

FANC directives relative to the arrangements and criteria for informing the FANC of significant events concerning radiation protection in radiotherapy

1. Introduction

The mission of the Federal Agency for Nuclear Control (FANC), as an independent competent authority, is to monitor compliance with and improve laws and regulations to protect the population, workers and the environment against the negative effects of ionising radiation.

Chapter X of the Royal Decree of 20 July 2001 laying down the general rules and regulations for the protection of the population, workers and the environment against the negative effects of ionising rays (RGPRI), describes the measures to be taken when an “event likely to threaten the security or health of people” occurs and stipulates that the Agency must be notified promptly of any such event (**art. 66.3** and **67.2** RGPRI).

The aim of these directives, drawn up in consultation with all the stakeholders in the radiotherapy sector, is to clarify and specify the reporting criteria and arrangements: what should be reported, when and how?

The Agency wishes to emphasise that the reporting system is not intended to punish people but is part of a **prevention and feedback approach**.

In the framework of radiotherapy, the systematic reporting of incidents and accidents enables the FANC to:

- Satisfy itself that the necessary measures have been taken locally (namely remedying the situation and preventing any reoccurrence);
- Take, if applicable, measures to avoid similar events reoccurring in other places;
- Analyse, in collaboration with the stakeholders, the events which occurred and to provide feed back to the sector (on an anonymous basis).

In addition to notifying the Agency (and complying with other notification requirements pursuant to other regulations: see below), it is essential, for quality assurance reasons, for each radiotherapy centre to have an internal system for recording and analysing all incidents, in accordance with the requirements of the College of Radiotherapy and the Agency.

Despite the detailed criteria set out below, it is sometimes difficult to distinguish between events which have to be reported to the Agency and those for which an internal record is sufficient. In case of doubt, one essential point to be taken into consideration is the **potential interest of the information for other centres** (even if the incident/accident was avoided), as part of a prevention and feedback approach.

2. Events to be reported to the Agency

Criterion 1 (all workers, whether or not they are occupationally exposed, employees and self-employed people alike):

Exposure or a badly controlled or uncontrolled situation, having resulted or likely to result in one of the applicable annual individual dose limits being exceeded (**art. 20.1 RGPRI**), including any accidental exposure of pregnant workers;

or

An unforeseen situation having resulted, in one operation, in an applicable annual individual dose limit being exceeded by 25% (**art. 20.1 RGPRI**).

Clarifications relative to criterion 1 and observations:

- A situation “likely” to result in dose limits being exceeded, is understood to refer, for example, to non-observance of security procedures or the incorrect functioning of security systems (e.g. curietherapy source retraction failure), even if there was no actual accidental exposure or if any such exposure was fortunately minimal.

- In the event of the accidental exposure of workers, the relevant regulatory obligations must be respected. It must be borne in mind that the responsibility for determining the doses incurred lies with the head of the physical monitoring department, in consultation with the authorised doctor with responsibility for the medical surveillance of workers. The individual with responsibility for physical checks is also responsible firstly for determining the circumstances in which the accidental exposure occurred, and secondly for examining the preventive measures needed to prevent such a mishap reoccurring (**art.23.1 and 23.2 RGPRI**). Operators must inform the Agency and the Administration of Hygiene and Occupational Health Services of the Federal Public Service (FPS) for Employment, Labour and Social Dialogue (**art.20.1.7RGPRI**) as soon as possible of any accidental exposure of workers.

In application of the FANC's directives to approved bodies, the latter are also required to inform the Agency promptly of any accidents.

Criterion 2 (exposure of patients for therapeutic purposes):

Badly controlled therapeutic situation or a malfunction during the use of a radioactive substance or a patient irradiation system having resulted or likely to result in:

- The occurrence of unexpected deterministic effects;

and/or

- The exposure of one or more patients to doses significantly higher or lower than the prescribed doses.

Clarifications relative to criterion 2 and observations:

- This criterion includes the unintentional exposure of the embryo or foetus of a pregnant patient.
- The occurrence of unexpected deterministic effects is distinguished from known, foreseeable occurrences linked to the administration of a treatment using ionising rays and which may appear, in particular at the level of healthy tissues next to the target volume. For example, a rash, temporary alopecia or a radiation cataract in the irradiated areas may be considered as foreseeable events, whereas tissue necrosis or a myelitis are unforeseen deterministic effects.
- The exposure of patients to doses which are significantly different, either higher or lower, from the prescribed doses ("deviations"), may not have a significant clinical influence, but reveals material and/or organisational problems.
- The scope of the events to be reported includes all stages of the treatment, from its planning to the final radiation session. As a general rule, the events to be reported include any abnormal situation (errors, misunderstandings, failures, etc.) where the actual dose delivered differs significantly from the foreseen dose. This implies that a medical prescription is always available and clear as regards volumes (where applicable, see ICRU 50-62), the total dose, the daily dose and the number of fractions. This formula includes all inconsistencies inherent in radiotherapy, in general, and in the technique used, in particular.
- Deviation criteria:
 - Deviation of 10% or more in relation to the planned total dose;
 - Deviation of 10% or more in relation to the foreseen total BED (Biological Effective Dose); this covers among other things prolonged interruptions and significant changes in the planned treatment);
 - Deviation of 20% or more in relation to the foreseen dose for a unique fraction (regardless of subsequent compensatory measures);
 - In addition, any systematic deviation in excess of generally accepted limits for the technique in question should be reported insofar as it affects a large group of patients.

- An event notification may result from:
 - An equipment problem (the design of the equipment – hardware and/or software – is called into question);
 - A procedural problem.

In the first case, the equipment problem must be reported to the Federal Agency for Medicines and Health Products (FAMHIP). If the problem concerns ionising rays, a copy of the report is forwarded by the FAMHIP to the FANC.

In the second case, the report has to be sent only to the FANC. Equipment problems due to inappropriate maintenance or gauging procedures are not caused by the equipment in itself. Therefore they do not need to be reported to the FAMHIP since the quality of the equipment is not called into question.

- Errors which do not concern the actual administration of ionising rays are not events which need to be reported, such as, for example, an error in a patient's date of birth or telephone number. Furthermore, a fall in the waiting room or treatment room is not considered as a "radiological" event. This type of event is subject to a different notification procedure, for example it is reported to the insurance company or in the framework of the hospital's quality system. Equally, a failure to inform patients of the date of their next consultation does not need to be reported.

1 This is a general condition referred to in particular in the ESTRO's "Quality Assurance in Radiotherapy" document, adopted by the ABRO and the College of Radiotherapy (at that time called the Peer Review Committee) in 1995.

Criterion 3 (public):

Badly controlled or uncontrolled situations, loss of control of a radioactive substance or a patient irradiation system having resulted or likely to result in an annual individual dose limit for the public being exceeded.

Clarifications relative to criterion 3 and observations:

- This criterion includes the accidental exposure of the embryo or foetus of a pregnant member of the public.
- In such a situation, the relevant regulatory obligations must be respected (**art.67.2 RGPR**). It must be borne in mind that the head of the physical monitoring department is responsible for deciding any emergency measures to be taken and determining the doses incurred. The individual responsible for physical checks is also responsible, on the one hand, for determining the circumstances in which the accidental exposure occurred and, on the other hand, for examining the preventive measures needed to prevent such a mishap reoccurring. The head of the centre must report the event to the Agency as soon as possible.

In application of the FANC's directives to approved bodies, the latter are also required to inform the Agency promptly of any accidents.

Criterion 4:

- 4.0. Loss of control of radioactive substances or of a system leading to exposure.
- 4.1. Loss or theft of sources, radioactive substances or generators of ionising rays.
- 4.2. Discovery of sources, radioactive substances or generators of ionising rays.
- 4.3. Dispersion of radioactive nuclides or contaminated material.
- 4.4. Unauthorised release of radioactivity into the environment.
- 4.5. Evacuation of radioactive waste towards unsuitable facilities.
- 4.6. Delivery not compliant with the permit issued regarding total activity or the nature of the radioactive nuclide.
- 4.7. Discovery of the loss of integrity of a contained radioactive source, irrespective of the cause of the loss of integrity.
- 4.8. Storage of sources, radioactive substances or generators of ionising rays at a location not authorised for that purpose.

Clarifications relative to criterion 4 and observations:

- The loss of control of radioactive substances may, for example, concern a patient carrying radioactive sources and leaving a hospital department whereas he should have been kept in a protected room (curietherapy by iridium, caesium, etc.).
- Discovery of radioactive sources: presence of radioactive substances in locations where their storage or use is not authorised. The discovery of a source may be reported by anyone who becomes aware of its existence.
- Dispersion of radioactive nuclides: the criterion concerns the dispersion of radioactive material outside areas where the risk of accidental dispersal is known, such as, for example, controlled or restricted areas, premises where the storage and use of uncontained sources are authorised.
- Unauthorised release of radioactivity into the environment: for example, the uncontrolled release of radioactive effluents into the sewerage system before decay or failing to comply with the release criteria specified in the permit. Effluent released at home by patients who have undergone a medical examination or received medical treatment involving radioactive nuclides are excluded from this criterion.
- Evacuation of waste towards unsuitable facilities: such events must be reported by the producer of the waste. Solid waste containing biological liquids (incontinence pads, bandages, compresses, etc.) evacuated at home by patients who have undergone a medical examination or received medical treatment involving radioactive nuclides is excluded from this criterion.
- Discovery of the loss of integrity of a contained radioactive source, including at the time of periodic leakage checks. This criterion covers cases of the destruction or deterioration of a contained source which as a result can no longer be considered as a contained source: for example the destruction or deterioration of a contained source by a fire, an explosion or a handling error having resulted in the source becoming uncontained.

Criterion 5:

Malicious acts or attempted malicious acts likely to affect the protection of workers, patients or the public against the effects of ionising radiation, including environmental damage.

Clarifications relative to criterion 5:

This criterion includes, for example, voluntarily installing a radioactive source in a location accessible to the public.

Criterion 6:

Any other event likely to affect radiation protection and deemed significant by the operator, the head of the radiotherapy department or the approved body.

Clarifications relative to criterion 6:

The following cases in particular fall within the scope of this category:

- The use of a dosimeter belonging to another person;
- Repetition of minor events, etc.

3. Other notifications

Reporting an event to the FANC does not release the party involved from other notification requirements pursuant to the RGPRI and other regulations in force (see names and addresses on the Agency's website), in particular:

- Physical monitoring department
- Medical services
- Pharmacovigilance
- Occupational health and labour inspectorate
- Emergency plan for nuclear risks
- Public Health FPS – Crisis Management

4. Notification time limits

Notifiable events must be reported as soon as the event is noted. However, several hours or several days may sometimes be necessary to ascertain the cause of the problem. In such cases, a preliminary notification must be submitted, indicating that the analysis of the causes of the equipment problem or procedure has not yet been completed.

In practice, the urgency of the notification will also be assessed in the light of the established or potential severity of the event and the rapidity of the reaction necessary to avoid the situation deteriorating, or to curtail its consequences.

In any event, notifiable events must be reported within not more than **2 working days after the detection of the event in question**.

5. FANC notification procedure

5.1. The declarant

Notifications to the Agency in connection with criterion 2 (patient exposure) are to be submitted by the head of the radiotherapy department. The same applies as regards notifications relating to any other criteria when they concern events having a potential interest for other centres (even if the incident/accident was avoided), with a view to prevention and feedback (for example incorrect functioning of a security system or a procedural error likely to reoccur and which might have led to a worker or a member of the public being exposed to radiation).

(Urgent) notifications relative to the loss or theft of radioactive substances must be submitted to the Agency by the radiotherapist concerned (**art. 66.3 RGRI**).

Operators are required to inform the Agency and the Administration of Hygiene and Occupational Health Services of the Federal Public Service (FPS) for Employment, Labour and Social Dialogue as soon as possible of any accidental exposure of a worker. Similarly, they must inform the Agency promptly of any accidental exposure of a member of the public and, in general, of any event likely to compromise the security or health of people. Defects of appliances must be reported to the Agency with responsibility for medical devices (FAMHIP). If this problem concerns ionising rays, a copy of the report must be forwarded by the AFMPS to the FANC.

The medical radiological physics expert must notify the Agency promptly in the event of any nonconformity identified in apparatuses requiring urgent action (**art. 51.6.5 RGPRI**).

In application of the FANC's directives to approved bodies, the latter are required to inform the Agency promptly of any accident or emergency. When they deem it worthwhile and necessary they should also inform the Agency of any anomaly or incident likely to have an impact on the safety of the facilities inspected.

5.2. The documents

The identity of the declarant of the significant event and of the head of the radiotherapy department, as well as information concerning the organisation (or if applicable the facilities), must be specified in the notification documents.

However, as the reporting system for significant events is based on the lessons learnt from an analysis of the events and not on the identification or the punishment of a specific person, the data relative to the other individuals involved in the event (workers, patients and public) are treated anonymously.

A "significant event notification" is sent to the FANC, even if the initial results of the investigations carried out to determine the circumstances of the event in question are not yet available.

The notification arrangements, the information to be included in the notification, as well as the **notification form** are available on the FANC's website (**www.fanc.fgov.be**). This document enables the Agency to obtain rapidly a minimum amount of information in order to perform its evaluation and information duties. It specifies the criterion or criteria concerned by the notification (several criteria are possible for the same event).

A **“significant event report”** is also drawn up and transmitted to the Agency, within 2 months of the notification. It includes an update of the notification, as well as a detailed analysis of the event and a presentation of the corrective measures implemented or planned.

6. Informing the public

As a general rule, it is the responsibility of the institution concerned to communicate the relevant information to the public, automatically and promptly, in cases considered appropriate. In these conditions the Agency limits itself to answering questions which it might be asked by the media. In some companies, a spontaneous communication by the Agency may prove to be appropriate; insofar as possible it will be preceded by a consultation with the services concerned.

7. Feedback to radiotherapy services

The Agency provides all the country's radiotherapy services with feedback (in total anonymity).

This feedback includes at least a description of the event in question and the exact type of equipment involved, as well as the various actions undertaken following the incident and any resultant recommendations.

The Agency also disseminates to all radiotherapy services in the country the information that it receives concerning incidents or accidents that have occurred elsewhere.