



STRENGTHENING THE CONTROL OF RADIATION THERAPY

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CONTENT

- Radiation therapy in France
- Event reporting
- ASN-SFRO experimental event rating scale
- ASN action plan

Background

- ~180 external radiation therapy centres
- 360 linear accelerators + 29 cobalt facilities in 2006
- 180 000 patients/year





Background

- Increasing number of patients (National Cancer Plan since 2002)
- An activity involving complex techniques (use of TPS software, IMRT), delivering higher and higher doses (for the benefit of the patient)
- ASN is the competent authority only since 2002,
- ASN is encouraging the centres to report on the events
- Communication about events : a very sensitive public issue, for the patients and their family and for the professionals,



ASN strategy : event reporting to improve safety, to organise the experience feedback and to ensure transparency (a similar approach to this in place in nuclear field in France)

- Event reporting + detailed report by the physician
- ASN reactive inspections, with the technical expertise of IRSN ⇒ requests for corrective actions
- Diffusion of the experience feedback towards the professionals and others centres
- Information of Health department and agencies (INCA, AFSSAPS, INVS)
- Information of the public on the actions undertaken by ASN but the patients have to be previously informed by their physician (mandatory)

Epinal accident (radiotherapy of prostate cancer)

- 1st episode (May 2004- August 2005) incident reported in July 2006 : confusion in the TPS software, Insufficient training of the staff, poor QA,... Doses +20%, 24 patients over exposed (4 deaths)
- 2nd episode (2001-2006) incident reported in February 2007 : repeated use of the portal imaging without taking into account the delivered doses...a new cohort of 397 patients under medical survey (dose +8%)
- 3rd episode (1989-2000) incident reported in July 2007 : use of a home-made TPS not updated after implementation of a new method for the positioning of patient (4500 patients involved among them 300 with up to 7% dose overexposure)

Around 30 radiotherapy events notified to ASN since 2005

Health effects

- 1 patient (most cases) or cohort (Epinal : 4500+397+24, Toulouse : 145)
- Deaths : Epinal (4), Lyon (1)
- or serious complications : Tours (1), Grenoble (1)
- No immediate known consequences (many events)
- Dose compensation or not

Identification of bad practices in external radiotherapy : in most cases, events are due to organisational and human factors

- Software user interfaces and instruction manuals not translated into French – poor ergonomics
- Insufficient training of the staff to the new software/new techniques – lack of QA
- Repeated use of the portal imaging without taking into account the delivered doses
- Error of communication between two operators (confusion of measurement unit: cm instead of mm)
- Error in the calibration of beams
- Misidentifying of patients (most events)



ASN action plan in coordination with the Health Ministry and Health Agencies

1. Event reporting and ASN communication

- June 2007 : Issue of a guide on reporting procedures about events related to radiation protection with operational criteria, including a request for a register of the events and for their analysis in all centres (www.asn.fr) ;
- July 2007 : Issue of an event rating scale adapted to the patients in radiation therapy activities - one year experimental use (www.asn.fr)



ASN-SFRO experimental scale

- 1990 : ASN participated in the development of INES, published by IAEA (events likely to affect the safety of basic nuclear installations).
- 2002 : ASN proposed a new scale, compatible with the INES scale, to deal with all events related to radiation protection, particularly the radiation protection of workers. These changes led to the publication of an additional guidance to the INES' users manual for the rating of radiation sources and transport events, but excluding patients, applied experimentally since 2006 in several countries, including France.
- 2006 : the INES advisory committee meeting in Paris agreed on the creation of a working group on the rating of events involving patients. This group first met on June 2007.



ASN-SFRO experimental scale

- July 2007 : ASN, with SFRO (professional organisation of oncologists), is proposing a scale compatible with the INES scale, but also incorporating clinical rating tables already used by practitioners (CTCAE-Cancer Therapy Evaluation Program)



ASN-SFRO experimental scale

- The events are rated on an 8-level severity scale (from 0 to 7)
- The scale refers to an international clinical classification :
Grade 1 (mild effects), Grade 2 (moderate effects), Grade 3 (severe effects), Grade 4 (serious or life-threatening effects) and Grade 5 (death)
- Taking account the unexpected or unpredictable effects due to inappropriate doses or irradiated volumes
- For confirmed effects, over-rating will be used to take into account of the number of patients concerned
- **Unlike the INES scale, the defence in depth criterion 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 the breach in the organisation of a department.**



ASN-SFRO experimental scale

Events	Level	Exemple
Death (grade 5) <i>Dose or irradiated volume >> normal</i>	5 à 7	Épinal 6
Serious life-threatening event, disabling complication (grade 4) <i>Dose or irradiated volume >> tolerable</i>	4	
Event leading to a severe impairment of one or more organs or functions (grade 3) <i>Dose or irradiated volume > tolérable</i>	3	

Event	Level	
Event leading to or likely to lead to a moderate impairment of an organ or function (grade 2) <i>Dose > recommended doses</i>	2	Toulouse
Event with no expected consequences or likely to lead to mild consequences (grade1) <i>Dose or volume error without expected consequences</i>	1	<i>non-compensatable target error during a session</i>
Event with no dosimetric consequences	0	<i>Error in identification of a patient (compensatable).</i>



ASN-SFRO experimental scale

Over rating to account for the number of patient involved

Events	N patients	Level
Death	> à 10	7
Death	>1	6
Death	1	5
Level 4	> 1	4+
Level 3		3+
Level 2		2+



ASN-SFRO experimental scale

- The scale : a tool shared with the oncologists (SFRO) during its preparation, its further use and its assessment (in July 2008)
- The scale : a tool shared with the medias, to facilitate the information of the public

ASN action plan

2. **To improve the safety of medical devices with AFSSAPS** (in charge of the control of medical devices)
 - Coordination with ASN and IRSN for the safety assessment concerning new medical devices
 - Discussion with manufacturers to improve the safety and the ergonomics of the software
 - Reinforcement of the quality control system (internal, external) of the medical devices, by including the softwares in the assessment



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ASN action plan

3. To improve the safety of treatments

- Preparation of a reference frame for the development of the quality assurance in the radiation therapy centre, including incidents analyzes (December 2007)
- Definition of mandatory quality criteria required for radiotherapy practices (enforced in 2008), including in vivo dosimetry (INCA)
- Development of a guide of tumors radiation therapy (optimization) prepared by oncologists (SFRO) whose publication is expected in November 2007
- January 2007, assessment of the additional means in medical radiological physic : communicated by ASN to Health ministry (Expectation of doubling the number of physicists in 5 years)



STRENGTHENING THE CONTROL OF RADIATION THERAPY ASN action plan

4. To reinforce ASN inspection

April to December 2007 : visit of the 180 radiotherapy centres for the assessment of the organisation of treatment procedures, considering organisational and human factors :

- Share of responsibilities between physicians, physicists, operators ;
- Staff training ;



STRENGTHENING THE CONTROL OF RADIATION THERAPY ASN action plan

- Existing written procedures for equipment calibration, for the preparation and realisation of the treatment, for internal control,
- Register of events and internal analysis procedure ;
- Method to register and to follow up of patients (during and after the treatment).



Some questions

- To make mandatory the reporting of event related to patient irradiation ?
- To prepare a scale for the rating of events related to patient ?
- To propose a safety guide for the definition of a reference frame for the development of quality assurance in radiation therapy centre
- To define recommendations for inspection in radiation therapy ?
- To organise the experience feedback of Member States ?