifying the event (and, if it is not the same person, the name and contact details of the person responsible for the nuclear activity);
- the nature of the nuclear activity;
- the notification criterion or criteria used (there can be several criteria);
- the type of device, source or radioactive substance concerned;
- in the event of loss or theft of a radioactive source, the information relative to the source in question;
- the circumstances of occurrence of the event and a description of the facts;
- the actual consequences observed;
- the immediate precautionary measures and corrective actions.

The notification form *(DEC/ESR)* and a template of the significant event report *(CRES)* are available on the website ***https://teleservices.asn.fr***.

2. ESR in the area of patient radiation protection (Criterion 2.1: radiotherapy)

The elements to be provided in the notification and the notification form are presented in **ASN Guide No. 16**. The notification contains the following information at least:

- the name, the contact details and the function of the person notifying the event (and, if it is not the same person, the name and contact details of the person responsible for the nuclear activity);
- the date of occurrence of the event;
- the proposed rating on the ASN-SFRO scale;
- the circumstances of event detection;
- the number of patients concerned;
- the circumstances of occurrence of the event and a description of the facts;

- the actual consequences observed;
- the immediate precautionary measures and corrective actions;
- for any event that could be rated level 2 or higher on the ASN-SFRO scale, the information concerning the pathology treated, the treatment plan and the dosimetry

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

- a significant radiation protection event (ESR) that could jeopardise the health of persons through exposure to ionising radiation,
- a medical devices vigilance report: any incident or accident incriminating a device which led to 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).

The template of the **significant event report** (*CRES/MED/RT)* is available on the website *https://teleservices.asn.fr*.

Appendix 3

REMINDER OF THE MAIN REPORTING OR NOTIFICATION OBLIGATIONS TO COMPLY WITH INDEPENDENTLY OF THE NOTIFICATION OF A SIGNIFICANT RADIATION PROTECTION EVENT TO ASN

The notification of a significant radiation protection event does not relieve the person or organisation producing or using the ionising radiation of the obligations imposed by other regulations or specific obligations imposed by the establishment concerned. The list proposed below is for information only. In no way does it constitute an exhaustive overview of the reporting systems imposed by the regulations in effect.

1. Applicable provisions regarding the protection of workers

- Notification to the local CPAM (state sickness fund) office where the victim is registered, of the occupational accidents provided for in Article L. 441-2 of the Social Security Code;
- Notification to the labour inspectors of exceedances of dose limit values provided for in Article R. 4453-34 of the Labour Code.

2. Applicable provisions regarding vigilance (health products)

Notifications to the French Health Products Safety Agency (ANSM) are mandatory, particularly regarding:

- medical devices vigilance applicable to 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);

3. Notification to the InVS (French health monitoring institute) of serious adverse events associated with medical treatment during investigations, treatments or prevention actions provided for in Article L. 1413-14 of the Public Health Code.

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AUTORITÉ
DE SÛRETÉ
NUCLÉAIRE

15 rue Louis Lejeune
92120 Montrouge

Public Information Center:
+33 (0)1 46 16 40 16 · info@asn.fr

ASN regional divisions:
asn.fr/contact

french-nuclear-safety.fr