Tools for risk assessment in radiation therapy

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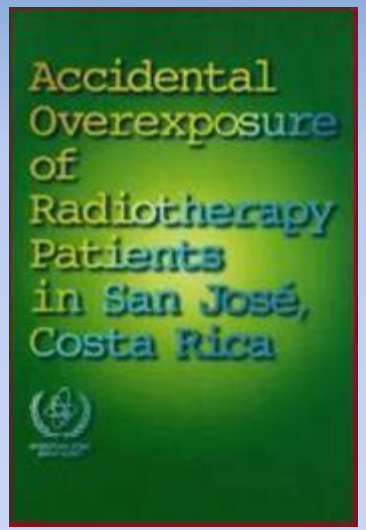
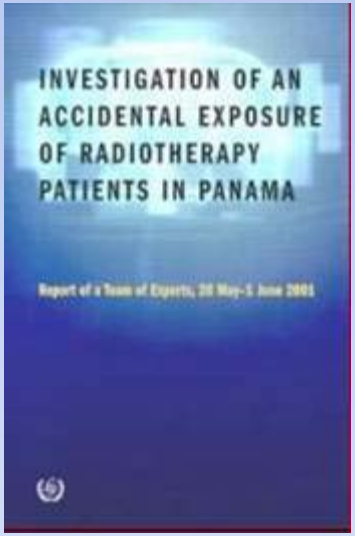
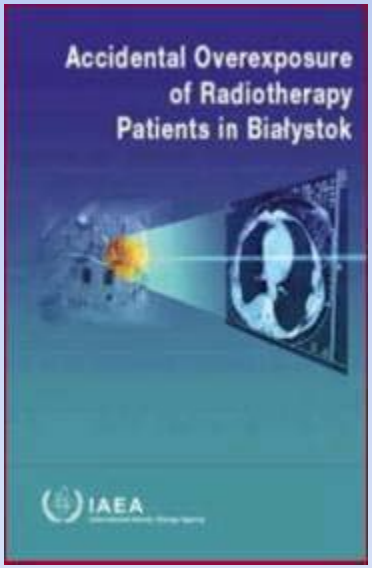
ICRP Committee 3

Major events from conventional radiotherapy, with severe consequences, have been reported for the last two decades

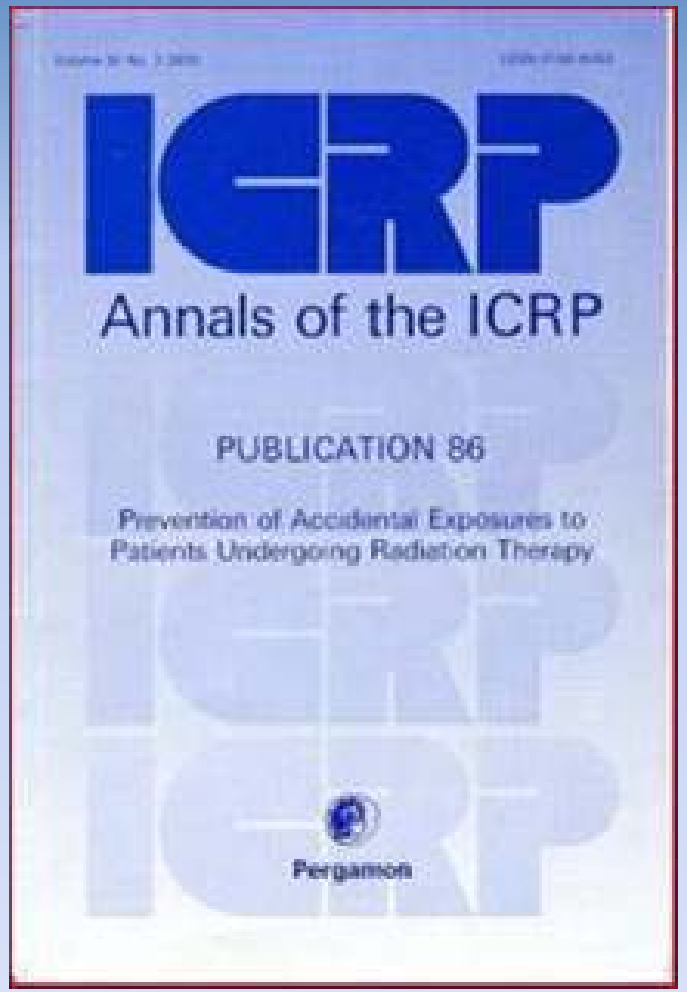
Lessons from accidental exposures with conventional techniques are available







In 2000 lessons were compiled by the ICRP in publication 86



Preventing accidental exposures from new external beam radiation therapy technologies

ICRP Publication 112

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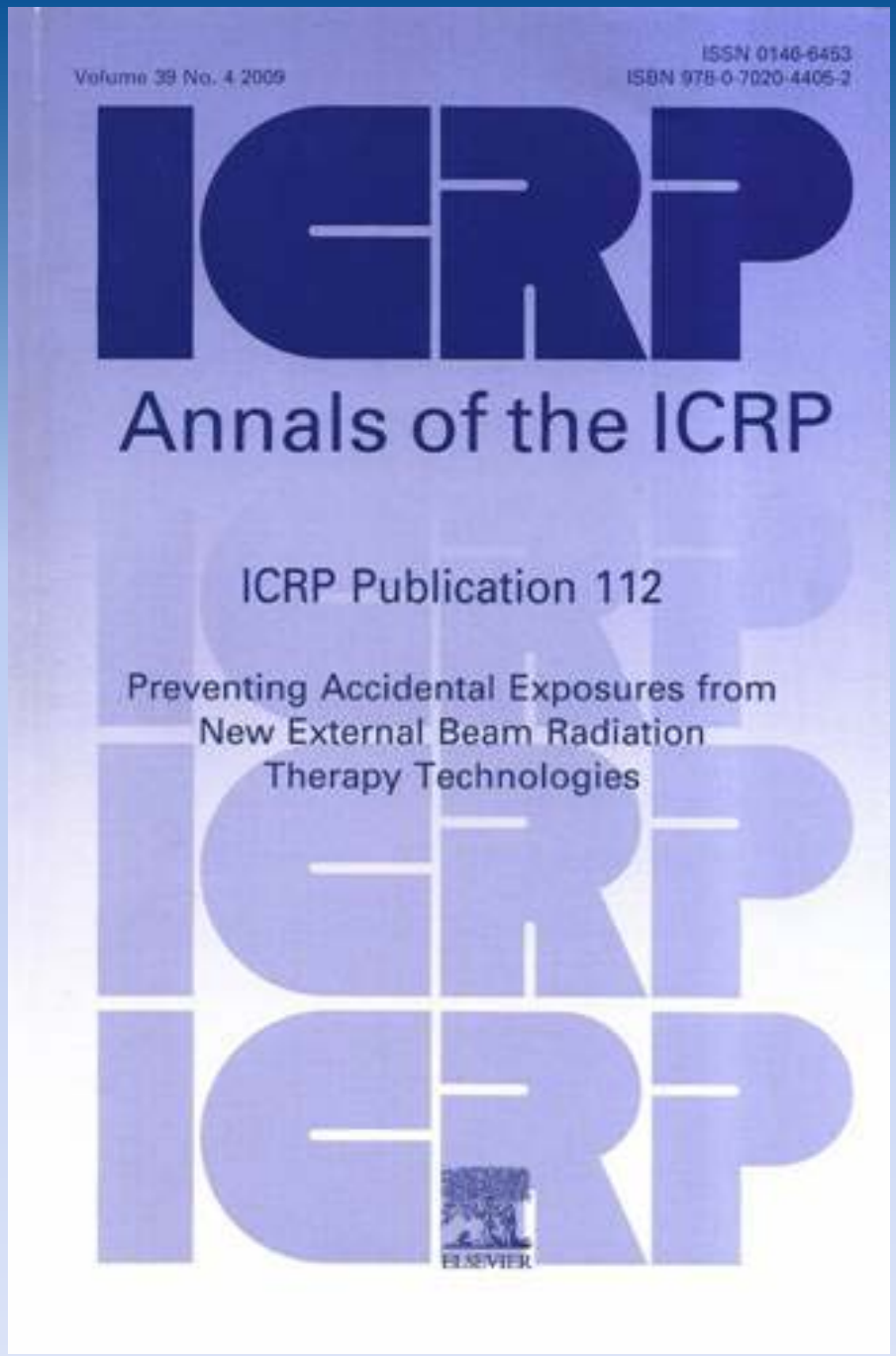
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Preventing Accidental Exposures from New External Beam Radiation Therapy Technologies
ELSEVIER

The information provided consists of

- A description of the events
- The initiators, that triggered the accidental exposure (initiating event)
- The lessons to avoid repeting it

Initial step in safety assessment is an exercise on applying the lessons

- Asking yourself
  - "What if this initiating event would occur in my department?"
  - "Would it be detected and stopped with no consequences?"
  - "What exactly would stop it in my department?"

In the preparation of the ICRP 112 report on the new technologies the following questions were asked

1. Are **lessons from conventional** techniques applicable to newer technologies?
2. Are there **new lessons** from new technologies?
3. Apart from these lessons from experience, is there **anything else** that can go wrong?"

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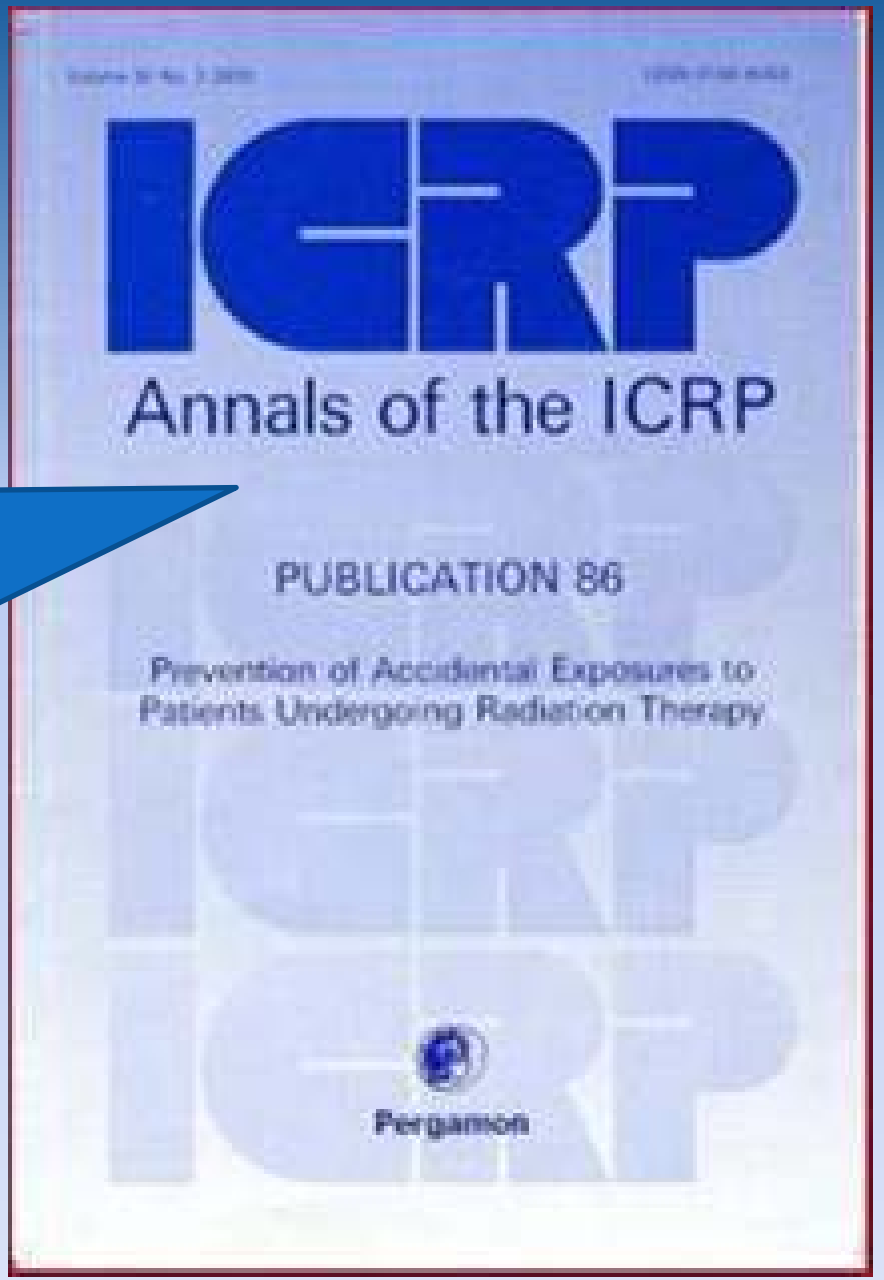
1st question

Are lessons from conventional techniques applicable to ***new technologies***?



Overall lesson from conventional techniques

- "…purchasing new equipment without a concomitant effort on education and training and on a programme of quality assurrance is dangerous".

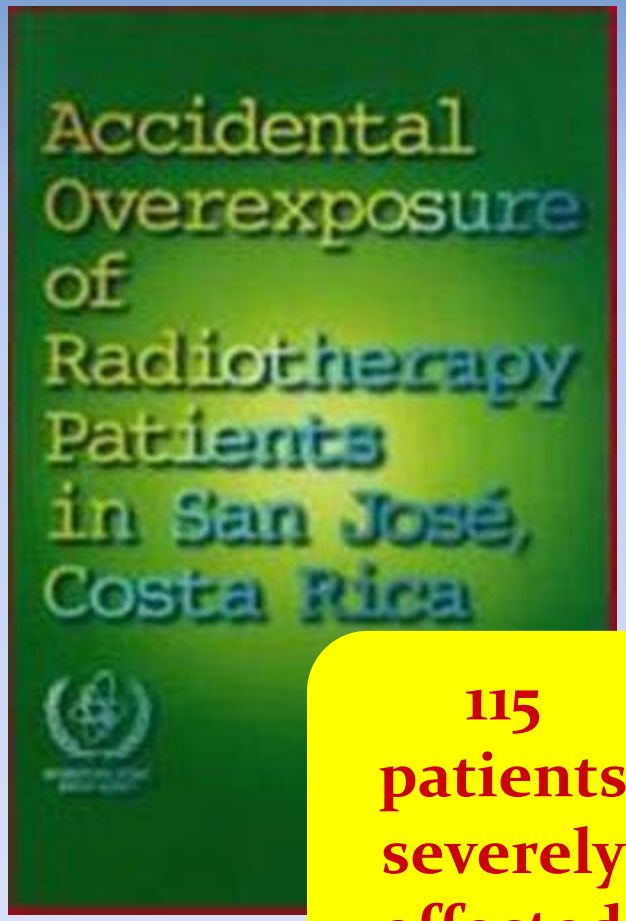
Is it valid for new technologies?

What about my department?

Was this criterion applied when the last equipment was purchased?

Lessons from conventional techniques valid for new technologies?

- Beam calibration: independent verification



115 patients severely affected

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Lessons from conventional techniques valid for new technologies?

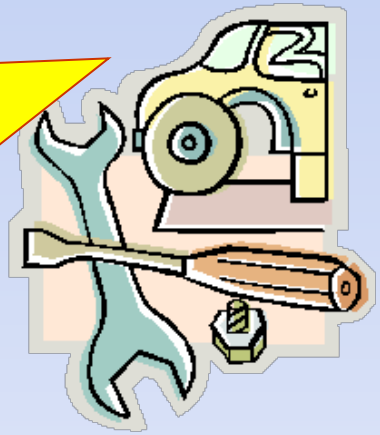
- Complete commissioning of the TPS
- Validation of any change of procedures

1045 patients underdosed in the UK
28 patients severely overdosed in Panama

Lessons from conventional techniques valid for new technologies?

- **Notification of maintenance and repairs** to the person responsible for radiotherapy physics, before resuming patient treatments

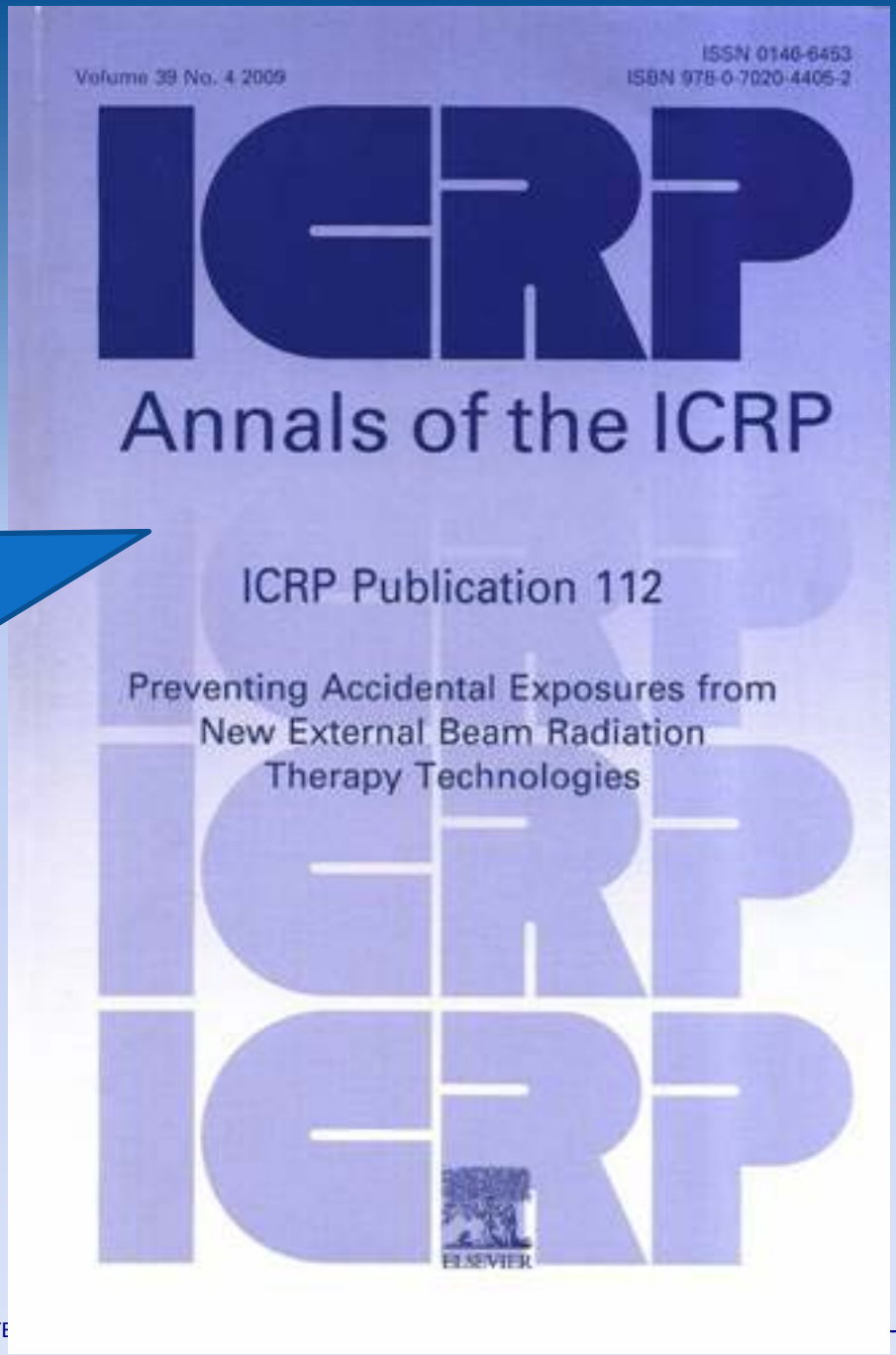
27 patients severely affected in Spain



In conclusion: most lessons from conventional techniques are applicable to new technologies

2nd question

Are there lessons from ***new technologies*** available?



Yes, the following

New lessons:

More and more accelerator functions are controlled by software

Computer program “crash” or “frozen”

Loss of data integrity

- When saving data on treatment plan, the computer got “frozen”. After restarting, data on collimator setting was “lost” from the data file
- As a result, open fields instead of small fields were applied, and one patient received 39 Gy in the first three sessions
- **Checking procedures are required for computer “crashes”. Irradiation parameters may be wrong upon**

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Loss of data integrity

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- **Lesson: Checking procedures are required for computer “crashes”. Irradiation parameters may be wrong upon**

- **Am I sure that my staff will check for data integrity after a “software program frozen” situation? How can I ensure it?**

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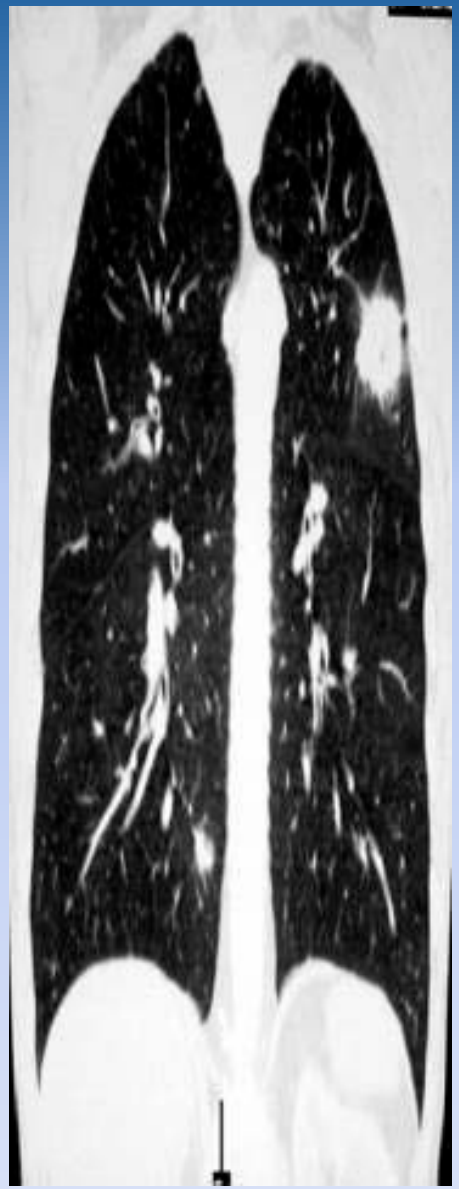
Errors from imaging: Wrong site treatment (right-left) Image distortion



Multiple imaging modalities: problem with consistency in identification and labelling

- Left-right error
- Distorsion of images when transferring them from the TPS to the “record and verify”
- Potential problems of image artefacts and wrong tissue density
- Wiith increased use of different imaging modalities, consistency in imaging identification and image labelling becomes more critical

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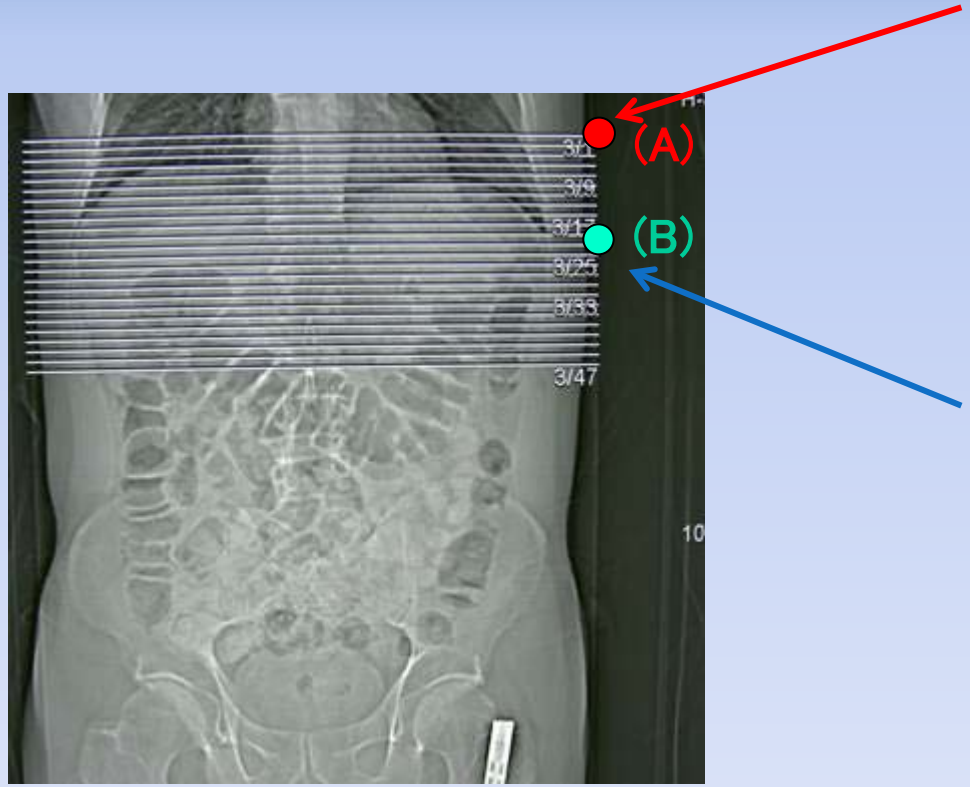
Several events due to

-poor understanding of new techniques and

-poor communication and recording

Marks for virtual simulation

- The tatoo for the initial plane of virtual simulation (A) was taken as the isocenter plane (B).
- Lesson: understanding and becoming fully familiar



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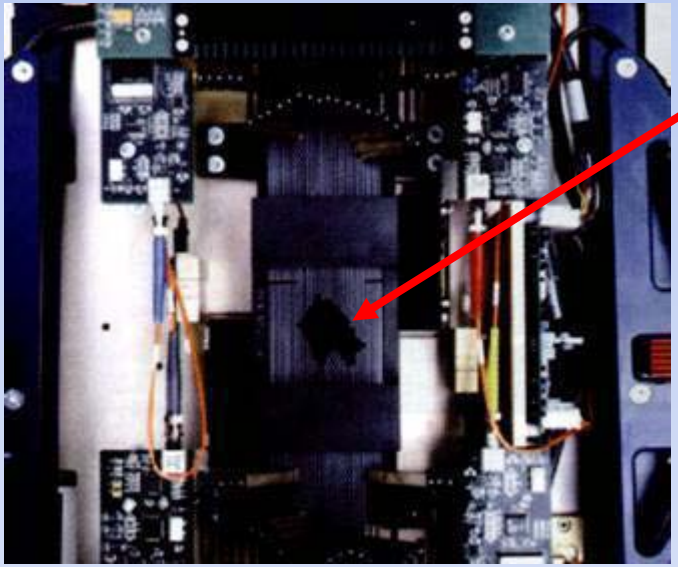
Calibration of very small beams (micro multileaf collimators)

- Partial volume irradiation of the chamber. Wrong absorbed dose determination
- Knowledge needs to be sharper, as well as the level of awareness of the task at hand
- Education and specific training essential for new technologies



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Dynamic wedges

- Erroneous selection of the type of wedges with the result of excessive monitor units
- 23 patients overdosed, four of them died in the first year

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Small fields in stereotactic treatment with applicator

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Confusion 40 mm - 40 cm
Patient died from the accidental exposure

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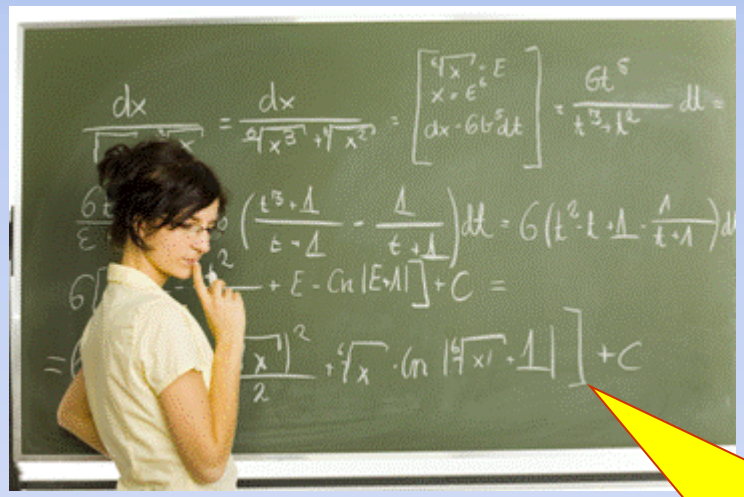
Lesson from poor understanding

No “quick” training…



… but solid training

All these new lessons are useful in preventing reported types of events,

- **They should be included in the training and in continued education programmes and**
- **Should be incorporated into the procedures**

- but

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The unknown or unreported

- What about other possible types of events, which went unreporte or which have not happened yet?
- Do we need to wait until they occur, to learn the lessons?

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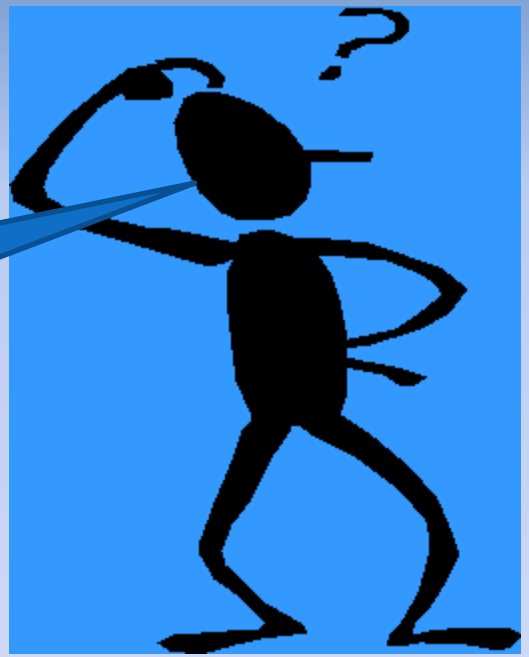
3rd question

Can we anticipate "what else can go wrong?"



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Three proactive methods have been adapted to radiation therapy

- Failure mode and effect analysis (FMEA)
- Risk matrix approach
- Probabilistic safety assessment (PSA)

Example: work done by the Ibero American FORO of Nuclear and Radiation Safety Regulatory Agencies and by the American Association of Physicists in Medicine, briefly described in ICRP 112

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All three have in common

- The identification of a list of potential events in every step of the radiation therapy process
- It produces a long list of potential events to deal with

Risk matrix

- A simple method easily applicable by individual radiotherapy departments
- It consists of a two-step screening to deal with comprehensive list of potential events
- With the first screning, the lower risk events are filtered out.
- A second screening is then applied to the shorter list of higher risk events

In addition: the risk matrix

- Analizes in detail each the provisions to detect errors
- It allows for **sensitivity analysis**, by identifying what would happen if a given check or safety provision (barrier) would not be present in the radiotherapy department or would be removed

IAEA-TECDOC N° xxxxx

Aplicación del método de la matriz de riesgo a la radioterapia

Texto principal

Probabilistic safety assessment

- The risk is quantitatively evaluated and common-cause failures are identified
- It is complex, requires much resources in terms of time, effort and expertise
- It is not amenable for individual radiotherapy departments, but could be used by professional bodies, for example for a new technology

IAEA-TECDOC-XXX

Análisis probabilista de seguridad de tratamientos de radioterapia con acelerador lineal

Texto principal

Take-home messages from ICRP publication 112

Introducing new technologies

- Decision to implement a new technology should be based on an evaluation of the expected benefit, rather than being driven by technology itself
- A step-by-step approach should be followed to ensure safe implementation.

Staff training, availability and dedication

- Replacement of proper training with a short briefing or demonstration should be avoided, because important safety implications of new techniques cannot be fully appreciated from a short briefing.

New protocols for

- Dosimetry protocols are needed for small and non-standard radiation fields.

Computers and data integrity

- Procedures should be in place to deal with situations created by computer “crashes” or program “frozen”

Overcoming the lack of experience when introducing new technologies

- Prospective safety assessments

Thank you

- More details in
  - Free educational material on the website
  - ICRP publication 112

www.icrp.org