IAEA TECDOC SERIES

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Application of the Risk Matrix Method to Radiotherapy

Principal Text

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APPLICATION OF THE RISK MATRIX METHOD TO RADIOTHERAPY

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IAEA-TECDOC-1685

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PRINCIPAL TEXT

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2016

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FOREWORD

The Fundamental Safety Principles (IAEA Safety Standards Series No. SF-1) and the Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (IAEA Safety Standards Series No. GSR Part 3) establish requirements on the protection of patients who are subject to medical exposure. In accordance with these requirements, and in line with the IAEA's responsibility to provide for the application of these standards, intensive work has been undertaken on the prevention of accidental exposure in radiotherapy, which has taken the form of a series of TECDOCs on lessons learned from research into very serious incidents and teaching materials arranged into regional courses, which are accessible on the IAEA's Radiation Protection of Patients web site. These lessons learned, while necessary, are not sufficient; information continues to be received concerning new types of accidental exposure, and there may be other types about which no reports have been published.

A more anticipatory approach is required that, in a systematic, exhaustive and structured way, attempts to pre-empt other errors that might occur so as to prevent them or detect them early on. One such approach is the risk matrix method which, being relatively simple, can be applied to any radiotherapy service. This is the focus of the present study, undertaken as part of the Extrabudgetary Programme on Nuclear and Radiation Safety and Security in Ibero-America.

The IAEA officers responsible for this publication were A. Nader and P. Ortiz López of the Division of Radiation, Transport and Waste Safety.

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1. INTRODUCTION

1.1 BACKGROUND

Radiotherapy, whether curative or palliative, has three important aspects: effectiveness of treatment, quality of life, and safety [1]. From the point of view of safety, radiotherapy is a very special case, as it is the only application of radiation whereby people are directly subjected to an intense radiation beam (teletherapy) or sources come into direct contact with tissue (brachytherapy), thus deliberately delivering very high doses of radiation (of the order of 20 to 80 Gy). Moreover, radiotherapy is unusual in that both overdoses and underdoses can have serious consequences [2].

Radiotherapy treatment is a very complex process, with a series of procedures involving interaction between various professionals from a multidisciplinary group. For example, in the case of external beam radiotherapy, treatment is fractionated into between 20 and 40 sessions, each of which requires many parameters to be selected. Every day a large number of patients must be treated, many of them with similar but different parameters, which increases the likelihood of human error.

For all these reasons, radiotherapy receives special attention in safety standards [3]. In particular, the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) establish requirements for the investigation of accidental medical exposure and the adoption of the corrective measures necessary to avoid a recurrence. In the context of radiotherapy, accidental medical exposure is defined as "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 by the medical practitioner or which may lead to undue acute secondary effects". More generally, the BSS define an accident as "any unintended event, including operating errors, equipment failures or other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection or safety".

There is ample literature containing detailed reports on cases of the most serious accidental exposure [4–8], along with a collection of summaries of around one hundred instances of accidental exposure [9]. These reports provide information on the lessons learned, the causes of such exposure and contributing factors, thus enabling preventive measures, such as the need for redundant and independent verification of aspects considered critical, to be identified.

These retrospective studies, while necessary, are insufficient as they do not cover other possible accidents, be they those that have not yet occurred or those that have not yet come to light. A systematic methodology is therefore required, which pre-empts such events and identifies weak or vulnerable aspects of the treatment process, with a view to taking measures to avoid accidental exposure.

One way of achieving this is through a probabilistic safety analysis (PSA), which has already been carried out for ^{60}Co external beam therapy [10] and high dose rate brachytherapy [11] and has recently been performed for electron accelerators [12] as part of the Ibero-American Forum's project series No. 1. These studies are laborious, highly complex and specific to each installation, requiring a group of PSA experts and taking months or even years to complete.

In addition to PSA, a simplified, manageable method is needed that may be performed by any hospital with its own staff and modest efforts. That is the aim of this report: it presents the risk matrix method, a tool for self-evaluation by radiotherapy services aimed at preventing errors or failures that may give rise to accidental exposure. In order to apply the method, the

department's radiotherapy doctors, medical physicists and radiotherapy technicians need to participate.

1.2 PROJECT OBJECTIVE

The objective of the project is to introduce a tool for self-evaluation by radiotherapy services that allows them to analyse errors or failures that might give rise to accidents. The results of applying this tool to a generic radiotherapy service are also presented. These results are used as a basis for a set of recommendations to strengthen quality and safety programmes in radiotherapy departments. Both operational experience (lessons learned from accidental exposure) and the results of PSA studies have been taken into account in applying the tool and formulating these recommendations.

1.3 SCOPE

The study examined situations within the radiotherapy process that could give rise to accidental exposure of patients, workers or the public, from installation of equipment through to completion of treatment.

Although medical procedures per se do not come within its scope, this report does cover all aspects that could give rise to an undesirable deviation from the treatment prescribed by a doctor. Analyses of accidents involving exposure to orphan sources and accidents that occur during the transport of radioactive sources are also excluded from this report.

1.4 STRUCTURE OF REPORT

The concepts, definitions and processes needed to understand the method are described in Chapter 2. Chapter 3 outlines the characteristics of a generic radiotherapy service to which the method was applied; the results[1] thereof are presented in Chapters 4 and 5. The resulting discussion, conclusions and recommendations are set out in Chapter 6.

The report contains appendices with the complete risk matrices for all accident sequences and a detailed analysis of those that present the highest risk. While the main body of the report has been translated from Spanish, the appendices are reproduced here in their original form.

[1] Please note that these results are based on the complete risk matrices for all accident sequences and a detailed analysis of those that present the highest risk. This information is included in the appendices of the original publication (IAEA-TECDOC-1685/S, Aplicación del método de la matriz de riesgo a la radioterapia), published in Spanish. These appendices have been included here in the original language.

2. METHOD

2.1 CONCEPTS AND DEFINITIONS

In this study, the risk matrix methodology was applied to a generic radiotherapy service taken as a reference. The risk matrix method has been widely applied in high-risk industries (chemical, petroleum, etc.) and in the banking and credit sector [13, 14]. It is used as a tool to establish risk management priorities for an installation based on a combined analysis of the frequency of an undesirable event and its consequences [15]. Although it does not enable risk to be quantified numerically, this method does make it possible to classify risk into levels, which is sufficient to establish priorities without conducting more precise, yet more costly, risk analyses.

In order to explain the method, a number of terms and concepts must first be defined. These are presented in the forthcoming subsections. However, a brief definition of the method can be given primarily using everyday language, as follows:

- The risk matrix is a method for screening events that might result in an accident, with a view to prioritizing safety efforts in those areas where the risk is greatest. The method is based on evaluating these events, taking into consideration the safety measures in place to tackle them and the potential consequences of the events.
- Screening is carried out in two stages. In the first stage, only the number of safety measures is taken into account, not the quality or robustness thereof. During this process, events are provisionally grouped and classified into various risk levels. This provisional classification serves as the basis for an in-depth analysis of the events, prioritizing them in order of risk from highest to lowest. The in-depth analysis examines the robustness of the safety measures; this is used to determine whether there is justification for lowering the provisional risk level assigned or, on the contrary, whether additional safety measures are required to achieve it.

2.1.1 Risk

In common parlance, risk is the possibility of harm occurring. To be more quantitative and precise, risk is defined by a mathematical expression that relates the frequency of an event with the probability of defences failing and with the consequences (harm) that may occur:

$$R = f \cap P \cap C$$

where ***f*** is the frequency of the initiating event, ***P*** is the probability of the defences or barriers in place failing and ***C*** is the severity of the consequences.

According to this definition, in order to evaluate the risk associated with any activity, the expected harm and the probability of it occurring must be quantified, and the resulting product will be the value for the risk in question. By quantifying risk, or classifying it into levels, an acceptability criterion can be established and a limit set for it; below this limit, an installation or process is considered acceptably safe. This means that events which cause very serious harm must have a very low probability for the risk to be acceptable, while a higher probability may be acceptable for events which cause slight harm.

2.1.2 Accident initiating event

An initiating event refers to any equipment failure, human error or external event that may lead to accidental exposure if the preventive measures in place fail.

2.1.3 Accident sequence

An accident sequence is a chain of events that begins with an initiating event and may culminate in an accident. This sequence includes the initiating event, the activation or failure of safety measures, the accidental exposure and the appearance of possible consequences. The risk matrix gives a combined evaluation of the initiating event, safety measures and consequences, allowing the resultant risk to be evaluated.

2.1.4 Safety barriers or defences

Barriers are the measures put in place to avoid, prevent, detect, control, and reduce or mitigate the consequences of an accident once an initiating event has occurred. Barriers may be technical or organizational measures. All defences form part of the principle of defence in depth[2]. When studying safety, it is important to recognize and distinguish between the following key words:

Avoidance: stopping an initiating event from occurring or making it impossible for an initiating event to occur. One example is devices that are fail-safe, i.e. their failure leads to an intrinsically safe state. Automation consists of allowing certain actions to be controlled by software rather than humans, thus eliminating the possibility of any initiating event that results from human error. Automation may bring risks of its own, however, which must be studied separately.

Prevention: making the initiating event less probable. This key word is generally applied to frequency reducers, which are measures intended to lower the frequency with which an initiating event occurs.

Detection and protection: detecting the occurrence of an initiating event and acting to prevent undesirable consequences (accidental exposure). These key words apply to direct barriers, which are defined below.

Detection and mitigation: identifying the fact that an initiating event has occurred and acting to mitigate undesirable consequences, by reducing either the severity of the harm or the number of people affected. Barriers intended to mitigate consequences are referred to in this document as “consequence reducers”, as described in section 2.2.8.2.

2.1.4.1 Classification by type of safety measure

Safety measures may be devices associated with equipment (interlocks or alarms) or written procedures that increase the reliability of human actions.

Interlocks are technological systems or devices with a protection function, which are capable of automatically detecting an unsafe situation and deactivating a radiation beam, returning a radioactive source to the shielded position or preventing a source from leaving the safe

[2] Defence in depth is defined as the practice of establishing two or more safety measures for the same safety function, such that the function is maintained even if one of the measures fails.

position (e.g. the interlock on the door of a treatment room, the low air pressure switch in a pneumatic system, software interlocks from the control processor, etc.).

Alarms are auditory or visual signals that warn of the presence of an initiating event and facilitate decision-making, but require human intervention. This category includes systems for communicating with and seeing patients (TV cameras and intercoms), radiation indicator lights at the entrance to treatment rooms, and area dosimeters, for example.

Work procedures are written instructions on how to carry out the tasks involved in the treatment process, with a view to avoiding errors or deviations during the various stages of the process. Examples are planning protocols, treatment simulation, patient monitoring, and many of the activities included in quality assurance programmes in general.

In terms of level of robustness, they are classified as follows (descending from highest to lowest):

- Type 1 barriers: interlocks;
- Type 2 barriers: alarms;
- Type 3 barriers: work procedures carried out by different people, for example, the procedure for calculating each patient's dose at a certain point is performed by somebody other than the person who did the planning;
- Type 4 barriers: work procedures carried out by the same person but at different stages or times, for example, the prescription is reviewed at various times by the same doctor who issued it, comparing it with the plan being followed.

2.1.4.2 Classification by the time of activation within the accident sequence

Safety measures may also be classified according to the time at which they are activated within the accident sequence.

Frequency reducers: measures to avoid or prevent an initiating event; as such, they take effect before the initiating event occurs. Their effectiveness is demonstrated by a reduction in the frequency of the event. Examples of frequency reducers include training staff in the use of calibration certificates, keeping workloads at a moderate level, establishing a working environment with no distractions, which is conducive to concentration, and undertaking preventive maintenance.

Direct barriers: measures to detect an initiating event and prevent its consequences, such as accidental exposure of patients. As such, direct barriers take effect after the initiating event has occurred but before it can have any consequences. Examples of direct barriers include redundant review of treatment planning, an irradiation interlock triggered by movement of the couch, or an equipment shutdown switch at the entrance to the treatment room.

Consequence reducers: measures to detect and mitigate the consequences of accidental exposure. Consequence reducers take effect once the event has occurred and its consequences have started to become apparent. Examples of consequence reducers include daily observation of a patient's tissue reactions by radiotherapy technicians, weekly medical follow-up review consultations and periodic quality control. This group also includes emergency procedures, such as actions to be taken if a source gets stuck.

Important observation: certain very general measures strengthen both the direct barriers and the frequency and consequence reducers, for example, keeping workloads to a moderate level. This measure allows human actions to be performed more carefully and reduces human errors — both those that constitute an initiating event and errors that could cause a direct barrier to fail or anomalous signs in the patient to be missed — which should mitigate the

consequences. Depending on the stage at which the human action takes place, the moderate workload will have helped to strengthen either a direct barrier or a reducer.

2.1.5 Consequences

Consequences are the potential harm that may result from an initiating event. When classifying consequences, the severity of their effects and the number of people affected were taken into account. Severity may range from the death of the irradiated individual to a simple loss of defence in depth, with no negative effects to human health.

2.2 DESCRIPTION OF THE METHOD

In order to apply the risk matrix method, every sequence of events arising from each initiating event (accident sequence) must be evaluated. Figure 1 shows how a given human error or equipment failure (initiating event), which occurs with a particular frequency (*f*), may give rise to undesirable consequences.

The radiotherapy service or equipment will have a set of defences, which may consist of one or several barriers (interlocks, alarms or procedures) to detect a problem and prevent an initiating event from becoming an accident. However, each of these barriers has a particular probability of failure (*P*), in which case an accident would occur, resulting in particular consequences (*C*).

The accident sequence is ultimately characterized in terms of level of risk (*R*), which is a function of the three independent variables: the frequency of the initiating event, the probability of barriers failing and the severity of the consequences. This function is also shown in Figure 1. In the risk matrix method, the variables are not quantified but are classified by level. In this study, four levels were established for each variable.

The levels for the variables of frequency and the probability of barriers failing are high (H), medium (M), low (L) and very low (VL); the levels for the consequences variable are very high (VH), high (H), medium (M) and low (L). The criteria for assigning these levels are described in sections 2.2.1 to 2.2.4.

Although these levels are decided by a group of experts, this group is usually multidisciplinary, comprising the service's doctors, medical physicists, dosimetrists and radiotherapy technicians. The participation of various specialists makes the process more objective.

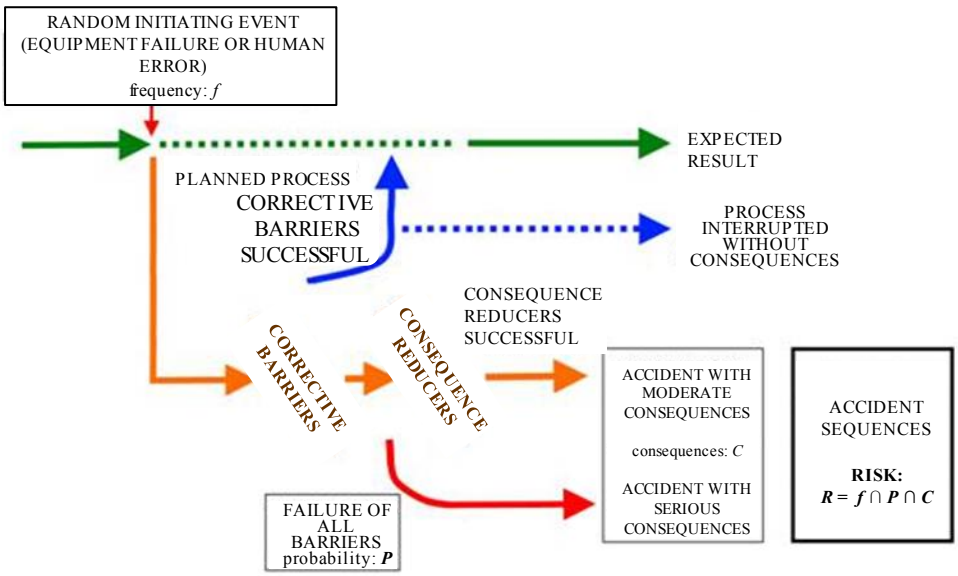


FIG. 1. Typical accidental exposure sequence.

2.2.1 How variables are combined

The risk matrix is a representation of all combinations of the levels for f, P and C and their resultant risk level. The risk level (R) is obtained by combining the different levels of the independent variables, i.e. the frequency of the initiating event (f), the probability of the defences in place failing (P) and the severity of the consequences (C), as follows:

First, two independent variables (f and P) are combined, and the result is then combined with the third variable, C, thereby giving a level for the dependent variable, i.e. the risk level. If the first two, f and P, have the same level (e.g. high), the resulting combination will have the same level (i.e. high). If the third variable has level H (high or serious consequences), the resulting combination of the three variables will have the same level i.e. the risk will be high, R_H.

If the independent variables have different levels, the combined level will lie between the two. For example, a high frequency with a very low probability will give a combined level of low. This low level combined with very serious or very high level consequences will result in a high risk level.

If no intermediate level exists, i.e. if the levels being combined are contiguous, a conservative criterion is generally applied. For instance, combining f_L with P_M should give a level between L and M, which does not exist. In this case, the higher level of the two is chosen, i.e. the medium level, M.

A conservative approach is taken in making this decision with a view to ensuring that, in case of doubt, the accident sequence will be selected by the matrix for further analysis, rather than being disregarded as a lower risk. In this way, all possible combinations of the three independent variables are compiled individually, with their resultant risk level to the right.

When the variables being combined have more than one intermediate level between them, it becomes necessary to choose between the two. Let us consider, for example, the combination $f_L \cap P_L \cap C_{VH}$. The level $f \cap P$ is L, and between this level and the consequence level, VH, there are two intermediate levels, M and H. In cases like this, the decision is based on giving greater weight to the probability level. In this example, it is L and, as we will see in due

course, this means that there are three barriers, which in general is sufficient for the risk of this sequence not to be high. None of the accidental exposure events with VH or catastrophic consequence levels had three barriers. As such, with this weighting given to P_L, the choice between H and M for the resulting risk level will tend towards M.

The three variables, each of which has four levels, can be combined in 64 different ways. These are arranged in the form of a matrix in Table 1 (the risk matrix). The four risk levels defined in this study are:

R_{VH}: Risk possibly "very high"
R_H: Risk possibly "high"
R_M: Risk "medium"
R_L: Risk "low"

The word "possibly" is used because, as explained above, the matrix is conservative, and the risk level that results from applying the matrix (first screening) is not definitive, that is to say, the real risk may be lower than that assigned by the matrix. The word "possibly" therefore needs to be included for R_{VH} and R_H. On the other hand, "possibly" does not need to be used for the two lower levels because, if the risk assigned is not high despite the conservative nature of the matrix, the real risk certainly will not be.

TABLE 1. RISK MATRIX

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_M
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_M
f_L	P_H	C_{VH}	R_H	f_L	P_H	C_H	R_H	f_L	P_H	C_M	R_M	f_L	P_H	C_L	R_M
f_{VL}	P_H	C_{VH}	R_H	f_{VL}	P_H	C_H	R_H	f_{VL}	P_H	C_M	R_M	f_{VL}	P_H	C_L	R_M
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_M
f_M	P_M	C_{VH}	R_H	f_M	P_M	C_H	R_H	f_M	P_M	C_M	R_M	f_M	P_M	C_L	R_M
f_L	P_M	C_{VH}	R_H	f_L	P_M	C_H	R_H	f_L	P_M	C_M	R_M	f_L	P_M	C_L	R_L
f_{VL}	P_M	C_{VH}	R_H	f_{VL}	P_M	C_H	R_M	f_{VL}	P_M	C_M	R_M	f_{VL}	P_M	C_L	R_L
f_H	P_L	C_{VH}	R_H	f_H	P_L	C_H	R_H	f_H	P_L	C_M	R_M	f_H	P_L	C_L	R_L
f_M	P_L	C_{VH}	R_H	f_M	P_L	C_H	R_H	f_M	P_L	C_M	R_M	f_M	P_L	C_L	R_L
f_L	P_L	C_{VH}	R_M	f_L	P_L	C_H	R_M	f_L	P_L	C_M	R_M	f_L	P_L	C_L	R_L
f_{VL}	P_L	C_{VH}	R_M	f_{VL}	P_L	C_H	R_M	f_{VL}	P_L	C_M	R_M	f_{VL}	P_L	C_L	R_L
f_H	P_{VL}	C_{VH}	R_H	f_H	P_{VL}	C_H	R_M	f_H	P_{VL}	C_M	R_M	f_H	P_{VL}	C_L	R_L
f_M	P_{VL}	C_{VH}	R_M	f_M	P_{VL}	C_H	R_M	f_M	P_{VL}	C_M	R_M	f_M	P_{VL}	C_L	R_L
f_L	P_{VL}	C_{VH}	R_M	f_L	P_{VL}	C_H	R_L	f_L	P_{VL}	C_M	R_L	f_L	P_{VL}	C_L	R_L
f_{VL}	P_{VL}	C_{VH}	R_M	f_{VL}	P_{VL}	C_H	R_L	f_{VL}	P_{VL}	C_M	R_L	f_{VL}	P_{VL}	C_L	R_L

2.2.2 Criterion for assigning frequency levels to initiating events

In studies of risk, it is assumed that initiating events occur randomly in time with a constant frequency (Poisson model). Records of incidents or accidents may give the most objective approximation for the frequency of a particular event, provided that the number of failures is averaged over a year. Regrettably, however, the existing records are not reliable enough to be taken as a basis for estimating frequency. For this reason, although numerical estimates do not have to be made in order to assign a guidance classification, if we wish to reduce the subjectivity of the experts, the frequency level can be assessed semiquantitatively using the

values for failure rates and the probabilities for human error published in the literature included in the bibliography [16–18].

In order to determine the frequency (***f***) of initiating events caused by equipment failure, the following equation may be used:

$$f = \frac{2n + 1}{2T} \qquad [4]$$

where:

n is the number of failures;

T is the period of time over which the failures occur (in years).

If initiating events are caused by human error, their frequency can be calculated using the following equation:

$$f = P_{HE}\, f_T \qquad [5]$$

where:

P_{HE} is the probability of human error in each task;

f_T is the annual frequency with which the task is performed.

The aforementioned literature gives values for failure rates for various types of equipment failure and probabilities of human error. Although not specific to the radiotherapy process, these values may be used to give a good approximation for the purposes of this study. Table 5 shows typical values for P_{HE} depending on the nature of the activity being performed.

In the methodology applied in this study, the values for the frequency of the initiating event are classified from very low to high, as follows:

- High frequency (f_H): the event occurs frequently;
- Medium frequency (f_M): the event occurs occasionally;
- Low frequency (f_L): it is unusual or rare for the initiating event to occur, although it is assumed to have occurred;
- Very low frequency (f_{VL}): it is very rare for the initiating event to occur. It is not known to have occurred, but it is considered a remote possibility.

In order to facilitate the assignment of levels and reduce subjectivity, the following semiquantitative criteria were used:

TABLE 2. CRITERIA FOR ASSIGNING FREQUENCY LEVELS

Qualitative frequency	Symbol	Probability of initiating event occurring	Number of events per year (based on a workload of 500 patients per year)
High	f_H	$P \geq 1/10$	More than 50 per year $f \geq 50$
Medium	f_M	$1/1000 < P < 1/10$	Between 1 and 50 per year $1 \leq f < 50$
Low	f_L	$1/100\,000 < P < 1/1000$	Between 1 per year and 1 every 100 years $0.01 \leq f < 1$
Very low	f_{VL}	$P < 1/100\,000$	Fewer than 1 every 100 years $f < 0.01$

When establishing frequency values for initiating events, the experience of participating countries was taken into account.

2.2.3 Criterion for assigning consequence severity levels

The criteria for establishing the severity levels of consequences for patients were defined specifically for this study, based on the magnitude of the dose deviations and the clinical manifestations expected in each case, after consulting various publications on the subject [2, 19].

In order to assign consequence severity levels (C), it was first assumed that an initiating event had already occurred and that all barriers had failed. The initiating events identified could have consequences for workers, patients and the public, although with a different impact in the case of patients, as they are always in the radiation beam or directly in contact with brachytherapy sources. Accordingly, two different consequence severity scales were devised: one for patients and another for workers and the public.

2.2.3.1 Severity of consequences for patients

1) Very high, catastrophic or very serious (C_{VH}): causing death or disabling injury to several patients. It is assumed that the magnitude of dosage errors is greater than 25% of the prescribed dose. May be caused by an underdose or an overdose.
2) High or serious (C_H): causing death or disabling injury to a single patient, affecting treatment in whole or in large part. This level also includes exposure affecting multiple patients where the dosage error is between 10 and 25% inclusive of the prescribed dose.
3) Medium or moderate (C_M): no clinical risk to the patient's life. Exposure affecting one patient during one session of treatment.
4) Low (C_L): defence in depth compromised. No deviation in dosage.

2.2.3.2 Severity of consequences for workers and the public

1) Very high, catastrophic or very serious (C_{VH}): causing severe deterministic effects, either fatal or causing permanent injury that reduces the quality of life of those affected.
2) High or serious (C_H): causing deterministic effects, but not life-threatening and causing no permanent injury affecting quality of life.
3) Medium or moderate (C_M): causing anomalous exposure (or exposure not normally expected, i.e. exposure that exceeds the dose restrictions or dose limit stipulated in regulations) that is below the threshold for deterministic effects. Represents only an increase in the probability of stochastic effects occurring.
4) Low (C_L): causing no effects on workers or the public but weakening safety measures.

2.2.4 Criterion for assigning the probability of failure of all barriers

Analysing a radiotherapy service's existing defences involves identifying what frequency reducers for initiating events, what direct barriers and what consequence reducers exist to prevent, control and mitigate each accident sequence analysed. In the risk matrix method, a level is assigned to the probability of failure of all direct barriers, which, as mentioned in section 2.1.4.2, serve to detect a particular initiating event and prevent an accident from occurring.

The probability of all barriers failing is given by the product of the probability of each of the existing barriers failing ($p = p_1 \cap p_2 \cap p_3 \cap \ldots \cap p_n$), assuming that the barriers are independent of one another. An important simplification in this method is that all barriers are independent

and have an equal probability of failure. Given that each p_i value is less than 1, the product, i.e. the total probability, decreases as the number of barriers increases. As such, decreasing values of p can be derived as a function of the increasing number of direct barriers, as shown below:

- High (P_H): there are no safety barriers;
- Medium (P_M): there are one or two safety barriers;
- Low (C_L): there are three safety barriers;
- Very low (P_{VL}): there are four or more safety barriers. There is sufficient defence in depth.

2.2.5 Criterion for preparing the list of initiating events

There are many methodologies for identifying the potential hazards associated with an activity. The main differences among them usually stem from the level of rigour and precision of the techniques and tools employed, the baseline information required and, as a consequence of all this, the level of detail of the results obtained.

The three most well known, systematic and structured methods for identifying initiating events are failure modes and effects analysis (FMEA), hazard and operability analysis (HAZOP), and what-if analysis. The task of identifying dangers must be undertaken for the entire process, systematically questioning each part of it with a view to identifying any possible hazard and its causes.

Two types of hazards or events can be identified:

- Events that trigger or initiate an accident. These must be intercepted by the defences in place to prevent or mitigate undesirable consequences;
- Events that cause one of the existing safety measures to fail. These lower the quality of the safety measures, which take effect as the initiating event develops into an accident.

In risk analysis, initiating events should be separated from defence failures so that evaluations can focus on analysing accident sequences triggered by initiating events. Moreover, the amount of detail obtained from applying the hazard identification technique is often very large, and initiating events are grouped to reduce them to a manageable number without losing any significant information.

The lists of initiating events given in Appendices I and III to this report are based on the results of FMEAs carried out at ^{60}Co external beam therapy units and linear accelerator units, as reported in Refs [10, 12]. The list of initiating events provided in the appendices was prepared as part of this study, based on an analysis using the what-if method applied to brachytherapy in a hypothetical radiotherapy service. In all cases, the generic lists prepared were supplemented with the following information[3]:

- Initiating events that occurred at other installations, as published [4–9];

[3] This list applies to the generic radiotherapy service defined in this study. As such, it must be adapted to the actual process used by the radiotherapy service in question, adding more initiating events if necessary or removing those that are not applicable.

- Participating experts' experience of events that occurred in participating countries, even if these events did not result in an accident thanks to safety devices and measures taking effect.

2.2.6 Obtaining the risk level for each accident sequence

Once the independent variables in the risk equation, f, P and C, have been evaluated and corresponding levels have been assigned, they are introduced into the risk matrix and the resulting risk is read directly from Table 1, based on the combination of levels for these independent variables. This process is carried out for each initiating event identified and a list of resulting risk levels for all accident sequences is thus obtained.

All sequences initially assigned with a high or very high risk level are selected for further analysis, which concludes the first screening phase referred to above. Methods for conducting further analysis, together with risk acceptability criteria, are described in sections 2.2.7 and 2.2.8. It should be noted that using this methodology makes it easier to classify accident sequences into risk levels, but it does not provide risk values. This means that two accident sequences falling in the same risk band or level do not necessarily have identical risk values.

2.2.7 Risk acceptability

Up to this point, the risk matrix methodology has been applied conservatively, not only because its rules for combining the levels of independent variables are conservative but also because, as described in section 2.2.3, assigning the level for the probability of all barriers failing is based only on the number of barriers and does not take account of their quality or robustness. The risk level assigned by the matrix may thus be higher than it actually is. This is intended to ensure that all sequences that might possibly require further analysis receive it. This conservative approach will be partly corrected by further study of the barriers' robustness, and by the presence of frequency and consequence reducers.

Once the first screening and analysis have been carried out, risk acceptability criteria are needed; any sequences that do not meet these criteria must have their safety measures enhanced. Priority is given first to adopting additional measures for accident sequences with a very high or high risk level. The second priority is to analyse events with a medium risk level, particularly those whose consequence severity levels are high or very high. This represents continuous improvement in the optimization process, increasing safety to a higher level.

TABLE 3. RISK ACCEPTABILITY CRITERIA AND CORRECTIVE ACTIONS

Risk band	Risk tolerability	Actions
R_{VH}	Unacceptable	The practice must be stopped and the necessary measures taken to reduce the risk before activities are resumed.
R_{H}	Unacceptable if the severity level of consequences is high or very high	Immediate measures are required to reduce the risk, otherwise the practice must be stopped.
	Unacceptable, temporarily tolerable under certain circumstances if the severity level of consequences is medium or low	Measures are required to reduce the risk within an appropriate time frame.
R_{M}	Tolerable depending on cost-benefit analysis	Improvements should be made or measures taken to reduce the risk as much as possible, taking into account cost-benefit criteria.
R_{L}	Negligible	No additional actions or safety measures are required.

2.2.8 Analysis of screening results and corrective actions

As explained above, the first step in analysis is to reconsider the risk level in the light of the quality and robustness of barriers and of frequency and consequence reducers. The aim is to ensure that all sequences meet the acceptability criterion. As a result, it should be possible to reclassify risk from an unacceptable to an acceptable level. In other words:

- For accident initiating events with very serious or very high-level consequences:
    a. If the frequency of the initiating event is medium, the probability of barriers failing must be very low;
    b. If the frequency of the initiating event is low, the probability of barriers failing must be low.
- For accident initiating events with high-level consequences:
    a. If the frequency of the initiating event is high, the probability of barriers failing must be very low;
    b. If the frequency of the initiating event is low, the probability of barriers failing must be low;
    c. If the frequency of the initiating event is very low, the probability of barriers failing must be medium.
- For accident initiating events with medium-level consequences:
    a. If the frequency of the initiating event is high, the probability of barriers failing must be low;
    b. If the frequency of the initiating event is medium, the probability of barriers failing must be medium;
    c. If the frequency of the initiating event is low, the probability of barriers failing may be high.

In order to carry out this analysis systematically, the methodology includes a set of key questions, which are listed below.

Questions to be answered in analysing sequences with an unacceptable risk level:

- Are the existing direct barriers sufficiently robust to assign a lower *P* level to the probability of all barriers failing than would be assigned under the criterion established in the methodology?
- Are the frequency and consequence reducers sufficiently robust to assign lower frequency and consequence levels, *f* and *C*, than would be assigned under the criterion established in the methodology?
- Is it possible to introduce new barriers or frequency or consequence reducers?
- What measures should be proposed to reduce the overall risk?

Measures taken to reduce the frequency of initiating events are linked to compliance with equipment maintenance policies and to lowering the probability of human error (staff selection and qualification, workload moderation, improvement of the working environment to avoid distractions and malpractice, and implementation of a quality assurance programme).

Measures to lower the probability of barriers failing are based on increasing the robustness of barriers and, where necessary, adding new ones. It is essential to ensure that barriers are used correctly and that compliance is monitored. Furthermore, in adding any barrier, the system as a whole must be considered, ensuring that the new barrier is harmonized with the others.

2.2.8.1 *First question: Are the existing direct barriers sufficiently robust to assign a lower P level to the probability of all barriers failing than would be assigned under the criterion established in the methodology?*

The objective of this first question in the analysis is to achieve a more realistic evaluation for the variable *P* in the risk equation, as the probability of all barriers failing depends greatly on the type of barrier that takes effect in the accident sequence being analysed.

Interlocks are the most robust form of barrier, followed by alarms and then procedures. Other important elements in evaluating the robustness of barriers are the principles of independence and diversity. For example, a group of barriers based on procedures is more robust if the actions detailed in the procedures are carried out by different people or at different stages or times.

In answering the first question, it is important to apply the criterion used by the radiotherapy experts who perform the evaluation. This is an indispensable element, as they are the ones most familiar with their practice. Table 4 shows a procedure that includes some factors for evaluating the robustness of a set of barriers and may serve as a reference to assist experts in answering this first question. These criteria for the robustness of barriers reveal whether the set of barriers is sufficiently robust. Below is an example of such criteria:

TABLE 4. CRITERIA FOR EVALUATING THE ROBUSTNESS OF A SET OF BARRIERS. RISK MATRIX METHODOLOGY

No.	Type of barrier	Robustness (in points)
1	Type 1 barriers: Interlocks	32
2	Type 2 barriers: Alarms	16
3	Type 3 barriers: Work procedures carried out by different people	8
4	Type 4 barriers: Work procedures carried out by the same person but at different stages or times	4

For the failure probability P_M:

- The set of barriers is considered robust if $P_1 \cap P_2 \geq 32$ points. This allows the probability to be reclassified from P_M to P_L;
- The set of barriers is considered to be very robust if $P_1 \cap P_2 > 64$ points. This allows the probability to be reclassified from P_M to P_{VL}.

For the failure probability P_L:

- The set of barriers is considered robust if $P_1 \cap P_2 \cap P_3 > 64$ points. This allows the probability to be reduced from P_L to P_{VL}.

2.2.8.2 *Second question. Robustness of reducers: Are the frequency and consequence reducers sufficiently robust to assign lower frequency and consequence levels, f and C, than would be assigned under the criterion established in the methodology?*

The objective of this analysis is to take account of the frequency and consequence reducers that form part of the defence in depth principle. Although these reducers were not taken into account in assigning levels to the variables *f* and *C*, any reduction in the levels of *f* and *C* implies a reduction in the resulting risk, such that if barriers are not robust enough, these reducers become key elements in reducing risk.

Frequency reducers

The importance of frequency reducers is very significant when the frequency assigned to initiating events is f_H, f_M or f_L, as the existence of at least three such reducers could suggest the possibility of classifying the frequency at a lower level than that initially assigned under the methodology. If the frequency assigned is f_{VL} it would not be effective to use frequency reducers, as this is the lowest frequency level within the methodology.

Consequence reducers

The importance of consequence reducers is very significant when the consequence severity level assigned to initiating events is C_H or C_{VH}. However, in these cases robustness cannot be measured only by the number of reducers, as it may be that these take effect once the expected consequences have already become apparent.

For example, even though the severity of consequences is reduced through annual and monthly quality ~~contr~~ol checks, the consequence severity level cannot be lowered from *very high* to *high*. This is because, although they reduce the number of patients affected and the magnitude of dose deviation, a number of patients still suffer serious consequences, resulting in death or disabling injury. As such, the effectiveness of a particular reducer in a specific accident sequence is more important than the number of consequence reducers. If the consequence severity level assigned is C_L or C_M it would not be very effective to use consequence reducers to achieve even lower levels.

2.2.8.3 Third question. Additional barriers and reducers: is it possible to introduce new barriers or new frequency or consequence reducers?

The aim of this analysis is to propose new safety measures to reduce the risk of the accident sequence in question. Suggestions for introducing new measures should be based on experience of international good practice and a cost-benefit criterion. Any new measure introduced implies a cost and the first two questions must therefore be answered before the measure is implemented. It is also necessary to bear in mind that any new safety measure must be harmonized with all the others and with the radiotherapy process itself.

2.2.8.4 Fourth question. Overall risk reduction and conclusions: what measures should be proposed to reduce the overall risk?

The answer to this question reveals which independent variable in the risk equation for each accident sequence (*f, P*, *C*) should be the focus of efforts to reduce risk to an acceptable safety level with the least expenditure of resources.

TABLE 5. TYPICAL VALUES FOR PROBABILITY OF HUMAN ERROR

Type of error	Type of behaviour	Nature of the task	Probability of human error
1	Extraordinary errors: not expected to be able to occur if an operator is not working under stress		10^{-5} (1 in 100 000)
2	Errors in simple tasks performed regularly in habitual places, with minimal stress		10^{-4} (1 in 10 000)
3	Errors of commission: e.g. pressing the wrong button or reading the screen incorrectly. Indicators include a task becoming more complex or less time being available	Simple but under stress	10^{-3} (1 in 1000)
		Complex but stress-free	3×10^{-3} (3 in 1000)
		Monotonous	9×10^{-3} (9 in 1000)

TABLE 5. TYPICAL VALUES FOR PROBABILITY OF HUMAN ERROR (cont.)

Type of error	Type of behaviour	Nature of the task	Probability of human error
4	Errors of omission: indicators are unfamiliar or complex tasks with little feedback and some distractions	Simple but under stress	10^{-2} (1 in 100)
		Complex but stress-free	3×10^{-2} (3 in 100)
		Complex and under stress	6×10^{-2} (6 in 100)
		Monotonous	9×10^{-2} (9 in 100)
5	Very complex tasks, considerable stress, little time available		10^{-1} (1 in 10)
6	Processes involving creative thought: complex and unfamiliar operations in which time is short and stress is high		10^{-1} to 1

These generic values based on types of task are taken from *Human error probability*, Annual Conference of Major Risk Facilities. Australia, 2008.

2.2.9 Analysis of the importance of barriers

The previous sections have covered the highest-risk accident sequences, which is useful in establishing an installation's risk profile, but there are other aspects to risk reduction such as the structural importance index. This is defined as the quotient between the number of sequences in which a barrier takes effect and the total number of sequences. This indicator is very useful: by identifying barriers that intervene after a large number of initiating events, the importance of keeping them operational can be evaluated, since focusing efforts on a single barrier would have an effect on the risk level of many initiating events.

3. DESCRIPTION OF THE GENERIC RADIOTHERAPY SERVICE TO WHICH THE METHOD WAS APPLIED

Once the methodology had been established, it was applied to a specific case. A generic radiotherapy service was envisaged, with characteristics such as might be found in the region, although the service is not necessarily representative of the region but rather of the highest level of service that may be expected. The service would include the following elements:

- The hypothetical service has enough radiotherapy doctors, medical physicists, and radiotherapy and mould technicians and a safety and quality assurance programme, with written procedures and a committee to monitor compliance;
- Equipment manuals are in the local language, in accordance with applicable IEC and ISO standards on accompanying documentation, the performance specifications and instructions for handling and maintenance, including translated instructions on protection and safety;
- The calibration of beams and radiation sources used in radiotherapy are traceable to a standards dosimetry laboratory;
- The quality assurance programme includes measuring physical parameters at commissioning and periodically thereafter, along with verifying relevant physical and clinical factors used in the diagnosis or treatment of patients, recording significant procedures and the results thereof in writing, and verifying that the calibration and operational state of dosimetry equipment are correct;
- There are guidelines for training radiation oncologists, medical physicists, and radiotherapy and mould technicians and technologists. In addition to education in the professional specialty, clinical practice and experience are covered, along with specific training on the apparatus being used, including the treatment planning system (TPS), the correct interpretation of dosimetry equipment calibration certificates and lessons learned from accidental exposure;
- There are procedures for the purchase and acceptance of equipment and accessories, and it is compulsory to validate changes to procedures that may have repercussions for dosage or dose distribution;
- Procedures are in place to remove obsolete or disused files or make them inaccessible;
- There are guidelines on keeping the workload moderate and creating conditions that facilitate conscious, careful work with no distractions.

It is assumed that full acceptance and commissioning tests are performed, along with periodic tests and tests following maintenance or repair. Periodic tests include the treatment geometry and radiation tests proposed in the revised version of IAEA-TECDOC-1040 (“Setting up a Radiotherapy Programme”) and IAEA-TECDOC-1151 [20, 21]. Tests are grouped as follows:

- Acceptance tests for diagnosis and treatment equipment and accessories, whereby all the specifications and compliance with the requirements of safety standards, such as those of the International Electrotechnical Commission (IEC), are verified;
- Commissioning tests to verify all the conditions and parameters for treatment, both in the treatment unit and in the planning and simulation system, and for the accessories;
- Periodic quality control tests, including physical and clinical aspects, tests following maintenance or repair, and written records in the form of procedures and test results;
- Safety critical verification, performed redundantly;
- Determination of absorbed dose in water, using local procedures based on international protocols such as those of the IAEA (TRS 277 or 398) [22, 23]. Dosimetry equipment similar to that required by IAEA-TECDOC-1040 (“Setting up a

Radiotherapy Programme") and IAEA-TECDOC-1151 [20, 21] is used. This determination is repeated by an independent person using a different measuring device;

- TLD postal dose audits and participation in intercomparisons. The initial postal audit and postal audits performed when sources are exchanged serve as a safety barrier if they are carried out and the results obtained before clinical use of the beam. Other audits serve to detect and lessen the consequences of any deviation;
- Determination of values for depth dose, symmetry and flatness tests, and field factors, and their comparison with the tables in BJR Supplement 25. Accessories, such as wedge and tray factors, are also measured, as is the effectiveness of immobilizers. The absorbed dose is also determined under reference conditions.

In commissioning the TPS, the protocols recommended by the IAEA, such as IAEA TRS 430 [24], are used, and a second, independent verification of the tables and basic parameters entered into the TPS during commissioning is carried out, along with manual verification of TPS calculations at specific points and measurements on phantom. Once the basic data have been introduced into the TPS, testing takes place, including:

- Manual calculation of absorbed dose at various points using the original basic data, compared with the results of TPS calculations made using the basic data entered into the system;
- Measurements on phantom to confirm the values calculated by the TPS for various configurations of beams and beam shapers.

When a computed tomography (CT) unit is used, whether within the radiotherapy service or in a diagnostic radiology service:

- There are procedures for calibrating the CT unit for radiotherapy, including geometric parameters such as density correction, using the Hounsfield scale, and use of CT images in the TPS.

In planning and preparing individual treatments:

- Standardized forms are used to collect and report treatment information. Independent verification (usually by the physicist) takes place for all treatment planning and manual calculations are made for one or two points;
- There are specific protocols for special treatment, such as emergencies or urgent cases treated with a single dose;
- Once planning is complete, a verification/simulation is carried out. Finally, the treatment is updated during the first session with the participation of the radiation oncologist, physicist, dosimetrist, radiotherapy technicians and mould technician, if relevant, including portal imaging. This update is repeated if changes are made to the treatment plan.

When treatment is given, use is made of the following:

- Redundant procedures for patient identification: identification carried by the patient and a photograph on the treatment chart;
- In vivo dosimetry, for accelerator treatment only (not for ^{60}Co teletherapy);
- Portal imaging (whether with electronic devices or portal imaging) performed during the first treatment session and weekly throughout the treatment process;
- Weekly verification of patient's treatment chart;
- Immobilizers and, if required, sedation for patients;
- Procedures to ensure that radiotherapy technicians observe the patient daily and that the radiation oncologist monitors patients weekly.

Elements that mitigate consequences, in the event that an initiating event results in accidental exposure:

- Daily observation of the patient by the operating technician;
- Weekly follow-up observation of the patient by the doctor;
- Weekly review of patient's treatment chart;
- Continuous observation of the patient through a lead glass window or via the viewing system TV monitor. Two technicians per piece of equipment on every shift. Use of intercom system for (two-way) communication with the patient. Emergency shutdown switch on the equipment.

In terms of maintenance and repair, the following measures are in place:

- A log of incidents involving the equipment;
- Requirement for control of the machine to be transferred between maintenance workers and radiotherapy staff, with a repair sheet, and for the physicist in charge to be notified so that the relevant parameters can be verified, depending on the repair carried out.

All these features of the generic service are reflected in the annexes, where the risk level is determined on the basis of initiating events, the frequency and consequences thereof, and the safety barriers in place.

4. RESULTS OF APPLYING THE METHOD TO EXTERNAL BEAM THERAPY TREATMENTS

4.1 GENERAL CONSIDERATIONS CONCERNING EVENTS WITH VERY SERIOUS CONSEQUENCES

Applying the risk matrix method to the generic radiotherapy service revealed that, in this service, events with catastrophic consequences in external beam therapy have a medium or low level risk. This is with the exception of one event concerning only ^{60}Co radiotherapy in cases involving manual treatment planning (^{60}Co PAC2.17 initiating event involves incorrect generation of data tables such as depth dose curves that are used in manual planning).

This means that failures at the teletherapy unit installation, calibration, commissioning, repair and maintenance stages, the potential consequences of which would affect multiple patients, have sufficient safety measures in place for this generic service. Some of the main examples of this type of event include those in San José, Costa Rica (beam calibration), Exeter, United Kingdom (lack of TPS commissioning programme), Riverside, USA (error in preparing dose rate data for all the treatments), Zaragoza, Spain (error in repairing an accelerator, followed by a failure to test the beam), Panama (change in the mode of use of a TPS without validation or tests before using it on patients), Białystok, Poland (power failure followed by anomalous indications on the control panel).

It is important to remember the main global safety measures included in the generic radiotherapy service which resulted from lessons learned from catastrophic events about which reports were published. These global measures include the following:

- Performance of two independent calibrations of the radiation beams. By independent, we mean that the calibration is performed by another person, with another instrument and, better still, using another method. A simple method which is within the reach of any radiotherapy service is a postal audit of dosimetry at the hospital, provided the result is received before the treatment of patients begins;
- During commissioning, independent verification of the basic data entered into the treatment planning system;
- During commissioning, verification of the TPS calculations via independent calculation of the absorbed doses at selected points and via measurements on a phantom;
- Preparation of written directives for the use of equipment without departing from the instructions. The guidelines should require that, when a departure from the usage instructions is unavoidable, the new way of using the equipment is validated and this is properly documented;
- Establishment of a procedure requiring that there be a written description of all maintenance work, repairs, software updates or any other change, and that this description is submitted to the person responsible for radiation physics before patient treatment is resumed so that the latter can decide which, if any, measurements need to be taken of the beam;
- Establishment of a procedure for removing obsolete files from the treatment planning system to prevent them from being used by mistake.

The sections below set out the results of applying the method, including more specific recommendations for treatment with linear accelerators and ^{60}Co units.

The fact that catastrophic events might be low risk in the generic service does not mean that these events can be disregarded; if one of the barriers identified in the study were to be weakened, or if the barriers were not in place in another service, the risk level of catastrophic events could rise to high, as shown in the following sections.

4.2 RADIOTHERAPY USING AN ACCELERATOR

This section sets out the principal results of applying the risk matrix method to radiotherapy treatments using external beams from an accelerator. The complete matrix is shown in Appendix I.

Following the methodology laid out in Chapter 2, the first screening involves evaluating the risk by deducing the probability of the barriers failing, based only on their number, without taking into account the robustness of each one. For events assigned a risk level of possibly high or very high, a detailed analysis is then performed of the quality of the barriers and the frequency and consequence reducers. The complete analysis is shown in Appendix I.

4.2.1 Statistical summary

Table 6 shows a statistical summary of applying the risk matrix method to treatments using external beams from electron accelerators.

TABLE 6. RESULTS SUMMARY OF APPLYING THE RISK MATRIX TO THERAPY WITH EXTERNAL BEAMS FROM AN ACCELERATOR

Number of events analysed		141		
With consequences for the patient	132		93.6%	
With consequences for the worker	5		3.5%	
With consequences for members of the public	4		2.8%	
With very serious consequences	45		32%	
With serious consequences	57		40%	
With moderate consequences	37		26%	
With low level consequences	2		1.4%	
Number of barriers analysed		100		
Number of frequency reducers analysed		37		
Number of consequence reducers analysed		26		
	First screening		Second screening	
Very high risk sequences	0	0%	0	0%
Very high risk with very serious consequences	0	0%	0	0%
Very high risk with serious consequences	0	0%	0	0%
Very high risk with moderate consequences	0	0%	0	0%
Very high risk with low level consequences	0	0%	0	0%
High risk sequences	27	19%	5	4%
High risk with very serious consequences	3	2%	0	0%

TABLE 6. RESULTS SUMMARY OF APPLYING THE RISK MATRIX TO THERAPY WITH EXTERNAL BEAMS FROM AN ACCELERATOR (cont.)

	First screening		Second screening	
High risk with serious consequences	20	14%	5	4%
High risk with moderate consequences	4	3%	0	0%
High risk with low level consequences	0	0%	0	0%
Medium risk sequences	104	74%	126	89%
Medium risk with very serious consequences	42	30%	45	32%
Medium risk with serious consequences	29	20%	44	31%
Medium risk with moderate consequences	31	22%	35	25%
Medium risk with low level consequences	2	1.4%	2	1.4%
Low risk sequences	10	7%	10	7%

Figure 2 displays these results in the form of graphs.

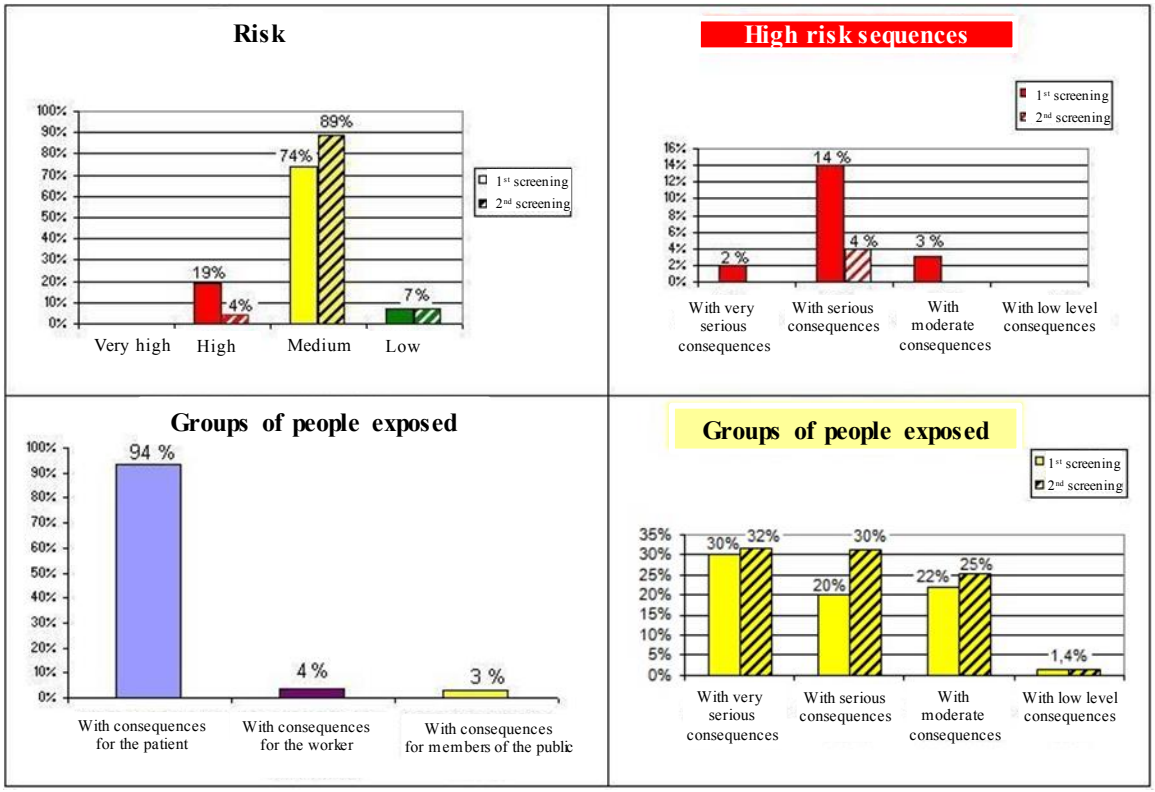


FIG. 2. Results summary of applying the risk matrix to radiotherapy using accelerators.

A list was generated of 141 possible initiating events that might cause accidental exposure. These events might occur at one of the stages in the treatment process, or during installation or commissioning. Of these 141 events, 93.6% would have consequences for the patient, 3.5% for the workers and 2.8% for members of the public.

Analysis was also performed for 100 direct barriers, 37 elements that help reduce the frequency of accident initiating events (frequency reducers) and 26 elements that could lessen the severity of potential consequences (consequence reducers).

As noted below, Table 6 shows that there are no very high risk sequences. We can also see that, after the second screening, the number of high risk sequences decreases (from 27 to 5) owing to the reclassification of 22 sequences to medium risk upon applying the methodology.

4.2.2 Events with very serious consequences

The 45 events identified in the study with catastrophic consequences have a medium or low level risk. However, if any of the barriers in place in this service were to be weakened, the risk level of events with very serious consequences could increase. Specifically, as can be seen in Table 7, of the 45 events with very serious consequences, there are 11 whose accident sequences would be reclassified as high risk if one of their barriers were to fail. Of these 11 accident sequences, eight would occur at the treatment unit commissioning and calibration stage, two would be related to the treatment planning system and computed tomography unit and one could result from a wide range of possible maintenance errors.

TABLE 7. INITIATING EVENTS WITH VERY SERIOUS CONSEQUENCES WHOSE RISK LEVEL WOULD CHANGE IF ONE BARRIER WERE TO FAIL

No.	Initiating event	f	C	No. of barriers	P		R	
					Baseline	With one barrier less	Baseline	With one barrier less
1	Error in the calibration coefficient of the dosimetry equipment (ionization chamber and electrometer) which leads to the dose/monitor unit ratio being determined incorrectly (PAC2.1)	f_{VL}	C_{VH}	3	P_L	P_M	R_M	R_H
2	Error in determining the calibration coefficient of the monitor chambers, which leads to the incorrect determination of the dose/monitor unit ratio (PAC2.5)	f_L	C_{VH}	3	P_L	P_M	R_M	R_H
4	Incorrect determination of field factors (PAC2.8)	f_L	C_{VH}	3	P_L	P_M	R_M	R_H
5	Incorrect determination of wedge transmission factors (PAC2.11)	f_{VL}	C_{VH}	3	P_L	P_M	R_M	R_H
6	Incorrect determination of multileaf collimator (MLC) transmission factors (PAC2.12)	f_{VL}	C_{VH}	3	P_L	P_M	R_M	R_H
7	Error in measuring the field profiles with wedges (physical, dynamic or virtual) (or points outside the centre of the beam) (PAC2.14)	f_{VL}	C_{VH}	3	P_L	P_M	R_M	R_H
8	Supply of ineffective patient immobilization devices (loose, inadequate fixation) (PAC2.17)	f_{VL}	C_{VH}	3	P_L	P_M	R_M	R_H
9	Error in recording the results of measurements taken during commissioning to be entered into the treatment planning system (TPS) (PAC2.18)	f_L	C_{VH}	3	P_L	P_M	R_M	R_H
10	Incomplete commissioning of CT unit, giving rise to errors in determining the density and geometry scales (PAC2.27)	f_{VL}	C_{VH}	3	P_L	P_M	R_M	R_H
11	Erroneous modification of equipment's critical parameters following maintenance or repair (PAC3.1)	f_L	C_{VH}	3	P_L	P_M	R_M	R_H

4.2.3 High risk events with serious consequences

A study of the risk matrix reveals events that are not catastrophic, but whose risk can be equally significant because they have a greater probability of occurring, even though they only affect a single patient. A characteristic of risk studies is that they do not examine only those events with the most serious consequences, but they also take into consideration the probabilities.

In the case of the hypothetical radiotherapy service, only five high risk initiating events were identified (see Table 6); it is highly probable, however, that other real services with fewer safety measures would have more high risk events. For each of these five initiating events, the variables that define the risk level (frequency (*f*), probability of barriers failing (*P*) and severity of potential consequences (*C*)) are presented.

TABLE 8. RELATIONSHIP BETWEEN HIGH RISK INITIATING EVENTS WITH SERIOUS CONSEQUENCES (second screening)

No.	Initiating event	*f*	*C*	*P*	*R*
	High risk events with serious consequences				
1	Failure to place reference marks from CT simulation on the patient or on immobilization devices, or their incorrect marking (PAC5.5)	f_M	C_H	P_M	R_H
2	Imprecise or wrong designation of volumes, stages, fractions and fields when editing the electronic treatment chart on the treatment computer (so-called case editing) (PAC9.2)	f_M	C_H	P_M	R_H
3	Incorrect placement of the patient on the treatment couch for the initial treatment session (PAC9.6)	f_M	C_H	P_M	R_H
4	Error in the final marking of the patient (PAC9.17)	f_L	C_H	P_H	R_H
5	Failure to make treatment plan changes resulting from the weekly evaluation of the patient by the radiation oncologist (PAC10.1)	f_L	C_H	P_M	R_H

As we can see, all of the high risk events are caused by human error; not one is a result of equipment failure. There are two reasons for this: 1) it has been assumed that the generic service's equipment complies with safety standards, such as those of the IEC, and that it includes a series of interlocks and alarms that reduce the probability of an accident caused by equipment failure to a minimum; and 2) the multidisciplinary nature of the treatment process (with a high dependence on human actions, in that communication among all the specialists plays a crucial role, and the many tasks and sub-tasks to be carried out every day, some of which are repetitive) means that errors might be made with considerable frequency. This tallies with the experience of accidents that have occurred in that, although some were initially caused by equipment failures, they were predominantly caused by human error. Each of the events is analysed briefly below:

– Initiating event PAC5.5: Failure to place reference marks from CT simulation on the patient or on immobilization devices, or their incorrect marking. =

  This event may occur during the anatomical data acquisition stage and, if it were not corrected, its consequences would be serious as they would affect a patient's entire course of treatment. The frequency of the initiating event is classified as medium, because it is assumed that it could occur more than once a year. In order to avoid the initiating event progressing, two barriers have been identified in the generic service, both of them part of

the initial treatment session: the first barrier is the positioning and immobilization of the patient in the presence of the radiation oncologist responsible for the patient, the medical physicist and the radiotherapy technicians, which facilitates the discovery of any error; the second barrier is the review of the portal images during this initial session by the radiation oncologist, who may also detect an error if the images do not correspond to the prescribed fields.

- Initiating event PAC9.2: Imprecise or wrong designation of volumes, stages, fractions and fields when editing the electronic treatment chart on the treatment computer (so-called case editing).

  When editing the electronic treatment chart, the radiotherapy technician must rename the volumes, phases, fractions and fields received from the TPS, adapting the names for the treatment unit, so that it can recognize them in daily treatment. This is necessary if the TPS and the treatment computer software are from different manufacturers, as is the case for the hypothetical service. The consequences of imprecise or wrong designation have been classified as serious, as they affect a patient's entire treatment. The barriers identified are in the initial treatment session, whereby the doctor, physicist and technician compare the data from the TPS with those on the electronic treatment chart to detect any errors. The technician will then review it during the daily administration of treatment, providing another opportunity to discover errors.

- Initiating event PAC9.6: Incorrect placement of the patient on the treatment couch for the initial treatment session.

  The consequences of this initiating event may be serious because the error occurring in the first session of treatment could be repeated in the remaining sessions. The barriers identified are both in the initial session; they consist of the radiation oncologist being present at the first positioning, and the review of the portal images by the radiation oncologist, also at the initial session.

- Initiating event PAC9.17: Error in the final marking of the patient.

  This error may occur at the end of the first positioning of the patient, and may comprise putting the marks, whether they be drawn on the skin or fiducial, outside the planning target volume (PTV), including normal tissue, possibly with critical organs. The consequences are assumed to be serious. In the generic service, there are no barriers against this initiating event.

- Initiating event PAC10.1: Failure to make the treatment plan changes prescribed by the radiation oncologist as a result of the weekly medical check.

  This event may occur when positioning the patient for daily treatment without taking into account a change prescribed by the radiation oncologist when carrying out one of the medical checks of the patient. The barrier identified takes effect in the daily administration of treatment; this barrier involves the technician being required to compare the initial data on the treatment chart from the TPS with the data on the electronic treatment chart to detect any errors.

4.2.4 Measures to reduce the risk of high risk initiating events

In Table 9, measures are proposed that would help reduce the risk of the initiating events discussed in section 4.2.3. First, possible safety barriers additional to the existing ones are listed; in cases where these are insufficient, account is taken of elements that reduce the frequency of the initiating event or its consequences, thus allowing the resulting risk level to be reduced.

TABLE 9. MEASURES TO REDUCE THE RISK OF HIGH RISK INITIATING EVENTS IN THE SECOND SCREENING

No.	Initiating event	Recommendations
1	Failure to place reference marks from CT simulation on the patient or on immobilization devices, or their incorrect marking (PAC5.5)	Another radiotherapy technician (not the same one that performed the CT) should independently review the reference marks from the CT
2	Imprecise or wrong designation of volumes, stages, fractions and fields when editing the electronic treatment chart on the treatment computer (so-called case editing) (PAC9.2)	Another radiotherapy technician (not the same one that edited the data) should independently review the treatment data editing
3	Incorrect placement of the patient on the treatment couch for the initial treatment session (PAC9.6)	Include on the treatment chart a photograph showing the exact positioning during CT simulation
4	Error in the final marking of the patient (PAC9.17)	No additional barriers have been identified, but the consequences can be reduced, i.e. they can be prevented from becoming serious, through the following: 1. Weekly medical checks by the radiation oncologist; 2. Observation of anomalous signs, such as skin pigmentation in the wrong place, by radiotherapy technicians; 3. Weekly portal imaging.
5	Failure to make treatment plan changes resulting from the weekly evaluation of the patient by the radiation oncologist (PAC10.1)	No additional barriers have been identified, but the consequences can be reduced, i.e. they can be prevented from becoming serious, through the following: 1. Weekly medical checks by the radiation oncologist; 2. Observation of anomalous signs, such as skin pigmentation in the wrong place, by radiotherapy technicians.

4.2.5 Analysis of the importance of barriers

Table 10 shows the list of barriers, in order of decreasing importance, as defined in Chapter 2.

TABLE 10. IMPORTANCE OF BARRIERS

No.	Barrier	Initiating events in which this barrier intervenes	
		No.	%
1	In vivo dosimetry at the initial treatment session to verify that the administered doses correspond to the planned doses, thus allowing dose administration errors to be detected.	36	26%
2	Portal imaging during the initial treatment session, for evaluation by the radiation oncologist and medical physicist in order to detect errors in the treatment geometry.	36	26%
3	Placement and immobilization of the patient in the treatment position for the initial session in the presence of the radiation oncologist, medical physicist and radiotherapy technicians.	27	19%
4	Daily testing of reference dose constancy and evaluation of beam quality, as part of QA checks.	23	16%
5	Joint evaluation of the dosimetry plan by the radiation oncologist and medical physicist.	23	16%
6	Use of test cases to compare, during commissioning, the doses calculated by the TPS with direct measurements.	22	16%
7	Independent verification of calculations from dosimetry planning of patient treatment, to be performed by a different medical physicist from the one that carried out the planning.	17	12%

TABLE 10. IMPORTANCE OF BARRIERS (cont.)

No.	Barrier	Initiating events in which this barrier intervenes	
		No.	%
8	Two independent beam calibrations, by different people and using different dosimetry equipment.	16	11%
9	Interlocks of the accelerator dosimetry control system that prevent the machine functioning when the dose does not correspond with the expected value (dosimetry interlock).	15	11%
10	Treatment simulation, whether virtual or real, allowing the detection of errors in geometry and positioning of the patient.	14	10%
11	Verification that the field light coincides with the field marks on the patient's skin.	10	7%
12	Manual record, independent of the treatment computer, by the radiotherapy technician.	10	7%
13	Delineation of volumes and critical organs in the treatment planning system by the radiation oncologist, whereby errors made in prior stages can be detected, i.e. during prescription of treatment or anatomical data collection.	9	6%
14	Redundant verification by another medical physicist of the data entered into the TPS.	8	6%
15	Treatment record and verify system which checks all the information about treatment administered to a patient in order to detect possible inconsistencies.	8	6%

The table below evaluates the effect on risk level when the barriers that intervene in over 15% of initiating events are removed (one at a time). There are also details of which initiating events would have their risk level changed upon the removal of each barrier. Initiating events whose risk level does not vary are less vulnerable if a single barrier fails.

TABLE 11. EFFECT OF REMOVING A BARRIER

Barrier being removed: In vivo dosimetry at the initial treatment session to verify that the administered doses correspond to the planned doses, thus allowing dose administration errors to be detected.

No.	Initiating events in which the barrier intervenes and whose risk level changes	Baseline risk level	Risk level without barrier
1	Error in the calibration coefficient of the dosimetry equipment (ionization chamber and electrometer) which leads to the dose/monitor unit ratio being determined incorrectly (PAC2.1)	R_M	R_H
2	Error in determining the calibration coefficient of the monitor chambers, which leads to the incorrect determination of the dose/monitor unit ratio (PAC2.5)	R_M	R_H
3	Error in determining the relative dose values (indices of uniformity, penumbra, homogeneity or symmetry, percentage depth dose, which are used as a basis for characterizing the beam energy) (PAC2.6)	R_M	R_H
4	Incorrect determination of field factors (PAC2.8)	R_M	R_H
5	Incorrect determination of wedge transmission factors (PAC2.11)	R_M	R_H
6	Incorrect determination of multileaf collimator transmission factors (PAC2.12)	R_M	R_H
7	Error in measuring the field profiles with wedges (physical, dynamic or virtual) (or off-axis points) (PAC2.14)	R_M	R_H
8	Error in recording the results of measurements taken during commissioning to be entered into the treatment planning system (TPS) (PAC2.18)	R_M	R_H
9	Incomplete commissioning of CT unit, giving rise to errors in determining the density and geometry scales (PAC2.27)	R_M	R_H

TABLE 11. EFFECT OF REMOVING A BARRIER (cont.)

Barrier being removed: In vivo dosimetry at the initial treatment session to verify that the administered doses correspond to the planned doses, thus allowing dose administration errors to be detected.

No.	Initiating events in which the barrier intervenes and whose risk level changes	Baseline risk level	Risk level without barrier
10	Accidental selection of a treatment unit that is not the intended one during the planning process (linac from another facility or from the service modelled in the TPS) (PAC7.3)	R_M	R_H
11	Configuration of the wrong number of fields (PAC7.8)	R_M	R_H
12	Error in drawing up the dosimetry and geometric aspects of the treatment plan, or in the protection of critical organs and normal tissue (PAC7.10)	R_M	R_H
13	Incorrect preparation of customized shaping blocks (PAC8.2)	R_L	R_M
14	Incorrect positioning of the blocks on the tray (PAC8.3)	R_L	R_M

Barrier being removed: Portal imaging during the initial treatment session, for evaluation by the radiation oncologist and medical physicist, whereby errors in the treatment geometry can be detected.

No.	Initiating events in which the barrier intervenes and whose risk level changes	Baseline risk level	Risk level without barrier
1	Supply of faulty patient immobilization devices (loose, inadequate fixation) (PAC2.17)	R_M	R_H
2	Incomplete commissioning of CT unit, with errors in the density and geometric scales (PAC2.27)	R_M	R_H
3	Error in identification or placement of immobilization devices during CT simulation (PAC5.2)	R_M	R_H
4	Use of the wrong references for CT simulation (PAC5.3)	R_M	R_H
5	Performance of CT simulation with the wrong geometric parameters (PAC5.4)	R_M	R_H
6	Incorrect positioning of the patient on the CT simulation couch through omission of the exact details of the case, or incorrect positioning of the patient, leading to an error in the CT images (PAC5.6)	R_M	R_H
7	Error through a change in information when transferring images from the CT simulation to the TPS (PAC5.7)	R_L	R_M
8	Acquisition of the wrong image through faults in the CT unit (PAC5.9)	R_M	R_H
9	Error in identification of the patient when preparing the treatment plan. Treatment planning for one patient using the data for another patient (PAC6.1)	R_M	R_H
10	Incorrect designation of the volumes (GTV (gross tumour volume) as CTV (clinical target volume) or vice versa) delineated in the TPS, through the wrong use of the acronym or colour code agreed upon in the service (PAC6.2)	R_M	R_H
11	Selection of the wrong beam orientation (PAC7.6)	R_M	R_H
12	Incorrect shaping of the treatment field when using the multileaf collimator and setting the collimator angle (PAC7.7)	R_M	R_H
13	Error in drawing up the dosimetry and geometric aspects of the treatment plan, or in the protection of critical organs and normal tissue (PAC7.10)	R_M	R_H
14	Failure to prepare the customized shaping blocks (PAC8.1)	R_L	R_M
15	Incorrect preparation of the customized shaping blocks (PAC8.2)	R_L	R_M
16	Incorrect positioning of the blocks on the tray (PAC8.3)	R_L	R_M
17	Incorrect selection of the angles of the treatment couch at the initial treatment session (PAC9.9)	R_M	R_H
18	Error in the placement of the shaping blocks (PAC9.10)	R_M	R_H

TABLE 11. EFFECT OF REMOVING A BARRIER (cont.)

Barrier being removed: Presence of the radiation oncologist, medical physicist and radiotherapy technicians when placing and immobilizing the patient in the treatment position for the initial session.

No.	Initiating events in which the barrier intervenes and whose risk level changes	Baseline risk level	Risk level without barrier
1	Omission from the treatment chart of dose values for organs at risk, or recording of the wrong values (PAC4.5)	R_M	R_H
2	Omission from the treatment chart of secondary volumes prescribed if there are various locations (PAC4.6)	R_M	R_H
3	Incorrect identification or placement of immobilization devices when performing CT simulation (PAC5.2)	R_M	R_H
4	Use of the wrong references when performing CT simulation (PAC5.3)	R_M	R_H
5	Performance of CT simulation with the wrong geometric parameters (PAC5.4)	R_M	R_H
6	Failure to note exact positioning details when placing the patient for CT simulation, or incorrect positioning of the patient, causing an error in the CT images (PAC5.6)	R_M	R_H
7	Error through a change in information when transferring images from the CT simulation to the TPS (PAC5.7)	R_L	R_M
8	Incorrect identification of the patient when preparing the treatment plan, and planning of treatment for one patient using the data for another (PAC6.1)	R_M	R_H
9	Failure to designate one or several secondary CTVs in the TPS (PAC6.3)	R_M	R_H
10	Selection of a different type of radiation from the one prescribed (photons instead of electrons or vice versa) (PAC7.4)	R_M	R_H
11	Selection of a different energy beam from the one prescribed (PAC7.5)	R_M	R_H
12	Selection of the wrong beam orientation (PAC7.6)	R_M	R_H
13	Incorrect shaping of the treatment field when using the multileaf collimator and setting the collimator angle (PAC7.7)	R_M	R_H
14	Configuration of the wrong number of fields (PAC7.8)	R_M	R_H
15	Incorrect selection of the angles of the treatment couch at the initial treatment session (PAC9.9)	R_M	R_H

Barrier being removed: Daily testing of reference dose constancy and evaluation of beam quality, as part of QA checks.

No.	Initiating events in which the barrier intervenes and whose risk level changes	Baseline risk level	Risk level without barrier
1	Error in the calibration coefficient of the dosimetry equipment (ionization chamber and electrometer) which leads to the dose/monitor unit ratio being determined incorrectly (PAC2.1)	R_M	R_H
2	Incorrect modification of equipment's critical parameters following maintenance or repair (PAC3.1)	R_M	R_H
3	Equipment failure, causing a variation in the energy of the electron beams generated by the accelerator (PAC10.29)	R_M	R_H
4	Equipment failure, causing a variation in the energy of the photon beams generated by the accelerator (PAC10.30)	R_M	R_H
5	Equipment failure that gives rise to a variation in the dose/monitor unit relationship, for the various energies of photon beams from the accelerator (PAC10.31)	R_M	R_H
6	Equipment failure, causing a variation in the dose/monitor unit relationship, for each energy of electron beams from the accelerator (PAC10.32)	R_M	R_H
7	Equipment failure, causing a variation in the symmetry of the electron beams of various energies (PAC10.33)	R_M	R_H
8	Equipment failure, causing a variation in the symmetry of the photon beams of various energies (PAC10.34)	R_M	R_H
9	Equipment failure, causing a variation in the flatness of the electron beams of various energies (PAC10.35)	R_M	R_H

TABLE 11. EFFECT OF REMOVING A BARRIER (cont.)

Barrier being removed: Daily testing of reference dose constancy and evaluation of beam quality, as part of QA checks.

No.	Initiating events in which the barrier intervenes and whose risk level changes	Baseline risk level	Risk level without barrier
10	Equipment failures that cause a variation in the flatness of the photon beams of various energies (PAC10.36)	R_M	R_H
11	Rotation of the primary collimator to an unintended position (PAC10.40)	R_M	R_H
12	Incorrect positioning of the multileaf collimator (MLC) leaves (PAC10.44)	R_M	R_H
13	Incorrect delimitation of the field through a fault in the diaphragms of the rectangular field (PAC10.45)	R_M	R_H

Barrier being removed: Use of test cases to compare, during commissioning, the doses calculated by the TPS with direct measurements

No.	Initiating events in which the barrier intervenes and whose risk level changes	Baseline risk level	Risk level without barrier
1	Error in determining the relative dose values, giving rise to an incorrect beam energy value (indices of uniformity, penumbra, homogeneity or symmetry, percentage depth dose) (PAC2.6)	R_M	R_H
2	Incorrect determination of field factors (PAC2.8)	R_M	R_H
3	Incorrect determination of wedge transmission factors (PAC2.11)	R_M	R_H
4	Incorrect determination of multileaf collimator (MLC) transmission factors (PAC2.12)	R_M	R_H
5	Error in measuring the field profiles with wedges (physical, dynamic or virtual) (or off-axis points) (PAC2.14)	R_M	R_H
6	Incorrect recording of measurement results to be entered into the treatment planning system (TPS) (PAC2.18)	R_M	R_H
7	Incomplete commissioning of CT unit, by failing to determine the density and geometric scales or making mistakes in the scales (PAC2.27)	R_M	R_H

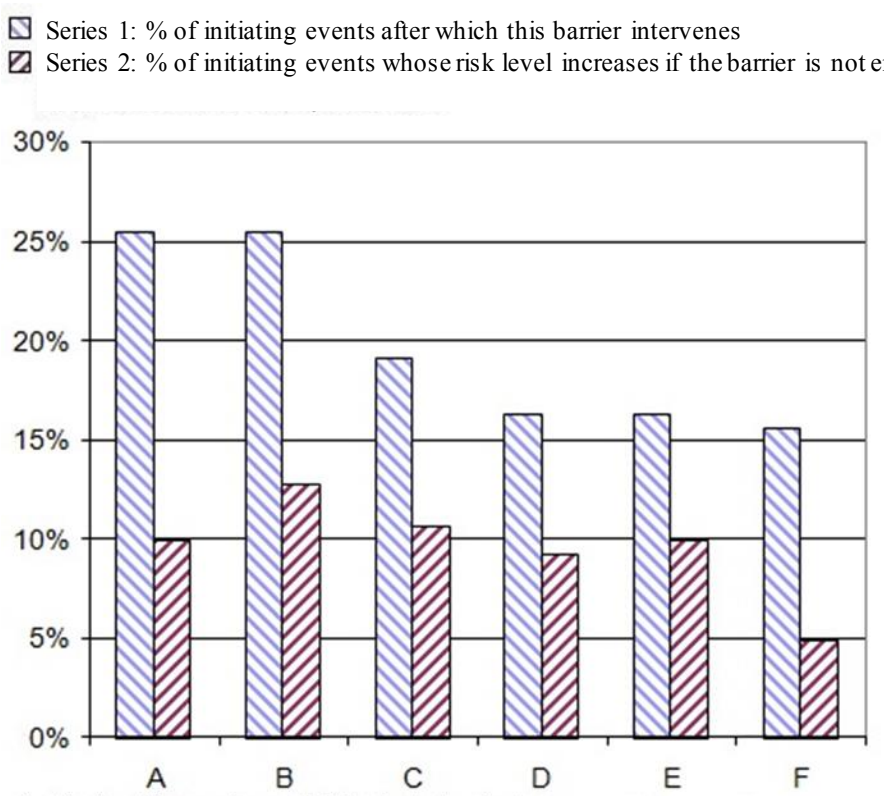
Barrier being removed: Joint evaluation of the dosimetry plan by the radiation oncologist and medical physicist.

No.	Initiating events in which the barrier intervenes and whose risk level changes	Baseline risk level	Risk level without barrier
1	Incorrect designation of the volumes (GTV as CTV or vice versa) delineated in the TPS, through wrong use of the acronym or colour code agreed upon in the service (PAC6.2)	R_M	R_H
2	Failure to designate one or several secondary CTVs in the TPS (PAC6.3)	R_M	R_H
3	Accidental selection of a treatment unit from another service or from the service modelled in the TPS during the planning process (PAC7.3)	R_M	R_H
4	Erroneous selection of a different type of radiation from the one prescribed (photons instead of electrons or vice versa) (PAC7.4)	R_M	R_H
5	Erroneous selection of a different beam energy from the one prescribed (PAC7.5)	R_M	R_H
6	Selection of the wrong beam direction (PAC7.6)	R_M	R_H
7	Incorrect shaping of the treatment field when using the multileaf collimator and setting the collimator angle (PAC7.7)	R_M	R_H
8	Configuration of the wrong number of fields (PAC7.8)	R_M	R_H
9	Error in the dosimetry and geometric planning of treatment, leading to inadequate protection of critical organs and normal tissue (PAC7.10)	R_M	R_H
10	Indication on the treatment chart of a different total treatment dose value from the one given in the clinical prescription of treatment (PAC4.2)	R_M	R_H

TABLE 11. EFFECT OF REMOVING A BARRIER (cont.)

Barrier being removed: Joint evaluation of the dosimetry plan by the radiation oncologist and medical physicist.			
No.	Initiating events in which the barrier intervenes and whose risk level changes	Baseline risk level	Risk level without barrier
11	Indication on the treatment chart of a different daily dose value from the one given in the clinical prescription (PAC4.3)	R_M	R_H
12	Indication on the treatment chart of a different dose fractionation value from the one given in the clinical prescription (PAC4.4)	R_M	R_H
13	Omission from the treatment chart of the value for permissible dose to organs at risk (OAR), or recording of an incorrect value (PAC4.5)	R_M	R_H
14	Omission from the treatment chart of a secondary treatment volume given in the clinical prescription, in the event that there are various locations (PAC4.6)	R_M	R_H

Below is a graph showing the importance of six of the barriers, in terms of the percentage of initiating events in which each one intervenes, and the percentage of initiating events whose risk level increases if the barrier fails.



A: In vivo dosimetry at the start of treatment
B: Portal imaging at the start of treatment
C: Initial treatment session attended by the radiation oncologist responsible for the case, along with the medical physicist and the radiotherapy technicians
D: QA dosimetric testing
E: Evaluation and approval of the treatment plan by the radiotherapy oncologist and medical physicist
F: Comparison, in test cases, between the doses calculated by the TPS and direct measurements taken during TPS commissioning

FIG. 3. Importance of the barriers and effect of their removal.

4.2.6 Analysis of the importance of consequence reducers

In the same way that the importance of the barriers has been analysed, the importance of the consequence reducers has also been analysed. Although these reducers do not prevent accidental exposure from occurring, they are crucial in mitigating the consequences of many such incidents. If this review is not carried out, or it is carried out without detecting possible anomalies, the consequences may be serious.

TABLE 12. IMPORTANCE OF CONSEQUENCE REDUCERS (>5%)

No.	Consequence reducer	Initiating events in which it intervenes	
		No.	%
1	Weekly medical review of the patient, whereby errors in the administration of treatment or in previous stages can be detected	100	71%
2	Daily positioning of the patient, whereby the radiotherapy technicians may detect errors in geometry or dose through visual signs (discolouration of skin, etc.)	66	47%
3	Weekly in vivo dosimetry in order to detect errors in the administered dose	38	27%
4	Periodic testing of reference dose constancy and evaluation of beam quality, as part of QA checks	33	23%
5	Weekly portal imaging, whereby errors in geometry can be detected	27	19%
6	QA testing of the TPS. If inconsistencies are detected during quality control of the TPS, in the testing performed periodically (daily, weekly, monthly, quarterly and annually), treatment is stopped	11	8%

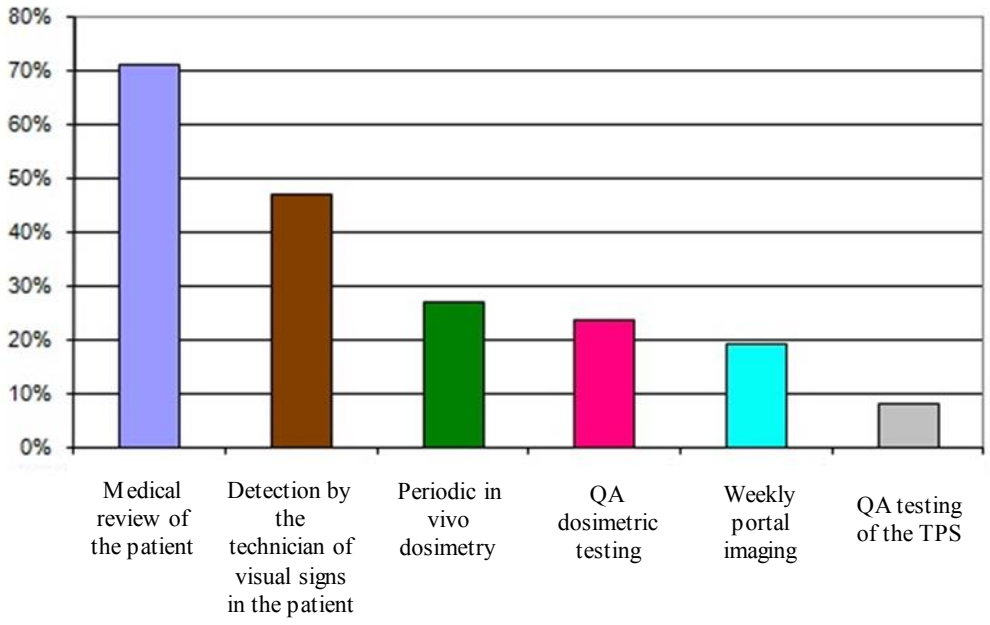


FIG. 4. Importance of consequence reducers.

4.3 ^{60}CO EXTERNAL BEAM RADIOTHERAPY

This section sets out the principal results of applying the risk matrix method to ^{60}Co external beam radiotherapy treatments. The complete matrix is shown in Appendix II.

Following the methodology laid out in Chapter 2, the first screening involves evaluating the risk by deducing the probability of the barriers failing, based only on their number, without taking into account the robustness of each one. For events assigned a risk level of possibly high or very high in the first screening, a detailed analysis is then performed of the quality of the barriers and the frequency and consequence reducers. The complete analysis is shown in Appendix II.

Logically, many of the results are compatible with those for treatment using accelerators as they share the same stages; however, we have chosen to keep the two sections separate for ease of reading for those services that have one or other type of equipment.

4.3.1 Statistical summary

Table 13 shows a statistical summary of applying the risk matrix method to ^{60}Co external beam treatments.

TABLE 13. RESULTS SUMMARY FOR THE ^{60}Co RISK MATRIX

Number of events analysed		132		
With consequences for the patient	121		92%	
With consequences for the worker	7		5%	
With consequences for members of the public	4		3%	
With very serious consequences	28		21%	
With serious consequences	54		41%	
With moderate consequences	49		37%	
With low level consequences	1		1%	
Number of barriers analysed		91		
Number of frequency reducers analysed		41		
Number of consequence reducers		50		
	First screening		Second screening	
Very high risk sequences	0	0%	0	0%
Very high risk with very serious consequences	0	0%	0	0%
Very high risk with serious consequences	0	0%	0	0%
Very high risk with moderate consequences	0	0%	0	0%
Very high risk with low level consequences	0	0%	0	0%
High risk sequences	49	37%	16	12%
High risk with very serious consequences	12	9%	1	1%
High risk with serious consequences	31	23%	12	9%
High risk with moderate consequences	6	5%	3	2%
High risk with low level consequences	0	0%	0	0%
Medium risk sequences	77	58%	110	83%
Medium risk with very serious consequences	16	12%	27	20%
Medium risk with serious consequences	19	14%	38	29%
Medium risk with moderate consequences	41	31%	44	33%
Medium risk with low level consequences	1	1%	1	1%
Low risk sequences	6	5%	6	5%

Figure 5 summarizes these results in the form of graphs.

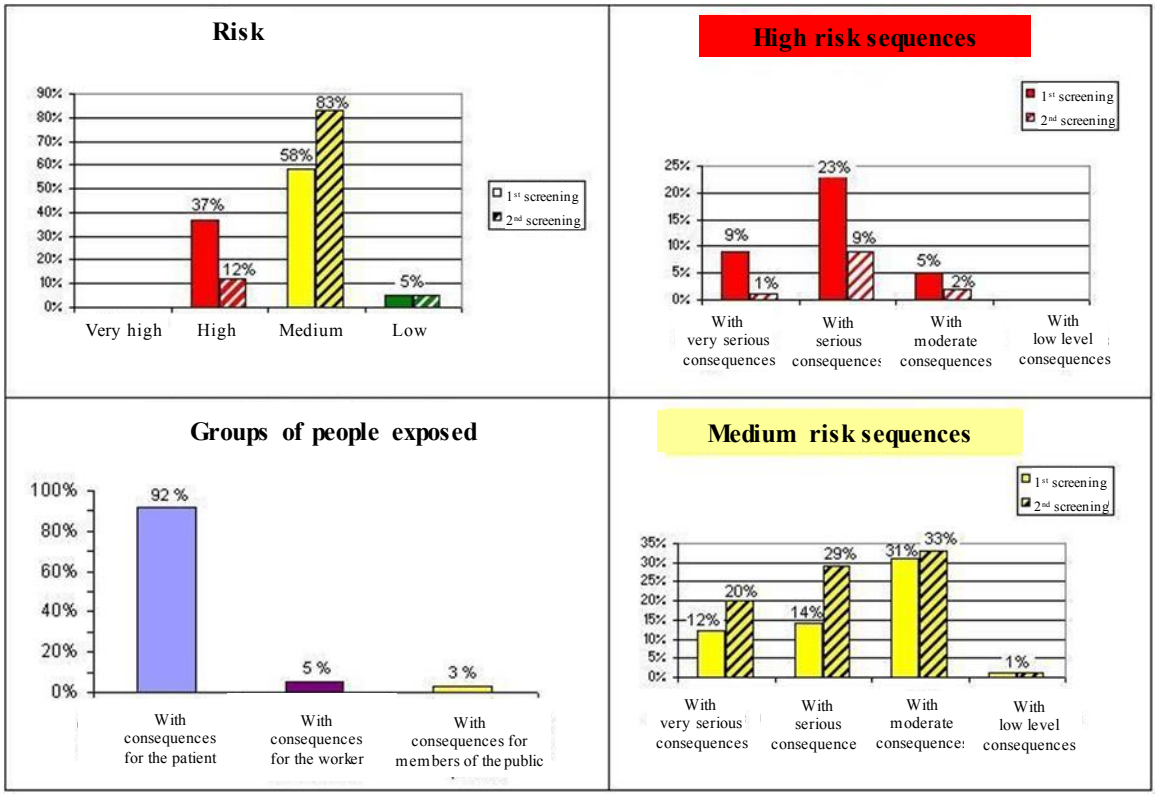


FIG. 5. General results of applying the risk matrix to ^{60}Co radiotherapy.

In the study, a list was generated of 132 initiating events that might cause accidental exposure. These events could occur at one of the stages in the treatment process, or during installation or commissioning. Of these 132 events, 92% would have consequences for the patient, 5% for the workers and 3% for members of the public.

Analysis was also performed for 91 direct safety barriers, 41 elements that help reduce the frequency of accident initiating events (frequency reducers) and 50 elements that could lessen the severity of potential consequences (consequence reducers).

4.3.2 Events with very serious consequences

Only one of the initiating events with very serious consequences was classified as high risk; this event is related to treatment planning using manual methods. Table 14 contains an analysis of what would happen in the events with very serious consequences if the barriers were to be weakened. Only one barrier in one of the 28 events with very serious consequences needs to fail for 15 accident sequences to become high risk. Of these 15 accident sequences, nine would occur at the machine commissioning and calibration stage, and six are related to the TPS.

TABLE 14. INITIATING EVENTS WITH VERY SERIOUS CONSEQUENCES WHOSE RISK LEVEL WOULD CHANGE IF SOME OF THE INITIAL BARRIERS WERE TO BE WEAKENED OR REMOVED

No.	Initiating event	f	C	No. of barriers	P		R	
					Baseline	With one barrier less	Baseline	With one barrier less
1	Error by the manufacturer in the source manufacturer's certificate (PAC1.3)	f_{VL}	C_{VH}	3	P_L	P_M	R_M	R_H
2	Radioactive source getting stuck during its exchange or loading (POE1.1)	f_{VL}	C_{VH}	3	P_L	P_M	R_M	R_H
3	Error when using the calibration certificate, e.g. taking of calibration coefficient, confusion of units mGy-cGy, confusion of N_k with $N_{D,w}$, P_o and T_o (PAC2.2)	f_L	C_{VH}	3	P_L	P_M	R_M	R_H
4	Misreading of decimal places on the timer during beam calibration (PAC2.5)	f_{VL}	C_{VH}	3	P_L	P_M	R_M	R_H
5	Error with the geometric parameters of the radiation beam (size of radiation field, coincidence of light field and radiation field, effective source position, beam verticality) (PAC2.8) NB: the generic radiotherapy service is assumed not to include in vivo dosimetry for radiotherapy treatments	f_L	C_{VH}	3	P_L	P_M	R_M	R_H
6	Incorrect determination of field factors (PAC2.9)	f_L	C_{VH}	3	P_L	P_M	R_M	R_H
7	Error in determining the geometric and mechanical parameters of the treatment unit (axis of rotation and translation, angular and linear scales, optical distance indicator, light indicator of beam axis (cross-hair), verification of laser indicators) (PAC2.10)	f_L	C_{VH}	3	P_L	P_M	R_M	R_H
8	Error in measuring the field and wedge profiles (or points outside the beam) (PAC2.14)	f_{VL}	C_{VH}	3	P_L	P_M	R_M	R_H
9	Supply of faulty patient immobilization devices (loose, inadequate fixation) (PAC2.15)	f_L	C_{VH}	3	P_L	P_M	R_M	R_H
10	Incorrect configuration of wedges during commissioning of the TPS	f_L	C_{VH}	3	P_L	P_M	R_M	R_H
11	Incorrect configuration of the shaping blocks and trays during commissioning of the TPS (PAC2.19)	f_L	C_{VH}	3	P_L	P_M	R_M	R_H
12	Incorrect configuration of the compensators or bolus during commissioning of the TPS (PAC2.20)	f_L	C_{VH}	3	P_L	P_M	R_M	R_H
13	Error in the ^{60}Co beam characterization and output data in the TPS (PAC2.21)	f_{VL}	C_{VH}	3	P_L	P_M	R_M	R_H
14	Error in entering the field factors into the TPS (PAC2.23)	f_L	C_{VH}	3	P_L	P_M	R_M	R_H
15	Changes in the mode of use of the treatment planning system (TPS) without validating the new mode before using it in the TPS for patient treatment planning (PAC7.2)	f_L	C_{VH}	3	P_L	P_M	R_M	R_H

4.3.3 List of high risk events

In the generic radiotherapy service, 16 initiating events have been identified as high risk. These are presented in the list below.

TABLE 15. LIST OF HIGH RISK INITIATING EVENTS (SECOND SCREENING)

No.	Initiating event	f	C	P	R
	High risk events with very serious consequences				
1	Incorrect generation of tables containing treatment planning data (e.g. depth dose curves) which are used in manual planning (PAC2.17). NB: this event relates to manual planning without the use of a TPS	f_{VL}	C_{VH}	P_M	R_H
	High risk events with serious consequences				
1	Failure to place reference marks from CT simulation on the patient or on immobilization devices, or their incorrect marking (PAC5.5)	f_M	C_H	P_M	R_H
2	Error in obtaining the anatomical contour of the patient, resulting in distortion of the contour's size and shape (when this is obtained manually, from the patient directly) (PAC5.10)	f_M	C_H	P_M	R_H
3	Incorrect use of the TPS when preparing the treatment plan for a specific patient (PAC7.1)	f_M	C_H	P_M	R_H
4	Selection of the wrong data when planning treatment, such as data for a different source from the one in the equipment, or for other equipment modelled in the TPS (PAC7.3)	f_M	C_H	P_M	R_H
5	Entry of incorrect data into the TPS for the calculation of treatment time (PAC7.12)	f_M	C_H	P_M	R_H
6	Error in documenting the results of treatment planning (e.g. treatment time, focus-to-surface distance, field size, gantry angle, collimator angle, shape of field, wedges, couch position) (PAC7.14)	f_M	C_H	P_M	R_H
7	Incorrect placement of the patient on the treatment couch for the initial treatment session (PAC9.2)	f_L	C_H	P_M	R_H
8	Selection of the wrong field dimensions at the initial treatment session (PAC9.6)	f_L	C_H	P_M	R_H
9	Failure to place beam modifiers (bolus, compensators) at the initial treatment session, or their incorrect placement (PAC9.9)	f_L	C_H	P_M	R_H
10	Error in the final marking of the patient (field perimeter, its edges or the centre) (PAC9.12)	f_L	C_H	P_H	R_H
11	Failure to make treatment plan changes resulting from the weekly medical check (PAC10.1)	f_M	C_H	P_H	R_H
12	Attempt to continue giving treatment sessions after the prescribed number of sessions has been reached (PAC10.18)[4].	f_M	C_H	P_L	R_H
	High risk events with moderate consequences				
1	Movement of the treatment couch because it was not secured when preparing the daily treatment (PAC10.4)	f_M	C_M	P_H	R_H
2	Omission of bolus or its incorrect placement (PAC10.12)	f_M	C_M	P_H	R_H
3	Incorrect recording of data from the daily session on the treatment chart (PAC10.26)	f_H	C_M	P_H	R_H

[4] Explanatory note on the expression "attempt": an attempt may result in an additional dose, or this error may be detected, thanks to the barriers in place, before it occurs. The initiating event therefore consists solely of the attempt to initiate, or the initiation of, the administration process, with opportunities for detection through the barriers in place.

Just as for treatment with an accelerator, the high risk events are due to human error and not equipment failure. Each of these events is analysed briefly below:

– Initiating event PAC2.17: Incorrect generation of tables containing data for manual planning of treatment (e.g. depth dose curves).

  This initiating event leads to systematic errors in treatment planning, with very serious consequences for multiple patients. The frequency is very low and the barrier is redundant verification of the records by another medical physicist.

– Initiating event PAC5.5: Failure to place reference marks from CT simulation on the patient or on immobilization devices, or their incorrect marking.

  This event may occur during the anatomical data acquisition stage and, if it were not corrected, its consequences would be serious as they would affect a patient's entire course of treatment. The frequency of the initiating event is classified as medium, because it is assumed that it could occur more than once a year. In order to avoid the initiating event progressing, two barriers have been identified in the generic service, both of them part of the initial treatment session: the first barrier is the positioning and immobilization of the patient in the presence of the radiation oncologist responsible for the patient, the medical physicist and the radiotherapy technicians, which facilitates the discovery of any error; the second barrier is the review of the portal images during this initial session by the radiation oncologist, who may also detect an error if the images do not correspond to the prescribed fields.

– Initiating event PAC5.10: Error in obtaining the anatomical contour of the patient, resulting in distortion of the contour's size and shape (when this is obtained manually, directly from the patient).

  This initiating event may occur in cases where the anatomical contour is obtained manually and not using the CT unit. The possible consequences would affect the patient's entire course of treatment, so the severity of the potential consequences would be high (C_H). The frequency of this event is assumed to be medium (at least once a year) and two barriers have been identified for its detection: treatment simulation and portal imaging at the initial treatment session.

– Initiating event PAC7.1: Incorrect use of the TPS when preparing the treatment plan for a specific patient.

  This event involves violating the procedure established for using the TPS for a particular patient and using a variant or modified version without validating it. The consequences of this event are considered to be serious, i.e. the severity is high and a single patient is affected. The following barriers have been identified: verification of the treatment plan by a different medical physicist from the one who planned the case, including a dose calculation at reference points, which is independent of the TPS calculation; and evaluation and approval of the treatment plan jointly by the physicist and radiation oncologist.

– Initiating event PAC7.3: Selection of the wrong data when planning treatment, such as data for a different source from the one in the equipment, or for other equipment modelled in the TPS.

  This event may occur if the treatment unit has data files that are not updated, or if a single TPS is used in a service that has several machines. An error of this type may give rise to a treatment calculation using incorrect data and incorrect values for dose, its distribution, or treatment times. The consequences associated with this initiating event have been deemed

serious. The following barriers have been identified: verification of the treatment plan by a different medical physicist from the one who planned the case, including a dose calculation at reference points, which is independent of the TPS calculation; and evaluation and approval of the treatment plan jointly by the physicist and radiation oncologist.

- Initiating event PAC7.12: Entry of incorrect data for the calculation of treatment time.

  The consequences of this error have been deemed serious as they may affect the patient's entire course of treatment. The following barriers have been identified: verification of the treatment plan by a different medical physicist from the one who planned the case, including a dose calculation at reference points, which is independent of the TPS calculation; and evaluation and approval of the treatment plan jointly by the physicist and radiation oncologist.

- Initiating event PAC7.14: Error in documenting the results of treatment planning (e.g. treatment time, focus-to-surface distance, field size, gantry angle, collimator angle, shape of field, wedges, couch position).

  This is a set of events that may occur when recording the main treatment parameters, i.e. after the radiation oncologist and physicist accept the treatment plan. The level of consequences is serious. Two barriers have been identified: 1) placement and immobilization of the patient in the treatment position at the initial session, in the presence of the radiation oncologist, the physicist and the radiotherapy technician; and 2) review of the portal image, also at the initial session, by the radiation oncologist.

- Initiating event PAC9.2: Incorrect placement of the patient on the treatment couch for the initial treatment session.

  NB: The consequences of this initiating event may be serious because the error occurring in the first session of treatment could be repeated in the remaining sessions. The barriers identified are both in the initial session; they consist of the radiation oncologist being present at the first positioning, and the review of the portal images by the radiation oncologist, also at the initial session.

- Initiating event PAC9.6: Selection of the wrong radiation field dimensions at the initial treatment session.

  Given that the error occurs at the first treatment session, the event affects all the sessions whose data are based on the first. The radiation oncologist being present at this first positioning, and evaluating the portal image also at this session are important barriers.

- Initiating event PAC9.9: Failure to place beam modifiers (bolus, compensators) at the initial treatment session.

  As this occurs at the first treatment session, the event affects all the sessions in the course of treatment; the consequences are therefore serious. The barrier identified is the participation of the radiation oncologist and the physicist in the first positioning.

- Initiating event PAC9.12: Error in the position of the final marks on the patient (field contour, edges of field or centre of field).

  The error comprises putting the fiducial marks, needed to reproduce the patient's treatment daily, in the wrong place. The consequences are a distorted dose distribution which affects the patient's entire treatment; the consequences may therefore be serious. No barriers have been identified in the generic service for this initiating event.

– Initiating event PAC10.1: Failure to apply the treatment plan changes prescribed by the radiation oncologist as a result of the weekly medical check.

  This event may occur when positioning the patient for daily treatment without taking into account a change prescribed by the radiation oncologist when carrying out one of the medical checks of the patient. No barriers have been identified in the generic service for this initiating event.

– Initiating event PAC10.18: Attempt to continue giving treatment sessions after the prescribed number of sessions has been reached.

  The error comprises attempting to give additional, unprescribed sessions, which would cause the prescribed radiation dose to be exceeded. The barrier to this event is the manual recording of daily treatment data by the radiotherapy technician[5].

– Initiating event PAC10.4: Movement of the treatment couch because it was not secured when preparing the daily treatment.

  The error comprises not securing the couch once the patient is positioned on it. The consequences are moderate since they affect only one treatment session, but the frequency is medium because the event may occur more than once in a year. No barriers have been identified in the generic service for this initiating event.

– Initiating event PAC10.12: Omission of a bolus or its erroneous placement at a treatment session.

  The consequences are moderate since they affect only one treatment session, but the frequency is medium because it is considered that the event may occur more than once in a year. No barriers have been identified in the generic service for this initiating event[6].

– Initiating event PAC10.26: Erroneous recording of data from the daily session on the treatment chart.

  The consequences may be that one session more or one session less is applied, which would alter the total dose, but if the event were a one-off, the severity of these consequences would be moderate. However, the frequency is high and no barriers have been foreseen in the generic service[6].

4.3.4 Measures to reduce the risk of high risk initiating events

Table 16 sets out possible measures to reduce the risk of the initiating events listed in the previous section. First of all, we have explored possible barriers additional to the existing ones. In cases where this measure is insufficient, we have tried to reduce the risk by taking into consideration elements that reduce the frequency of the initiating event or its potential consequences.

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[5] Explanatory note: in some of the radiotherapy services that participated in the project, the patient alerting the technician to the fact that the treatment should have already finished was considered to be a barrier. However, there is no general agreement that a patient's actions can be considered as a barrier upon which safety depends.

[6] Although this event also occurs in treatments using an accelerator, the resulting risk is not high in these treatments as there are more barriers.

TABLE 16. MEASURES TO REDUCE THE RISK OF INITIATING EVENTS THAT REMAINS HIGH AFTER THE SECOND SCREENING

No.	Initiating event	Recommendations
1	Generation of tables containing incorrect data for treatment planning (e.g. depth dose curves) which are used in manual planning (PAC2.17)	Carry out planning with test cases and compare the results with direct measurements. The test cases can be prepared based on IAEA recommendations (TRS-430). Given the high risk associated with this accident sequence, it is advisable to have a computerized TPS for treatment planning.
2	Failure to place reference marks from CT simulation on the patient or on immobilization devices, or their incorrect marking (PAC5.5)	Introduce into the procedures a redundant review of the CT reference marks, by a different technician from the one who carried out the CT
3	Error in obtaining the anatomical contour of the patient, resulting in distortion of the contour's size and shape (when this is obtained manually, from the patient directly) (PAC5.10)	In order to reduce the risk, the frequency of this initiating event needs to be reduced, which is difficult as the probability of these human errors is inevitably high The frequency can be reduced by minimizing the number of times the task is performed. This is achieved by obtaining the contour from CT images
4	Incorrect use of the TPS when preparing the treatment plan for a specific patient (PAC7.1)	Carry out in vivo dosimetry at the initial treatment session
5	Selection of the wrong data when planning treatment, such as data for a different source from the one in the equipment, or for other equipment modelled in the TPS (PAC7.3)	Carry out in vivo dosimetry at the initial treatment session
6	Entry of incorrect data for the calculation of treatment time (PAC7.12)	Carry out in vivo dosimetry at the initial treatment session
7	Error in documenting the results of treatment planning (e.g. treatment time, focus-to-surface distance, field size, gantry angle, collimator angle, shape of field, wedges, couch position) (PAC7.14)	Carry out in vivo dosimetry at the initial treatment session
8	Incorrect placement of the patient on the treatment couch for the initial treatment session (PAC9.2)	Include on the treatment chart a photograph showing the exact positioning during the CT simulation This measure would reduce the frequency of the initiating event. This would bring the total number of reducers to three, which would cause the frequency to drop from medium to low and the risk from high to medium
9	Selection of the wrong radiation field dimensions at the initial treatment session (PAC9.6)	Design a technological modification to the treatment unit that allows an alarm or interlock to be activated, constituting an additional barrier
10	Failure to place beam modifiers (bolus, compensators) at the initial treatment session (PAC9.9)	Carry out in vivo dosimetry at the initial treatment session
11	Error in the position of the final marks on the patient (PAC9.12)	No measures have been identified to reduce the probability of this accident sequence, but the following consequence reducers can be strengthened: • Weekly medical review of the patient in order to detect errors in the administration of treatment or in previous stages; • Daily positioning of the patient, whereby the radiotherapy technicians may detect errors in geometry or dose through visual signs (discolouration of skin, etc.)
12	Failure to apply the treatment plan changes prescribed by the radiation oncologist as a result of the weekly medical check (PAC10.1)	No measures have been identified to reduce the probability of this accident sequence, but the following consequence reducers can be strengthened: • Weekly medical review of the patient in order to detect errors in the administration of treatment or in prior stages; • Daily positioning of the patient, whereby the radiotherapy technicians may detect errors in geometry or dose through visual signs (discolouration of skin, etc.)

TABLE 16. MEASURES TO REDUCE THE RISK OF INITIATING EVENTS THAT REMAINS HIGH AFTER THE SECOND SCREENING (cont.)

No.	Initiating event	Recommendations
13	Erroneous attempt to administer one or more daily treatment sessions after the prescribed number of sessions has been reached (PAC10.18)	Design a modification to the treatment unit that allows an alarm or interlock to be activated, constituting an additional barrier
14	Movement of the treatment couch because it was not secured when preparing the daily treatment (PAC10.4)	Design a modification for the treatment unit that allows an alarm or interlock to be activated, constituting an additional barrier
15	Omission of a bolus or its incorrect placement at a treatment session (PAC10.12)	Develop a procedure for the unequivocal identification of the bolus (e.g. barcode attached to each bolus, which the technician can verify after it has been placed on the patient to check that it corresponds to the number written on the treatment chart)
16	Incorrect recording of data from the daily session on the treatment chart (PAC10.26)	Design a modification to the equipment that activates an alarm or interlock to serve as a barrier to this accident sequence (e.g. a treatment record and verify system that gives an alert for this error)

4.3.5 Analysis of the importance of barriers

The following table shows the barriers in the order of the structural importance index defined in Chapter 2.

TABLE 17. IMPORTANCE OF BARRIERS

No.	Barrier	Initiating events in which this barrier intervenes	
		No.	%
1	Portal image evaluated by the radiation oncologist and physicist at the initial treatment session to detect errors in the treatment geometry	35	27%
2	Participation of the radiation oncologist, physicist and radiotherapy technicians in placing and immobilizing the patient during the initial treatment session	31	23%
3	Evaluation of the treatment plan by the radiation oncologist, physicist and radiotherapy technicians	24	18%
4	Treatment planning for test cases and comparison with direct measurements as part of the commissioning of the TPS	19	14%
5	Treatment simulation (either virtual or real simulation)	16	12%
6	Verification of the TPS calculations for individual patients through a dose calculation at reference points using a calculation method independent of the TPS, and performed by someone other than the person who did the planning	15	11%
7	Two radiation beam calibrations, independent of one another, carried out by a different person and using a different dosimetry system	14	11%
8	Verification, using the field light, that the field to be treated coincides with the field marks on the patient's skin	11	8%
9	Delineation of treatment volumes and critical organs in the TPS by the radiation oncologist, who can detect errors made at previous stages, such as treatment prescription and computed tomography image acquisition	8	6%
10	Manual recording of data from daily treatment on the treatment chart	7	5%
11	Redundant verification by another physicist of the data entered into the TPS	6	5%

To complement the analysis of the table above, the following table contains an evaluation of the effect on risk level if each of the barriers that intervenes in over 15% of initiating events is removed. There are specific details of which initiating events would have their risk level changed if the barrier were weakened or removed. Initiating events whose risk level does not vary are less affected by the failure of a single barrier.

TABLE 18. EFFECT OF REMOVING A BARRIER

Barrier being removed: Portal image evaluated by the radiation oncologist and physicist at the initial session			
No.	Initiating events in which the barrier intervenes and whose risk level changes	Baseline risk level	Risk level without barrier
1	Error in determining the geometric parameters of the radiation beam (size of radiation field, coincidence between light field and radiation field, effective source position, beam verticality) (PAC2.8)	R_M	R_H
2	Error in determining the geometric and mechanical parameters of the treatment unit (errors in the axis of rotation and translation, in the angular and linear scales, including the optical distance indicator, in the light indicator of the beam axis (cross-hair), and in the verification of the lasers) (PAC2.10)	R_M	R_H
3	Supply of ineffective standard patient immobilization devices (loose, inadequate fixation) (PAC2.15).	R_M	R_H
4	Incomplete commissioning of the CT unit, giving rise to errors in the density and geometry scales (PAC2.24)	R_M	R_H
5	Error in identification or placement of immobilization devices in the CT simulator (PAC5.2)	R_M	R_H
6	Use of the wrong references for the CT simulator (PAC5.3)	R_M	R_H
7	Performance of CT simulation with the wrong geometric parameters, different from those of the treatment unit, such as a couch that is not flat or is narrower, a different beam projection or different laser lights (PAC5.4)	R_M	R_H
8	Error in positioning the patient on the CT simulator couch through the omission of positioning data, or incorrect positioning of the patient, causing an error in the CT images (PAC5.6)	R_M	R_H
9	Error through a change in information when transferring images from the CT simulator to the TPS (PAC5.7)	R_M	R_H
10	Error in the recording of patient positioning data in the CT simulator, through either omission of data, or recording of incorrect data (PAC5.8)	R_M	R_H
11	Acquisition of an incorrect image through faults in the CT unit (PAC5.9)	R_M	R_H
12	Error in identifying the patient when preparing the treatment plan, or treatment planning for one patient using the data for another (PAC6.1)	R_M	R_H
13	Incorrect designation of the volumes (GTV as CTV or vice versa) delineated in the TPS through the use of the wrong acronym or colour code agreed upon in the service (PAC6.2)	R_M	R_H
14	Incorrect digitalization of the individual anatomical contour, target volume and critical organs (when these are obtained directly from the patient) (PAC6.5)	R_M	R_H
15	Incorrect interpretation of data on the patient and treatment prescription taken directly from the patient instead of obtaining images through a CT unit (anatomical location, position of patient, depth of prescription point) (PAC7.4)	R_L	R_M
16	Selection of the wrong orientation of the field(s) (PAC7.5)	R_M	R_H
17	Error in developing the treatment plan, related to the protection of critical organs and normal tissue (PAC7.8)	R_M	R_H
18	Failure to prepare the customized shaping blocks (PAC8.1)	R_M	R_H
19	Error in preparing the customized accessories (bolus, compensators, immobilizers, shaping blocks). One such error may be preparing the devices using different specifications from those prescribed (different size or thickness) (PAC8.2)	R_M	R_H
20	Incorrect positioning of the protection blocks on the tray (PAC8.3)	R_M	R_H
21	Error in placement of the patient with respect to the planned isocentre (isocentric treatment, constant source-to-isocentre distance), leading to an error (greater than 3 mm) in the positioning of the patient at the initial treatment session (PAC9.3)	R_M	R_H
22	Errors in placement of the patient for non-isocentric treatments (constant source-to-surface distance), such as incorrect (greater than 3 mm) positioning of the patient owing to errors at the initial treatment session (PAC9.4)	R_M	R_H
23	Selection of the wrong angles of the treatment couch during the initial treatment session (PAC9.5)	R_M	R_H
24	Error in the placement of the shaping blocks (PAC9.8)	R_M	R_H

TABLE 18. EFFECT OF REMOVING A BARRIER (cont.)

No.	Initiating events in which the barrier intervenes and whose risk level changes	Baseline risk level	Risk level without barrier
Barrier being removed: Participation of the radiation oncologist, physicist and radiotherapy technicians in placing and immobilizing the patient at the initial treatment session.			
1	Omission from the treatment chart of the permissible dose for organs at risk, or assignment of an incorrect value (PAC4.5)	R_M	R_H
2	Omission from the treatment chart of a secondary volume prescribed by the radiation oncologist, in cases where there are several volumes (PAC4.6)	R_M	R_H
3	Error in identifying the immobilization devices when performing CT simulation or when putting these devices in place (PAC5.2)	R_M	R_H
4	Use of the wrong references for CT simulation (PAC5.3)	R_M	R_H
5	Performance of CT simulation with the wrong geometric parameters (PAC5.4)	R_M	R_H
6	Omission of patient positioning details for CT simulation, or incorrect positioning of the patient, causing an error in the CT images (PAC5.6)	R_M	R_H
7	Error through a change in information when transferring images from the CT simulator to the TPS (PAC5.7)	R_L	R_M
8	Error in recording data on the exact positioning of the patient during CT simulation, through omission of data or indication of incorrect data (PAC5.8)	R_M	R_H
9	Error in identification of the patient when preparing the treatment plan. Treatment planning for one patient using the data for another patient (PAC6.1)	R_M	R_H
10	Failure to designate one or several secondary volumes (secondary CTVs) in the TPS (PAC6.3)	R_M	R_H
11	Incorrect digitalization of the individual anatomical contour, the target volume and critical organs (when these are obtained directly from the patient rather than CT) (PAC6.5)	R_M	R_H
12	Incorrect interpretation of data on the patient and treatment prescription when these are obtained directly from the patient rather than a CT unit (anatomical location, position of patient, depth of prescription point) (PAC7.4)	R_L	R_M
13	Selection of the wrong direction of the field(s) (PAC7.5)	R_M	R_H
14	Configuration of the wrong number of fields (PAC7.6)	R_M	R_H
15	Failure to perform planning for secondary locations required (PAC7.7)	R_M	R_H
16	Incorrect planning for special situations or techniques (e.g. treatment with single doses in emergencies) (PAC7.9)	R_M	R_H
17	Selection of the wrong angles of the treatment couch at the initial treatment session (PAC9.5)	R_M	R_H
18	Failure to put the wedges in place at the initial treatment session, or their incorrect placement (PAC9.7)	R_M	R_H

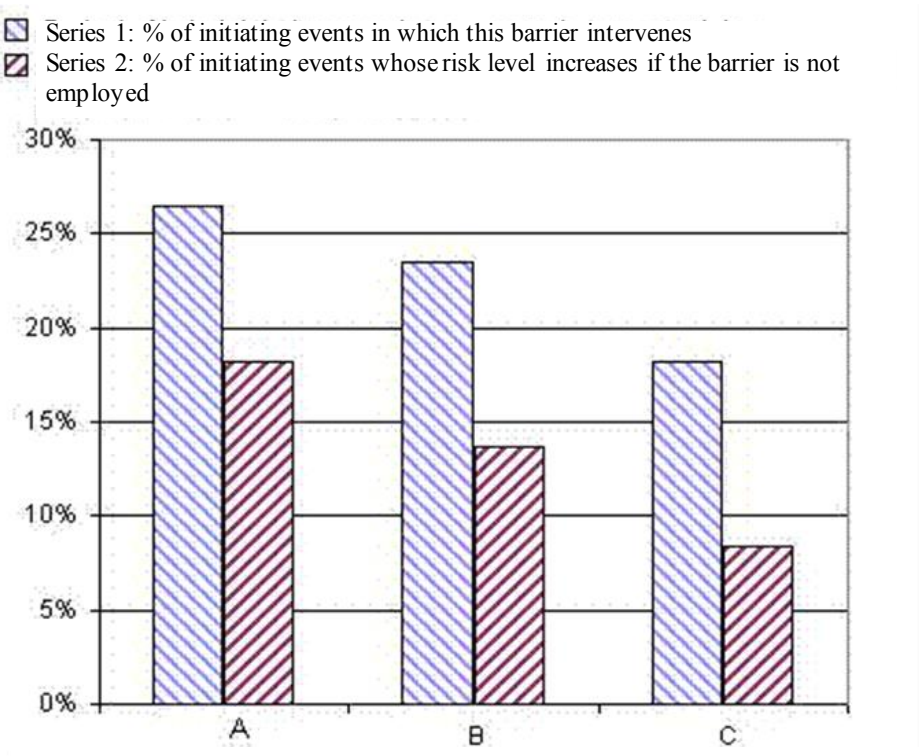
Barrier being removed: Evaluation of dosimetry planning jointly by the physicist and radiation oncologist.

No.	Initiating events in which the barrier intervenes and whose risk level changes	Baseline risk level	Risk level without barrier
1	Recording on the treatment chart of a total dose value that does not correspond to the prescription (PAC4.2)	R_M	R_H
2	Recording on the treatment chart of a daily dose value that does not correspond to the prescription (PAC4.3)	R_M	R_H
3	Recording on the treatment chart of a dose fractionation that does not correspond to the prescription (PAC4.4)	R_M	R_H
4	Configuration of the wrong number of fields (PAC7.6)	R_M	R_H
5	Failure to perform planning for secondary volumes required (PAC7.7)	R_M	R_H
6	Error in the development of dosimetry and geometric aspects of the treatment plan, as regards the protection of critical organs and normal tissue (PAC7.8)	R_M	R_H

TABLE 18. EFFECT OF REMOVING A BARRIER (cont.)

Barrier being removed: Evaluation of dosimetry planning jointly by the physicist and radiation oncologist.			
No.	Initiating events in which the barrier intervenes and whose risk level changes	Baseline risk level	Risk level without barrier
7	Incorrect planning for special situations or techniques (e.g. emergency single doses) (PAC7.9)	R_M	R_H
8	Use of an incorrect value for cobalt source decay in the manual calculation of treatment times (without a TPS) (PAC7.10)	R_M	R_H
9	Unnecessary manual correction of TPS calculations through ignorance of the system (e.g. duplicate corrections for squaring of distance, decay, etc.) (PAC7.11)	R_M	R_H
10	Failure in the treatment planning system (PAC7.15)	R_M	R_H
11	Modification of a patient's treatment plan based on the medical review record of another patient (PAC10.27)	R_M	R_H

The graph below shows the percentage of initiating events in which the barrier intervenes, and the percentage whose level increases if the barrier is weakened.



A: Portal imaging at the start of treatment
B: Initial treatment session attended by the radiation oncologist responsible for the case, the medical physicist and the radiotherapy technicians
C: Evaluation and approval of the treatment plan by the radiotherapy oncologist and medical physicist

FIG. 6. Significance of removing a barrier.

4.3.6 Analysis of the importance of consequence reducers

Table 19 and Figure 7 show the structural importance of consequence reducers.

TABLE 19. IMPORTANCE OF CONSEQUENCE REDUCERS (>5%)

No.	Barrier	Initiating events in which it intervenes	
		No.	%
1	Weekly medical review of the patient whereby errors in the administration of treatment can be detected	83	63%
2	Daily positioning of the patient, whereby the radiotherapy technicians may detect errors in geometry or dose through visual signs (discolouration of skin, etc.)	66	50%
3	Weekly portal imaging, whereby errors in geometry can be detected	30	23%
4	Annual external audit	15	11%
5	Monthly and annual QA dosimetry testing	13	10%
6	QA testing (daily, weekly, monthly, quarterly and annually) of the TPS. When a significant inconsistency is detected, treatment is stopped	8	6%
7	Monthly and annual QA mechanical testing of treatment unit	6	5%

The graph below shows the importance of consequence reducers.

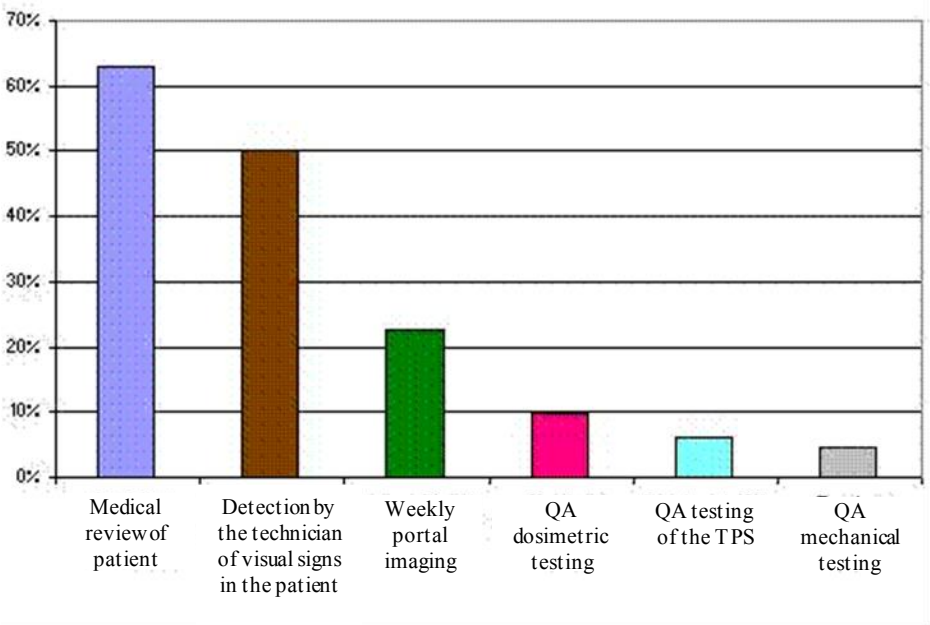


FIG. 7. Importance of consequence reducers.

5. RESULTS OF APPLYING THE METHODOLOGY TO BRACHYTHERAPY TREATMENTS

5.1 HIGH DOSE RATE BRACHYTHERAPY

This section sets out the principal results of applying the risk matrix method to high dose rate (HDR) radiotherapy treatments. The complete matrix is shown in Appendix III.

5.1.1 Statistical summary

Table 20 shows a statistical summary of applying the risk matrix method to high dose rate (HDR) brachytherapy treatments.

TABLE 20. RESULTS SUMMARY FOR THE HDR BRACHYTHERAPY RISK MATRIX

Number of events analysed	115	
With consequences for the patient	92	80%
With consequences for the worker	16	14%
With consequences for members of the public	7	6%
With very serious consequences	25	22%
With serious consequences	43	38%
With moderate consequences	45	39%
With low level consequences	2	2%
Number of barriers analysed	74	
Number of frequency reducers analysed	62	
Number of consequence reducers analysed	26	

	First screening		Second screening	
Very high risk sequences	0	0%	0	0%
Very high risk with very serious consequences	0	0%	0	0%
Very high risk with serious consequences	0	0%	0	0%
Very high risk with moderate consequences	0	0%	0	0%
Very high risk with low level consequences	0	0%	0	0%
High risk sequences	37	32%	5	4%
High risk with very serious consequences	13	11%	1	1%
High risk with serious consequences	24	21%	4	4%
High risk with moderate consequences	0	0%	0	0%
High risk with low level consequences	0	0%	0	0%
Medium risk sequences	75	65%	107	93%
Medium risk with very serious consequences	12	10%	24	21%
Medium risk with serious consequences	18	16%	38	34%
Medium risk with moderate consequences	43	37%	43	37%
Medium risk with low level consequences	2	2%	2	2%
Low risk sequences	3	3%	3	3%

Figure 8 summarizes these results in the form of graphs.

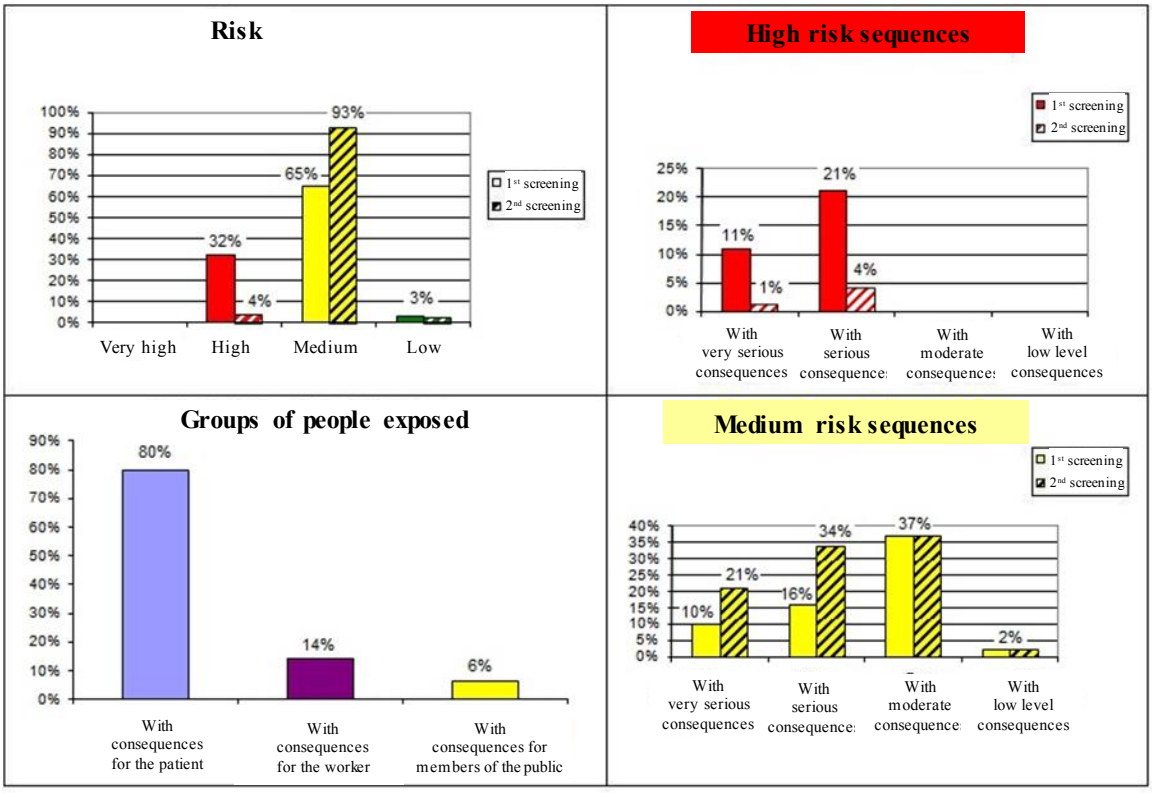


FIG. 8. General results of applying the risk matrix to HDR brachytherapy.

In the study, a list was generated of 115 initiating events that might cause accidental exposure. These events could occur at one of the stages in the treatment process, or during installation or commissioning. Of these 115 events, 80% would have consequences for the patient, 14% for the workers and 6% for members of the public.

Analysis was also performed for 74 direct safety barriers, 62 elements that help reduce the frequency of accident initiating events (frequency reducers) and 26 elements that could lessen the severity of potential consequences (consequence reducers).

5.1.2 Events with very serious consequences

Only one of the initiating events with very serious consequences remained classified as high risk in the second screening. This event takes place during the commissioning of the imaging equipment. Table 21 shows the results of analysing what would happen to other events with very serious consequences if the barriers were to be weakened. For example, some of the barriers are so important that the failure of one of them would be enough to cause nine of the remaining 24 events with very serious consequences to become high risk. One of these nine accident sequences would originate at the equipment installation stage (initiating event PAC1.2), seven at the acceptance and commissioning stage, and one during work to exchange the source.

TABLE 21. INITIATING EVENTS WITH VERY SERIOUS CONSEQUENCES WHOSE RISK LEVEL WOULD CHANGE IF ONE OF THE INITIAL BARRIERS WERE TO BE WEAKENED OR REMOVED

No.	Initiating event	f	C	Number of barriers	P		R	
					Baseline	With one barrier less	Baseline	With one barrier less
1	Entry of incorrect source data into the brachytherapy equipment control panel during commissioning of the equipment (PAC1.2)	f_L	C_{VH}	3	P_L	R_M	P_M	R_H
2	Entry of incorrect values for the electromechanical parameters of the equipment during commissioning, causing the incorrect positioning of the source (e.g. optical pair, length of cable, length of transfer tubes, stepper motor, etc.) (PAC1.4)	f_L	C_{VH}	3	P_L	R_M	P_M	R_H
3	Supply of applicators and accessories with manufacturing defects (geometric dimensions of the applicator, obstructions, etc.) (PAC2.8)	f_{VL}	C_{VH}	3	P_L	R_M	P_M	R_H
4	Error in entering the dose rate constant into the TPS (PAC2.12)	f_M	C_{VH}	4	P_{VL}	R_M	P_L	R_H
5	Error in entering the radial function into the planner during its commissioning (PAC2.13)	f_{VL}	C_{VH}	3	P_L	R_M	P_M	R_H
6	Error in entering the anisotropy function into the planner during its commissioning (PAC2.14)	f_{VL}	C_{VH}	3	P_L	R_M	P_M	R_H
7	Fault in the TPS when calculating the geometric function values based on the formula (PAC2.17) [7]	f_{VL}	C_{VH}	3	P_L	R_M	P_M	R_H
8	Calculation error in the TPS when generating the dose matrices[7] (PAC2.18)	f_{VL}	C_{VH}	3	P_L	R_M	P_M	R_H
9	Lodging of the source during work to exchange it (POE3.1)	f_{VL}	C_{VH}	3	P_L	R_M	P_M	R_H

5.1.3 List of high risk events

In the first screening, 37 events were identified as high risk; these underwent a specific and detailed analysis (second screening) which is summarized in Appendix III. As a result of this analysis, five initiating events remained high risk for the HDR brachytherapy unit of the generic radiotherapy service. These are listed below:

[7] Assuming that the TPS calculation algorithm is correct and a check was performed during commissioning, a fault may occur for reasons such as the following: 1) hidden defect in the program, which is only activated when certain conditions coincide; 2) corruption of the program, by a virus for example; 3) sudden interruption of the calculation process, whereby it "freezes" and the data integrity is lost when it is restarted, along with other unexpected causes.

TABLE 22. HIGH RISK INITIATING EVENTS (AFTER THE SECOND SCREENING)

No.	Initiating event	f	C	P	R
	High risk events with very serious consequences				
1	Incomplete commissioning of the imaging equipment (e.g. errors in the density and geometric scales of the CT images) (PAC2.11)	f_L	C_{VH}	P_M	R_H
	High risk events with serious consequences				
1	Disconnection of the source from the transfer cable during a treatment (PAC9.6)	f_{VL}	C_H	P_H	R_H
2	The source getting stuck inside an interstitial implant after completion of treatment (PAC9.13)	f_{VL}	C_H	P_H	R_H
3	Disconnection of the source from the transfer cable, leaving it in an intracavitary or surface implant after completion of treatment (PAC9.15)	f_L	C_H	P_H	R_H
4	Disconnection of the source from the transfer cable, leaving it in an interstitial implant after completion of treatment (PAC9.16)	f_{VL}	C_H	P_H	R_H

Each of these events is analysed briefly below:

– Initiating event PAC2.11: Incomplete commissioning of the imaging equipment (e.g. errors in the density and geometric scales of the CT images).

  This initiating event occurs during commissioning of the imaging equipment, whereby a group of parameters (e.g. CT density and geometric scales) are determined for entry into the treatment planner. Errors in these parameters will be passed on to treatment planning. An error in the density will cause the attenuation to be calculated incorrectly for this tissue, giving rise to incorrect doses and a distortion in the distribution; if the errors are geometric, they will result directly in the wrong dose distribution. The frequency of this event is estimated to be low and the consequences may be very serious, as they can cause death or disabling injury to multiple patients. Only one barrier has been identified in the hypothetical radiotherapy service: this comprises comparing the geometric dimensions and densities of a phantom known beforehand with those obtained using CT, prior to the clinical use of the equipment.

– Initiating event PAC9.6: Disconnection of the source from the transfer cable during a treatment.

  This is a fault in the HDR brachytherapy unit which causes the source to become uncoupled from the transfer cable connecting it to the unit's stepper motor, which means that the source cannot be moved to the positions established in the treatment plan or returned to its shielded housing in the HDR unit. This causes the total dose to be incorrect, affecting the entire treatment of the patient concerned. The frequency of this initiating event is estimated to be very low and the consequences may be serious owing to the dose deviations to the target volume and to the organs at risk. No barrier has been identified to this event in the hypothetical radiotherapy service.

– Initiating event PAC9.13: The source getting stuck inside an interstitial implant after completion of treatment.

  This initiating event might occur at the end of irradiation, once treatment is complete. It involves the source getting stuck inside the implant without returning to the work container, thus giving the patient a higher dose than planned. It can get stuck because of an obstruction in the transfer tube or implant, or owing to a machine failure. If this occurs, the applicator with the source inside will need to be extracted through an emergency surgical procedure; although the problem is detected immediately, there is some delay in

extracting the applicator, resulting in a considerable overdose that could cause death or disabling injury. Since the failure of the treatment machine is much less likely than an obstruction in the transfer tube or implant, the frequency of obstruction is used, which is very low in any case. No barriers have been identified to tackle this event in the hypothetical radiotherapy service.

– Initiating event PAC9.15: Disconnection of the source from the transfer cable, leaving it in an intracavitary or surface implant after completion of treatment.

  This initiating event might occur at the end of irradiation, once treatment is complete if, through a mechanical fault in the weld connecting the source to the transfer cable, the source remains inside the implant, resulting in a higher dose than planned. For the same reasons as the previous event (PAC9.13) the overdose would be considerable, potentially causing death or disabling injury. Although the frequency of this initiating event could be estimated to be very low, this is an accident that has actually occurred. The frequency is therefore taken to be low, as a conservative measure. No barriers have been identified to tackle this event in the hypothetical radiotherapy service.

– Initiating event PAC9.16: Disconnection of the source from the transfer cable, leaving it in an interstitial implant after completion of treatment.

  This initiating event is similar to the previous one, but an applicator for interstitial, rather than intracavitary implants is used. It could happen once treatment is complete, through a mechanical fault in the weld connecting the source to the transfer cable. The source may remain inside the implant, causing a higher dose than planned. For the same reasons as the previous event (PAC9.13), the overdose would be considerable, potentially causing death or disabling injury. No barriers have been identified to tackle this event in the hypothetical radiotherapy service.

5.1.4 Measures to reduce the risk of high risk initiating events

Table 23 proposes measures to reduce the risk of the initiating events listed in the previous section. First of all, possible barriers additional to the existing ones have been explored. In cases where this measure is insufficient, elements that reduce the frequency of the initiating event or its potential consequences have been sought.

TABLE 23. MEASURES TO REDUCE THE RISK OF INITIATING EVENTS CLASSIFIED AS HIGH RISK IN THE SECOND SCREENING

No.	Initiating event	Recommendations
1	Incomplete commissioning of the imaging equipment (e.g. errors in the density and geometric scales of the CT images) (PAC2.11)	Review the results of calibrating the density and geometric scales. This review should be redundant and independent, carried out by a different medical physicist.
2	Disconnection of the source from the transfer cable during treatment (PAC9.6)	Since no barriers have been identified for this accident sequence, strengthening of the following consequence reducers is proposed: • alarm on the console that immediately warns of the non-return of the source; • signal on the area detector that indicates the source is outside the shielding; • emergency procedure for the manual extraction of the source, and frequent simulations to ensure that all equipment operators for all shifts can execute the procedure quickly and correctly; • correction of the treatment plan for successive applications.
3	The source getting stuck inside an interstitial implant after completion of treatment (PAC9.13)	Since no barriers have been identified for this accident sequence, strengthening of the following consequence reducers is proposed: • alarm on the console that immediately warns of the non-return of the source; • signal on the area detector that indicates the source is outside the shielding; • emergency procedure for the manual extraction of the source, and frequent simulations to ensure that all equipment operators for all shifts can execute the procedure quickly and correctly; • correction of the treatment plan for successive applications.
4	Disconnection of the source from the transfer cable, leaving it in an intracavitary or surface implant after completion of treatment (PAC9.15)	Since no barriers have been identified for this accident sequence, strengthening of the following consequence reducers is proposed: • alarm on the control panel alerting of differences between the running of the stepper motor and the indication of the optical pair during retraction of the source; • radiation detector incorporated into the equipment; • signal on the area detector that indicates the source is outside the shielding; • emergency procedure for the manual extraction of the source, and frequent simulations to ensure that all equipment operators for all shifts can execute the procedure quickly and correctly.
5	Disconnection of the source from the transfer cable, leaving it in an interstitial implant after completion of treatment (PAC9.16)	Since no barriers have been identified for this accident sequence, strengthening of the following consequence reducers is proposed: • alarm on the control panel alerting of differences between the running of the stepper motor and the indication of the optical pair during retraction of the source; • radiation detector signal incorporated into the equipment; • signal on the area detector that indicates the source is outside the shielding; • emergency procedure for the manual extraction of the source, and frequent simulations to ensure that all equipment operators for all shifts can execute the procedure quickly and correctly.

5.1.5 Analysis of the importance of barriers

The following table shows the barriers in the order of the structural importance index defined in Chapter 2.

TABLE 24. IMPORTANCE OF BARRIERS

No.	Barrier	Initiating events in which this barrier intervenes	
		No.	%
1	Joint evaluation of the treatment plan by the radiation oncologist and medical physicist. During this evaluation, any sequence initiated in the stages prior to the dosimetry planning stage can be detected.	33	29%
2	Verification of calculations resulting from dosimetry planning of treatment, through independent calculations by a different medical physicist from the one who planned the case.	17	15%
3	Area detector that gives an alert if the source has not been retracted to the shielded position.	12	11%
4	Light indicator showing that the source is in the treatment position. This indicator must be placed at the entrance to the treatment room.	10	9%
5	Independent, redundant verification of the calibration results by another medical physicist and using another dosimetry system.	8	7%
6	Calibration of the source during commissioning, and comparison of the result with the kerma rate value given on the certificate.	7	6%
7	Comparison of the basic treatment parameters taken from the planning carried out by the TPS, with the plan corrected by the unit control panel of the treatment machine[8]	7	6%
8	Verification of the kerma rate at surrounding points, comparing the TPS calculation results for this source with published values (e.g. F. Williamson and Z. Li, "Monte Carlo aided dosimetry of the microselectron pulsed and high dose-rate Ir-192 sources," Med. Phys. 22, 809–819 ~1).	7	6%
9	Use of the medical images for the location and geometric reconstruction of the implant coordinates by the dosimetrist or the medical physicist.	6	5%

The table below shows the effect that removing one of the barriers that intervene in over 15% of initiating events would have on the risk level. There are specific details of which initiating events would have their risk level raised if the barrier were weakened or removed. Initiating events whose risk level does not vary are less affected by, that is to say less vulnerable to, the failure of a single barrier.

TABLE 25. EFFECT OF REMOVING A BARRIER

Barrier being removed: Joint evaluation of the treatment plan by the radiation oncologist and medical physicist			
No.	Initiating events in which the barrier intervenes and whose risk level changes	Baseline risk level	Risk level without barrier
1	Omission of organs at risk when transcribing the clinical prescription data onto the treatment chart (PAC4.2)	R_M	R_H
2	Recording on the treatment chart of a different total dose, fractional dose or fractionation value from the prescribed one (PAC4.3)	R_M	R_H
3	Transcription of the wrong value for the dose that shall not be exceeded in organs at risk, which is different from the value assigned by the doctor, or omission of this value from the treatment chart (PAC4.4)	R_M	R_H

[8] In HDR brachytherapy equipment, the values given by the equipment's control panel can be used to verify the basic treatment parameters taken from the TPS.

TABLE 25. EFFECT OF REMOVING A BARRIER (cont.)

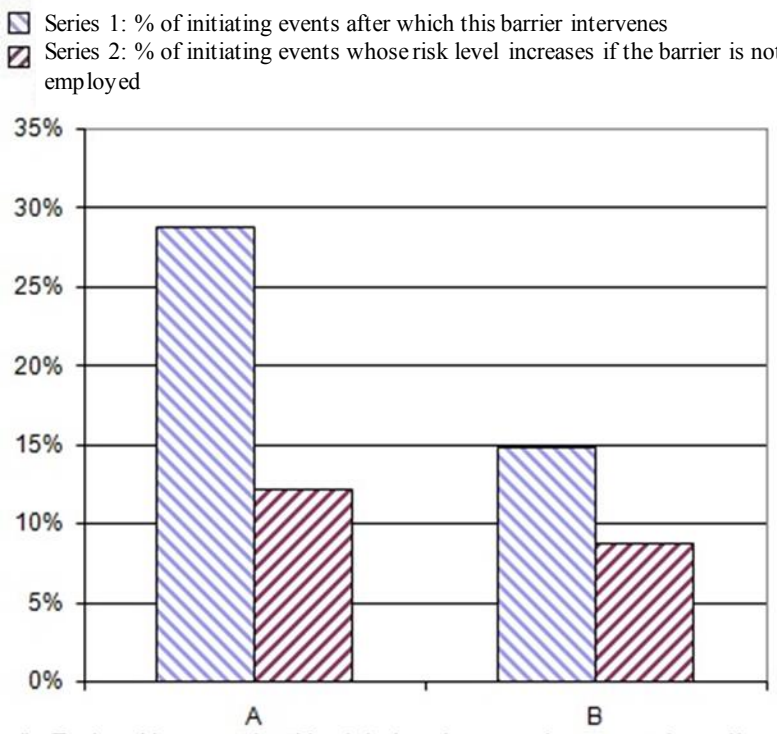
Barrier being removed: Joint evaluation of the treatment plan by the radiation oncologist and medical physicist			
No.	Initiating events in which the barrier intervenes and whose risk level changes	Baseline risk level	Risk level without barrier
4	Error in selecting or positioning the implants. This type of error is significant in cases where the implant is not removed at the end of each treatment session, and in cases involving a single application or treatment with brachytherapy alone (PAC5.2b)	R_M	R_H
5	Error in the placement of the dummy sources. This type of error is important in cases where the implant is not removed at the end of each treatment session, and in cases involving a single application or treatment with brachytherapy alone (PAC5.3b)	R_M	R_H
6	Incorrect reconstruction of the position of implants using the images (PAC6.4a)	R_M	R_H
7	Incorrect reconstruction of the position of dummy sources using the images (PAC6.5a)	R_M	R_H
8	Errors in defining the prescribed treatment volumes and organs at risk using the images (PAC6.6a)	R_M	R_H
9	Errors in placing points of interest using the images (e.g. points A and B, or points on the lymphatic trapezoid) (PAC6.7a)	R_M	R_H
10	Incorrect interpretation of the treatment data contained in the therapeutic intent when carrying out treatment planning (e.g. dose to be administered, fractions, volumes to be irradiated or protected, and technique to be employed) (PAC7.1)	R_M	R_H
11	Errors in placing reference points for optimization (e.g. errors in placing the dose points around a vaginal cylinder). This type of error is significant in cases where the implant is not removed at the end of each treatment session, and in cases involving a single application or treatment with brachytherapy alone (PAC7.3b)	R_M	R_H
12	Errors in placing the normalization points. This type of error is significant in cases where the implant is not removed at the end of each treatment session, and in cases involving a single application or treatment with brachytherapy alone (PAC7.4b)	R_M	R_H
13	Entry of an incorrect value for total dose or fractionation into the TPS prescription module[9] (e.g. through a lapse) (PAC7.5)	R_M	R_H
14	Incorrect transfer of planning results to the treatment plan chart. This type of error is significant in cases where the implant is not removed at the end of each treatment session, and in cases involving a single application or treatment with brachytherapy alone (PAC8.1b)	R_M	R_H

[9] The prescription module is part of the TPS; it is used to enter the data needed to develop the treatment plan for a patient, such as total dose, fractional dose, etc. and can provide the dwelling time and position of the source for each specific treatment.

TABLE 25. EFFECT OF REMOVING A BARRIER (cont.)

Barrier being removed: Verification of calculations resulting from dosimetry planning of treatment, through independent calculations by a different medical physicist from the one who planned the case			
No.	Initiating events in which the barrier intervenes and whose risk level changes	Baseline risk level	Risk level without barrier
1	Incorrect entry of the dose rate constant into the TPS (PAC2.12)	R_M	R_H
2	Calculation error in the TPS when obtaining the geometric function values based on the formula[7] (PAC2.17)	R_M	R_H
3	Incorrect generation of dose matrices by the TPS (PAC2.18)	R_M	R_H
4	Accidental recording of a total treatment dose, fractional dose or fractionation value that is different from the one prescribed on the treatment chart (PAC4.3).	R_M	R_H
5	Transcription of the wrong value for dose to organs at risk that shall not be exceeded, which is different from the one assigned by the doctor, or omission of this value from the treatment chart (PAC4.4)	R_M	R_H
6	Incorrect transcription of treatment data from the therapeutic intent into the TPS for treatment planning (e.g. dose to be administered, fractions, volumes to be irradiated or protected, and technique to be employed) (PAC7.1)	R_M	R_H
7	Error in placing the points to be used in optimization (e.g. the points around a vaginal cylinder). This type of error is significant in cases where the implant is not removed at the end of each treatment session, and in cases involving a single application or treatment with brachytherapy alone (PAC7.3b)	R_M	R_H
8	Error in placing the normalization points. This type of error is important in cases where the implant is not removed at the end of each treatment session, and in cases involving a single application or treatment with brachytherapy alone (PAC7.4b)	R_M	R_H
9	Entry of incorrect values for total dose and fractionation into the TPS prescription module (e.g. through a lapse) (PAC7.5)	R_M	R_H
10	Errors in transferring the planning results onto the treatment chart. This type of error is significant in cases where the implant is not removed at the end of each treatment session, and in cases involving a single application or treatment with brachytherapy alone (PAC8.1b)	R_M	R_H

The graph below shows the percentage of initiating events in which the barrier intervenes, and the percentage of events whose risk level increases if the barrier is weakened.



A: Evaluation and approval of the treatment plan by the radiation oncologist and medical physicist
B: Verification of the calculations resulting from the dosimetric planning of patient treatment, through an independent calculation by a different medical physicist from the one who planned the case

FIG. 9. Significance of removing a barrier

5.1.6 Analysis of the importance of consequence reducers

Table 26 and Figure 10 show the structural importance of consequence reducers.

TABLE 26. IMPORTANCE OF CONSEQUENCE REDUCERS (>5%)

No.	Consequence reducers	Initiating events in which the reducer intervenes	
		No.	%
1	Medical review of the patient at each treatment session	44	38%
2	Annual verification of the TPS database as part of the QA programme	8	7%
3	Area detector signal	8	7%
4	External audit of the service's dosimetry using different equipment	7	6%
5	Emergency procedure for manual extraction of the source	6	5%
6	Procedure for emergency intervention by the technician	6	5%

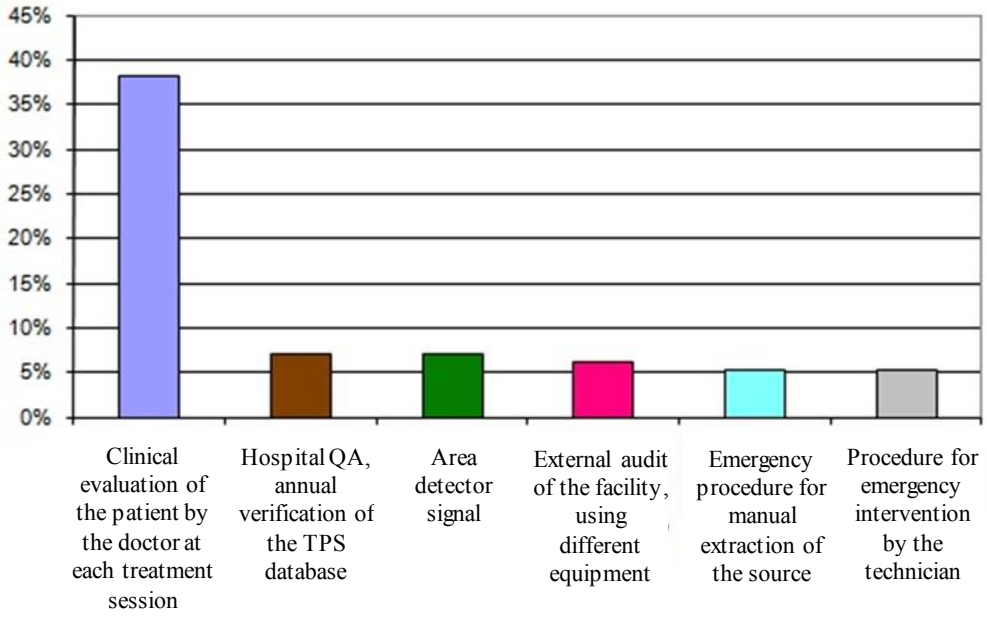


FIG. 10. Importance of consequence reducers.

5.2 LOW DOSE RATE AND PERMANENT BRACHYTHERAPY

This section sets out the principal results of applying the risk matrix method to low dose rate (LDR) and permanent brachytherapy treatments. The complete matrix is shown in Appendix IV.

5.2.1 Statistical summary

Table 27 shows a statistical summary of applying the risk matrix method to LDR and permanent brachytherapy treatments.

TABLE 27. RISK MATRIX RESULTS SUMMARY, LOW DOSE RATE AND PERMANENT BRACHYTHERAPY

Number of events analysed	80	
With consequences for the patient	61	76%
With consequences for the worker	10	13%
With consequences for members of the public	9	11%
With very serious consequences	20	25%
With serious consequences	39	49%
With moderate consequences	20	25%
With low level consequences	1	1%
Number of barriers analysed	70	
Number of frequency reducers analysed	41	
Number of consequence reducers analysed	21	

TABLE 27. RISK MATRIX RESULTS SUMMARY, LOW DOSE RATE AND PERMANENT BRACHYTHERAPY (cont.)

	First screening		Second screening	
Very high risk sequences	0	0%	0	0%
Very high risk with very serious consequences	0	0%	0	0%
Very high risk with serious consequences	0	0%	0	0%
Very high risk with moderate consequences	0	0%	0	0%
Very high risk with low level consequences	0	0%	0	0%
High risk sequences	38	48%	11	14%
Very high risk with very serious consequences	9	11%	2	3%
High risk with serious consequences	29	36%	9	11%
High risk with moderate consequences	0	0%	0	0%
High risk with low level consequences	0	0%	0	0%
Medium risk sequences	41	51%	68	85%
Medium risk with very serious consequences	11	14%	18	23%
Medium risk with serious consequences	9	11%	29	36%
Medium risk with moderate consequences	20	25%	20	25%
Medium risk with low level consequences	1	1%	1	1%
Low risk sequences	1	1%	1	1%

Figure 11 summarizes these results in the form of graphs.

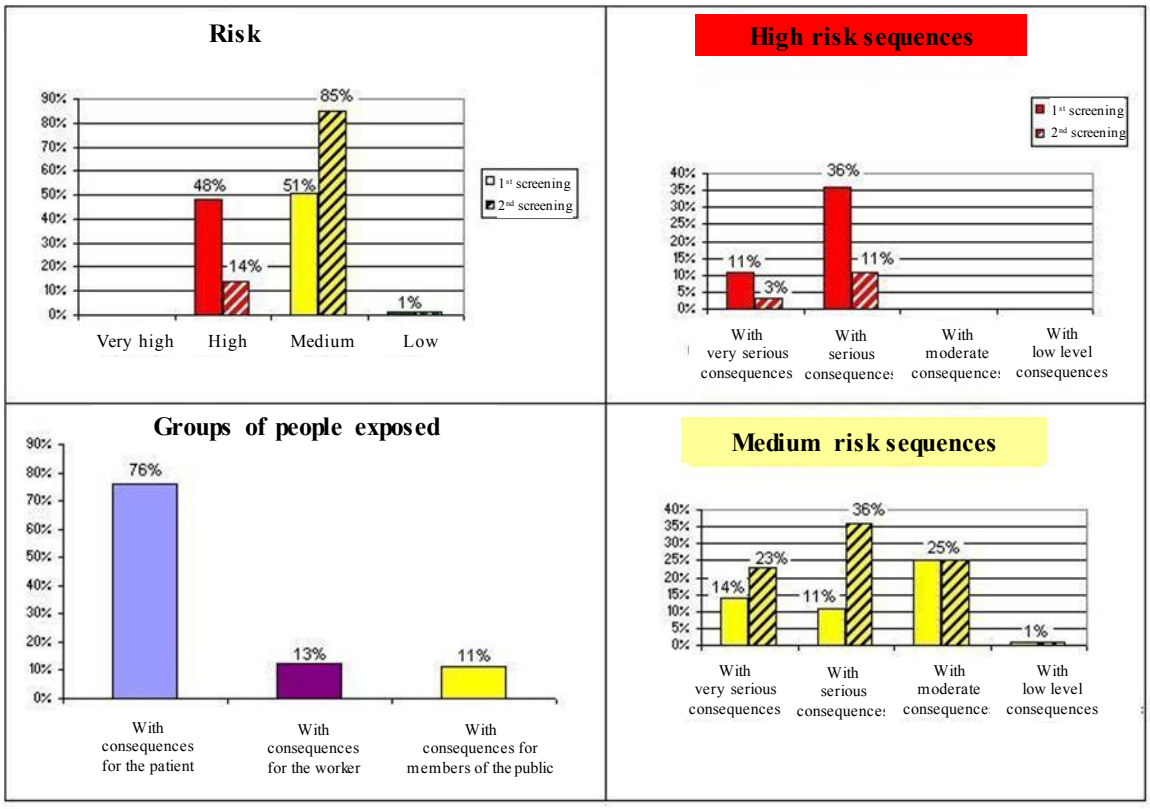


FIG. 11. General results of applying the risk matrix to LDR and permanent brachytherapy.

In the study, a list was generated of 80 initiating events that might cause accidental exposure. These events could occur at one of the stages in the LDR or permanent brachytherapy treatment process, or during installation or commissioning. Of these 80 events, 76% would have consequences for the patient, 13% for the workers and 11% for members of the public.

Analysis was also performed for 70 direct safety barriers, 41 elements that help reduce the frequency of accident initiating events (frequency reducers) and 21 elements that could lessen the severity of potential consequences (consequence reducers).

5.2.2 Events with very serious consequences

One of the nine accident sequences with very serious consequences identified in the first screening would originate at the equipment installation stage (initiating event PAC1.2), seven at the acceptance and commissioning stage, and one during work to exchange the source.

Only two of the initiating events with very serious consequences remained classified as high risk after the second screening. Table 28 shows the results of analysing what would happen to other events with very serious consequences if the barriers were to be weakened. Some of the barriers are so important that the failure of one of them would be enough to cause six of the 20 events with very serious consequences to go from medium risk to high risk.

TABLE 28. INITIATING EVENTS WITH VERY SERIOUS CONSEQUENCES WHOSE RISK LEVEL WOULD CHANGE IF SOME OF THE INITIAL BARRIERS WERE TO BE WEAKENED OR REMOVED

No.	Initiating event	f	C	No. barr.	P		R	
					Baseline	With one barrier less	Baseline	With one barrier less
1	Supply of sources with manufacturing defects that affect dose determination and distribution during treatment (PAC1.2)	f_{VL}	C_{VH}	3	P_L	P_M	R_M	R_H
2	Error when using deficient or unclear records to enter values (e.g. air kerma rate in reference conditions) into the TPS (PAC2.9)	f_L	C_{VH}	3	P_L	P_M	R_M	R_H
3	Error in entering the radial function into the planner (PAC2.13)	f_{VL}	C_{VH}	3	P_L	P_M	R_M	R_H
4	Error in inputting the anisotropy function into the planner (PAC2.14)	f_{VL}	C_{VH}	3	P_L	P_M	R_M	R_H
5	Calculation error in the TPS when calculating the geometric function values based on the formula[7] (PAC2.15)	f_{VL}	C_{VH}	3	P_L	P_M	R_M	R_H
6	Calculation error in the TPS when generating the values for the dose matrices[7] (PAC2.16)	f_{VL}	C_{VH}	3	P_L	P_M	R_M	R_H

5.2.3 High risk events

In the LDR and permanent brachytherapy of the generic radiotherapy service, 11 events have been identified whose risk is high. These events are listed below:

TABLE 29. LIST OF HIGH RISK INITIATING EVENTS (SECOND SCREENING)

No.	Initiating event	f	C	P	R
	High risk events with very serious consequences				
1	Generation of incorrect data for treatment planning (source intensity decay table). This event refers only to manual treatment planning without a TPS (PAC2.10)	f_L	C_{VH}	P_M	R_H
2	Incomplete commissioning of the imaging equipment (which would give rise to errors in the density and geometric scales in the CT unit, for example) (PAC2.17)	f_L	C_{VH}	P_M	R_H
	High risk events with serious consequences				
1	Errors in reconstructing the positioning coordinates of implants using images, which affect the location of the reference points (PAC6.4)	f_M	C_H	P_M	R_H
2	Errors in reconstructing the positioning coordinates of dummy sources in the TPS using images (PAC6.5)	f_M	C_H	P_M	R_H
3	Errors in delineating the prescribed volumes and organs at risk in the TPS using images taken (PAC6.6)	f_M	C_H	P_M	R_H
4	Incorrect placement of some of the points of interest using images (e.g. points A and B, or points on the lymphatic trapezoid, etc.) (PAC6.7)	f_M	C_H	P_M	R_H
5	Implementation of planning using the data for a different patient from the one on the prescription (PAC7.2)	f_L	C_H	P_M	R_H
6	Errors in recording the planning results on the treatment chart (PAC8.1).	f_M	C_H	P_M	R_H
7	Detachment of a source from its applicator or implant (e.g. through breakage or poor fitting of the plastic catheters) during treatment (PAC9.7)	f_L	C_H	P_H	R_H
8	Movement of the patient during treatment, causing displacement of the implant with respect to the position designated in the therapeutic intent (PAC9.9)	f_M	C_H	P_M	R_H
9	Accidental implantation of a different number of seeds than planned (PAC9.15)	f_M	C_H	P_M	R_H

Each of these events is analysed briefly below:

– Initiating event PAC2.10: Generation of incorrect data for treatment planning (source intensity decay table). This event refers only to manual treatment planning without a TPS.

  The data obtained during the commissioning of sources are, in some cases, used in the generation of data tables to draw up manual plans. If the tabulated data contain errors, these will be transmitted to the manual plans, affecting all the patients treated with them. The frequency is estimated to be low, but the consequences could be very serious as the possible errors in some of the geometric and dosimetry treatment parameters may be such that they cause the disabling injury or death of multiple patients. Only one barrier has been identified in the hypothetical reference service: redundant review by another medical physicist of the data tables for manual calculations.

– Initiating event PAC2.17: Incomplete commissioning of the imaging equipment (which would give rise to errors in the density and geometric scales in the CT unit, for example).

  This initiating event occurs during the commissioning of image acquisition equipment such as the CT unit, when determining the density and geometric scales that are subsequently entered into the treatment planning process, thus affecting the planning

results. Although its frequency is estimated to be low, the consequences may be very serious as they can cause the disabling injury or death of multiple patients. Only one barrier has been identified in the hypothetical radiotherapy service: comparison of the geometric dimensions and densities of a phantom known beforehand with those obtained using the CT unit, prior to the clinical use of the imaging equipment for radiotherapy purposes.

– Initiating event PAC6.4: Errors in reconstructing the positioning coordinates of implants using the image taken, which would affect the location of the reference points.

  Once the CT or X-ray images are available, the dosimetrist uses the planner to reconstruct the image of the implant in order to identify the position of the applicator with the simulated sources and the position of the target volume and the organs at risk. Various mistakes can be made in this process, which result in the coordinates for these elements not lining up with those of the actual implant or with the patient's anatomy. This affects the treatment plan and the dose to the target volume and the critical organs. The frequency is estimated to be medium and the consequences may be serious. In the hypothetical radiotherapy service, only one barrier has been identified in which the error may be discovered: "evaluation of the treatment plan by the radiation oncologist and the medical physicist".

– Initiating event PAC6.5: Errors in reconstructing the positioning coordinates of dummy sources using images.

  When reconstructing the implant in the TPS, an error can be made in the coordinates of the position of the dummy sources. This error is heavily influenced by the quality of the images used and by the capacities of the dosimetrist. It affects the plan that is developed based on this position and, consequently, the dose administered to the target volume and the critical organs. The frequency is estimated to be medium and the consequences may be serious. In the hypothetical radiotherapy service, only one barrier has been identified in which the error may be discovered: "evaluation of the treatment plan by the radiation oncologist and the medical physicist".

– Initiating event PAC6.6: Errors in entering the prescribed volumes and organs at risk into the TPS using images.

  After reconstructing the coordinates of the implant with the dummy sources, the prescribed volumes and organs at risk will need to be identified in the TPS. If this operation is performed incorrectly, an error will be introduced to the treatment plan and the patient may receive an incorrect dose (too high or too low). The frequency of this type of error is estimated to be medium and the consequences may be serious. In the hypothetical radiotherapy service, only one barrier has been identified in which the error may be discovered: "evaluation of the treatment plan by the radiation oncologist and the medical physicist".

– Initiating event PAC6.7: Incorrect placement of any of the points of interest using images (e.g. points A and B, or points on the lymphatic trapezoid).

  Such errors may be made when entering these points into the TPS, which would affect the dose distribution in the treatment plan. The frequency is estimated to be medium and the consequences may be serious. In the hypothetical radiotherapy service, only one barrier has been identified in which the error may be discovered: "evaluation of the treatment plan by the radiation oncologist and the medical physicist".

- Initiating event PAC7.2: Implementation of treatment planning using the data for a different patient from the one on the prescription.

  The error comprises entering data into the TPS for a different patient from the one on the prescription, which leads to a treatment plan that does not correspond to the patient it is meant to treat. The frequency of the initiating event is estimated to be low and the consequences may be serious. In the hypothetical radiotherapy service, only one barrier has been identified in which the error may be discovered: "Allocation of a unique number to identify each patient and verification that the number on the images corresponds to the one on the TPS identification system".

- Initiating event PAC8.1: Errors in recording the planning results on the treatment chart (PAC8.1).

  This event occurs if the results of treatment planning are documented incorrectly on the treatment chart, causing these errors to be incorporated into the treatment and, as a result, incorrect doses to be administered to the target volume and the organs at risk. The frequency is estimated to be medium and the consequences may be serious. In the hypothetical radiotherapy service, two barriers have been identified in which the error may be discovered: 1) approval of the treatment plan by the doctor and the physicist; and 2) comparison of treatment times with those of similar cases.

- Initiating event PAC9.7: Detachment of a source from its applicator or implant (e.g. through breakage or poor fitting of the plastic catheters) during treatment.

  This event comprises a failure of the catheters or implants, causing a displacement of the sources from the treatment position. This event is classified as low frequency and the consequences may be serious if there is an underdose to the target volume or an overdose to the critical organs. No barriers have been identified for this type of failure in the hypothetical radiotherapy service.

- Initiating event PAC9.9: Movement of the patient during treatment, causing displacement of the implant with respect to the position designated in the therapeutic intent.

  Once the treatment begins, the patient is subject to movements (voluntary or involuntary) that may entail the movement of the implant and therefore deviations of the absorbed doses in the target volume and the organs at risk. The frequency is estimated to be medium and the consequences may be serious if there is an underdose to the target volume or an overdose to the critical organs. In the hypothetical radiotherapy service, one barrier has been identified that could prevent this displacement: fixation of the implant, for example, using a clamp in gynaecological implants.

- Initiating event PAC9.15: Accidental implantation of a different number of seeds than planned.

  In the case of permanent implants, errors may occur in the number of implanted sources (seeds) being different to the number planned. This event is classified as medium frequency and the consequences may be serious if there is an underdose to the target volume or an overdose to the critical organs. In the hypothetical radiotherapy service, two barriers have been identified in which the error may be discovered: 1) Imaging at the implantation stage so as to verify the number of seeds against the plan as they are being implanted; and 2) Redundant review, after implantation, of the plan and its correspondence with the therapeutic intent.

5.2.4 Measures to reduce the risk of high risk initiating events

Table 30 sets out possible measures to reduce the risk of the initiating events listed in the previous section. First of all, possible barriers additional to the existing ones have been explored. In cases where this measure is insufficient, possible elements that reduce the frequency of the initiating event or its potential consequences have been sought.

TABLE 30. MEASURES TO REDUCE THE RISK OF INITIATING EVENTS CLASSIFIED AS HIGH RISK IN THE SECOND SCREENING

No.	Initiating event	Recommendations
1	Generation of incorrect data for treatment planning (source intensity decay table). This event refers only to manual treatment planning without a TPS (PAC2.10)	Plan several representative or "test" cases manually and compare the results with those of the same plans drawn up using a TPS. If there is no TPS, one belonging to another radiotherapy service will need to be used.
2	Incomplete commissioning of the imaging equipment (which would give rise to errors in the density and geometric scales in the CT, for example) (PAC2.17)	Perform calibration of the density and geometric scales, with a redundant and independent review by another medical physicist.
3	Errors in reconstructing the positioning coordinates of implants using the images taken, which affect the location of the reference points (PAC6.4)	Carry out a redundant review of the reconstruction of the implant coordinates by the medical physicist and a different technician from the one who performed the reconstruction.
4	Errors in reconstructing the positioning coordinates of dummy sources using images (PAC6.5)	A redundant review of the reconstruction of the implant coordinates should be carried out by the medical physicist and a different technician from the one who performed the reconstruction.
5	Errors in entering the prescribed volumes and organs at risk into the TPS using images (PAC6.6)	A redundant review of the reconstruction of the implant coordinates should be carried out by the medical physicist and a different technician from the one who performed the reconstruction.
6	Incorrect placement of any of the points of interest using the images (e.g. points A and B, or points on the lymphatic trapezoid) (PAC6.7)	A redundant review of the reconstruction of the implant coordinates should be carried out by the medical physicist and a different technician from the one who performed the reconstruction.
7	Implementation of treatment planning using the data for a different patient from the one on the prescription (PAC7.2)	Carry out the treatment following a procedure that rules out the use of images from different patients at the same time. This can be achieved by ensuring that the workflow is uninterrupted and that it covers the whole treatment process for each patient, from surgical implantation to planning.
8	Errors in recording the planning results on the treatment chart (PAC8.1).	Import the planning results directly from the TPS, with no need to transcribe the plan parameters.
9	Detachment of sources during administration of treatment (e.g. through breakage or poor fitting of the plastic catheters) (PAC9.7)	Take daily images to verify the status of the implant and the sources during the treatment administration period.
10	Movement of the patient during treatment, causing displacement of the implant with respect to the position designated in the therapeutic intent (PAC9.9)	Take daily images to verify the status of the implant and the sources during the treatment administration period.
11	Accidental implantation of a different number of seeds than planned (PAC9.15)	Take images at intervals established by the doctor to verify the status of the implanted sources during the treatment administration period.

5.2.5 Analysis of the importance of barriers

The following table shows the barriers in the order of the structural importance index defined in Chapter 2.

TABLE 31. IMPORTANCE OF BARRIERS

No.	Barrier	Initiating events after which the barrier intervenes	
		No.	%
1	Evaluation of the treatment plan by the doctor and the physicist	27	34%
2	Verification of the results of dosimetry planning of treatment against an independent calculation performed by a different medical physicist from the one that carried out the planning	14	18%
3	Calibration of the source and comparison of the resulting value with the kerma rate on its certificate	7	9%
4	Independent, redundant verification of the calibration results by another medical physicist and using another dosimetry system	6	8%
5	Verification of the value obtained using the TPS for dose rate at points situated around the source, against published values	6	8%
6	Verification of the number of seeds implanted against the number in the plan	6	8%
7	Use of patient images (including the implant and the dummy sources) so that the dosimetrist or medical physicist can locate and geometrically reconstruct the implant	5	6%
8	Comparison of treatment times with the usual times for similar cases, by an experienced operator	4	5%
9	Detection of radiation levels once the sources are implanted, using an area monitor in the hospital room	4	5%
10	Verification of the number of seeds implanted and the concordance between the mould used and the one foreseen in the treatment plan, against the images obtained at the implantation stage	4	5%

The table below shows the effect that removing each of the barriers would have on the risk level. Only the barriers that intervene in over 15% of the initiating events are listed, and the initiating events whose risk level would change if the barrier were to be weakened or removed are identified. Initiating events whose risk level does not vary are less vulnerable if a single barrier fails.

TABLE 32. EFFECT OF REMOVING A BARRIER

Barrier being removed: Evaluation of the treatment plan by the radiation oncologist and the physicist			
No.	Initiating events in which the barrier intervenes and whose risk level changes	Baseline risk level	Risk level without barrier
1	Supply of sources with manufacturing defects which would affect the dose distribution of treatments (PAC1.2)	R_M	R_H
2	Use of deficient data records (e.g. air kerma rate in reference conditions) and their entry into the TPS with errors (PAC2.9)	R_M	R_H
3	Errors in entering the radial function into the planner (PAC2.13)	R_M	R_H
4	Errors in entering the anisotropy function into the planner (PAC2.14)	R_M	R_H
5	Errors in the TPS when calculating the geometric function values based on the formula[7] (PAC2.15)	R_M	R_H
6	Error in the TPS when generating the values for the dose matrices[7] (PAC2.16)	R_M	R_H
7	Omission of the organs at risk from the treatment chart, even though they appear on the clinical prescription for treatment (PAC4.2)	R_M	R_H

TABLE 32. EFFECT OF REMOVING A BARRIER (cont.)

Barrier being removed: Evaluation of the treatment plan by the radiation oncologist and the physicist			
No.	Initiating events in which the barrier intervenes and whose risk level changes	Baseline risk level	Risk level without barrier
8	Recording of an incorrect total treatment dose, fractional dose or fractionation value that is different from the value prescribed (PAC4.3)	R_M	R_H
9	Recording of an incorrect value for the dose that should not be exceeded in organs at risk, assigned by the doctor, or omission of this value (PAC4.4)	R_M	R_H
10	Selection of an incorrect applicator or its poor positioning, giving rise to a displacement of the implant in the patient (PAC5.2)	R_M	R_H
11	Incorrect placement of dummy sources (PAC5.4)	R_M	R_H
12	Erroneous interpretation of the data in the therapeutic intent when carrying out treatment planning (e.g. dose to be administered, fractions, volumes to be irradiated or protected, and technique to be employed) (PAC7.1)	R_M	R_H
13	Error in placing reference points for optimization (e.g. incorrect placement of dose points around a vaginal cylinder) (PAC7.3)	R_M	R_H
14	Incorrect placement of normalization points (PAC7.4)	R_M	R_H
15	Entry of the wrong total dose and fractionation into the TPS prescription module (e.g. through a lapse) (PAC7.5)	R_M	R_H
16	Introduction of an error when calculating treatment time (owing, for example, to errors in calculating the decay of sources) when performing calculations manually or with calculation tools such as Excel spreadsheets (PAC7.7)	R_M	R_H
17	Entry of the wrong number of seeds into the TPS (different from the number implanted) in cases of treatment with permanent implants (PAC7.8)	R_M	R_H
Barrier being removed: Verification of the calculation results obtained from the dosimetry planning of treatment, against the values obtained through independent calculation by a different medical physicist from the one who carried out the planning (verification of dose at one or several points)			
No.	Initiating events in which the barrier intervenes and whose risk level changes	Baseline risk level	Risk level without barrier
1	Supply of sources with manufacturing defects which would affect the dose distributions of treatments (PAC1.2)	R_M	R_H
2	Use of deficient data records (e.g. air kerma rate in reference conditions) and their entry into the TPS with errors (PAC2.9)	R_M	R_H
3	Fault in the TPS when calculating the geometric function values based on the formula (PAC2.15)	R_M	R_H
4	Fault in the TPS when generating the values for the dose matrices (PAC2.16)	R_M	R_H
5	Recording of an incorrect value for total treatment dose, fractional dose or fractionation that is different from the value prescribed (PAC4.3)	R_M	R_H
6	Transcription of an incorrect value for the dose that shall not be exceeded in organs at risk, which is different from the one assigned by the doctor, or omission of this value from the treatment chart (PAC4.4)	R_M	R_H
7	Misinterpretation of the data in the therapeutic intent when carrying out treatment planning (e.g. dose to be administered, fractions, volumes to be irradiated or protected, and technique to be employed) (PAC7.1)	R_M	R_H
8	Error in placing reference points for optimization (e.g. incorrect placement of dose points around a vaginal cylinder) (PAC7.3)	R_M	R_H
9	Errors in the placement of normalization points (PAC7.4)	R_M	R_H
10	Entry of incorrect values for total dose and fractionation into the TPS prescription module (e.g. through a lapse) (PAC7.5)	R_M	R_H
11	Fault in the TPS in calculating an incorrect treatment time (PAC7.6)	R_M	R_H
12	Introduction of an error when calculating treatment time (owing, for example, to errors in calculating the decay of sources) when performing calculations manually or with calculation tools such as Excel spreadsheets (PAC7.7)	R_M	R_H

The graph below shows the percentage of initiating events after which the barrier intervenes, and the percentage whose risk level increases if the barrier is weakened.

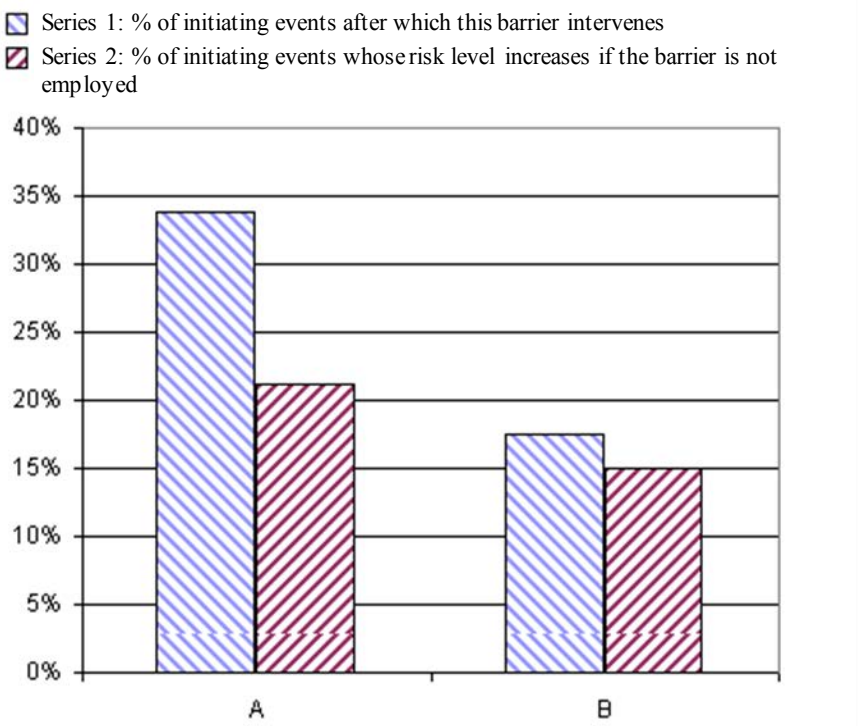


FIG. 12. Significance of removing a barrier.

5.2.6 Analysis of the importance of consequence reducers

Table 33 and Figure 13 show the structural importance of consequence reducers.

TABLE 33. IMPORTANCE OF CONSEQUENCE REDUCERS (>5%)

No.	Consequence reducer	Initiating events after which it intervenes	
		No.	%
1	Medical check during treatment	39	49%
2	Record of location of sources in their store and procedure whereby the entry and exit of every source to and from the store is recorded	6	8%
3	Hospital QA, annual verification of TPS database	5	6%
4	External audit of the facility, using different equipment	4	5%

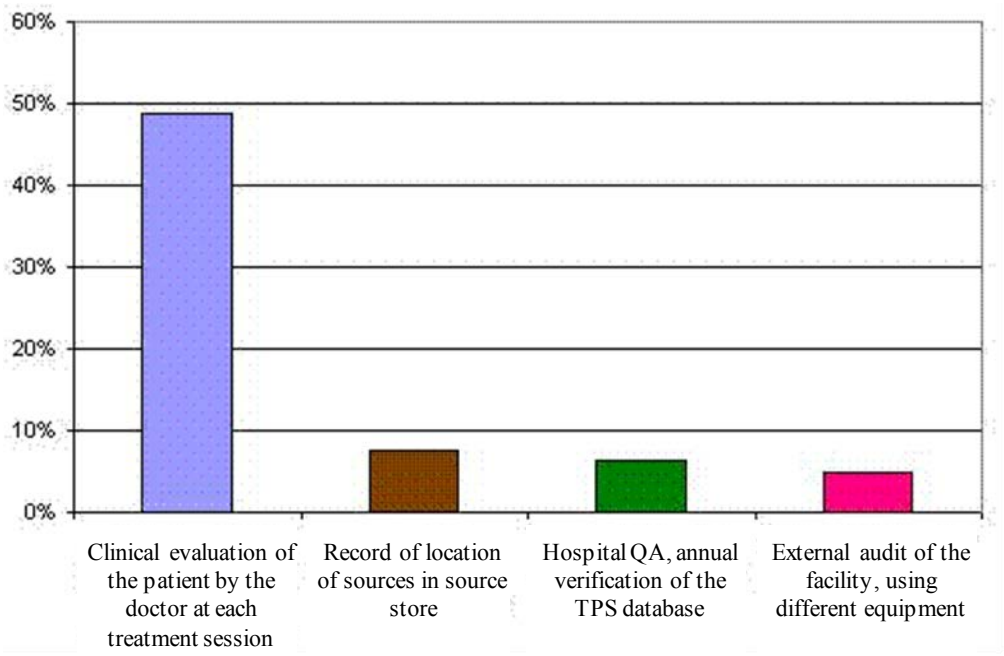


FIG. 13. Importance of consequence reducers.

6. CONCLUSIONS

6.1 SYSTEMATIC AND ANTICIPATORY SEARCH

The risk matrix, like any anticipatory risk analysis method, principally involves looking for anything that could cause accidental exposure, with the aim of foreseeing and preventing it. To this end, every step of the treatment process is investigated, leaving no gaps.

If the staff involved in the analysis belong to all the groups represented in the service (doctors, technicians, physicists), they will gain a complete picture of the process and the importance of their tasks both to the overall risk and to those stages of the process in which they are not directly involved. The risk matrix therefore offers a means of making all staff within the service aware of the safety requirements and risks associated with their work.

6.2 IDENTIFICATION OF AND SCREENING FOR IMPORTANT FACTORS

This exhaustive search results in a high number of events and accident sequences, which can only be dealt with effectively and manageably within a radiotherapy service if there is a selective screening method to identify accident sequences that require attention and potential safety measures to be introduced or made more robust. Such a method is provided by the risk matrix, through preliminary screening followed by a more detailed analysis of the events identified (second screening). Applying this method to radiotherapy has confirmed that these two screenings provide a rational and selective pathway for precise identification of the most vulnerable areas in which efforts should be concentrated.

6.3 SIMPLICITY OF THE METHOD AND APPLICABILITY IN RADIOTHERAPY SERVICES

The risk matrix does not require any highly specialized knowledge of risk analysis. A group made up of radiation oncologists, physicists and technicians from the service can apply the method by dedicating a reasonable amount of time to it, as has been demonstrated in pilot programmes at various hospitals in countries taking part in the project. All that is needed is a training workshop lasting a few days and, preferably, an instructor to work alongside staff and resolve any practical queries, at least initially.

6.4 CONFIRMATION OF EXISTING KNOWLEDGE

For any method to be accepted and incorporated into practice, it must meet two conditions: reliability and utility. Reliability is demonstrated if the method can confirm what is already known from experience. Utility is demonstrated if new light is thrown on the subject and new knowledge gained that can be used to improve safety.

Events reported and lessons learned from them constitute the existing knowledge; these lessons are assumed to have been incorporated into the hypothetical service. As such, this service already has safety measures in place to ensure that these very serious events, which affect multiple patients, have a medium risk level, as confirmed by applying the risk matrix.

The first priority is to ensure that events with very serious or catastrophic consequences do not have a high or very high risk level. To do this, effective barriers must be maintained to counter errors in installation, calibration, commissioning, entry of basic data into the TPS, maintenance or periodic quality checks, which often affect multiple patients, as summarized in section 4.1.

6.5 RECOMMENDATIONS RESULTING FROM APPLICATION TO A GENERIC RADIOTHERAPY SERVICE

6.5.1 Awareness of high risk events that affect a single patient

Applying the risk matrix illustrates that other events with serious consequences, which are less catastrophic but more probable, may result in a higher risk. Such events have drawn less attention in the past: because they affect only one patient, they have received less publicity. Here, the method makes a clear contribution.

6.5.2 External beam therapy

6.5.2.1 Events that remain high risk after selective detailed analysis (second screening)

These events are related to errors in delineating volumes, marking patients or misinterpreting marks, the result of which is that some areas are irradiated unnecessarily or part of the target volume is not irradiated, or that changes to treatment prescribed by the radiation oncologist at one of the medical reviews during the course of treatment are omitted.

Additional barriers to lower the risk level of such events consist of an independent review of the reference marks, editing of the treatment data by a different technician from the one who originally prepared them, and inclusion of a photograph on the treatment chart showing the exact positioning.

Consequence reducers, comprising weekly medical checks, observation of anomalous signs on the patient by radiotherapy technicians, and weekly acquisition and evaluation of portal images, are equally important.

Some events were identified that only affect ^{60}Co external beam therapy and which remained high risk after analysis. These events comprise the selection of a different ^{60}Co unit in the TPS from the one intended (if there is more than one unit), entry of incorrect data into the TPS to calculate treatment time, or selection of the wrong parameters in the treatment unit during administration of daily treatment.

The inclusion of in vivo dosimetry in the initial ^{60}Co external beam therapy treatment session would be an effective barrier to reduce these risks. In the case of accelerator therapy, the existence of in vivo dosimetry within the generic radiotherapy service has already been assumed.

6.5.2.2 Importance of barriers to ensure that risk is neither high nor very high

The risk matrix method ranks barriers according to the number of events in which each takes effect, allowing resources to be allocated selectively to those that affect the most events. As an example, some barriers, such as in vivo dosimetry and joint evaluation of portal images by the radiation oncologist and the physicist, affect up to 36 different initiating events each, and the daily testing of dose constancy at the reference point affects 23 events.

The risk of initiating events with serious or very serious consequences would increase to a high level if the following barriers were absent or weakened:

- Implementation of test cases and verification during commissioning of the TPS;
- Daily testing to verify dose constancy at the reference point;
- Joint evaluation of the dosimetry plan by the radiation oncologist and physicist;
- Joint evaluation of the portal image at the initial session by the radiation oncologist and physicist;
- Joint participation by the radiation oncologist, physicist and radiotherapy

technicians in placing and immobilizing the patient in the treatment position for the initial session;
- In vivo dosimetry at the initial treatment session.

6.5.3 Brachytherapy

The accident sequence identified as the most significant in retrospective studies and through experience is one or more sources remaining inside the patient once treatment is complete. This sequence is not one of the high risk sequences for the hypothetical service because, thanks to lessons learned by the service, a barrier is in place that consists of checking the patients and their clothing at the end of treatment.

Checking the patients and their clothing with a portable detector at the end of treatment once sources have been removed is an essential barrier for any brachytherapy treatment.

6.5.4 Events that remain high risk after analysis

A high risk event common to high dose rate (HDR) and low dose rate (LDR) brachytherapy is incomplete commissioning of imaging equipment (which would give rise to errors in the density and geometric scales in the CT unit, for example).

One possible barrier would be to have a calibration procedure and to apply it to calibrating the density and geometric scales, and also an independent review by a different medical physicist.

In HDR brachytherapy, the most significant high risk events result from the source becoming disconnected from the transfer cable while treatment is under way and remaining in the implant, whether interstitial, intracavitary or surface.

Given that no barriers have been identified for this accident sequence, it is possible to strengthen the consequence reducers, such as being alert to the console alarm and area detector, checking the patients and their clothing with a portable detector at the end of treatment, and carrying out periodic drills of the emergency plan to ensure that all equipment operators take prompt and correct action.

The high risk events identified in LDR brachytherapy are making mistakes in reconstructing coordinates for implants, reference points or points of interest for doses, planning with data from a different patient than the one who appears on the prescription, wrongly recording the results of planning on the treatment chart, a source becoming detached from its applicator or implant (e.g. through breakage or poor fitting of the plastic catheters), the patient moving during treatment causing the implant to be displaced, and lastly, with permanent implants, mistakenly implanting a different number of seeds than planned.

Barriers:

- Review of the reconstruction of coordinates for implants and dummy sources by a different person from the one who calculated the reconstruction;
- Imaging at the beginning and in the middle of treatment, comparing the number and position of implanted sources with those planned.

6.5.4.1 Importance of barriers to ensure that risk level is neither high nor very high

The barriers that intervene in the most accident sequences are the joint evaluation of the treatment plan by the radiation oncologist and the physicist and the independent verification of the plan calculations by a different physicist from the one who prepared the plan.

Barriers and reducers:

- Joint evaluation of the treatment plan by the radiation oncologist and the medical physicist;
- Verification of calculations resulting from the dosimetry planning of treatment through independent calculations by a different medical physicist from the one who planned the case.

6.6 FINAL CONSIDERATIONS

6.6.1 For radiotherapy services

The reliability of all the safety measures described in this study rests on the assumption that there is an organization that clearly establishes responsibilities, including responsibility for ensuring that these measures are taken and remain effective, and provides training for staff so that they know how to carry them out correctly. In particular, training is needed for radiation oncologists, medical physicists, dosimetrists, radiotherapy and mould technicians, engineers and maintenance technicians.

The organization also needs a safety culture that translates into a moderate workload compatible with a careful environment free of distractions, an adequate preventive and corrective maintenance programme, external audits and, in particular, the presence of two technicians per piece of equipment on every shift, which allows for redundant verification that procedures are being carried out correctly. One of the two technicians should be the one who participated in the initial treatment session.

6.6.2 For regulators

In carrying out their regulatory functions of licensing and inspection, regulatory bodies have the opportunity to make use of the information provided in this study and to verify those key aspects that influence risk reduction. The conclusions of the study should be taken into consideration, and regulators' evaluation and inspection methods should be reviewed in the light thereof.

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REFERENCES

[1] HORIOT, J.C., Radiotherapy: still young and almost a hundred years. The Magazine of the World Health Organization, 48th year, No. 3 (1995).

[2] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Prevention of Accidental Exposure to Patients Undergoing Radiation Therapy, ICRP Publication 86. Annals of the ICRP **30** (3), Pergamon Press, Oxford (2002).

[3] FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115, IAEA, Vienna (1996).

[4] INTERNATIONAL ATOMIC ENERGY AGENCY, Accidental Overexposure of Radiotherapy Patients in San José, Costa Rica, IAEA, Vienna (1998).

[5] INTERNATIONAL ATOMIC ENERGY AGENCY, Investigation of an Accidental Exposure of Radiotherapy Patients in Panama, IAEA, Vienna (2001).

[6] SPANISH SOCIETY OF MEDICAL PHYSICS, The accident of the linear accelerator in the Hospital Clínico de Zaragoza. A report of the SEFM, Spain (1991).

[7] ASH, D., BATES, T., Report on the clinical effects of inadvertent radiation underdosage in 1045 patients, Clinical Oncology 6 (1994) 214–225.

[8] INTERNATIONAL ATOMIC ENERGY AGENCY, Accidental overexposure of radiotherapy patients in Bialystok, IAEA, Vienna (2004).

[9] INTERNATIONAL ATOMIC ENERGY AGENCY, Lessons learned from accidental exposures in radiotherapy, Safety Reports Series No. 17, IAEA, Vienna (2000).

[10] VILARAGUT, J.J., FERRO R., LOZANO, B., De la FUENTE, A., DUMÉNIGO, C., TRONCOSO, M., PEREZ, Y., ALEMAÑY, J., LEÓN, L., AMADOR, R.M., LASO, R., LABRADOR, F., BLANCO, A., BETANCOURT, L., CASTRO, D., SILVESTRE, I., Results of the probabilistic safety assessment to the cobalt-therapy process, NUCLEUS No. 36 (2004).

[11] THOMADSEN, B., et al., Analysis of Treatment Delivery Errors in Brachytherapy Using Formal Risk Analysis, Int. J. Radiation Oncology Biol. Phys., **57** 5 (2003) 1492-1508.

[12] VILARAGUT, J.J., FERRO, R., RODRÍGUEZ, M., ORTIZ, P., RAMÍREZ, M.L., PÉREZ, A., BARRIENTOS, M., SAMOANO, F., DELGADO, J.M., PAPADÓPULOS, S., PEREIRA, P.P., LÓPEZ, R., LARRINAGA, E., RIVERO, J.J, ALEMAÑY, J., Probabilistic safety analysis (PSA) of the radiotherapy treatment process using a linear accelerator for medical uses [in Spanish]. Proceedings of the Congress of the International Radiation Protection Association (IRPA 12), Buenos Aires (2008).

[13] LIÑAN, A., RODRÍGUEZ, C., BARBARÍN, J. M., HUERTA, O., Environmental

risk analysis and its application to the storage and management of industrial chlorine [in Spanish], Ciencia [Science] journal, Autonomous University of Nuevo León (UANL) V 2 (2002) 218-224.

[14] KOLLURU, R., BARTELL, S., PITBLADO, R., STRICOFF, S., Risk Assessment and Management Handbook, McGraw-Hill, New York (1996).

[15] VILARAGUT, J.J., FERRO, R., TRONCOSO, M., Application of risk matrices to evaluate the safety of treatment using teletherapy [in Spanish], Nucleus journal No. 39 (2006).

[16] INTERNATIONAL ATOMIC ENERGY AGENCY, Component Reliability Data for use in Probabilistic Safety Assessment, IAEA-TECDOC-478, IAEA, Vienna (1988).

[17] GERTMAN, D.I., BLACKMAN, H.S., Human Reliability and Safety Analysis Data Handbook, John Wiley & Sons, Inc., New York (1994).

[18] PERDOMO OJEDA, M., FERRO FERNÁNDEZ, R., Common Cause Failures and Human Errors [in Spanish], Ediciones Universitarias UGMA, Universidad Gran Mariscal de Ayacucho University, Barcelona, Venezuela (1996).

[19] COHEN, L., SCHULTHEISS, T.E., KENNAUGH, R.C., A radiation overdose incident: initial data, Int J Radiat Oncol Biol Phys. 33 (1995) 217–224.

[20] INTERNATIONAL ATOMIC ENERGY AGENCY, Design and Implementation of a Radiotherapy Programme: Clinical, Medical Physics, Radiation Protection and Safety Aspects, IAEA-TECDOC-1040, IAEA, Vienna (1998).

[21] INTERNATIONAL ATOMIC ENERGY AGENCY, Physical aspects of quality assurance in radiotherapy: Quality control protocol [in Spanish], IAEA-TECDOC-1151, IAEA, Vienna (2000).

[22] INTERNATIONAL ATOMIC ENERGY AGENCY, Absorbed Dose Determination in Photon and Electron Beams, Technical Reports Series No. 277, IAEA, Vienna (1997).

[23] INTERNATIONAL ATOMIC ENERGY AGENCY, Absorbed Dose Determination in External Beam Radiotherapy, Technical Reports Series No. 398, IAEA, Vienna (2000).

[24] INTERNATIONAL ATOMIC ENERGY AGENCY, Commissioning and Quality Assurance of Computerized Planning Systems for Radiation Treatment of Cancer, Technical Reports Series No. 430, IAEA, Vienna (2004).

[25] INTERNATIONAL COMMISSION ON RADIATION UNITS AND MEASUREMENTS, Prescribing, Recording and Reporting Photon Beam Therapy, Rep. 50, ICRU, Bethesda, MD (1993).

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