Risk management for external beam radiotherapy
Recommendations (draft)

Jean-Luc Godet
ASN - France
Risk management for external beam radiotherapy

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Introduction

Importance of risk management:
- an evidence from human activities presenting a high level of risk (civil aviation, nuclear industry but also in the manufacture of medical devices emitting ionising radiations)
- no doubt in radiotherapy, to prevent adverse effects (Epinal events), where events detection are more difficult (the consequences of events are not always visible to the patient and can appear in a very long time)

Drat ACCIRAD recommendation:
- Based on the reviews and the experience of selected institutes and ACCIRAD members and international experts
How to prepare/get prepared for making proactive and reactive risk assessment?

Risk assessment: a part of the quality management system (QMS)

- Quality assurance programme, including risk assessment, will be mandatory (new BSS).
- ISO standard 9001 is recognized as the best normative reference for a QMS.
- The QMS should be integrated within the accreditation/certification processes of the healthcare organization.

A good practice: a dedicated QMS with appropriate terminology including the definition of responsibilities, control of records, internal and external audit, and continuous improvement of patient safety with corrective actions and actions to prevent adverse events.

➢ The role of National Authority (Radiation Protection/Healthcare).
How to prepare/get prepared for making proactive and reactive risk assessment?

Helping local institute

- Organizing effective dissemination of information on risk assessment to increase the awareness of professional.
- Implementing training actions, both initial and continuous training.
- Introducing and promoting general methodologies for proactive and reactive risk analysis, including pedagogical examples.

A good practice: the development of tools as a methodology dedicated to radiotherapy (SP, Fr).

- The role of Professional societies, in collaboration with national authorities in charge of Radiation Protection and Healthcare.
How to prepare/get prepared for making proactive and reactive risk assessment?

Helping national professional societies and authorities

- An European project to develop a dedicated methodology for risk assessment, used as a reference method for the national developments (promoting harmonization and avoiding a lot of duplicate work and waste of resources).
- A cooperation for establishing harmonized classification scales (severity, probability, risk, etc, …) and in particular, to define what is a significant event that should be reported to authorities.

The role of ESTRO, EFOMP, HERCA and the Commission
How to implement risk management?

Methodological issues to be considered

1. Need to consider a complete approach based on both proactive risk assessment and reactive analysis of events. Why?
   - Proactive step is well adapted to analyse possible equipment failures and organisational and human errors, and the identification of barriers;
   - Reactive step is well adapted to analyse a specific event, based on the research of causes, the identification barriers that failed and corrective measures required and for updating the proactive analysis.

2. For both proactive risk assessment and the reactive analysis of events, a systemic approach is needed, including considerations of equipment failure, human error, and organizational factors.
How to implement risk management?

Methodological issues to be considered

1. For proactive risk assessment, as the *minimum approach*, the following sequence of procedures is recommended:
   
   – Potential failures or hazards are identified with peer experts’ advice, analysis of feedback data or making use of checklists available of published risk assessment studies;
   
   – The impact of potential failures or hazards on the system (i.e. the evaluation of consequences) is identified by deductive (bottom up approach) and qualitative methods, either FMEA (or FMECA) or PRA methodology.
   
   – For prioritization target, in both FMECA and PRA methods, an additional step of the criticality (C) evaluation is carried out.
How to implement risk management?

Methodological issues to be considered

2. After having received experience on the minimum approach of proactive risk assessment, a deeper analysis is recommended to take into account combinations of failures and probabilistic assessment and also the failures of barriers (reactive or corrective measures). For the deeper analysis (a deep defence approach), either Fault Tree or Event Tree method, or the Probabilistic Risk Matrix method can be used.
How to implement risk management?

Helping the local institute on methodological issues

- Professional societies and national authorities should issue recommendations to facilitate the implementation of the risk analysis process:
  - on the working process itself, drawing the attention on prerequisites (training issues for example) and on the involvement of all categories of professionals as physician, medical physicist, therapists;
  - on the “relevant time” to start a proactive risk analysis: modification in the treatment process, implementation of a new equipment or a new practice;
  - on the way to select relevant event for which reactive analysis is needed.
How to follow up/monitor the results, how to learn, benefit, improve the system?

Traceability

• The results on PRA, particularly the proactive measures such as barriers identified as a result of analysis, should be integrated in the internal quality documentation supporting the different steps of the treatment.

Clinical Audit

• The implementation of QMS in radiotherapy and associated risk analysis should be regularly checked by professionals in the frame of clinical audit as referred in the directive EURATOM 97/43

Control

• Regulatory inspections should focus on the organisation put in place to deal with QMS and risk analysis
How to follow up/monitor the results, how to learn, benefit, improve the system?

Feedback experience

Professional societies and national competent authorities should undertake joint actions in order to collect and disseminate feedback and experiences on proactive risk analysis from radiotherapy centres, and to identify and promote good practices.

Dialogues with manufacturers should also be recommended.
Vigilance in radiotherapy: feedback of notified events

Newsletters about the safety of patients undergoing radiotherapy are compiled by the ASN in collaboration with radiotherapy professionals.

N°1
Patient identification
March 2011

N°2
The first radiotherapy session
(or verification session)

N°3
How to analyse your significant radiation protection events?
“Roadmap” for risk management at radiotherapy institution

Step 1: Ensure commitment of management and allocation of specific resources (engagement letter, QMS)

Step 2: Promote safety culture which encourages to carry out proactive and reactive risk analysis and to report events (information to staff, engagement letter for no sanction for error)

Step 3: Establish Risk Management Committee and define the process of risk management

Step 4: Ensure that process description are available for the main activities

Step 5: Include the results of proactive risk assessment and the feedback from event analysis in the training of staff
“Roadmap” for risk management at radiotherapy institution

Step 6: For proactive risk assessment, establish a multidisciplinary team including all staff involved.

Step 7: Involve a Risk Manager experienced in the method which will be used.

Step 8: Select a methodology and train staff on it.

Step 9: Start making proactive risk assessment:
- *when start operation of a new department, updated after one year of operation.*
- *in the case of changes on process, equipment or protocols*.

Step 10: Start making reactive analysis of events
- *As soon as possible after an event detection,*
- *must include all people involved in the event.*