RISK ANALYSIS METHODS: THEIR IMPORTANCE FOR THE SAFETY ASSESSMENT OF PRACTICES USING RADIATION

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Abstract. Radiation safety has been based for many years on verification of compliance with regulatory requirements, codes of practice and international standards, which can be considered prescriptive methods. Accident analyses have been published, lessons have been learned and safety assessments have incorporated the need to check whether a facility is ready to avoid accidents similar to the reported ones. These approaches can be also called "reactive methods". They have in common the fundamental limitation of being restricted to reported experience, but do not take into account other potential events, which were never published or never happened, i.e. latent risks. Moreover, they focus on accident sequences with major consequences and low probability but may not pay enough attention to other sequences leading to lower, but still significant consequences with higher probability. More proactive approaches are, therefore, needed, to assess risk in radiation facilities.

They aim at identifying all potential equipment faults and human error, which can lead to predefined unwanted consequences and are based on the general risk equation: Risk = Probability of occurrence of an accidental sequence * magnitude of the consequences. In this work, a review is given of the experience obtained by the countries of the Ibero American Forum of Nuclear and Radiation Safety Regulatory Organizations, by applying proactive methods to radiotherapy practice. In particular, probabilistic safety assessment (PSA) used for external beam treatments with linear electron accelerators and two studies, on cobalt 60 therapy and brachytherapy using the risk-matrix approach are presented. The work has identified event sequences, their likelihood of occurrence, the consequences, the efficiency of interlocks and control checks and the global importance in terms of overall risk, to facilitate decision making and implementation of preventive measures. A comparison is presented of advantages and limitations of each method, in terms of feasibility of application in practice and of resources required. Finally, ways are proposed to extend this experience to other countries of the Latin American and other

regions.

KEYWORDS: safety assessment; risk analysis methods; radiotherapy.

1. Introduction

Safety in radiotherapy has received emphasis by international organizations and professional bodies worldwide. The International Basic Safety Standards for the Protection against Ionizing Radiation and for the Safety of Radiation Sources (the Basic Safety Standards, BSS) require that licensees shall perform a safety assessment of the radiation sources under their responsibility and specifies further that these assessments shall include, a systematic critical review of … the ways in which structures, systems, components and procedures related to protection or safety might fail, … and the consequences of such failures.

In spite of this requirement, more than 10 years after BSS were issued, systematic safety assessments are still scarce for radiotherapy, either because the tools for these assessments are not well developed or adapted for radiotherapy or because technical data to perform this assessment are not yet available. Due to the absence of systematic approaches, efforts have been restricted to apply the lessons learned from major accidental exposure. Basically, this approach is deterministic in nature. A scenario of major consequences in terms of radiation exposure, which has been learned evaluated from reported events, is postulated and measures are taken to avoiding reoccurrence or reducing their probability to a very low value. Consequently with this approach regulations require prevention of these scenarios by defense in depth, i.e. multiple barriers or multiple barriers or safety measures[1].

Assessments focused only on major accidental exposures may overlook others with significant, but less severe consequences, which due to their higher probability of occurrence and the absence of sufficient barriers, their combined risk may be higher than that of the major accidental exposures. This insight can only be obtained by more systematic approaches, such as the ones presented in this report.

Lessons from major accidental exposures reported in the open bibliography [2,3,4,5] point to the fact that the event sequences leading to them had not been anticipated and, as a result, no sufficient layers of defense were placed. In this report, a proactive approach to safety assessment is presented, which up to date has been used to a very limited extent in radiotherapy. The approach includes two methodologies for risk analysis, which have been adapted to radiotherapy.

2. Risk analysis methods

2.1. Approach for safety evaluation: Strengths and limitations.

Three methods are available to assess or verify the safety in facilities using radiation: prescriptive, reactive and proactive approaches. All three are useful but there are strengths and limitations for each of them.

2.1.1. *Prescriptive approach*

The prescriptive approach is used to verify compliance with al list of requirements given by regulations, design codes or standards, in which the results of historical evidence and of research and development are reflected. The nature of the method is to check whether pre-established requirements are satisfactorily met. The effectiveness of this method has been shown in practice over many years. However, this method can be suplemented and strengthened by other methods that go beyond compliance with requirements but proactively search for potential weaknesses.

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[1] Defense in depth is defined in the International Basic Safety Standards as "the application of more than a single safety measure for a given safety objective so that the objective is achieved even if one of the protective measures fails". In radiotherapy, examples of safety measures are an interlock of the beam monitoring system or double-check procedure.

2.1.2. *Reactive approach*

This approach is carried out by searching for solutions to the problems revealed by previous major accidental exposures, and are aimed at avoiding their reoccurrence. Classical methods of "root cause analysis" fall into this approach. This method has the advantage of easily sensitizing high-level administrators in hospitals who will be willing to provide the necessary resources to prevent them

Their main limitation is given by the fact that only well documented accidents can be analyzed, and these are usually the most important, catastrophic-type of events. Many other events that have occurred but were not adequately reported cannot be rigorously analyzed and lessons cannot be drawn and used.

More recently, information on near misses without consequences is collected using anonym reporting systems, such as the Radiation Oncology Safety Information System (ROSIS), so that lessons can be learned without waiting for a major accidental exposure to happen.

2.1.3. *Proactive approach*

The proactive approach is based on a search for all potential failures and errors, estimating their risk and prioritizing efforts to avoid accidental exposure from those events leading to higher risk. The approach provides a kind of "made-to-measure" assessment for each particular facility. The main limitations of the method is that, in general, it is highly time-consuming and requires the involvement of a multidisciplinary group of specialists, being for this reason costly and likely to be unaffordable for small hospitals and clinics with limited human and material resources.

In this report emphasis is made on concrete examples of techniques to incorporate proactive approaches into safety assessments in radiotherapy, and efforts are made to make the benefit of proactive methods affordable to individual hospitals. This is not meant to replace reactive approaches, but rather both methods should be used and combined in an effective manner, in order to raise the technical level and accuracy of the safety assessments.

2.2. **Common aspects.**

Any risk analysis and risk reduction method should follow a common step-by-step process to systematically and thoroughly analyze a given practice. The steps are the followings:

1. Risk identification

2. Risk quantification

3. Result analysis and decision making.

4. Implementation of risk reduction measures

2.2.1. *Identification of potencial risks.*

In this stage all possible equipment faults and human errors which may lead to undesirable, previously postulated consequences, are identified. In the case of radiotherapy, the undesirable consequences are those defined in the BSS, i.e. "any therapeutic treatment delivered to either the wrong patient or the wrong tissue, …, or with a dose or dose fractionation differing substantially from the values prescribed …".

There are a number of tools for risk identification reported in the literature [6,7]. For this work, the technique called "failure mode and effects analysis" (FMEA) was chosen. FMEA is a standardized method to identify, in a systematic manner, potential faults of equipment, systems or processes and analyze the effects of these faults, with respect to a given undesired outcome. FMEA is carried out in three steps:

1. All possible failure modes and human errors are identified in every equipment and every task of the treatment process

2. When a failure mode is identified, its causes, consequences and existing defenses are analyzed and recorded in an organized way

3. This process is repeated for every fault of the equipment and for all pieces of the equipment of the system or treatment step

4. When the system or treatment step is completed the next one is started until the whole treatment process is done

FMEA proceeds as brain storming sessions in technical meetings. The analysis is performed at independent sessions for each of the systems included in the scope of the study, with participation of a multidisciplinary group. In the case of radiotherapy, multidisciplinary groups included a radiation oncologist, technologist, physicists and risk analysis specialist. FMEA results are documented in tabular form.

2.2.2. Risk quantification.

In this stage a risk estimation is made from the general equation of risk:

$$R = f \bullet C. \qquad (1)$$

Where:

R: risk of the evaluated event sequence.

f: probability of occurrence of the event sequence leading to the accidental exposure

C: magnitude of the consequences associated to the occurrence of the accidental exposure

For this work, two quantification techniques were selected to be applied to the radiotherapy practice: the "probabilistic safety assessment" (PSA) and the "risk matrix" method.

The PSA combines risk analysis tools to perform a systematic, exhaustive and structured investigation of the various scenarios, which may lead to undesirable consequences (accidental event sequences) starting from equipment faults and human errors. The PSA provides qualitative and quantitative information on the minimum cut sets of equipment faults and human error, which can cause an accidental sequence, the frequency of occurrence of the accidental exposure and faults and errors, which contribute most to the risk and a comparison of options to identify those with higher effectiveness in improving safety.

The risk matrix approach is a semi-quantitative technique, which, instead of quantifying absolute risks, uses a scale of risk levels or bands, such as "very high, high, low and very low", which is used afterwards in the stages of decision making and implementation of safety measures.

2.2.3. Result analysis and decision making.

At this stage, quantified results are evaluated and measures to reduce risks are proposed. Criteria for risk acceptability are used based on national regulations or international standards or recommendations. Figure 1 contains acceptability criteria for risk management taken from the literature [8-9].
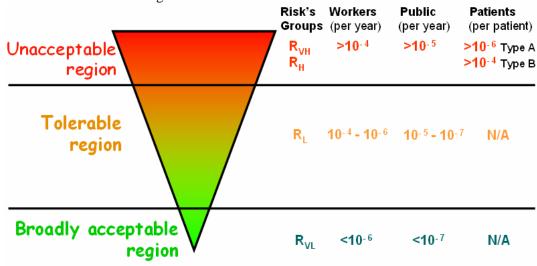
Figure 1: Criteria for risk management.

Nevertheless, establishing goals in terms of absolute values has the disadvantage of leading to promoting compliance with the absolute target values rather than focusing on the insights that the safety analysis may reveal. In addition, there are considerable uncertainties associated to the data and models used in the quantification, which render absolute value analysis less relevant than the relative contributions to risk. This facilitates identification of the elements that are more important to safety.

When PSA is applied, importance and sensitivity analysis reveal how many times a risk can be reduced or increase when a given defense is added or eliminated, which provides a powerful tool for decision making. When the risk matrix method is applied, result analysis shows how the risk band can change when some defenses are added or eliminated. In this case, sensitivity analysis allows evaluation on how the risk moves from one level to next when the level of one of the independent variables is changed.

2.2.4. Implementación of risk-reducing measures

At this stage, measures proposed in the previous step are applied. Since implementation of safety measures is to be done at a real facility, and the safety assessment of this study was done for a hypothetical facility, the last stage was not in the scope of this work. However, once the risk analysis has been performed, the high-level administration of the hospital would have a list of priorities to reduce the risk of the facility and be able to put the method in practice.

2.3. Application of risk quantification techniques to radiotherapy.

The Ibero American Forum of nuclear and radiation safety regulatory agencies (the FORO) has decided to adapt safety assessment techniques to hypothetical radiotherapy facilities, with the objective of promoting the application to the FORO´s countries. In that sense, three applications have been carried out so far: 1) application of PSA to radiotherapy treatments with linear accelerators, 2) application of the "risk matrix method" to external beam therapy treatments with 60Co and 3) to brachytherapy treatments.

2.3.1. Probabilistic safety assessment methods.

The probabilistic safety assessment combines different tools in a proactive research of the accidental sequences that can occur from a combination of equipment fault and human errors. PSA involves three fundamental tasks: identification of initiating events that may trigger accident sequences, determination of these sequences and calculation of frequency of occurrence.

The identification of initiating events was performed using Failure Modes and Effects Analysis (FMEA), a standard method to identify potential failure of an equipment, system or process and to analyze the resulting effects. Once the initiating events have been identified, the sequence of events that can evolve if no obstacle stops this development, i.e., if safety measures fail to work. To track and visualize these sequences "event trees" are drawn.

Once the event sequences have been drawn, the frequency of occurrence of the accidental exposure from each sequence is quantified. This frequency is computed by multiplying the frequency of the initiating event by the probability of failure of all safety measures involved in the sequence. The most significant events were determined through sensitivity and importance analyses, i.e. evaluation of how many times a risk is reduced or increased when a safety measure is added or removed.

2.3.2. Risk matrix methods: the concept and the risk matrix table

Similar to PSA, the risk matrix approach begins with identifying possible equipment faults and human errors that potentially lead to an accidental exposure. For this purpose, the tasks performed in each step of the radiotherapy process are analyzed and equipment faults and human errors in each of the tasks are identified.

The risk matrix approach is kept much simpler, as compared with PSA, in order to be usable in each individual radiotherapy department. The quantitative assessment of probabilities is replaced by a simpler, semi quantitative, four-level scale (for example, very low, low, high and very high) and the complex algebraic analysis of the event sequence done in PSA is replaced by a logical combination of the four levels of the frequency of the initiating event, the likelihood of failure of the safety provisions and the severity of the consequences. This combination results in a global risk for each initiating

event. The global risk is also four-level scaled. The logical combination can be understood by means of the following three combination examples.

- For a potential error (initiating event), which is very unlike to occur (frequency very low), and its consequences are very low, the risk may be negligible. There is no much to worry about an event sequence with low effects, which, in addition, are very unlikely to be caused. The result of the combination is "very low risk".

- The opposite can be said of an event sequence of very severe consequences and high likelihood of occurrence. This event sequence would raise much concern, the risk should be considered to be "very high", as there is a need to add safety measures to drastically reduce the risk by making the accidental exposure extremely unlike.

- Not so obvious is the case of an event sequence, which is very unlikely to occur, but the consequences are very severe. Should the risk be considered "high"? Should preventive measures be applied? The answer is, yes. An event sequence with very severe consequences can not be left unattended, even if it is very unlike to occur, i.e., the frequency is very low. In this case, the risk is also considered "high", and it is necessary to ensure that the event sequence be stopped by means of safety measures in order to prevent the very severe consequences.

This type of logical thinking is applied to all possible combinations of likelihood and severity and the results expressed in tabular form, called "risk matrix" (table 1). In the table, f stands for frequency, C for consequences, P for probability of failure of existing safety measures, and R for risk. The subscripts refer to the scale, VL stands for very low, L for low, M for medium, H for high and VH for very high. The resulting table is presented below:

Table 1: Complete risk matrix containing all combinations of the four levels of frequency of occurrence of the initiating even (f), the four levels of probability of failure of the set of safety measures (p) and the four levels of severity of consequences (C), if the initiating event results in an accidental exposure. The last column provides the four-level risks.

f_H	p_H	C_{VH}	R_{VH}	f_H	p_H	C_H	R_{VH}	f_H	p_H	C_M	R_H	f_H	p_H	C_L	R_L
f_M	p_H	C_{VH}	R_{VH}	f_M	p_H	C_H	R_H	f_M	p_H	C_M	R_H	f_M	p_H	C_L	R_L
f_L	p_H	C_{VH}	R_H	f_L	p_H	C_H	R_H	f_L	p_H	C_M	R_L	f_L	p_H	C_L	R_L
f_{VL}	p_H	C_{VH}	R_H	f_{VL}	p_H	C_H	R_H	f_{VL}	p_H	C_M	R_L	f_{VL}	p_H	C_L	R_L
f_H	p_M	C_{VH}	R_{VH}	f_H	p_M	C_H	R_H	f_H	p_M	C_M	R_H	f_H	p_M	C_L	R_L
f_M	p_M	C_{VH}	R_H	f_M	p_M	C_H	R_H	f_M	p_M	C_M	R_L	f_M	p_M	C_L	R_L
f_L	p_M	C_{VH}	R_H	f_L	p_M	C_H	R_H	f_L	p_M	C_M	R_L	f_L	p_M	C_L	R_{VL}
f_{VL}	p_M	C_{VH}	R_H	f_{VL}	p_M	C_H	R_L	f_{VL}	p_M	C_M	R_L	f_{VL}	p_M	C_L	R_{VL}
f_H	p_L	C_{VH}	R_H	f_H	p_L	C_H	R_H	f_H	p_L	C_M	R_L	f_H	p_L	C_L	R_{VL}
f_M	p_L	C_{VH}	R_H	f_M	p_L	C_H	R_H	f_M	p_L	C_M	R_L	f_M	p_L	C_L	R^{VL}
f_L	p_L	C_{VH}	R_L	f_L	p_L	C_H	R_L	f_L	p_L	C_M	R_L	f_L	p_L	C_L	R_{VL}
f_{VL}	p_L	C_{VH}	R_L	f_{VL}	p_L	C_H	R_L	f_{VL}	p_L	C_M	R_L	f_{VL}	p_L	C_L	R_{VL}
f_H	p_{VL}	C_{VH}	R_H	f_H	p_{VL}	C_H	R_L	f_H	p_{VL}	C_M	R_L	f_H	p_{VL}	C_L	R_{VL}
f_M	p_{VL}	C_{VH}	R_L	f_M	p_{VL}	C_H	R_L	f_M	p_{VL}	C_M	R_L	f_M	p_{VL}	C_L	R_{VL}
f_L	p_{VL}	C_{VH}	R_L	f_L	p_{VL}	C_H	R_{VL}	f_L	p_{VL}	C_M	R_{VL}	f_L	p_{VL}	C_L	R_{VL}
f_{VL}	p_{VL}	C_{VH}	R_L	f_{VL}	p_{VL}	C_H	R_{VL}	f_{VL}	p_{VL}	C_M	R_{VL}	f_{VL}	p_{VL}	C_L	R_{VL}

2.3.3. *Strengths and limitations of the risk-analysis techniques used in this study*

Probabilistic Safety Assessment.

PSA provides quantitative information with numerical values about how much a given safety measure reduces the risk or how much the absence of a given safety measure may increase the risk. With this information, the cost-benefit analysis is objective and precise. PSA identifies common cause to more than one event sequence, and points out the importance and priority of the safety measures to treat the common cause. Moreover, PSA combines several tools to evaluate safety (qualitative, quantitative, and graphical) which allow complementary inputs to cover the limitations of each tool, if used separately. In spite of the fact that PSA is an ideal technique for safety assessment, its application is very complex, demands a time-consuming work and requires experts from outside the hospital. This has been the reason why PSA that very few studies have been performed for this type of facilities.

Risk matrix assessment.

The method is relatively easy to apply by any individual radiotherapy department. Once the initiating events and typical safety measures are identified for a generic radiotherapy department, any individual hospital can perform a tailored self evaluation. Although the risk matrix approach does not provide numerical values, it classifies events in four risk levels or bands, which facilitates screening for importance and helps allocation of resources and priorities.

Both methods are complementary

All methods have in common the task of identifying initiating events and typical safety measures. Effort invested in one of them can be to a large extent be used for the other, although it is not strictly necessary to perform both. For instance, initiating events and safety measures identified by FMEA for a PSA study can be used for any other method and vice versa, and in particular for the risk matrix assessment.

3. Conclusions

Up to present, safety assessment has been performed by incorporating lessons from reported accidental exposures (reactive approach). However, accidental exposures continue to occur in the practice of radiotherapy, thus indicating that other equipment faults and human error than those reported are possible. These faults and errors can be anticipated by a proactive systematic approach.

Risk analysis techniques are a valuable resource for risk identification, quantification and risk reduction management. The Ibero-American Forum of Nuclear and Radiation Safety Agencies has promoted the adaptation and use of these techniques to radiotherapy treatments with accelerators, 60Co and brachytherapy.

In this work, a way to introduce risk analysis techniques to radiotherapy has been developed, to supplement prescriptive and reactive approaches. Two proactive methods, traditionally used in conventional industries, the PSA and risk matrix, have been adapted for radiotherapy treatments.

Risk analysis tools contribute to identify vulnerable aspects of radiotherapy treatments and provide a fundament for decision making in choosing safety measures, with the help of quantitative criteria showing relative impact of these defenses on risk reduction. They are also useful to improve quality assurance in medical exposure for both hospitals and regulatory bodies.

The positive statements made on proactive methods should not be construed to conclude that one method is to replace the others, but rather the strength of these approaches resides in the synergy among them to improve overall safety in radiotherapy practice.

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