RISK ASSESSMENT IN RADIATION THERAPY OF PATIENTS USING PROBABILISTIC SAFETY ANALYSIS OF RADIOTHERAPY DEVICES

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Objectives

• Patients safety;
• Accidents in Radiation Therapy;
• How to prevent accidents in Radiation Therapy;
• PSA in nuclear power plants;
• PSA in Radiation Therapy.
Patient Safety

• The problem of safety in radiation therapy remains one of the most important when considering the possible ramifications of the related emergency situations.

• Reporting the accidents that took place talking about significant injury of patients (with subsequent death) during radiation accidents in radiotherapy.
Accidents in Radiation Therapy

- Presentations of Tommy Knöös on MedPhys in Baltic country 2010
Accidents in Radiation Therapy

Accelerator interlock failure (Poland, 2001)

- Initial event – power failure involving a clinic.
- At restoration of electrical power, the accelerator was restarted. Some tests were completed and indicating a low dose rate, leading to the filament current limitation being increased to a high level by staff so that the remaining treatments could be completed.
- Combination of two independent events:
  - A fault in a fuse of the power supply to the beam monitoring system, leading to a high dose rate;
  - A diode was broken in the safety interlock chain.
- 5 patients had irradiation.

Accidents in Radiation Therapy

How to Prevent Accidents in Radiation Therapy

- Acceptance & commissioning.

- Quality assurance program
  - Daily;
  - Weekly;
  - Monthly;
  - Quarterly;
  - Annually.

Is it enough?
How to Prevent Accidents in Radiation Therapy

What about modern radiotherapy equipment and techniques?

• MLC with or without IMRT (IMAT)

• Robotic radiosurgery system CyberKnife
How to Prevent Accidents in Radiation Therapy

• Task Group 100 of American Association Physics in Medicine propose incorporated risk management into the existing Quality Assurance programs.

• Today there are many works on the assessment of risk in brachytherapy, as well as works on risk analysis in the MLC tracking system.
Methods of Risk Analysis:

- Failure modes and effects analysis (FMEA);
- Root-causes analysis;
- Processing tree analysis;
- Fault tree analysis (FTA);
- Probabilistic safety assessment (PSA).

There are proactive methods of safety assessment

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

Examples: 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
PSA of nuclear power plants

• The accident at Three Mile Island in the United States, 1979.
  ✓ One of the main goals after the accident was the development of models of PSA to identify the accident sequences for different types of reactor.

• The accident at Chernobyl, Ukraine, 1986.
  ✓ It was defined qualitative and quantitative safety objectives.

Steps in conducting a PSA level 1:

- Identification and grouping of initiating events;
- Accident sequence analysis;
- System analysis; Analysis of dependent failures;
- Analysis of passive systems, components and structures;
- Human reliability assessment;
- Data required for a PSA;
- Analysis of computer based systems;
- Analysis of internal and external hazards;
- Quantification of accident sequences;
- Sensitivity, uncertainty and importance analysis;
- Interpretation of the results of a PSA;
- Audit of the PSA quality assurance.

Rate of the patients’ complementary mortality related to their radiotherapeutic treatment as the target indicator that would characterize the final state of the radiotherapeutic instrument’s use for patients’ exposure. This indicator characterizes the probability of the system’s malfunction that can result in:

- the patient’s overexposure (overexposure of critical organs and overexposure of the tumor);
- the tumor’s underexposure;
- patient’s physical injury.
• **Physical injury** includes events which can lead to an injury or a death of the patient that are not related to radiation exposure, but are directly related to the operation of radiotherapy equipment:

  ✓ the falling out of the secondary collimator, of the wedge, of the applicator;
  ✓ squeezing of the patient by gantry, by the robot arm (in case the CyberKnife® equipment is used) etc;
  ✓ falling down of the patient from the table as the result of the table’s movement error etc.
PSA in Radiation Therapy

- The complementary death appearance frequency (CDAF) is defined with the following expression:

\[ \text{CDAF} = \frac{\text{DE}}{\text{PN}}, \]

where: DE - the number of events of complementary deaths resulting from the equipment failures and from the errors of the attending personnel, PN - total amount of patients treated with specific radiotherapy device.

- The conditional complementary death appearance probability (CCDAP) may be defined as a probability that a death occurs provided that specific scenario took place.
PSA in Radiation Therapy

• The accident’s initial events (IE) as those that lead to deviations from the normal therapy treatment, which result in complementary risk for the patient to die.

Systems and links in the patient’s therapy clinical chain, to which the accident’s initial events can be tied, are these:

✓ patient’s stimulation, with the appropriate patient’s preparation and the commissioning of the computerized tomographic system or the MRI unit;
✓ system of the therapy’s planning, with the commissioning process taken into account;
✓ authorization of the respective therapy plan;
✓ generation of DRRs (digitally reconstructed radiograms);
✓ delivery treatment, including the system’s calibration, commissioning and the quality assessment procedures.
The scheme and process of treating a patient for radiotherapy equipment

1. Patient Preparation
2. Simulation
3. CT, MRI
4. Planning
5. Commissioning TPS
6. Plan Authorization
7. Generation DRR
8. QA
9. Delivery Plan
10. Calibration System
11. Commissioning System
PSA in Radiation Therapy

Questions???

• When the PSA should be done?

• How often PSA should be done?

• How fully PSA should be done?
PSA in Radiation Therapy

**Difficulties!!!**

- The lack of databases concerned with the failures of equipment (of the components of the equipment) constitutes a problem that arises in the process of conducting the risk evaluation procedure (especially when the PSA model is used), since such databases serve as the source of identification of the accidents’ initial events and of the equipment’s fault rate values. That is why such databases of different radiotherapy systems’ failures have to be created.
Thank you for your attention!!!