

Preventing accidental exposures in radiotherapy when using newer technologies and techniques

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Prevention of Accidental Exposures to
Patients Undergoing Radiation Therapy



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INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION

Accidental exposures when using new technologies are being reported

1. Are the lessons from conventional techniques applicable to newer technologies?
2. Are there data and lessons from new technologies?
3. Are there rational approaches to select verifications for newer technologies and for dealing with increased complexity?
4. Which are the main points on prevention?

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INTERNATIONAL COMMISSION ON
RADIOLOGICAL PROTECTION

MINIMIZING THE RISK OF
UNINTENDED EXPOSURES FROM
NEW RADIATION THERAPY
TECHNOLOGIES

DRAFT 4 (OCTOBER, 2008)

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1st question: can the main safety measures for conventional techniques still valid for new technologies?

1. Verification of absorbed dose at reference point
2. Formal commissioning of TPSs
3. Notification of repairs to the physicist, to check the beam before resuming patient treatments

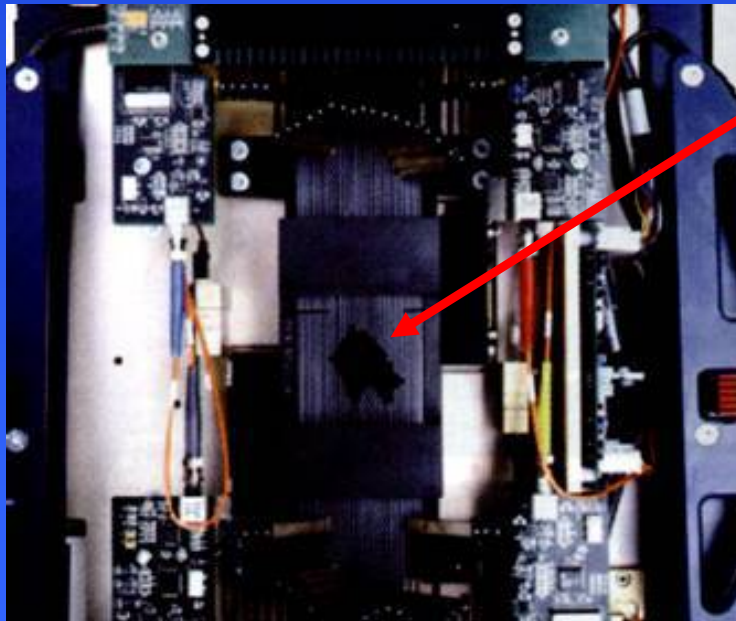
Ist question: can the main safety measures for conventional techniques still valid for new technologies?

3. Manual calculation of absorbed dose to one point for each treatment plan (?)
4. In vivo dosimetry (?)

2nd question
**Are there any lessons from
reported accidental
exposures and near misses
with new technologies?**

Case 1. Calibration of very small beams (micro multileaf collimators)

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



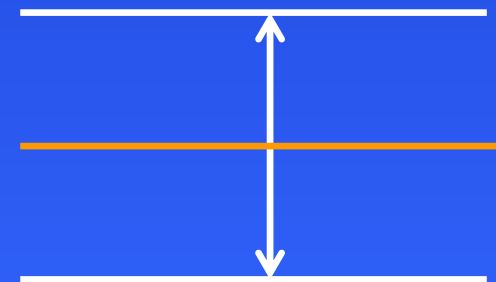
Case 2. Intraoperative radiotherapy

- Supply of wrong calibration file for a given applicator
- Measurements revealed a discrepancy, the physicist asked the installation engineer and received an erroneous advice. The hospital accepted the advice. The problem was discovered later at a survey



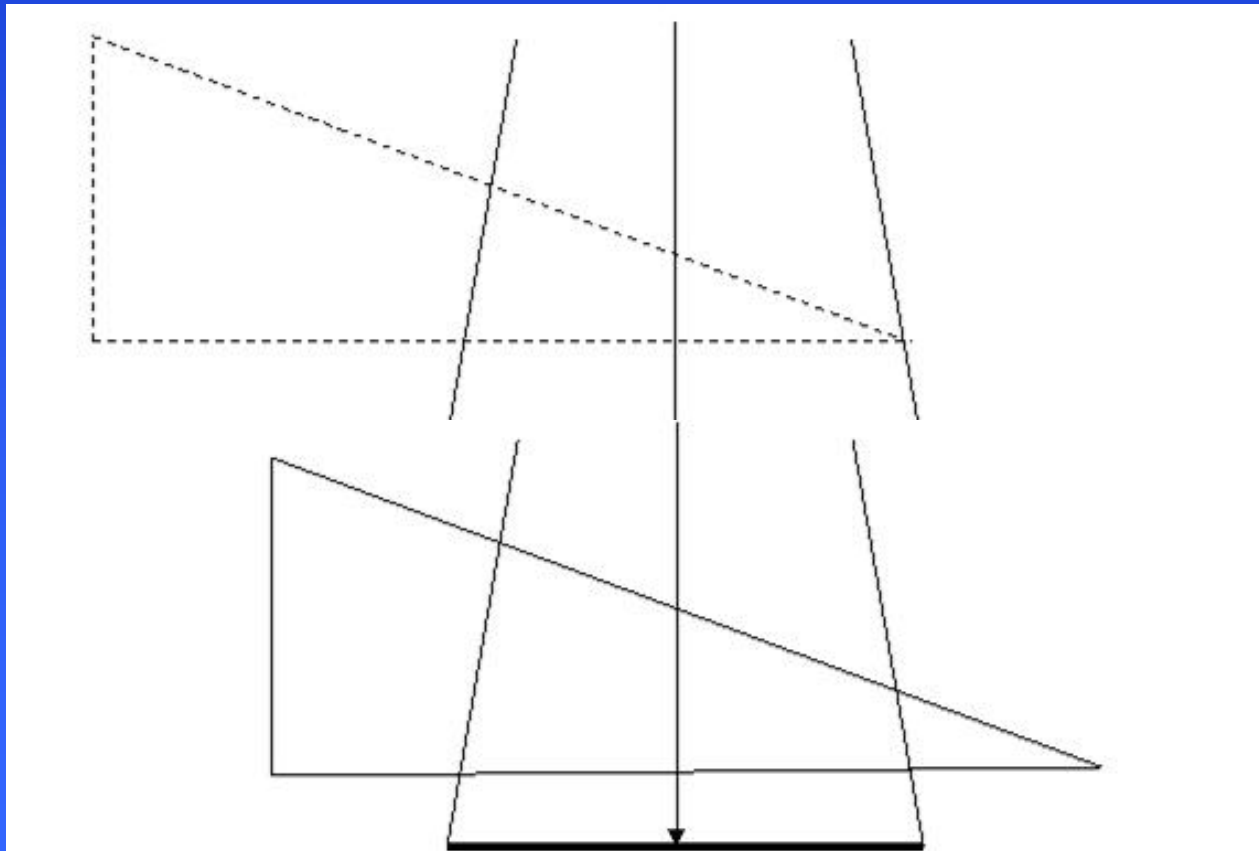
Case 3. Tomotherapy output drift

- Misadjustment of the tolerance limits of a dose rate interlock. Critical in tomotherapy
- Attention to understanding the interlocks and to acceptance tests



Case 4. Dynamic wedges

- Erroneous selection of wedges with the result of excessive monitor units



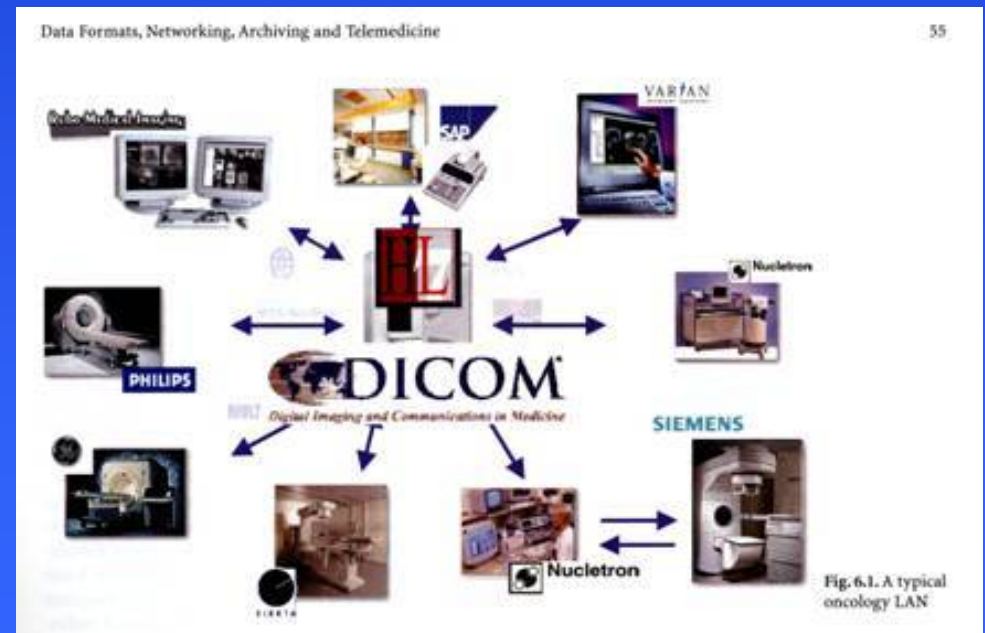
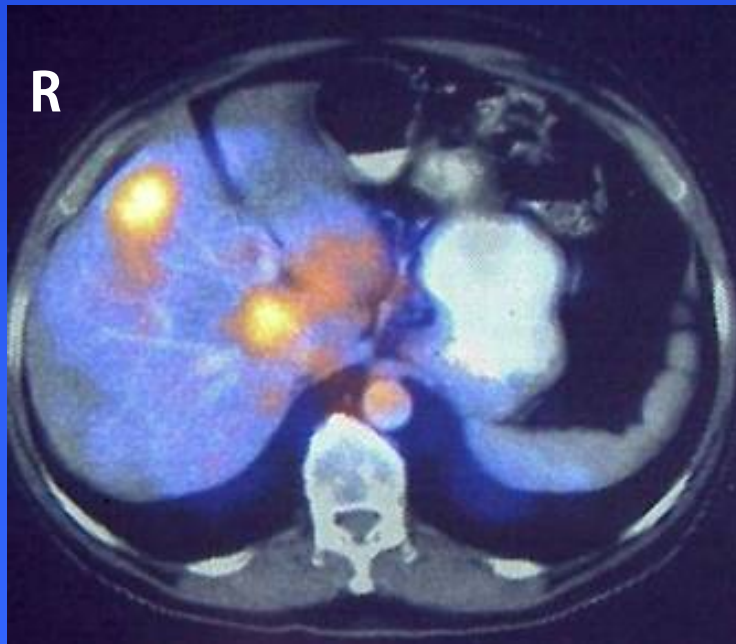
Case 5. IMRT

- Computer crash with loss of data integrity. The collimator setting was “lost” from the data file and an open field was treated
- Specific test procedures for computer crash needed



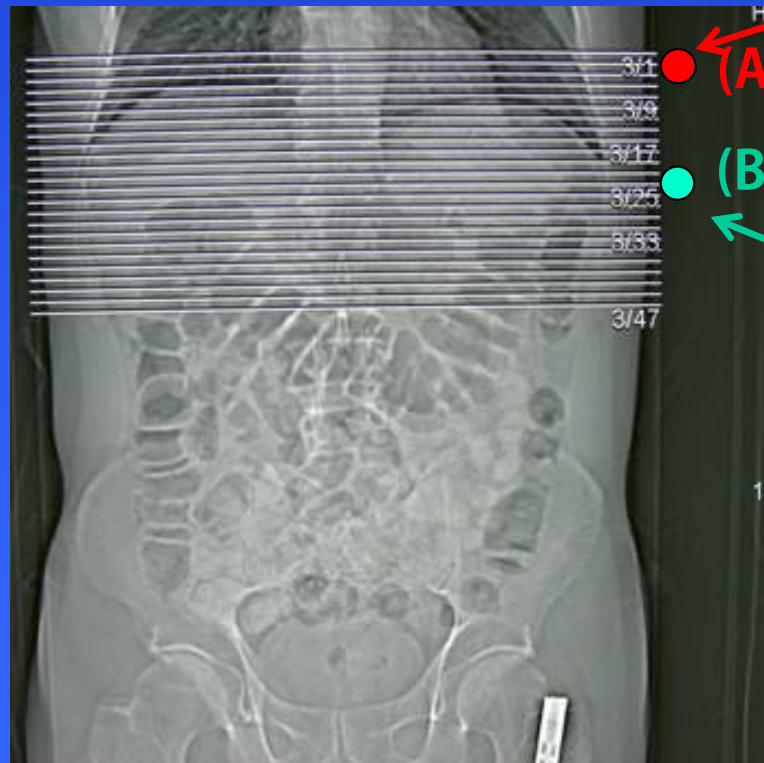
Case 6. Multiple imaging modalities

- Left-right error.
- Consistency in imaging identification and labelling becomes more critical with increased use of imaging modalities



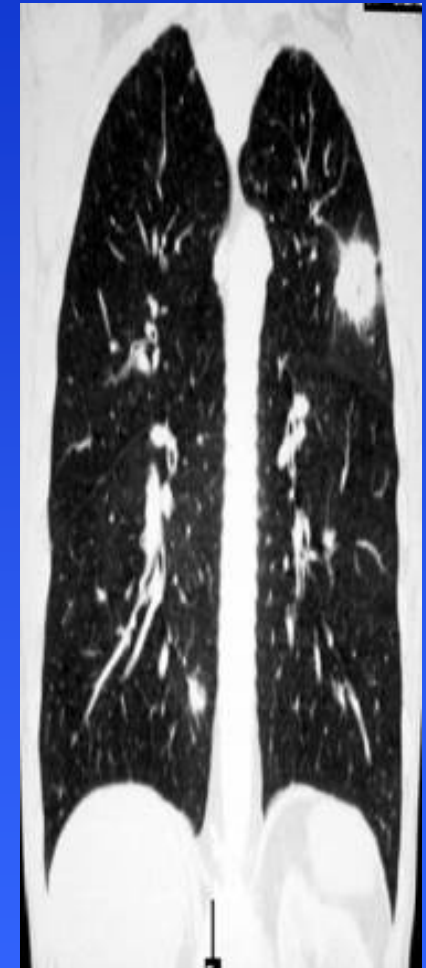
Case 7. Reference markers in virtual simulation

- The tattoo for the initial plane of virtual simulation (A) was taken as the isocenter plane (B).
- Becoming fully familiar with details of new techniques is essential

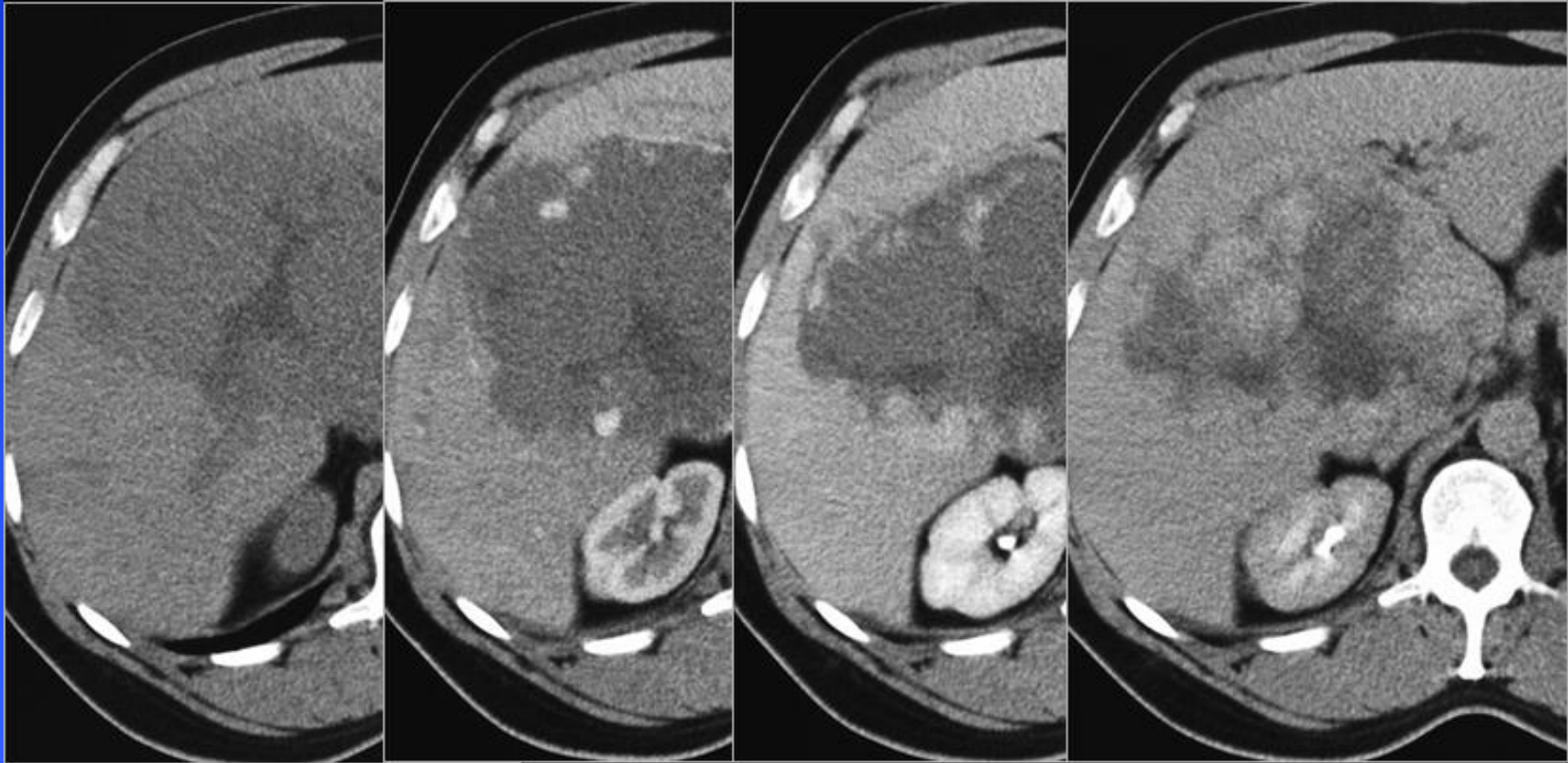


Case 8. Image reconstrucción

- Geometric distortion of CT images, when being uploaded in the graphics memory of the TPS
- Misplacement of the field coordinates
- Specific verifications required



Case 10. Increased use of images in daily treatment verification



- Significant radiation dose as compared to the total treatment dose

Case 9. Record and verify systems

- Old system: TPS calculation for normalized dose (1Gy) followed by manual scaling up to the prescribed dose
- New system: direct scaling up by the TPS and automatic transfer
- Unusual treatment modality. Scaling up was done twice
- A control check procedure was not followed

VCI	On/off	Priority	Organ Type	Max Dose	Penalty	Min Dose	Penalty	DVH Points
[1] Target								
GTV	<input checked="" type="checkbox"/>	3	2 3	78.0	3000.0	76.0		3000.0
CTV	<input checked="" type="checkbox"/>	2	2 3	88.0	800.0	88.0		500.0
PTV	<input checked="" type="checkbox"/>	3	2 3	60.0	400.0	60.0		1500.0
[2] Organs at risk								
BLADDER	<input type="checkbox"/>	5	1 2 3	30.0	800.0	0.0		0.0
UNSPECIFIED	<input checked="" type="checkbox"/>	1	1 2 3	35.0	100.0	0.0		0.0
RECTUM	<input type="checkbox"/>	4	1 2 3	40.0	700.0	0.0		0.0
[3] Unclassified								

Case 11. Small field size in stereotactic treatment

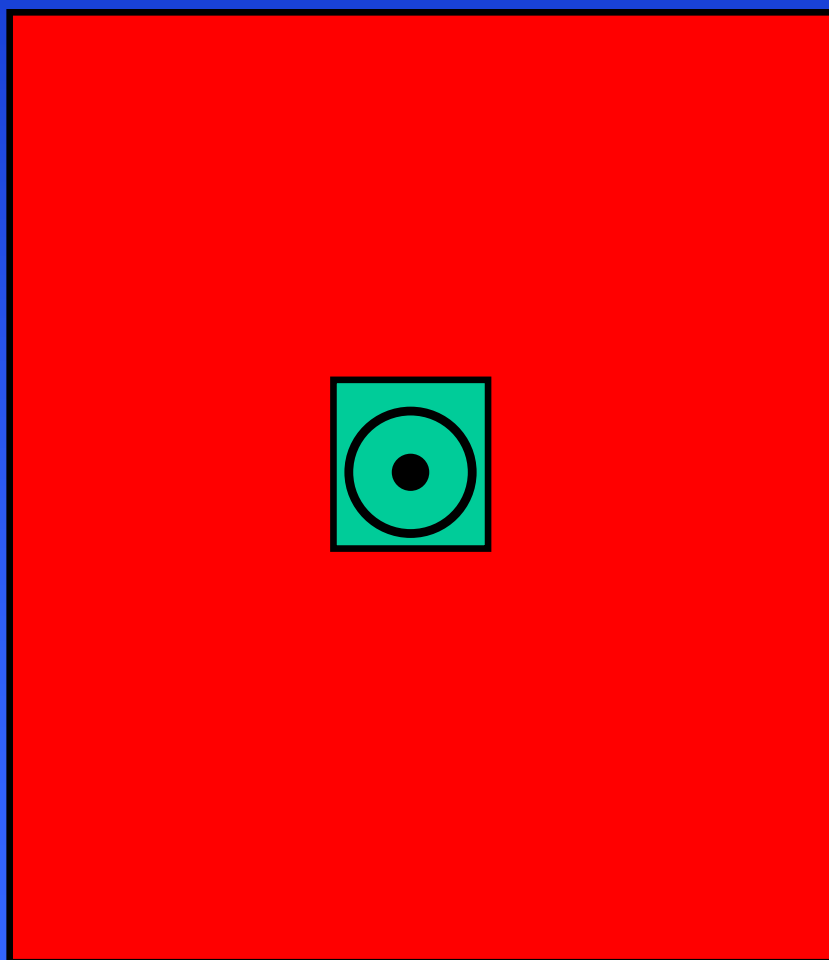
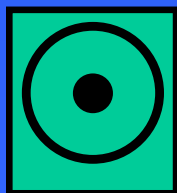


Case 11. Field size in stereotactic treatment

40 (cm)



40 (mm)



**These lessons: provide confidence
against reported risks, but**

In other words ...

1. What else can go wrong?
2. What about unreported events?
3. What about other possible events, which never happened but are possible?
Do we need to wait until they occur to learn the lesson?
4. ¿What should be the strategy with regard to ever increasing complexity?
¿Do we need to make the list of verifications larger and larger for new technologies?

**3rd question:
are there rational approaches to
select verifications for newer
technologies and for dealing
with increased complexity?**

Confidence can be achieved if

- Treatment process is analyzed, step-by-step
- The question “what can go wrong”, is answered for each step
- Potential consequences are assessed for each event sequence
- Safety measures that may stop event sequences are identified
- Safety measures are prioritized in terms of probability and consequences

Proactive methods of safety assessment

- Failure mode and effect analysis (FMEA)
- Probabilistic Safety Assessment (PSA)
- Risk Matrix Approach

Examples from Ibero American FORO of Nuclear and Radiation Safety Regulatory Agencies and from AAPM are given

**4th question: what are the ten
main points for prevention?**

Ten main points

1. The following conclusion from ICRP 86 is even more relevant and important, for new technologies:
“purchasing new equipment without a concomitant effort on education and training and on a programme of quality assurance is dangerous”.

Ten main points

2. Increased complexity requires a combined strategy
 - Interlocks, alerts and warnings, self-test capabilities for equipment, easy-to-understand user interfaces, language understandable to the user
 - General education and specific equipment training, with formal involvement of manufacturers
 - Risk-informed and cost-effective approaches to prioritize checks and verifications (proactive safety assessments)

Ten main points

3. Hospital administrators and heads of radiation therapy departments should provide for an environment inviting concentration and ensure supervision of compliance with QA procedures.

Ten main points

4. The overall responsibility to deliver the correct dose remains with the user at the hospital.

When deviations are found between hospital's and the manufacturer's data, the hospital should investigate and understand their cause before treating patients

Manufacturers and suppliers, however, have subsidiary responsibility for providing correct assistance

Ten main points

5. Tumour dose escalation implies a reduction of geometrical margins, which is only possible with conformal therapy, image-guided patient positioning and immobilization.

Without these features, tumour dose escalation could lead to severe radiation injuries

Ten main points

6. A programme for purchasing, acceptance testing and commissioning should not only embrace the treatment machine but also **treatment planning systems**, “record and verify” systems, imaging equipment used in radiation therapy, software, procedures and **entire processes**.
- There is a need for **re-commissioning** after equipment modifications or **software updates**

Ten main points

7. Procedures should be in place to deal with computer crashes, which may cause loss of data integrity.

Ten main points

8. Increased use of imaging requires dose assessment and integration into the treatment planning and delivery

Specific procedures are needed for consistent left-right identification and for geometrical accuracy and CT tissue density estimation.

Ten main points

9. When conventional tests and verification methods are not suitable for new technologies, equivalent measures to maintain the level of safety are required

This may require **new tests** or modification and **re-validation** the old ones.

Ten main points

10. Timely and effective sharing of operational experience is especially critical in the phase of introducing new techniques and technologies

Proactive safety assessments are most suitable for new technologies

Recap

- Most lessons from conventional techniques are applicable
- New data and lessons for new technologies has become available
- Proactive approaches provide a rational choice of safety measures

Thank you for your attention

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