



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. ■