RADIATION SAFETY ISSUES LINKED TO THE OMNIPRESENCE OF COMPUTERS

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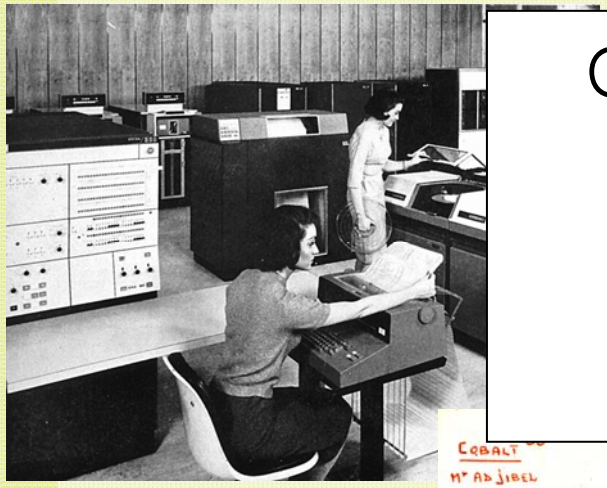
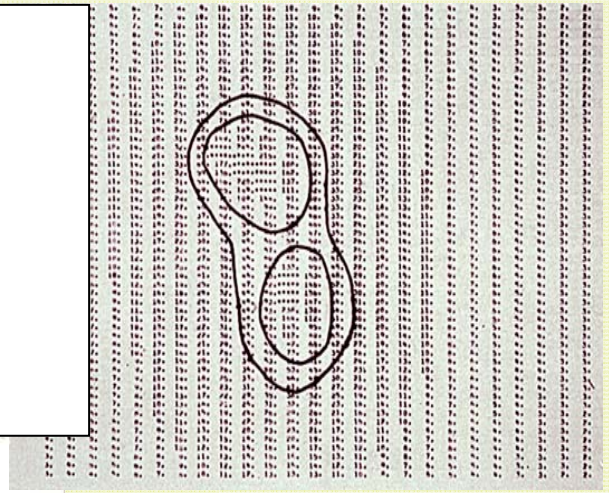
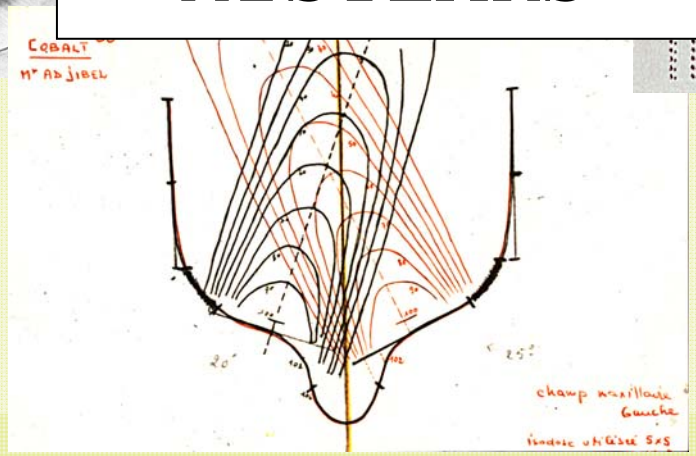
Earlier use of computers in radiotherapy

- 1950-1960 : replacement of tedious manual superimposition of isodose charts



COMPUTERS
NEVER
MAKE
MISTEAKS



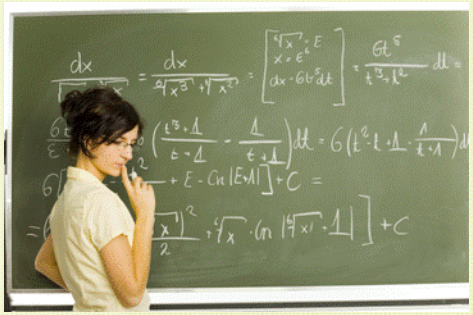


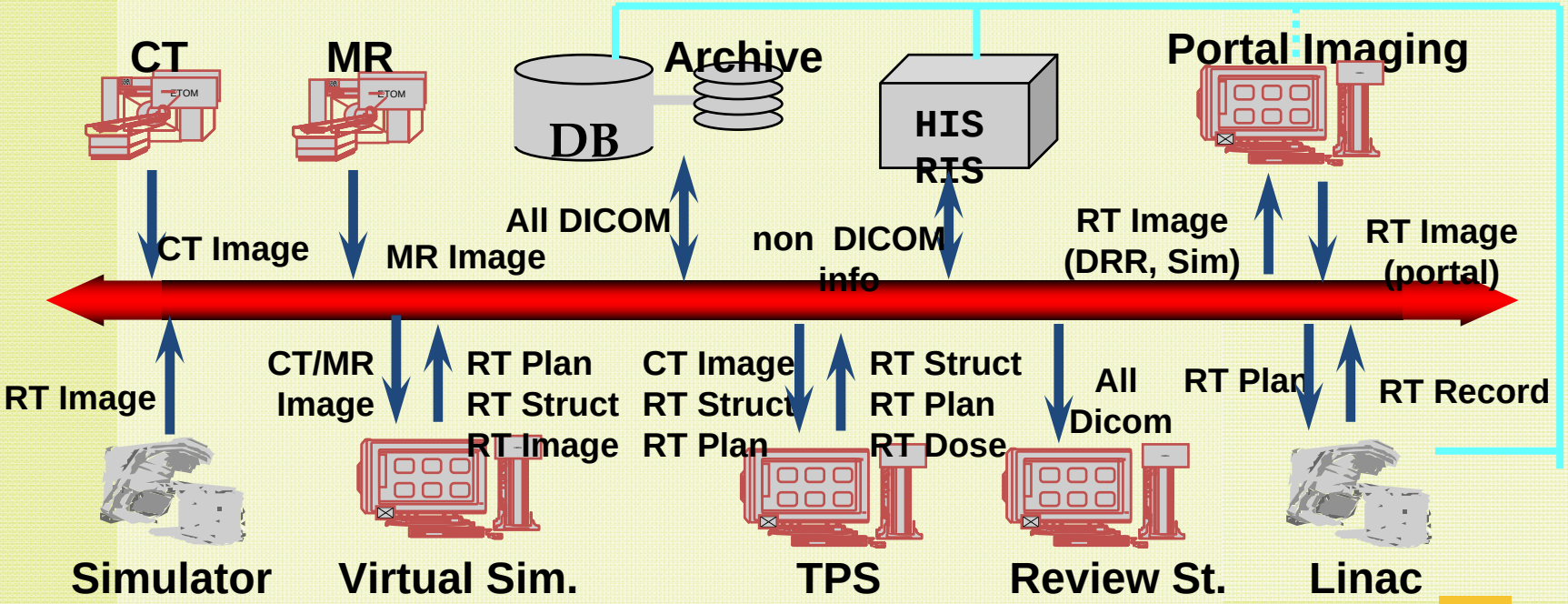
Today's omnipresence of computers

- computerized water phantoms
- computerized imaging systems
- treatment planning systems (TPS)
- Record and Verify Systems (RVS)
- computer driven accelerators (IMRT)
- patient setup and dose verification with robots and digital imaging
- computer-based data management
- …

Network integration

- complex workflow
  - large variety of equipment and data
  - numerous data exchanges
  - various categories of professionals





DICOM RT exchanges in Radiotherapy

Learning from experience (1)

1982-1991 Exeter UK	Underdosage (-5 to -30%) due to a **wrong interpretation** of the TPS treatment time calculation algorithm for isocentric treatments (1045 patients)
2000 Panama	Overexposure (by a factor 2) of 28 patients treated with irregular field, due to a **misuse of the TPS** and absence of interlock for this situation
2003 Grenoble France	Overexposure (+20%) of one patient planned with a motorized wedge filter but treated without wedge because of a **data exchange failure** between TPS and RVS
2004-2005 Epinal France	Overexposure (>+20%) of 24 patients planned with mechanical wedges but treated with dynamic wedges, because of **incorrect interpretation** of the TPS requirement
2005 Glasgow UK	Overexposure (+57%) of one patient due to application of an **inadvertent manual correction** to monitor units calculated by TPS and transferred to RVS

Examples of severe accidents *caused by* computer systems

Learning from experience (2)

2005 New York USA	Overexposure of a head and neck patient during at least 3 consecutive fractions (around 13 Gy/fraction instead of 2 Gy) due to absence of leaf movement (open field) for an IMRT **plan that was modified** on TPS **and retransferred** to RVS after a computer crash occurred
2007 USA	High dose irradiation of the wrong size of the brain due to incorrect MR image transfer (**understatement of orientation issues**) for one patient scanned "Head first" and treated "Feet first"
2007 NewYork State USA	Overexposure (45 Gy instead of 25 Gy) during brachytherapy complementary vaginal irradiation (after 56 Gy IMRT) due to **lack of consistency** between the TPS dose rate factor and the units used for source specification

Examples of severe accidents *caused by* computer systems

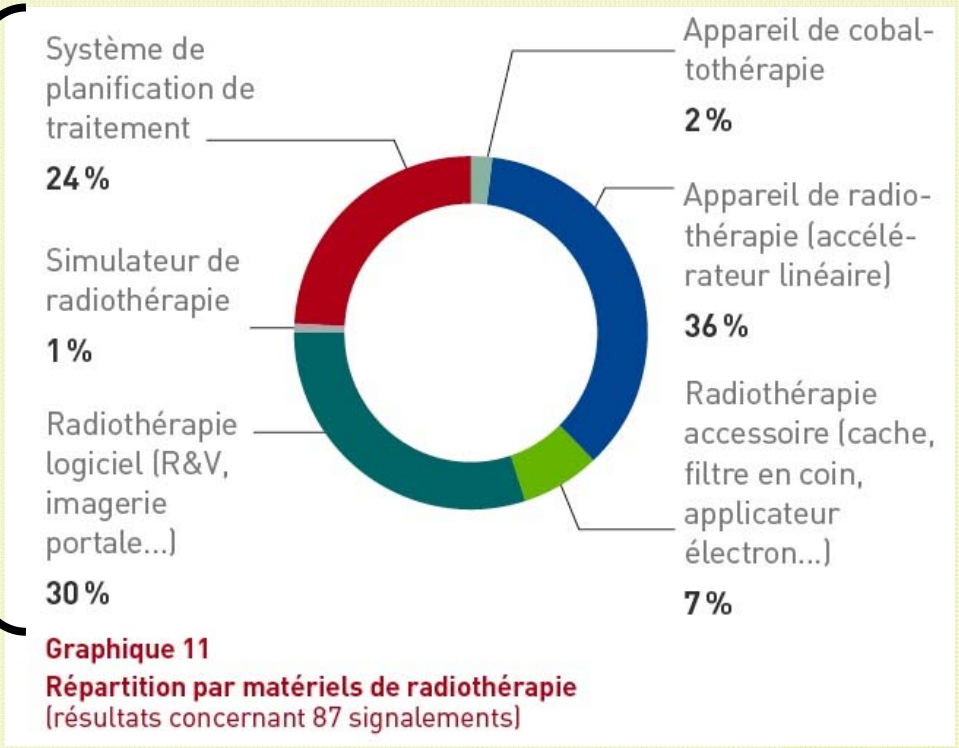
Many « medical events » reports on problems in **data transfer with RVS** :
examples from the ROSIS database :

- treating the wrong patient, error when replanning patient on another machine…

Learning from experience (3)

France : reports to ASN and AFSSAPS

TPS+RVS
= 54%

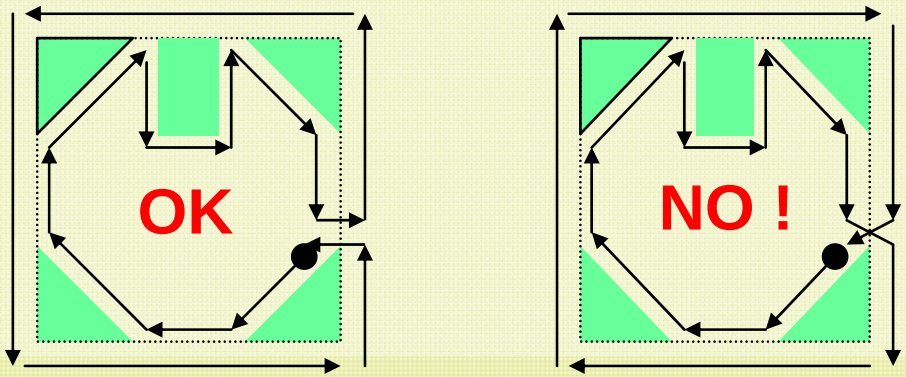


Graphique 11
Répartition par matériels de radiothérapie
(résultats concernant 87 signalements)

analysis of medical events reports
from 06/2007 to 07/2008
(radiovigilance - external radiotherapy)

Learning from experience (4) common features

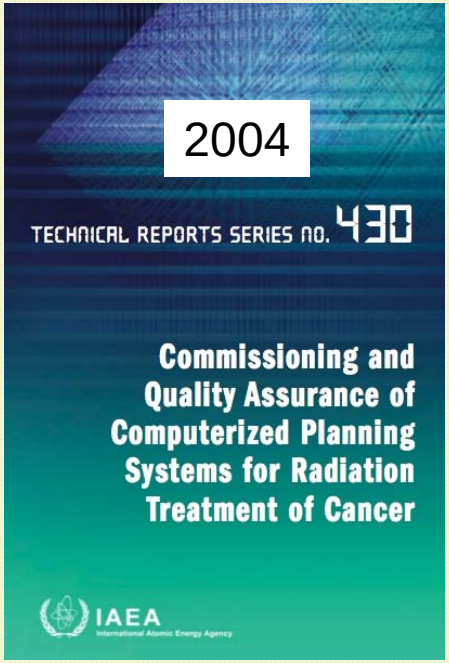
- dose (treatment time or MU) or location error
- not directly associated with TPS or RVS malfunctions
- partly due to lack of safety interlocks or explicit warnings
- mostly user's misunderstanding
- special circumstances (change of practice)
- lack of independent check

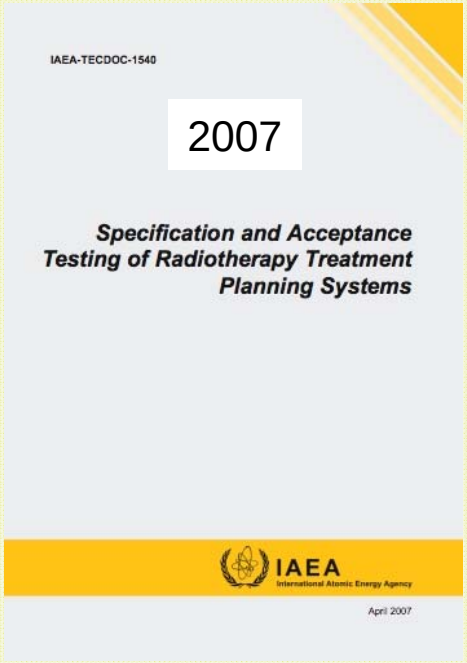


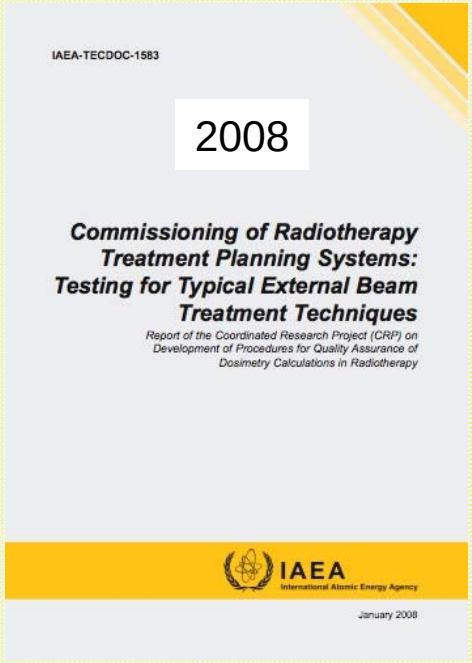
What is different ?

- abandon of manual practice
  => loss of human « common sense »
- too many data to be manually scrutinized
- unawareness of consequences of embedded algorithms
- simple modifications become complex
- « invisible » data exchanges

Recommendations mostly related to treatment planning systems







- safety aspects <=> following IEC standard
- check of algorithms accuracy (geometry+ dose)

French regulations (TPS and RVS)

- AFSSAPS « decision » - 27/07/2007
  - constancy check of
    - conversion curves from HU to density
    - MU calculations (wedge, blocks, inhomogenities…)
    - MU transferred to RVS
  - for all photon and electron energies
  - after each modification of any hard or soft component
  - at least once a year

These (minimal) tests do not cover all critical situations but they are useful to bring the potential risks of computer-based systems to users' attention and to induce a cultural change.

Preventive actions (1)

- **On the user's side**
  - ✓ commissioning serving as training period (understanding features and trapping pitfalls)
  - ✓ systematic recording of all unusual events (log book)
  - ✓ systematic critical review of TPS and RVS data for individual patients
  - ✓ redundancy : MU calculation with independent system and in-vivo measurements

"TPS and RVS must be considered potentially as dangerous as treatment machines. Commissioning such systems is very much like performing measurements (e.g. "tuning an algorithm" or "computing an output curve"). A clear understanding of the system response to any user's action is required before clinical application."

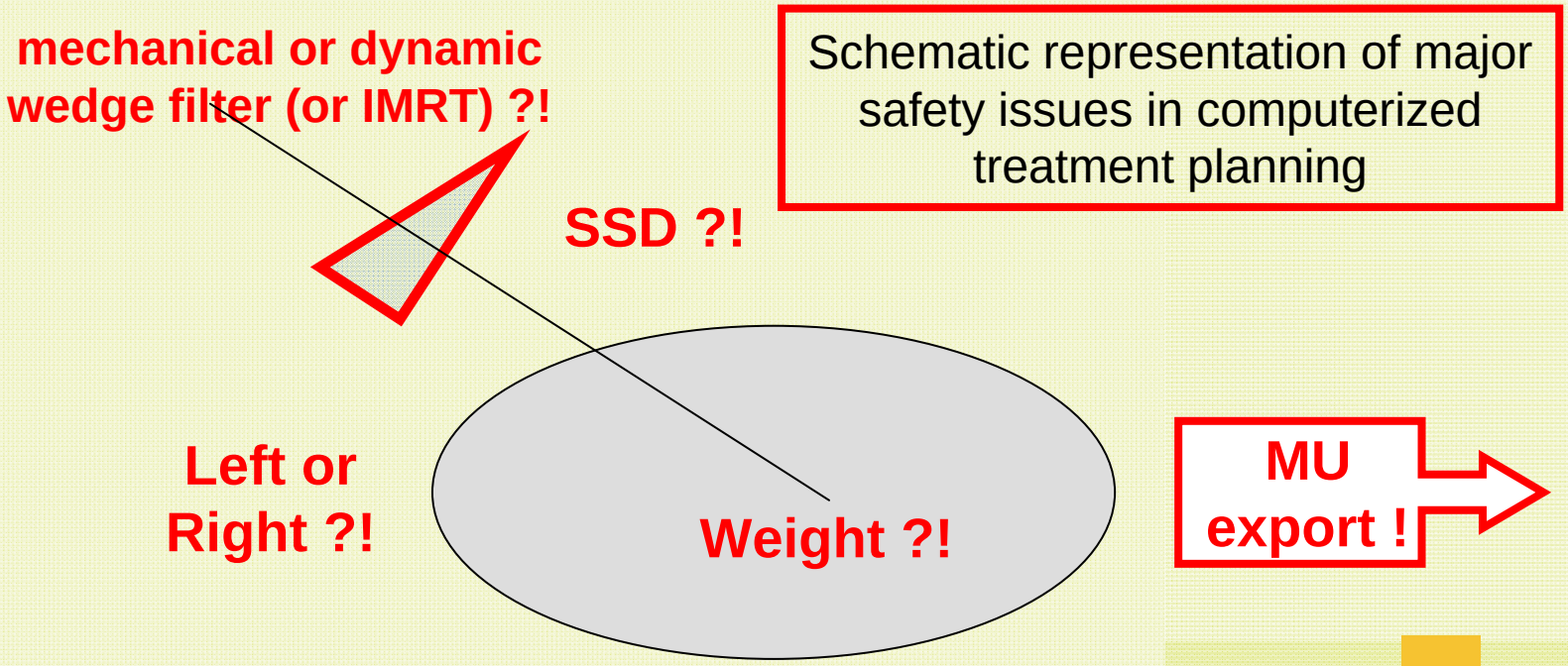
Rosenwald and Gaboriaud, ICCR, Toronto, 2006

Risk analysis : critical issues

The output of modern treatment machines is not any longer driven by physics laws; it depends on the algorithm used by the manufacturer (and ignored by the user)

example : Output for Varian EDW is function of starting position of moving jaw

Output for Siemens virtual wedge is almost independent of opening



Schematic representation of major safety issues in computerized treatment planning

see new ICRP and SFPM reports

Preventive actions (2)

- **On the manufacturer's side** :

  => major responsibility of developers and vendors

  - ✓ following IEC standards
  - ✓ refining man-user interfaces (explicit terms, alerts,...)
  - ✓ providing generic data and benchmark examples
  - ✓ addressing risk issues and demonstrating main pitfalls during acceptance phase and for each new release
  - ✓ providing tools for internal and external checks (e.g. communication)

The INSPIRA project

INformatics for the Safety of Processes and Installations in RAdiotherapy

- workflow management tools
- software filters for automatic detection of inconsistencies with respect to a knowledge database (Verify Process System)
- automated tools for assesment of the risks related to individual treatments (complications, second cancer)
- automation of patient set-up with integrated verification

Approved : 20/11/2009
Duration : 2009-2013

Conclusions

- The use of computers generates new risks
- Systematic testing is time consuming and not necessarily very effective
- Its main advantage is to force the user to acquire a better knowledge of the system
- Impredictable errors are inevitable
- Attention must be focused on the most critical issues
- Computer-based additional safety tools will help to increase the overall safety