

ASN-SFRO SCALE FOR DEALING WITH RADIATION PROTECTION EVENTS AFFECTING PATIENTS UNDERGOING A RADIOTHERAPY PROCEDURE

1 - PURPOSE OF THE ASN-SFRO SCALE

The purpose of the ASN-SFRO scale is to inform the public about radiation protection events affecting patients undergoing a radiotherapy procedure. It was published in July 2007 and has been tested for a 12-month trial period. The scale has been jointly evaluated by ASN, SFPM (French society of medical physicists) and SFRO. The definitive scale has been published on ASN website in July 2008.

2 - PRESENTATION OF THE ASN-SFRO SCALE

The events are rated on eight levels on the ASN/SFRO scale:

- ♦ **level 0 and 1** are used to rate events with no clinical consequence;
- ♦ **levels 2 to 3** correspond to events categorised as “incidents”;
- ♦ **levels 4 to 7** correspond to events categorised as “accidents”.

The severity of the effects is assessed with reference to the international clinical classification (CTCAE¹ grades) already used by practitioners.

The effects considered in the declaration submitted to ASN are the unexpected or unforeseeable effects due to inappropriate doses or irradiated volumes. Not included however, are any side-effects, whatever their grade, that may for example result from a strategy agreed by the practitioner and patient, with no error in the irradiated volume or delivered dose (accepted risk).

For patients affected by a radiotherapy event, the effects or complications may not be immediate. A provisional rating followed by a final rating several months later may therefore be necessary.

For confirmed effects, over-rating will be used to take account of the number of patients concerned.

Unlike the INES scale, the defence in depth criterion (assessment of the level of safety of the installation) is not incorporated into this rating system, in order to prevent any confusion between the seriousness of a medical condition and a failure of the installation or breakdown in the organisation of a department.

¹ Cancer Therapy Evaluation Program, August 2006, <http://ctep.cancer.gov>

ASN-SFRO SCALE

| | EVENTS (UNFORESEENS, UNEXPECTEDS) | CAUSES | CONSEQUENCES (CTCAE V3.0 GRADE) |
|---------------------|---|--|---|
| 5 to 7 ¹ | Death | Dose (or irradiated volume) for higher than normal leading to fatal complications or sequelae | Death |
| 4 ² | Serious life-threatening event, disabling complication or sequelae | Dose or irradiated volume far higher than tolerable doses or volumes | Acute or late serious effect, either unexpected or unforeseeable, grade 4 |
| 3 ² | Event leading to a severe impairment of one or more organs or functions | Dose or irradiated volume higher than tolerable doses or volumes | Acute or late severe effect, either unexpected or unforeseeable, grade 3 |
| 2 ² | Event leading to or liable to lead to a moderate impairment of an organ or function | Dose higher than recommended doses, or irradiation of a volume liable to lead to unexpected but moderate complications | Acute or late moderate, unexpected or unforeseeable effect, grade 2 or no disablement |
| 1 | Event with dosimetric consequence but no expected clinical consequence | Dose or volume error (for example, error of dose or target non-compensable on all of the treatment) | No expected symptom |
| 0 | Event without consequence for the patient | Error of dose (monitor unit, wedge filter...) compensable on all of the treatment. Error of identification of a patient treated for the same pathology (compensable) | |

(1) In the event of death of several patients:

- the minimum level 5 is raised to 6 if the number of patients is higher than 1 but no more than 10,
- the minimum level 5 is raised to 7 if the number of patients is higher than 10.

(2) If the number of patients is higher than 1, a + sign is added to the chosen level (for example: 3 becomes 3+).

3 - RATING CRITERIA

In the same way as the INES scale, the ASN-SFRO scale was designed so that the rating criteria for an event concern not only its confirmed consequences, but also its potential effects.

The number of patients exposed is also taken into account.

Criteria concerning confirmed consequences

When the effects are confirmed, the rating refers to the various clinical classification grades, as follows:

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

Dosimetric criteria and potential effects

When the effects are not yet confirmed, dose or irradiated volume criteria are chosen 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 treated is analysed, taking account of the presence or otherwise of any organs particularly sensitive to radiation.

For any significant or extremely significant discrepancies, the event will be rated level 2 or 3, or possibly 4.

If there is a high level of uncertainty over whether or not possible effects may have occurred, the event is rated level 1 or 2 (depending on the conditions of the event).

Criteria concerning the number of patients exposed

For confirmed effects of a level of 5 or more, the minimum rating level defined 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 10 or more.
- For confirmed effects of level 2, 3 or 4, the rating level is given the + sign when the number of patients concerned is greater than 1.

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

The event will eventually be re-rated if there are any confirmed effects that may be linked to the over-exposure or exposure error.

4 - SUMMARY OF EVENTS FROM JULY 2007 TO JULY 2008

ASN was notified of 181 events during the period where the experimental scale has been used (July 2007-July 2008):

- 175 were rated level 0 or 1;
- 6 were rated level 2.



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