SCALES USED
TO CLASSIFY NUCLEAR INCIDENTS AND ACCIDENTS AND RADIATION PROTECTION EVENTS IN THE CONTEXT OF RADIOTHERAPY PROCEDURES

The need to inform the public of the severity of nuclear events, in particular after the Chernobyl accident (1986), made it necessary to develop classification scales. The first scale was introduced in 1987 by the French High Council for Nuclear Safety and Information (CSSIN[1]). The French Nuclear Safety Authority (ASN) played an essential role in 1991 in the establishment of the INES international nuclear event scale (INES[2]) published by IAEA.

In 2002, ASN proposed a new scale to cover radiation protection events (irradiation, contamination), including those affecting workers, whatever the event location.

In July 2007, in collaboration with the French Society of Radiation Oncology (SFRO[3]), ASN introduced a scale intended to classify radiation protection events affecting patients undergoing radiotherapy procedures. It was published in 2008.

In July 2008, IAEA published a revised INES scale more suitable for dealing with events occurring in the field of transport or entailing exposure of individuals to radioactive sources.

In September 2008, ASN proposed that the French High Committee for Transparency and Information on Nuclear Security (HCTISN) participate in the work that ASN has been carrying out since 2007 with the aim of introducing an index for the measurement of radioactivity in the environment.

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

OBJECTIVE OF THE ASN-SFRO SCALE

The objective of the ASN-SFRO scale is to inform the public about radiation protection events affecting patients undergoing radiotherapy procedures.

Introduced in July 2007 by ASN in collaboration with SFRO, it was tested over a period of 12 months. After joint assessment with SFRO and the French society of medical physics (SFPM), the final version of the scale was published on the ASN website in July 2008.

DESCRIPTION OF THE ASN-SFRO SCALE

Events are classified on the ASN/SFRO scale in eight levels.

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

The severity of the effects is assessed with reference to the international clinical classification (CTCAE[4] grades) already used by practitioners.

ASN-SFRO SCALE APPLICATION

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

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

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

(1) CSSIN: Conseil Supérieur de la Sûreté et de l'Information Nucléaires (Fench Higher Council for Nuclear Safety and Information) • (2) INES: International Nuclear Event Scale • (3) SFRO: Société Française de Radiothérapie Oncologique (French Society for Oncological Radiotherapy) • (4) CTCAE: Common Terminology Criteria for Adverse Events, Cancer Therapy Evaluation Program, August 2006, http://ctep.cancer.gov

The effects taken into consideration in the notification to ASN are unexpected or unpredictable effects due to inappropriate doses or irradiated volumes. No account is taken of any side-effects, regardless of their grade, resulting from the treatment strategy adopted by the practitioner with the agreement of the patient and which occurred irrespective of any error in irradiated volume or dose delivered (accepted risk).
For patients affected by a radiotherapy event, the appearance of any side-effects or complications may not be immediate. Therefore an event may be temporarily rated at a given level and then modified according to the changing state of health of the patient.
Unlike the INES scale, the defence-in-depth criterion (assessment of the safety level of the radiotherapy activity) is not included for this classification, in order to avoid confusion between medical seriousness and failure of the installation or of the organization of the unit.

CLASSIFICATION CRITERIA

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

CRITERIA CONCERNING ESTABLISHED CONSEQUENCES

When the effects are established, the classification refers to the various clinical classification grades of 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**, corresponding to grade 2, includes moderate acute effects or delayed effects such as moderate radiation-induced stenosis, low-discomfort tissue alteration (cutaneous fibrosis) or minimal or absence of alteration of quality of life;
• **level 3**, corresponding to grade 3, includes severe acute effects or delayed effects such as treatable non-life-threatening tissue necrosis with moderate alteration of quality of life (severe proctitis, severe cystitis, etc.);
• **level 4**, corresponding to grade 4, includes serious acute effects or delayed effects such as radiation-induced myelitis, untreatable life-threatening extensive tissue necrosis with substantial or major alteration of quality of life (serious proctitis, serious cystitis, etc.);
• **levels 5, 6 and 7**, corresponding to grade 5, include one or more deaths.

DOSIMETRIC CRITERIA AND POTENTIAL EFFECTS

When effects are not yet established, dose or irradiated volume criteria are applied for provisional classification. The difference between the received dose and the planned dose is assessed on the basis of accepted or tolerated deviations given current practices or available references.

Similarly, the difference between the actual irradiated volume and the volume that should have been treated is analysed taking into account whether organs particularly sensitive to radiation are included.

For significant or highly significant deviations, the event is classified at level 2, 3 or even 4.

If there is a high level of uncertainty about the occurrence of possible effects, the event is classified at level 1 or level 2 (depending on the conditions of the event).

CRITERIA CONCERNING THE NUMBER OF EXPOSED PATIENTS

For established effects of levels 2, 3 or 4, a + sign is added to the classification level when the number of patients concerned is greater than 1.

For an event which led to the death of several patients, the level 5 classification is increased by:
• **+ 1** if the number of patients concerned is greater than 1 and less than 10;
• **+ 2** if the number of patients concerned is greater than 10.

To avoid any confusion about the seriousness of effects, the criterion of a level increase according to the number of cases is not applied to potential effects, unless information about the delivered dose and/or the irradiated volume already enables a prognosis in terms of deaths, serious or severe effects.

SUMMARY OF EVENTS IN 2009

131 events were notified to ASN in 2009, of which 123 were classified at level 0 or 1 and eight at level 2 of the ASN-SFRO scale. ■

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