



ASN actions in External Radiotherapy

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- **Background**

- ~178 external radiotherapy centres (2009)
- Increasing number of patients treated for cancer (~ 200 000/year in 2009)
- More and more complex techniques (use of Treatment Planification Software, Intensity Modulated Radiotherapy, thomotherapy or cyberknife machines), delivering higher doses (for the benefit of the patient)
- Severe events notified 2005-2007 (Grenoble, Lyon, Epinal, Toulouse)

- **Issues**

- 1. Incident reporting and public information
- 2. Reinforcement of national regulation
- 3. Development of ASN inspection in radiotherapy



Issue No.1

Reporting radiotherapy events

- Since 2007 (all medical practices) : radiation protection events have to be reported including a detailed report produced by the physician (ASN guide on reporting criteria on www.asn.fr)
- ASN may organize reactive inspections and request for corrective actions
- ASN issues the experience feedback to the professionals and others centres and transmits information to Health Department and Health Agencies
- a new scale ASN/SFRO has been developed to rate the severity of the events (www.asn.fr), updated in July, 2008



Summary of events notified to ASN in 2008

- 208 events were notified, from only 31% of the French centres (56 centres over 178) :
 - 4 events : level 2 (moderate effects)
 - 204 events : level 1 or 0 (no expected consequences)
- The majority of events are due to Human and Organisational Factors. They affected only one patient and did not have medical consequences.
- Among them, 6 events occurred due to a medical device failure (software).



ASN Strategy for the information of the public

Level 0 and level 1	Level ≥ 2 or patients cohort
<p>A summary of events each quarter (anonymous) on www.asn.fr</p> <p>Identification of the main causes</p>	<p>Technical note (including the name of the center) on www.asn.fr, or a press release</p>

Issue No. 2

Reinforcement of national regulation

- June 2008 : The authorisation of radiotherapy practices by Health Ministry requires mandatory criteria (2012)
 - Human resources : minimal number of patients/year (600), permanent presence of medical physician and medical physicist, and number of therapists (2/accelerator)
 - Technical criteria : minimal number of accelerators (2), in vivo dosimetry, double check of monitor units, availability of CT, ...
- 1st quarter 2009 : ASN has suspended the use of accelerators in 3 centers (Blois, Roanne and Gap) because of the total absence of medical physicist
- July 2009 : after ASN consultation, a transitional period (2009-2012) for medical physicist has been defined by Health ministry
 - minimum (centre with one accelerator) : 1 medical physicist and 1 dosimetrist and collaboration contract with another center

March 2009 : an ASN technical decision on quality assurance has been published together with 2 related guides (www.asn.fr) :

- guide on the management of safety and quality of care in RTH
- guide on the risk assessment for patients in external RTH

Issue No. 3

Development of inspection program

- 2007, 2008 and 2009 : inspection of the 178 radiotherapy centres considering organisational and human factors.
- 2007 Inspection national synthesis published in April 08 on www.asn.fr : for many centers, there is a need to strengthen radiophysics staff, lack of written treatment procedures and the process of recording and analyzing events were still not implemented.
- 2008 Inspection national synthesis will be published in Dec 09 on www.asn.fr : the safety culture is in progress in many centers (process of recording and analyzing events, “security” of treatment and internal control procedures) but some centers are still in difficult situation (lack of medical physicist)
- 2009-2010 : Inspection program will focus on the implementation of quality assurance and on the presence of medical physicist and dosimetrist (transitional criteria)

Public Information : Publication of inspection letters since July 2008 on ASN Website



Conclusions (1) : situation in France

1. An important work has been carried out in France to strengthen the safety of treatments, after the Epinal accident (2006). ASN is very involved in the national action plan managed by the INCa President, under the responsibility of the Health Ministry.
2. Since 2007, inspection in radiotherapy has become the first priority for ASN.
 - Safety culture is in progress in many centres considering the progressive implementation of events notification to ASN and quality management.
 - Several radiotherapy centres are still in a difficult situation mainly due to the lack of Medical Physicists. ASN considers that 5 to 10 years will be needed to improve the situation concerning Medical physicist staff.

Conclusions (2) : next challenges for ASN

3. ASN emphasizes the further needs of exchange at International and European levels on Quality Assurance Program, on Risk analysis and on Information of public and patient :

- The new BSS Euratom, in preparation, might offer an appropriated frame for this purpose.
- The new HERCA MEDICAL WG, just set up in December 1st, should be an appropriated “informal network” to organize feedback on national experiences between Regulatory Control Authorities.

4. Next challenges for ASN : the organization at national level of feed back experience with professionals and IRSN and the improvement of ASN inspectors competences.