HERCA

Accidental and unintended exposures of individuals subject to medical exposure – notification and recording of significant events

26 – 27 October 2016, Montrouge, France

Use of INES for medical events

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INES – The International Nuclear and Radiological Event Scale

INES

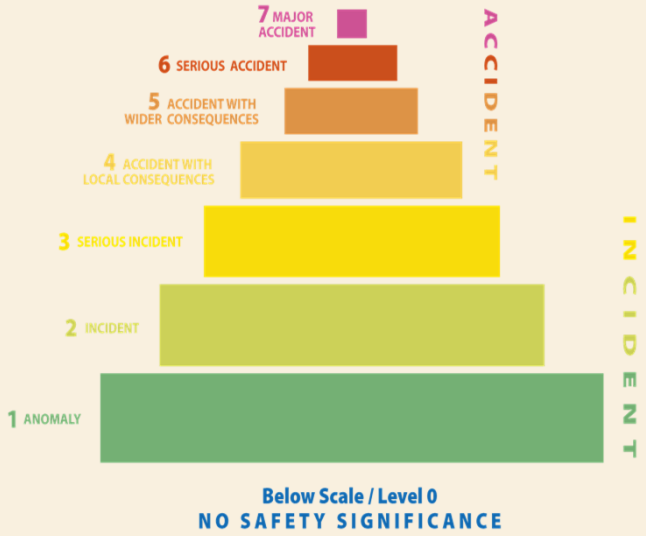
a scale used

as a communication tool

to explain to the public

the safety significance

of nuclear and radiological events



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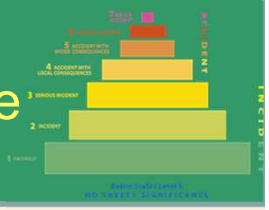
INES – The International Nuclear and Radiological Event Scale



- INES is a 7 level scale
  - Levels 1 to 3 are termed incidents
  - Levels 4 to 7 are termed accidents
  - Below Scale/Level 0 refers to events of no safety significance

Events that have no safety relevance with respect to radiation or nuclear safety are not classified on the scale.

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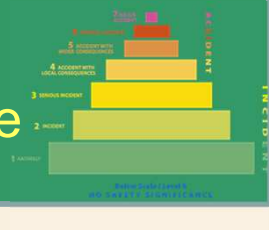

Events are considered and rated in terms of their impact to three different areas:

- impact on people and the environment
  - amount of radioactive material released
  - doses and the number of people involved
- impact on radiological barriers and control
- impact on defence in depth

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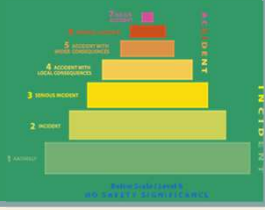
Scope of INES



INES is applicable to events associated with sources of radiation, whether or not the event occurs at a facility

covering

- activities at nuclear facilities
- wide spectrum of practices in industry and medicine
- transport of radioactive material

It is intended for use in civil applications and relates only to the safety aspects of the event

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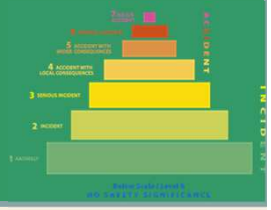
Scope of INES



INES User's Manual, 2008 Edition

For medical appliances, the current guidance can be used only for the rating of events resulting

in actual exposure of workers and the public

or

involving deficiencies in the safety provisions

<u>It does not cover the actual or potential consequences on patients exposed as part of a medical procedure</u>

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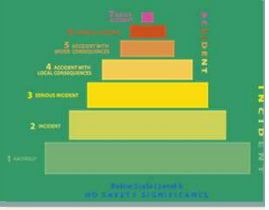
ASN-SFRO Scale 2007



-SFRO LE	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+).*

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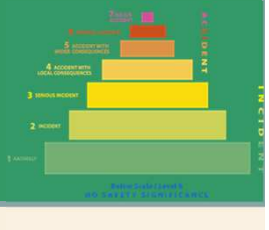
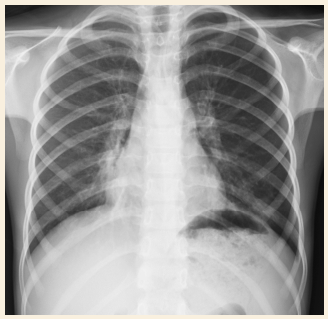
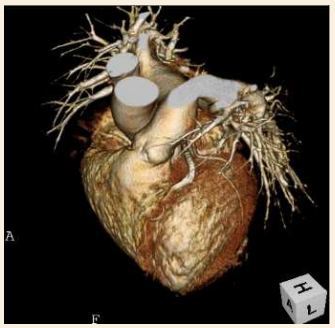
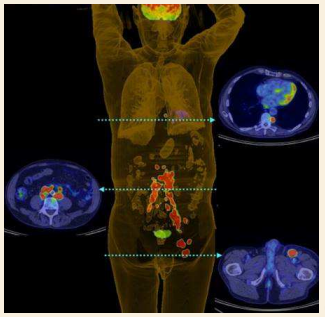
Extension of the scope



Following discussion on a French proposal,
the Technical Meeting of the INES National Officers
in May 2006
recommended to form
a working group of medical specialists
to explore the possibility of extending INES to cover the actual or potential consequences on patients







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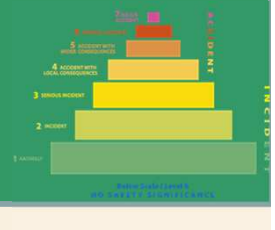
Extension of the scope



2006 - 2012

5 meetings of the working group

consisting of experts in INES, representatives of regulatory bodies, WHO, ICRP Committee 3 - Protection in Medicine and Radiation Protection of Patients Unit of the IAEA

The working group developed
draft technical guidance document

The use of the INES Scale for unplanned events affecting patients undergoing a medical procedure

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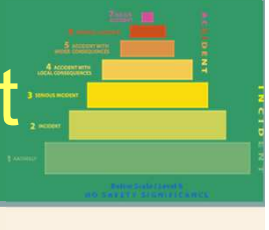
Practical evaluation of the guidance document



Practical evaluation took place in eight countries over a 15 month-period
(February 2013 – June 2014)

Group members:

M. Valero, M. L. Ramirez Vera, S. Carbonnelle, M. Eiras, A. Lorin, S. Richter, P. Milligan, C. Prieto-Martin, B. Ott, P. Tandon, M. H. Marechal, S. Mortin

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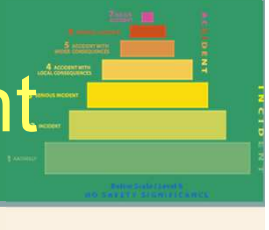
Practical evaluation of the guidance document



Objective of the practical evaluation was:

- to **evaluate usability** of the document for rating on INES events involving actual or potential consequences on patients exposed to ionizing radiation as part of a medical procedure
- to **acquire experience** which will serve to propose changes of the document if needed

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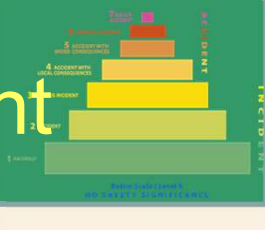
Practical evaluation of the guidance document

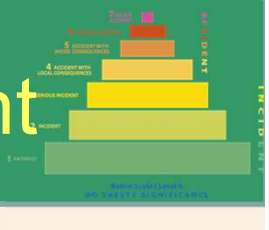


June 2014

Final meeting:

- noted that a total number of 74 events had been collected and rated on INES
- followed up on experience gained during the practical evaluation
- analyzed comments received on the guidance document

Practical evaluation of the guidance document



Term
event affecting patients undergoing a medical procedure

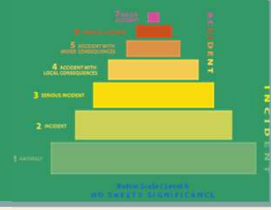
was replaced with **medical event**

to encompass events that result in unexpected or unforeseeable effects likely or clearly due to

- inappropriate doses or irradiated volumes in radiotherapy
- misadministrations in nuclear medicine
- unintended exposures in diagnostic and interventional radiology

IAEA BSS

General Safety Requirements Part 3



Requirement 41: Unintended and accidental medical exposures

3.180. Registrants and licensees shall promptly investigate any of the following unintended or accidental medical exposures:

(a) **Any medical treatment delivered to the wrong individual or to the wrong tissue or organ of the patient, or using the wrong radiopharmaceutical, or with an activity, a dose or dose fractionation differing substantially from (over or under) the values prescribed by the radiological medical practitioner, or that could lead to unduly severe secondary effects;**

(b) **Any diagnostic radiological procedure or image guided interventional procedure in which the wrong individual or the wrong tissue or organ of the patient is subject to exposure;**

(c) Any exposure for diagnostic purposes that is substantially greater than was intended;

(d) Any exposure arising from an image guided interventional procedure that is substantially greater than was intended;

(e) Any inadvertent exposure of the embryo or fetus in the course of performing a radiological procedure;

(f) **Any failure of medical radiological equipment, failure of software or system failure, or accident, error, mishap or other unusual occurrence with the potential for subjecting the patient to a medical exposure that is substantially different from what was intended.**

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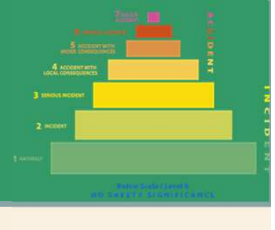
Practical evaluation of the guidance document

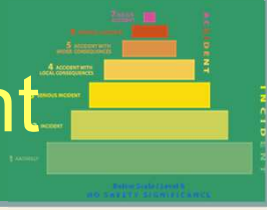


Final meeting outcome 1

to split the draft technical guidance document in two parts:

- part 1: "**Rationale**" containing justification for using INES for rating events involving actual or potential consequences on patients exposed to ionizing radiation as part of a medical procedure and explanation of basis for rating as well as of defence in depth approach and safety culture
- Part 2 : "**Additional Rating Guidance**" containing the rating methodology and examples

Practical evaluation of the guidance document



Final meeting outcome 2

There are many studies identifying safety layers in radiotherapy but scientific basis for safety layers in radiology and nuclear medicine is insufficient.

The meeting decided that
the Additional Rating Guidance
should include criteria and worked examples on:

- impact on patient for all practices
- impact to the defence in depth only for radiotherapy

Practical evaluation of the guidance document

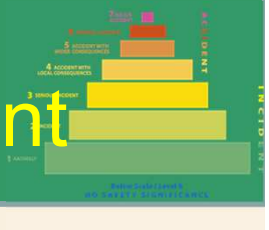
Recommendation of the working group
to the INES National Officers Technical Meeting 2014

Apply a graded approach - extend the scope of INES to medical events for the time being on

- impact on patient for all practices
- impact to the defence in depth
  only for radiotherapy

Defence in depth criteria for other practices (nuclear medicine, diagnostic and interventional radiology) will be developed and included later depending on the available scientific data

Practical evaluation of the guidance document

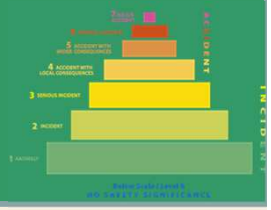


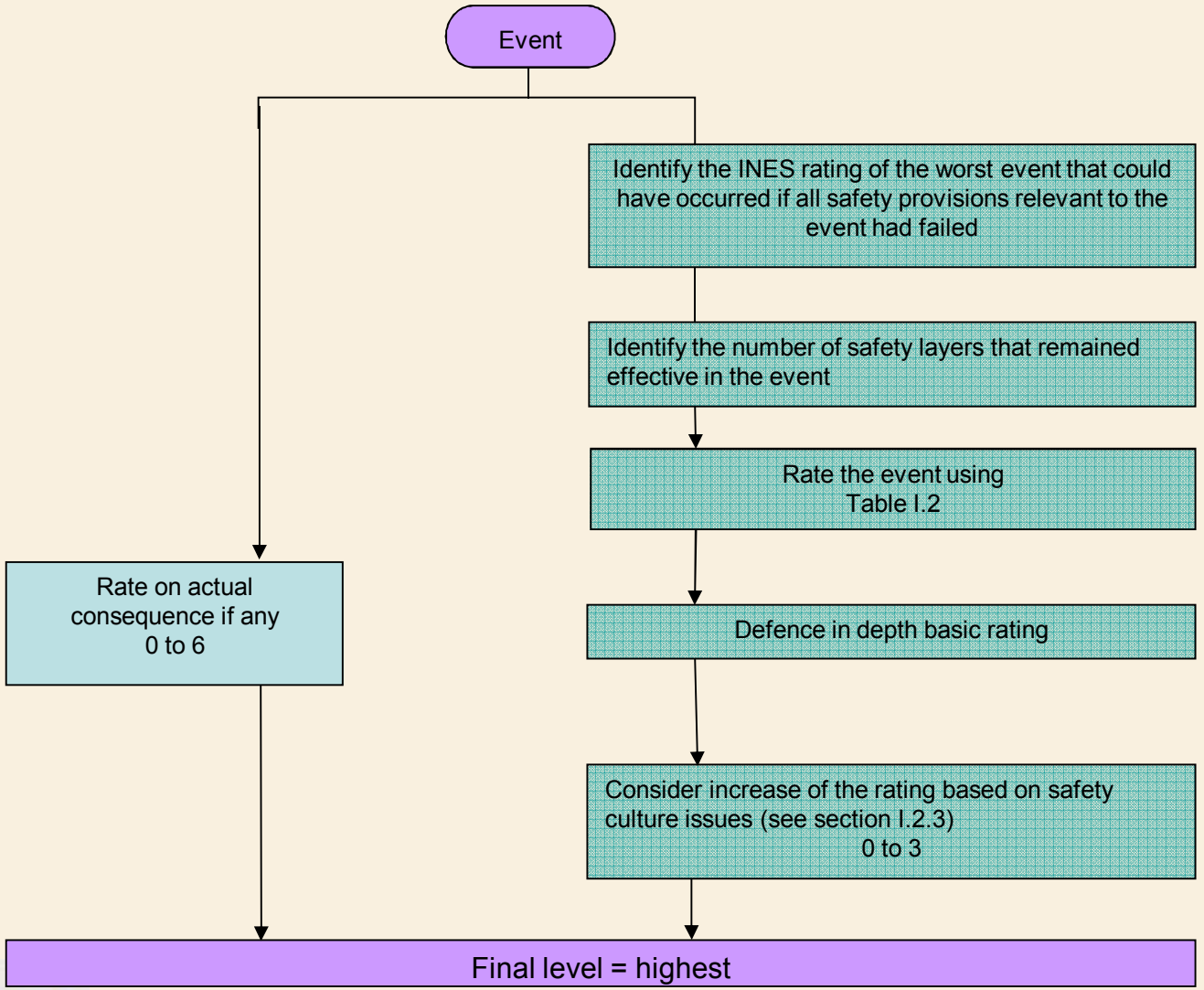
Recommendation of the working group
to the INES National Officers Technical Meeting 2014

- conducting a **broad trial** should be considered
- could include events reported in SAFRON or SAFRAD

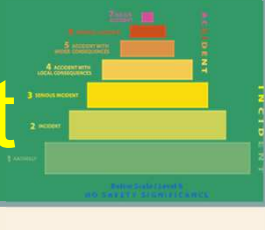
To achieve a successful outcome of this trial **a strong involvement of IAEA and INES community** is necessary

General rating procedure





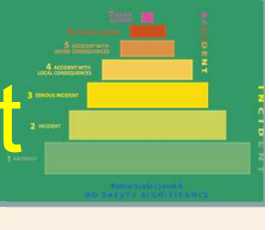
Final methodology - impact on patient



Impact on a patient is defined by:

- the occurrence or likely occurrence of a deterministic effect, including death
- an increased risk of stochastic effects in case of unduly delivered dose but below thresholds defined by ICRP for deterministic effects
- in radiotherapy, possible or actual recurrence of tumor in case of under-dosage to the target volume

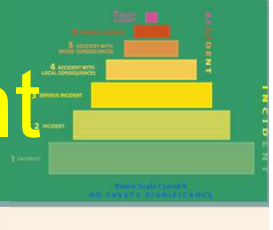
Final methodology – impact on patient



The evaluation of impact on patient should consider:

- Clinical patient status: type of treatment, actual consequences and adverse reactions;
- the elements from dosimetric evaluation leading to determination of likely late consequences related to event;
- medical grading scale CTCAE or effective dose
- the number of patients involved if relevant

Final methodology – impact on patient



- Dosimetric reconstruction should be conducted by a **medical physicist**
  - in radiotherapy comparison of the treatment “realized” vs. “planned”
  - in diagnostic or interventional radiology, analysis of dosimetric indicator from radiological equipment
  - activity and type of radiopharmaceuticals in nuclear medicine
- Assessment of consequences/detriment for the patient should be done by a **medical practitioner**
- When impact to defence in depth is considered, a **multidisciplinary team** should be involved

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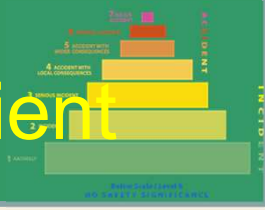
Summary of rating considering impact on patient



Detriment	Minimum Rating	Number of Individuals	Actual Rating
Lethal *(CTCAE 5)* or **Life threatening effect *(CTCAE 4)*** or **Underdosage in radiotherapy**	**4**	**Few tens or more**	**6**
		Between several and a few tens	**5**
		Less than several	**4**
Non-lethal severe deterministic effect *(CTCAE 3)*	**3**	**Few tens or more**	**5**
		Between several and a few tens	**4**
		Less than several	**3**
Moderate deterministic effect *(CTCAE 2)* or **Significant increase in stochastic risk for a *pediatric patient (effective dose > 100 mSv)***	**2**	**100 or more**	**4**
		10 or more	**3**
		Less than 10	**2**
Mild deterministic effect *(CTCAE 1)* or **Significant increase in stochastic risk for an *adult (effective dose > 100 mSv)***	**1**	**100 or more**	**3**
		10 or more	**2**
		Less than 10	**1**

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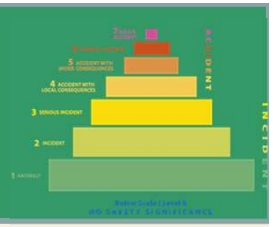
Examples of safety layers in radiotherapy



Detailed examples of safety layers related to radiotherapy are provided in:

- FORO; Aplicación del método de la matríz de riesgo a la radioterapia Volumen 1 y 2 apéndices http://www.foroiberam.org/
- AAPM – Quality and Safety in Radiotherapy: Learning the New Approaches in Task Group 100 and Beyond, June 2013 (ISBN: 978-1-888340-49-5), B. R. Thomadsen, P. Dunscombe, E. Ford, S. Huq, T. Pawlicki and S. Sutlief
- Consensus recommendations for incident learning database structures in radiation oncology, E. C. Ford, L. Fong de Los Santos, T. Pawlicki, S. Sutlief, P. Dunscombe, Med. Phys. 39 (12), December 2012
- SAFRON

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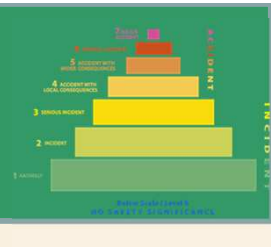
Examples of safety layers in radiotherapy



Patient Assessment

- Verification of patient ID
- Peer review of treatment decision

Imaging for RT Planning

- Documentation of patient positioning and immobilization and ancillary devices
- Marking reference point on patient and/or localization device

Treatment planning

- Procedures for preparation of treatment- treatment planning
- Warnings in TPS software
- Verification of imaging data for planning
- Preliminary prescription parameters, constraints & technique
- Preliminary evaluation of treatment plan by physicist and by physician

Equipment and Software Quality control

- Acceptance testing
- Commissioning
- Regular external audit including dosimetric audit

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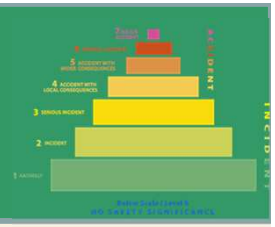
Examples of safety layers in radiotherapy



Treatment Delivery

- Use of a R&V system with appropriate warnings
- Automatic transfers between TPS and R&V system or afterloading system for brachytherapy
- Verification of correct transfer of information (manual transfer from the patient prescription file to the treatment chart or the record and verify system)
- Procedures for patient and beam set up including lining beams with skin reference points, daily check of light beams on skin, checking picture of field
- Verification of patient ID
- Time-out (e.g. verification of clinical parameters, treatment consent, etc.)
- In-vivo dosimetry

Post –Treatment Completion

- Verification of patient ID
- Final chart check
- Follow up patient management visit
- Application/System training
- Ongoing quality control checks (e.g. daily, monthly, annual QA, etc.) including interlocks

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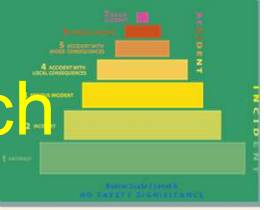
Rating of events using the safety layers approach



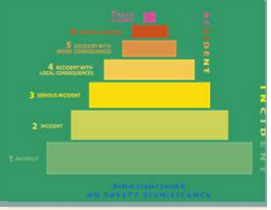
INES User's Manual, Table 11

	Rating of maximum potential consequences		
Number of remaining safety layers	(1) Levels 5, 6, 7[b]	(2) Levels 3, 4	(3) Levels 2 or 1
More than 3	0	0	0
3	1	0	0
2	2	1	0
1 or 0	3[a]	2[a]	1[a]

[a] These ratings cannot be increased due to additional factors because they are already the upper limit for defence in depth.

[b] medical events cannot be rated higher than Level 6

What is it required to rate medical events on INES?



- **Reporting criteria**: notification criteria of event qualified as “significant” have to be defined by national regulatory bodies
- **Training for the final users**
  - ✓ Professionals involved in medical uses of radiation on the difference between INES scale and medical grading scale derived from CTCAE and on concept of safety layers and defence in depth
  - ✓ INES national officers and members of regulatory authority to whom a medical event will be reported on how is the process of radiation in radiotherapy, interventional radiology and diagnostic imaging organized
- **A close cooperation between professional societies and regulatory authorities**

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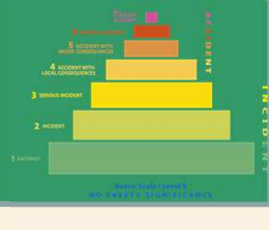
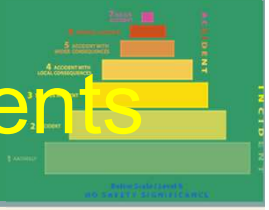
INES is a communication tool



For events rated on INES using current guidance (other than medical vents) it has been agreed that internationally should be communicated:

- **Events rated at INES level 2 and above**
- **Events attracting international public interest**

Rationale of extending INES to medical events



- Medical applications are by far the largest use of radiation (more than 10 million medical exposures per day in the world, more all 95% of human exposures from man-made sources are medical exposures)
- Medical applications are performed in all the countries of the world in contrary to some other uses of radiation
- There has been more severe acute effects and deaths from medical use of radiation over the last 50 years than from any other activity related to radiation

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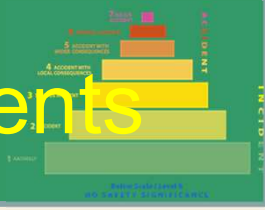
Rationale of extending INES to medical events



- There is a need to communicate to the public the safety significance of medical event in understandable words,
- There is a need to have a common language among policy makers, patients advocate groups, professionals and competent authorities (health and /or radiation regulatory bodies)
- There is a need to have international or worldwide common language/criteria

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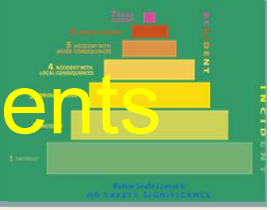
Rationale of extending INES to medical events



- It can be used as a learning tool to improve safety of medical exposures (i.e. the use of the concept of safety layers)
- Comparison cannot be avoided with all other uses related to radiation so it will allow putting medical events into the proper perspective
- Since most of the medical events should be level 0/1/2, it will also allow putting events occurring in different medical practices into the proper perspective showing/demonstrating to the public the safety of medical practices

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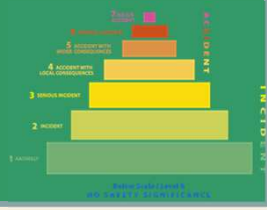
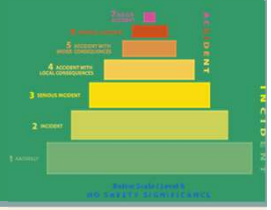
Future perspective



INES National Officers Technical Meeting 2014

- TM endorses the proposal to apply the methodology to rate events involving actual or potential consequences on patients for all medical fields (radiotherapy, nuclear medicine and radiology) and to limit the methodology for defence in depth to radiotherapy only

Future perspective



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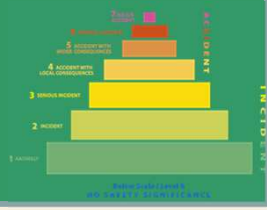
- TM urges the Secretariat to finalise the Rationale and Additional Rating Guidance documents. Once they become available, TM invites all Member States to use the Additional Rating Guidance and to report on its use to the Secretariat

Future perspective



INES National Officers Technical Meeting 2016

- It is expected that experience on using INES to rate medical events will be presented
- Conclusions should be further promoted will be brought


obrigado
Dank U
Merci
mahalo
Köszi
спасибо
Grazie
Thank you
mauruuru
Takk
Gracias
Dziękuję
Děkuju
danke
Kiitos