Probabilistic Safety Assessment (PSA) of the radiotherapy treatment process with an Electron Linear Accelerator (LINAC) for Medical Uses.

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Abstract. This paper presents the results of the Probabilistic Safety Assessment (PSA) to the radiotherapy treatment process with an Electron Linear Accelerator (LINAC) for Medical Uses, which was conducted in the framework of the Extra budgetary Programme on Nuclear and Radiological Safety in Iberian-America. The PSA tools were used to evaluate occupational, public and medical exposures during treatment. The study focused on the radiological protection of patients. Equipment Failure Modes and Human Errors were evaluated for each system and treatment phase by FMEA. It was aimed at obtaining an exhaustive list of deviations with a reasonable probability of occurrence and which might produce significant adverse outcomes. Separate events trees were constructed for each initiating event group. Each event tree had a different structure since the initiating events were grouped according to mitigation requirements. Fault tree models were constructed for each top event. The fault trees were developed up to the level of components. In addition to hardware faults, the fault trees included human errors associated with the response to accidents, and human errors associated with the treatment. Each accident sequence was quantified. The combination of the initiating event and top events through one fault tree was the method used to analyse the accident sequences. After combining the appropriate models, a Boolean reduction was conducted by computer software to produce sequence cut sets. Several findings were analysed concerning the treatment process and the study proposed safety recommendations to avoid them.

KEYWORDS: PSA; Risk, Radiotherapy; Safety.

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1. Background

Reports of accidents in Radiotherapy have shown learned lessons about problems that have occurred and propose safety measures to avoid them [1-5]. Unfortunately these measures do not avoid completely other accidents, which can be originated by other root causes as is shown by experience. It is necessary, therefore, to find proactive methods and tools to analyze the vulnerabilities of the facilities and adopt measures that could avoid radiological accidental exposures.

Probabilistic Safety Assessment (PSA) is a proactive tool that has been successfully used in aeronautics, and nuclear and petrochemical industries. It can evaluate safety in an exhaustive and structured way, combining assessment of the effects of equipment faults, procedures and human errors and providing an insight into the strengths and vulnerabilities of the process being studied, the dominant contributors to the overall risk and the options to reduce it.

For these reasons, the Iberian-American Forum of Nuclear and Radiation Safety Regulatory Organizations, as part of its effort to promote the use of prospective safety analysis in radiotherapy, has realized a Project on Probabilistic Safety Assessment (PSA) during the radiotherapy treatment process with an Electron Linear Accelerator (LINAC) for Medical Uses (PSA-LINAC). That PSA analyzed the potential exposures during treatment originated by equipment failures or human errors during the different steps of the process.

This paper summarizes some of the main outcomes of that PSA Project.

2. Purpose and scope

The purpose of this Project was to conduct the safety analysis of the radiotherapy treatment with LINAC applying Probabilistic Safety Assessments tools for identifying the equipment failures or human errors that could lead to accidental exposures; as well as for assigning priorities for the regulatory control, prevention and mitigation in radiotherapy.

The study was focused in the analysis of the radiotherapy treatment process with a linear accelerator using as a reference a radiotherapy model established considering typical practices of the countries represented in the Project as well as practices that could be of interest for the present analysis. In this scope the analysis of some tasks that are external to the treatment (i.e. commissioning, calibrations or maintenance) was not included. It was assumed that they are performed successfully. It was so to focus efforts on those accidental exposures with less information from lessons learned out of documented accidents and with less perception about their likelihood. Issues not considered in the scope of this project could be dealt with by further PSA through other endeavours.

The PSA model included the human actions of the radiotherapy treatment team described in the project's scope, excluding those human actions that are part of the medical decision making process (for example dose prescription); because it was assumed the decisions were right, in conformance with the medical purpose.

3. Methods

The procedure for Probabilistic Safety Assessment [6] involves three fundamental tasks: the identification and definition of initiating events that may trigger accident sequences, the delineation of these sequences and the calculation of the accidental exposure frequency from each sequence.

The identification of the initiating events was performed using failure mode and effects analysis (FMEA) that is a standard method for identifying potential failures of an item of equipment, a system or a process and for analyzing the resulting effects [7]. As noted above, the FMEA method for identifying initiating events was applied to both, the hardware failure and the human actions required during the treatment process as considered in the scope of the Project.

The initiating events that were identified through the FMEA were grouped with the purpose of facilitating their use and treatment according to the following aspects:

- Similarity of safety barriers that avoid or mitigate the potential consequence
- Similarity of accidental exposures that the initiating events can yield.
- Possibility for modelling accidental sequences by a single event tree.

Each group of initiating events was treated as a single initiating event, and modelled as a logical fault trees, in a way such that no significant information resulting from FMEA was missed. Finally, a list of initiating events leading to potential exposures was obtained.

Events trees were used to delineate the possible accident sequences resulting from failures of relevant safety barriers currently implemented to avoid the progress of the initiating events that could lead to the accidental exposures.

Once this qualitative process was concluded the accident sequences were quantified to determine their annual frequency. The frequency of each accident sequence was calculated as the product of the initiating event frequency times the probability of failure of the barriers that are expected to act during the evolution of such sequence. Where no data was available for direct estimation of such probability, fault trees were used to model it, graphically and through logic gates, and combine the equipment failures and human errors that are root causes for the failure of the relevant barriers.

As a result of this quantification, the minimal cut sets were obtained (i.e. the minimum combination of component failures and human errors which produce an accident sequence). Once the event sequences had been identified and quantified, the most safety significant events were determined through importance analyses.

Generic Data Bases from several sources [8-11] were used to estimate the reliability of equipment as it is typically recommended for topical PSA that are applied for the first time; due to the low statistical significance of specific data on reliability of equipment and human errors in radiotherapy. For human error probabilities, screening values were used, i.e. conservative values which allow filtering the most important human actions, focusing efforts on them in further detailed analysis. These allow carrying out relative analysis from the absolute results obtained, since the whole quantification was done using the same type of data.

3.1 Definition of undesired events

The undesired events for this study are defined as accidental radiological exposures during treatment with LINAC which respond to the criteria indicated bellow. These criteria are based on the experience of several studies and publications [12-20] and on the consensus of the experts who participated in this PSA Project:

Criterion No.1: Group of people that receive accidental exposures

a. *Workers (Z1):* Any accidental exposure of oncologist, physicist, dosimetrist, therapist, nurses and paramedic of the radiotherapy service. Accidental exposures of biomedical engineer or equipment manufacturer engineer during setup, and maintenance of LINAC are not included.

b. *Members of public (Z2):* Any accidental exposure of member of public during the treatment process due to failure of safety systems and procedures established to avoid that exposure, for example inadvertent entrance of a patient's comforter to the treatment room. Irradiation of member of public due to poor shielding is not included. Amongst members of public were

included; patient's comforters, hospital workers who are not included in the radiotherapy practice, service and non-specialised maintenance workers, and visitors.

c. *Patients (Z3):* Any accidental exposure of patients, which is a deviation in more than 10% of the total prescribed dose. This misadministration may constitute an error in treatment delivery by over-dosage or under-dosage to the target volume; radiation dose to normal tissue outside intended treatment volume, not irradiated portion to intended target volume, or inhomogeneous dose to intended target volume.

Criterion No. 2. Effect of misadministration on patient's treatment and number of affected patients [15]:

- *Individual Episodic (Z3A):* Misadministration which affects a single treatment of one patient (lower than ±10 % of the whole treatment). It can be recovered during the whole treatment and is not considered an accidental exposure.

- *Programmatic (Z3B):* Misadministration which is higher than ±10 % of the whole treatment of a patient.

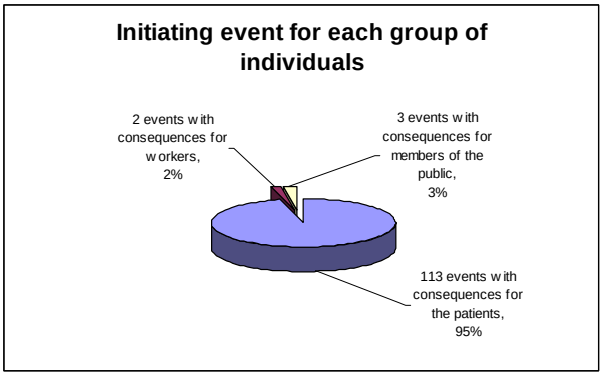
- *Systematic (Z3C):* Misadministration which can affect all patients treated on a specific service and it is higher than ±10 % of the whole treatment.

- *Collective Episodic (Z3D):* Misadministration which affects all treatments on a specific service, but it can be recovered during the whole treatment and is not an accidental exposure (lower than ±10 % of the whole treatment).

4. Results.

During FMEA 453 failure modes or errors were identified which potentially might cause the undesired consequences. These were grouped into 118 initiating events. Likewise, 259 failure modes and human errors which can lead to the failure of the safety barriers were identified. Out of the 118 initiating events, 113 might lead to consequences for the patients, 2 for workers and 3 for members of the public, see Fig. 1.

Figure 1: Initiating event for each group of individuals.



The frequencies of the initiating events were determined as the product of their probability of occurrence and the annual frequency of the task where such initiating event could originate. The probability of occurrence was obtained by means of fault trees using generic data as noted above. The tasks' frequencies were obtained considering the average of the reference radiotherapy services.

In the PSA's models 120 barriers were considered. Success/failure assessments of the barriers allowed identification of 434 accident sequences, out of which 115 can lead to systematic accidental exposures, 143 can lead to programmatic accidental exposures, 2 can lead to worker exposures and 3 can lead to exposures of members of the public. The remaining sequences represent misadministration that can be recovered during the progress of treatment and thus are not considered as accidental exposures within the scope of the study.

The results of the quantification of frequencies of accidental exposures are shown in Fig. 2- Fig. 5.

Fig. 2 shows the frequencies for patients accidental exposures (Z3) are dominant compared to the accidental exposures for workers (Z1) or members of the public (Z2).

Fig. 3 shows the quantification results referred to the type of misadministration.

Figure 2: Contributions of accidental exposures by groups of individuals with respect to the total annual frequency of potential exposures during treatment with LINAC

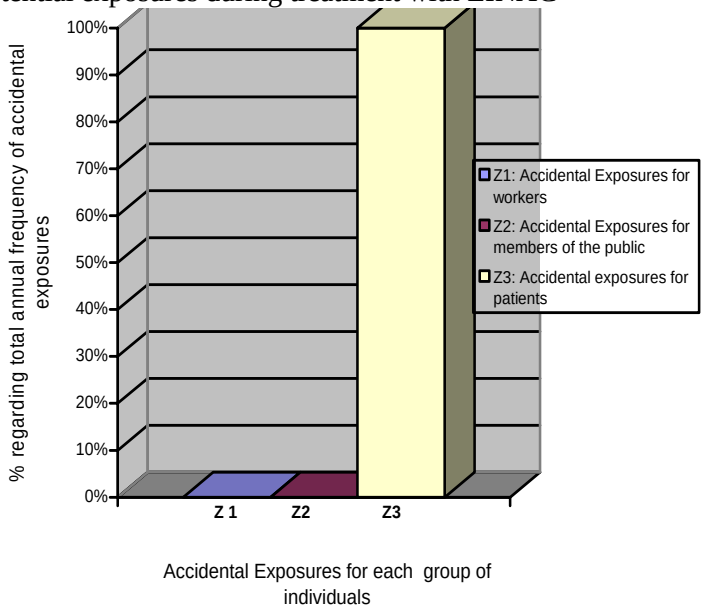
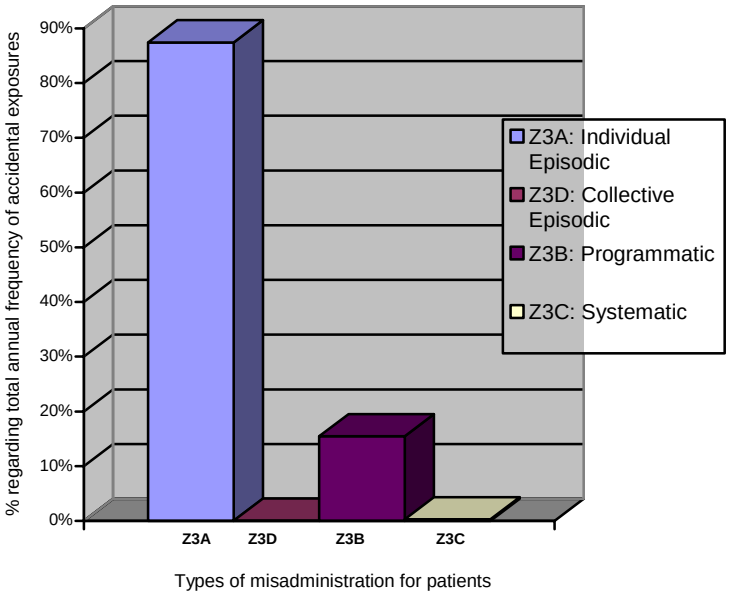


Figure 3: Contributions for different types of misadministration.



The results of the quantification of the accident sequences for programmatic exposures in the different stages of the treatment process are grouped in Fig 4. The results for systematic exposures are grouped in Fig 5.

Figure 4: Results of the quantification by treatment stage for programmatic accidental exposures of patients

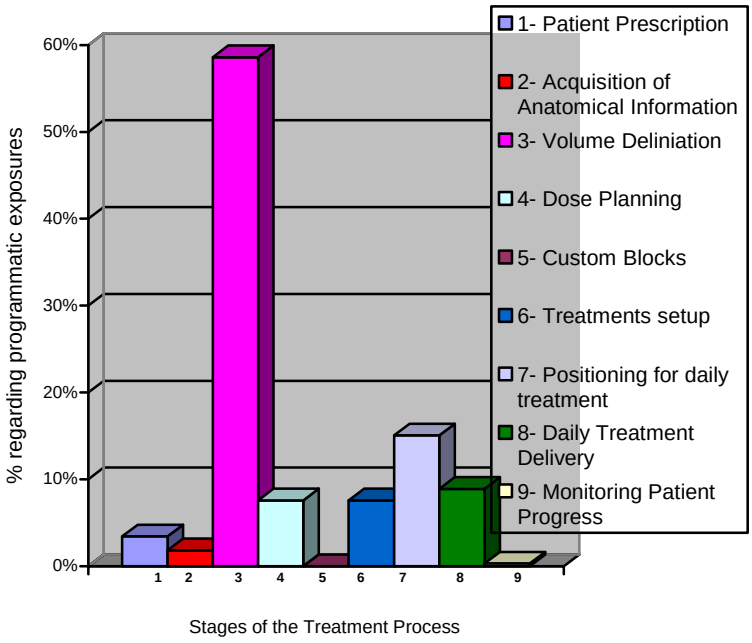
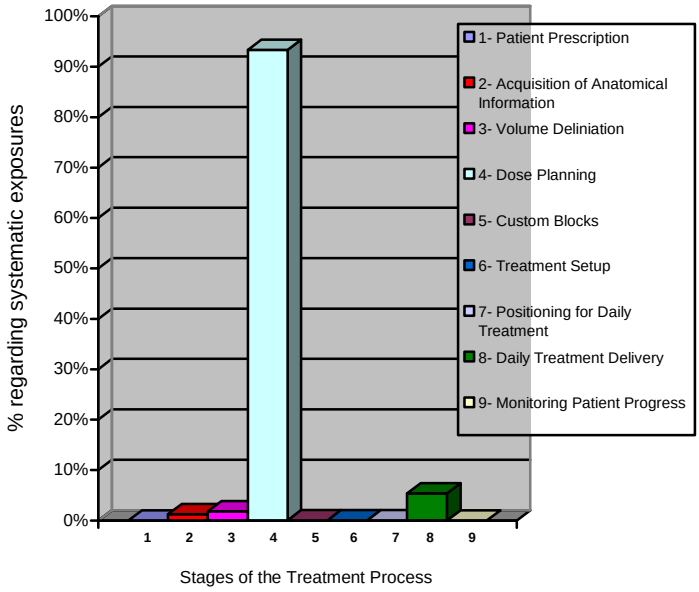


Figure 5: Results of the quantification by treatment stage for systematic accidental exposures of patients



5. Discussion

The 25 most probable types of accidental exposures involve patients (higher than 0.1 % of the annual total frequency of accidental exposures). None of the 25 is associated to initiating events triggered by equipment faults. Out of those 25; 24 are programmatic exposures.

The biggest contribution on the patient is episodic misadministration (87.5%). This type of misadministration is not accidental because it can be compensated during whole treatment progress.

Programmatic misadministration (Z3B) represents a 15.46 % of annual total frequency of accidental exposures. This type of misadministration is considered an accident because it affects patient's treatment in more than 10% of the whole treatment

The PSA study shows that *21 different event sequences are responsible for 90% of the potentially programmatic accidental exposures (Z3B). Three safety measures were identified that can avoid 55% of severe accidental exposures involving the whole course treatment of a single patient (programmatic).* These measures are the following:

- clinical evaluation by the radiation oncologist;
- in vivo dosimetry using reliable, calibrated detectors;
- approval of the treatment plan at a discussion/meeting of radiation oncologist and physicist.

On the other hand, the PSA shows that as few as *nine different event sequences are responsible for 90% of the potentially systematic accidental exposures (Z3C). Three safety measures can avoid 77% of the systematic or catastrophic accidental exposures*. These three measures are:

- Periodic quality control of the PC, digitizer, revalidation of the external beam (i.e. to check the constancy of external beam dose calculations to safeguard against inadvertent alteration or corruption [15]), transfer of the treatment plan;
- Validation after any modification of the TPS;
- Analysis of any change in the procedure for the use of the TPS.

The PSA study confirmed the need for proper commissioning of TPS in accordance with well proven protocols. This measure, together with regular quality control, would reduce by a factor of 21 the risk of catastrophic consequences; in particular, validation procedures for any change in the mode of use of the TPS can avoid catastrophic events similar to the Panama accidental exposure [4].

A number of errors relate to unclear delineation of target volumes and bear a significant contribution to accidental programmatic exposure. It is recommended: 1) to use a color code for those volumes and to make it mandatory in the radiotherapy department; 2) to include in TPS acceptance tests a verification of compliance with ICRU 62 [16] in connection with terminology; and 3) to incorporate into the design of the TPS interlocks and warnings to restrict manipulation of treatment volumes to alert staff on the potential omission of secondary treatment volumes.

The following safety measures have a preventive effect on a large number of initiating event sequences: 1) portal imaging at the initial session and periodically thereafter; 2) dosimetric tests; and 3) interlocks of the beam monitoring system. Absence of such safety measures increases the risk of initiating events where they apply by factors of 90, 30 and 6, respectively.

Independent review of the TPS calculation would substantially reduce the risk of accidental exposure. Absence of this safety measure increases the risk by a factor of 10.

The 'record and verify' system of medical accelerators drastically reduces the risk of nine initiating events related to daily treatment session delivery. Absence of this system increases the risk by a factor of 75, according to the computations of probabilities made in this research. New equipment should, therefore, include record and verify systems.

The presence of two technologists during treatment preparation and delivery is very important. Failure to comply with this good practice increases the risk of accidental exposure by a factor of 10. At least one of the two technologists should be the same during the whole course of treatment, from the initial setup until the end of treatment.

Conclusions

The PSA identified potential causes for accidents during treatment delivery and gave priorities for their attention regarding relevance and contribution to risk of accidental exposures. The study shows that PSA is an effective tool for evaluating and improving the safety of the radiotherapy treatment, complementing other traditional methods for evaluation of the radiological protection of patients. Also has been proved to be an excellent tool to improve the regulations and the control inspections.

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