SEVERITY SCALES FOR
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 rating scales. The first scale was introduced in 1987 by the CSSIN[1]. The Autorité de sûreté nucléaire (ASN – French Nuclear Safety Authority) played an essential role in the 1990s in the establishment of the INES[2] International Nuclear and Radiological Event Classification scale published by the IAEA[3].

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The INES NUCLEAR INCIDENT AND ACCIDENT RATING SCALE

DESCRIPTION AND OBJECTIVES

In the same way as for natural phenomena such as earthquakes, wind and avalanches, in 1987 France set up a nuclear event severity scale, from which the IAEA drew extensively its inspiration to design the INES scale. INES, internationally used since 1991, is based on both objective and qualitative criteria. Applied by sixty countries, it is intended to **facilitate media and public perception of the significance of nuclear incidents and accidents.**

It is not a tool for assessment or measurement of nuclear safety and radiation protection and cannot be used as a basis for compensation or penalties.

Under no circumstances can INES be used to draw international comparisons. In particular no cause-and-effect relationships can be established between the number of notified incidents without safety significance and the probability of occurrence of a serious accident at an installation.

INES SCALE APPLICATION

	OFF-SITE CONSEQUENCES	ON-SITE CONSEQUENCES	DEGRADATION OF DEFENCE IN DEPTH
7 MAJOR ACCIDENT	Major release: considerable effects on health and on the environment		
6 SERIOUS ACCIDENT	Significant release likely to require full implementation of planned countermeasures		
5 ACCIDENT WITH WIDER CONSEQUENCES	Limited release likely to require partial implementation of planned countermeasures	Severe damage to reactor core/to radiological barriers	
4 ACCIDENT WITH LOCAL CONSEQUENCES	Minor release: public exposure close to the prescribed limits	Significant damage to reactor core/to radiological barriers/lethal exposure of a worker	
3 SERIOUS INCIDENT	Very slight release: public exposure equivalent to at least a percentage of the limits defined by the IAEA manual	Serious contamination/Acute effects on the health of a worker	Near-accident/loss of barriers
2 INCIDENT		Significant contamination/overexposure of a worker	Incidents with significant failures in safety provisions
1 ANOMALY			Anomaly beyond from authorized operating conditions
0 DEVIATION		No safety significance	
EVENT BELOW SCALE	No safety significance		

(1) CSSIN : *Conseil Supérieur de la Sûreté et de l'Information Nucléaires* (French Higher Council for Nuclear Safety and Information) • (2) INES : International Nuclear Event Scale • (3) INES Guide available on IAEA website (http://www-ns.iaea.org/tech-areas/emergency/ines.htm) • (4) SFRO: *Société Française de Radiothérapie Oncologique* (French Society for Oncological Radiotherapy) • (5) HCTISN: *Haut Comité pour la Transparence et l'Information sur la Sécurité Nucléaire* (French High Committee for Transparency and Information on Nuclear Safety)

NATURE OF EVENTS RATED ON INES

IINES enables ASN to rate, according to their significance, all events[6] occurring in civil basic nuclear installations (BNI) and during transport of radioactive materials. Since 1 July 2008, INES can also be used by the 60 member countries of the IAEA for the classification of radiation protection events related to the use of radioactive sources in medical (excluding patients), industrial and research facilities. The application of INES to BNIs is based on three classification criteria (columns 2, 3 and 4 of the table on the front):

- **the off-site consequences,** assessed in terms of releases of radioactivity that can affect the public and the environment;
- **the on-site consequences,** potentially affecting workers and installations;
- **degradation of the defence in depth** of the installation, consisting of successive barriers (safety systems, procedures, technical and administrative controls, etc.) interposed between radioactive substances and the environment. For transport of radioactive materials on public roads, only the criteria relating to off-site consequences and degradation of defence in depth are assessed for application of INES.

The classification criteria for radiation protection events are given in the table hereinafter.

EXAMPLES OF EVENTS RATED ON INES

Level 0. In France: several hundred events are rated at level 0 each year. They concern deviations from normal operation of installations or the normal course of transport that have no significance in terms of safety.

Level 1. In France: about a hundred events are classified at level 1 each year. They include anomalies, deviation from the authorized operating conditions of installations or from the normal course of transport because of equipment failure, human error or inadequate implementation of procedures.

Level 2. In France: 2006: improper use of a MOX fuel fabrication scrap crusher at the plutonium technology unit (ATPu) at the Cadarache site, resulting from the application of inappropriate and informal procedures and instructions. 2005: anomaly concerning certain safety system pumps of EDF 900 MWe reactors, potentially leading, under certain accident conditions, to the loss of the cooling water recirculation function. 2004: generic anomaly affecting certain electrical marshalling boxes in EDF NPP, potentially preventing operation of various equipment (motors, valves) under accidental conditions leading to the presence of water or water steam in the reactor building.

Level 3. In France: 2008: irradiation by a cobalt 60 source of a worker in an irradiation bunker on the ONERA site in Toulouse. 2002: incident classified by the competent Swedish authority during transport by the carrier Federal Express (FedEx) between Sweden and the United States via Paris Roissy airport of a package showing on arrival a dose rate above the authorized regulatory limit. 1981: fire in a storage silo at La Hague. **In other countries:** 2008: abnormal release of iodine 131 by the building chimney of the *Institut des radioéléments* (IRE – radioelement institute) at Fleurus (Belgium) during a transfer of liquid discharges between tanks. 2005: detection of a radioactive leak in piping in the Thorp fuel reprocessing plant at Sellafield (United Kingdom). 2002: discovery in the reactor of the Davis Besse NPP (United States) of a cavity in the vessel closure head due to metal corrosion by boric acid.

Level 4. In France: 1980: damage to the core of reactor A1 at Saint-Laurent NPP. **In other countries:** 1999: criticality accident at a fuel fabrication plant in Tokai-Mura, Japan, with acute irradiation of three workers, two of whom died. 1973: release of radioactive materials following an exothermic reaction in a reprocessing tank at the Windscale NPP (United Kingdom).

Level 5. In France: none. **In other countries:** 1979: partial reactor core meltdown at Three Mile Island NPP (United States).

Level 6. In France: none. **In other countries:** 1957: explosion of a tank containing radioactive materials at the Kyshtym reprocessing plant (USSR).

Level 7. In France: none. **In other countries:** 1986: explosion of the reactor 4 at Chernobyl NPP (Ukraine).

USE OF INES IN FRANCE

All events significant for nuclear safety are notified to ASN by the licensees within 48 hours, with a proposed INES classification.
ASN retains sole responsibility for the final classification decision.
The use of INES enables ASN to identify the events and incidents of sufficient importance for it to issue a communication.

- **All events classified at level 1** and above are reported in incident notices published on the ASN website www.asn.fr.
- **Events classified at level 2** and above are also reported by press releases and notified to IAEA.
- **Events classified at level 0** are not reported in incident notices, unless they are of particular interest.

International transport events rated at level 1 and above concerning a foreign country are also notified to IAEA. In the case of the loss of radioactive sources, events at all INES levels are notified to IAEA. ■

(6) The INES user's manual extended to radiation protection events is available on the IAEA website www-ns.iaea.org/tech-areas/emergency/ines.htm

EXPERIMENTAL INES RATING OF RADIATION PROTECTION EVENTS

Since 1st July 2008, 60 IAEA member countries, already INES users, use INES to classify radiation protection events (excluding patients) taking into account radioactive sources and transport of radioactive materials. In France, an implementation guide for this new scale is in preparation. Radiotherapy events affecting patients are classified on the ASN-SFRO scale issued by ASN in July 2008.

EVENT	NUMBER OF PERSONS EXPOSED AND FINAL RATING		
	MINIMUM RATING	NUMBER OF PERSONS	FINAL RATING*
Death or lethal dose received		> 10	6
	4	> 1	5
		1	4
Deterministic effect or potential deterministic effect given the received dose		> 10	5
	3	> 1	4
		1	3
Exposure greater than 1 Sv or 1 Gy		> 100	6
	4	> 10	5
		≤ 10	4
Exposure greater than 100 mSv		> 100	5
	3	> 10	4
		≤ 10	3
Worker exposure to a dose above the annual regulatory limit or exposure of a member of the public to a dose greater than 10 mSv		> 100	4
	2	> 10	3
		≤ 10	2
Worker exposure to a dose greater than one quarter of the annual regulatory limit or exposure of a member of the public to a dose above the annual dose limit		> 100	3
	1**	> 10	2
		≤ 10	1

** The highest classification is selected.*
*** When a dose limit is exceeded as a result of accumulated exposure over a given period of time, ASN systematically assigns a level 1 classification because of inadequate safety culture.*

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The need to inform the public of the severity of nuclear events, in particular after the Chernobyl accident (1986), made it necessary to develop rating scales. The first scale was introduced in 1987 by the CSSIN[1]. The Autorité de sûreté nucléaire (ASN – French Nuclear Safety Authority) played an essential role in the 1990s in the establishment of the INES[2] International Nuclear and Radiological Event Classification scale published by the IAEA[3].

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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 the SFRO, it was tested over a period of 12 months. After joint assessment with the SFRO and the *Société française de physique médicale* (SFPM – French society for medical physics), the final version of the scale was published on the ASN website in July 2008.

DESCRIPTION OF THE ASN-SFRO SCALE

Events are rated on the ASN/SFRO scale in eight levels:

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

The seriousness of the effects is assessed by reference to the international clinical classification (CTCAE[5] grades) already used by practitioners.

The effects taken into consideration in the notification to ASN are

(5) CTCAE: Common Terminology Criteria for Adverse Events, Cancer Therapy Evaluation Program, August 2006, http://ctep.cancer.gov

ASN-SFRO SCALE

Level		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 fuction	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 consequence	Dose or volume error (e.g. dose error or target error in a session not compensable over the treatment as a whole)	No symptom expected
0	EVENT	Event with no consequence 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+).*

unexpected or unpredictable effects due to inappropriate doses or irradiated volumes. Any side effects, whatever their grade, are not included, for example those resulting from a strategy agreed between the practitioner and the patient, other than any error of irradiated volumes or delivered dose (accepted risk).
For patients affected by a radiotherapy event, the effects or complications may be deferred in time. A provisional rating followed by final rating after a few months may be necessary in such cases.
For established effects, the rating level is raised to take the number of patients into consideration.
Unlike INES, the defence-in-depth criterion (assessment of the safety level of the installation) 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.

RATING CRITERIA

Like INES, the ASN-SFRO scale has been designed so that the event rating criteria concern not only the established consequences but also the potential effects of the events.

The number of patients exposed is also taken into account.

CRITERIA CONCERNING ESTABLISHED CONSEQUENCES

Established effects are classified in reference to the clinical classification grades:
• **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 rating. 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 analyzed 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 level 5 or above, the minimum defined classification level 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.

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

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 or serious or severe effects.

The event will have eventually a final rating according to knowledge of any established effects associated with the overexposure or the exposure error.

SUMMARY OF EVENTS OVER THE PERIOD OF USE OF THE EXPERIMENTAL SCALE BETWEEN 1st JULY 2007 AND 1st JULY 2008

181 events were notified to ASN during the year of experimentation, of which 175 were rated at level 0 or 1 and six at level 2 of the ASN-SFRO scale. ■

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