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General guidelines on risk management in external beam radiotherapy

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FOREWORD

Luxembourg, January 2015

Radiotherapy has been used for treating cancer patients for more than a century. Today, radiotherapy is one of the primary treatment options in cancer management, effectively saving and prolonging lives. Radiotherapy is widely recognised as one of the safest areas of modern medicine; however, when errors occur, the consequences for the patient can be significant. There is a long history of managing risks and errors in radiotherapy and different terminology and approaches have been used for this purpose.

The European Medical Exposure Directive of 1997 (Council Directive 97/43/Euratom) requires that Member States take "all reasonable steps to reduce the probability and the magnitude of accidental or unintended [radiation] doses of patients" in radiotherapy. The main aim of these guidelines is to help national authorities and radiotherapy services plan and undertake activities to fulfil the above legal obligation.

These guidelines are based on a thorough review of available international and national documents, recommendations and guidelines, as well as on the results of two detailed questionnaires distributed in EU Member States. The guidelines introduce the main concepts surrounding the prevention of accidental exposures and present general information on risk management. More detailed technical information and summaries of the results of the two questionnaires are presented in the Technical Supplement.

These guidelines have been prepared by the ACCIRAD consortium, composed of two radiotherapy institutions, two radiation safety authorities, one research centre specializing in information technology and the European Society for Radiotherapy and Oncology (ESTRO). A panel of experts from four countries and five international organizations supported the consortium. The draft guidelines were presented at a dedicated workshop (Poznan, 4-6 June 2013) where they were carefully reviewed. The guidelines were also distributed to the relevant international and European organisations for comments and feedback and were formally endorsed by ESTRO.

The publication of the guidelines in the Commission's Radiation Protection series of publications has been recommended by the Group of Experts established under Article 31 of the Euratom Treaty. The electronic version of the technical supplement is available on the Commission webpage as a useful collection of supporting information gathered by the ACCIRAD consortium.

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CONTENT

EXECUTIVE SUMMARY

These guidelines are the main outcome of EC project ENER/D4/160-2011, “Guidelines on a risk analysis of accidental and unintended exposures in radiotherapy (ACCIRAD)”. The objective of the project was:

- to perform an EU-wide study on the implementation of the requirements of Article 11 of the Council Directive 97/43/EURATOM (Medical Exposure Directive, MED) and
- to develop guidelines on risk analysis of accidental and unintended exposures in external beam radiotherapy.

The guidelines are based on a thorough review of available international and national documents, recommendations and guidelines, the results of two questionnaires to the EU Member States, critical review by several international organizations, and various discussions and considerations in the context of the EC project, including the international Workshop.

Radiotherapy is one of the primary treatment options in cancer management, effectively saving and prolonging lives while preserving quality of life. Best available practices indicate that more than 50 % of patients should receive radiotherapy at least once during the treatment of their cancer. Radiotherapy is widely recognised to be one of the safest areas of modern medicine and errors in radiotherapy are very rare. However, when errors do occur, the consequences for the patient can be significant, and may also affect large numbers of patients, bringing harm and even death in the worst case. The potential for adverse error-events[1] and near misses in radiotherapy is real and should be studied because radiotherapy is a highly-complex, multi-step process, which requires input from numerous individuals from a variety of different areas during both the planning and delivery of treatment.

Radiotherapy has a long history of examining the risks and documenting adverse error-events. Several different methods of risk assessment (study of risk), either generic or tailored specifically to the needs of external beam radiotherapy, are available. Some of these methods are currently being evaluated in pilot programs while others are already in routine use. Likewise, several different systems for reporting adverse error-events and near misses in radiotherapy have been developed and are in use. However, despite these achievements, we still lack a worldwide consensus on the definitions of the basic terminology of adverse error-events and near misses, and in how to classify and report these events. There has been a need to review the available systems, both for risk assessment and the analysis and reporting of the events, in order to elaborate a well-accepted recommended approach.

The objective of these guidelines is to support EU Member States in implementing the legislative requirements stipulated in Article 11 of the MED (and the future update of analogous requirements in the European Basic Safety Standard, BSS), whose aim is to reduce the probability and the magnitude of adverse error-events in radiotherapy. Consequently, this document provides basic information and recommendations for overall risk management in radiotherapy, with a focus on proactive risk assessment and reactive analysis of events. Furthermore, systems for reporting of events, with the related terminology and classification systems, are covered. Other preventative measures are also briefly discussed in order to assure that all aspects of risk management are covered. By definition, the scope of these guidelines is limited to external beam radiotherapy; however, the guidance provided here is, in principle, also applicable to other modalities of radiotherapy, such as brachytherapy.

The guidelines are intended to provide a concise summary of the aforementioned topics, with a focus on the key information underlying the recommendations given. In addition, detailed

[1] In this report, the term “adverse error-event” is recommended to replace the term “accident”.

information on the methods for risk assessment and reactive analysis of events, related terminology, classification systems, and reporting and learning systems, as reviewed within the ACCIRAD project, are presented in the Technical Supplement to the guidelines. The Technical Supplement gives also some more details on the legislative and normative basis, the other preventive measures, and the results of the European questionnaires on risk management.

With regards to the legislative and normative basis, the European regulatory framework, in particular EURATOM BSS, consistent with the international BSS, provides a firm basis to undertake risk assessment and analysis of adverse error-events and near misses.

The use of consistent terminology is considered to be of utmost importance, as uniform terms are absolutely vital to understanding the methodologies, and to comparing the results of the risk assessments, and learning from reported adverse error-events and near misses. Specific efforts have been undertaken, therefore, to review and discuss the basic terms used in both proactive risk assessment and reactive analysis of events, including classification and reporting of events. Recommended terms and definitions for the key concepts are presented. However, it is important to recognize the difficulties of reaching a consensus given the wide variety of terms in current use and the related difficulty of understanding the meaning of these diverse terms. The recommended terms and definitions are presented in the list of definitions, and in the appropriate sections of the guidelines (sections 4 and 5). In particular, one important conclusion regarding terminology merits emphasis: the use of the term "accident", which—in agreement with other fields of medicine—should not be used in radiotherapy but should rather be replaced with the term “adverse error-event”.

The term risk management refers to all the various organizational structures and processes that are designed to improve safety and prevent or reduce risks, or that limit the consequences of risks (i.e., all risk preventive measures). Risk management is, therefore, part of the overall quality management program. As such, it requires appropriate education and training of staff and is closely linked to important quality assurance tools, such as quality control and audits. Proactive risk assessment and reactive analysis of events—the main focus of these guidelines—are two specific tools that form part of overall risk management. Reporting and analysis of adverse error-events and near misses are also a part of risk management and the main function of these processes is to help institutions and their staff learn from errors in order to improve safety and to prevent recurrence.

Proactive risk assessment and the reactive analysis of events should be used in parallel in order to provide optimum results for risk management. The aim of the whole process is as follows:

- to identify hazards and failures
- to evaluate the consequences of a hazard and/or failure,
- to define the likelihood and severity of those hazards/failures in order to calculate the associated risks and to prioritize prevention efforts,
- to define how to decide (method, criteria) which risk reduction actions should be implemented and
- to use feedback from reporting and analysis of events as appropriate.

Different methods of risk assessment are available, but none of these alone can achieve all the aims described above. Rather, a combination of methods (the most common ones are described in these guidelines) is needed to perform a complete evaluation. To understand how these risk assessment methods are applied in radiotherapy, besides general concepts of risk (e.g. hazard, failure mode, barrier), the guidelines describes the different steps involved, including important concepts such as likelihood and severity scales and a criticality matrix. A more comprehensive discussion of available methods of risk assessment is presented in the Technical Supplement. As a result, these guidelines, together with the Technical Supplement, provide users with the key information needed to select an appropriate method and to implement it. For proactive risk assessment, two radiotherapy-

specific methods are available: dedicated Failure Mode, Effect and Criticality Analysis (FMECA) and dedicated risk matrix. Given their specificity, these two methods probably provide the easiest approach to proactive risk assessment. Both methods are briefly introduced here and full details are given in the Technical Supplement.

The reactive (retrospective, a posterior) analysis of events is directly related to the recording and reporting of events. During the radiotherapy process, when something goes wrong and results in an adverse error-event or a near miss, the event is initially recorded and reported within the radiotherapy department. This initial report triggers, or is accompanied by, a preliminary analysis of the causes and consequences of the event, and "immediate" corrective actions. However, given that this initial analysis might not provide a full understanding of the event and its causes, a more detailed analysis is often required. After this detailed analysis has been completed, the final reporting of the event takes place through the local and/or external reporting systems (e.g., international systems such as Safety in Radiation Oncology, SAFRON, and Radiation Oncology Safety Information System, ROSIS), with the primarily purpose of more widely disseminating the lessons learned to other professionals. In both the initial and final reporting of adverse error-events and near misses, it is important to document all findings and corrective actions in order to prevent the re-occurrence of such events (or their occurrence elsewhere), and, especially, to share the lessons learned as a result of the event.

The primary purpose of *event reporting* systems is to learn from experience, that is, from past errors. For this reason, such systems should more accurately be called reporting and learning systems. How an organization learns from its own and from other's experience is a critical safety feature and an expression of its safety culture. In these guidelines, the various characteristics of reporting and learning systems are discussed. The conclusion that can be made is that a successful reporting system should be non-punitive, confidential, and its main aim should be to promote learning through information sharing and feedback.

The purpose of *classification systems* for event reporting is to organize such reports, to facilitate the analysis of events, and finally, to improve safety through this analysis. These objectives may best be achieved by using existing general classification systems that have been modified to include radiotherapy-specific details. Classification of events based on how the event affects the patient (i.e., consequences) is a common approach, although other factors, such as causes and contributing factors or the stage in the process, have also been used in classification. In radiotherapy, a fully developed classification system should include the following items: causes, contributing factors, description of the event (date, stage in the process, sequence of events leading to the event, etc.), a description of how the event was discovered, severity of consequences, probability of recurrence, management of the event, and recommendations to avoid future repetition.

In addition to proactive risk assessments and reactive analysis of events—and the associated need for consistent classification, reporting, and learning systems—there are a number of measures or interventions which are likely to be effective at reducing risks and preventing adverse error-events and near misses in the radiotherapy process. The general hierarchy showing the effectiveness of preventive measures is presented here, while the Technical Supplement contains a more detailed discussion of the topic, including several important examples (quality assurance, quality control, and clinical audit).

These guidelines present numerous *recommendations* on the risk assessment and analysis and reporting of events for external radiotherapy. Two levels of recommendations are given: (1) Recommendations to institutions that provide radiotherapy services, whose primary responsibility is patient safety, (2) Recommendations to national authorities, which focus on the need for strong support at the national or regional level to promote a culture that values risk management and safety. In addition, a few recommendations on reporting and learning systems are given separately.

The recommendations for *risk management at the institutional level* emphasize the fundamental importance of having a dedicated quality management system. Both proactive

risk assessment and reactive analysis of events are important risk management tools and the two should be used in combination (an integrated approach to risk management); likewise, the importance of reporting events should also be stressed. In this sense, the leadership of top management is crucial, and sufficient staff and time—including appropriate training of the staff—should be allocated to risk assessment and analysis and reporting of events. The personnel resources needed, including the aforementioned training activities, will primarily depend on the methods selected, but will also depend on the existing knowledge and skills of the staff—the guidelines provide illustrative staffing figures in terms of man-months. A risk management committee and a multidisciplinary working group supported by a risk manager are considered necessary to implement and carry out the practical work. For this reason, detailed advice on the various steps required for implementation is provided. To provide institutions with a basic (i.e., minimum) approach to proactive risk assessment, two optional methods are proposed. However, it is recommended that institutions take a more comprehensive approach to assessment once they have gained experience from implementing this basic risk assessment model. In terms of performing the reactive analysis of events, no specific methods are recommended, although there are several methods considered useful and these merit mention. In terms of event reporting, institutions are encouraged to report events to the international SAFRON system in order to ensure that the international radiotherapy community can benefit from the lessons learned and, thereby, improve safety.

The recommendations on *risk management at the national level* call for the development—or updating of—a national strategy on quality and risk management to promote a safety culture in radiotherapy. Given that risks and adverse error-events are often due to a mixture of equipment failure and organizational and human factors, close collaboration between national authorities (i.e., those that regulate healthcare, radiation protection, and medical devices) and professional societies is strongly recommended, as is improved dialogue between national authorities, medical professional societies, medical users of radiation, and manufacturers. Among the many stakeholders, representatives from patient organizations and hospital administrators should also be involved. The main components of the national strategy are presented in detail, including issues related to informing patients and the public of adverse events. Clinical audits and regulatory inspections are also considered to play an important role in the national strategy.

The recommendations on *classification and reporting* systems highlight the need for harmonized terminology, a few desirable characteristics of the systems and systematic and timely dissemination of information. A collection of recommended terms is presented.

LIST OF DEFINITIONS

Term or concept	Equivalent term in EU BSS	Definition
Risk management, for patient safety in external beam radiotherapy		Identifying, assessing, analyzing, understanding, and acting on risk issues in order to reach an optimal balance of risk, benefits and costs. Only risks related to the use of radiation are considered. Risk management thus comprise all the aspects of the organization to improve safety including, as specific tools, proactive risk assessment (study of risk) and reactive analysis of adverse error-events and near misses.
Proactive risk assessment, Risk assessment	Study of risk	Proactive (a priori) assessment of risk. It is a process that helps organizations to understand the range of risks that they face, both internally and externally, their capacity to control those risks, the likelihood of the risk occurring and the potential impact thereof. This involves quantifying risks and using judgment, assessing and balancing risks and benefits and weighing these against cost.
Analysis of events	Analysis of events	Reactive (retrospective, a posteriori) analysis (or assessment) of adverse error-events and near misses to determine causes and to prevent reoccurrence.
Adverse error-event	Event involving accidental or unintended medical exposures	An event that results in unintended harm—either minor or serious—to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient. All treatment-related side effects are excluded[2].
Event		Something that happens to or involves a patient (WHO, 2009a,b). A circumstance that could have resulted, or did result, in unnecessary harm to a patient.
Near miss event (Near miss)	Event potentially involving accidental or unintended medical exposures	An event which could have resulted in unintended harm to the patient but which did not reach the patient (i.e. without consequence for the patient).
Minor or no harm event	Event involving accidental or unintended medical exposures	An event that reaches the patient but does not harm the patient
Significant event (Notifiable event)	Significant event	An event that should be notified to authorities according to national criteria defined by regulation.

[2] WHO defines a side effect as a known effect, other than that primarily intended.

Term or concept	Equivalent term in EU BSS	Definition
Error		A failure to carry out a planned action as intended or application of an incorrect plan. Errors may manifest by doing the wrong thing (commission) or by failing to do the right thing (omission), at either the planning or execution phase (WHO, 2009a,b).
Active failure, direct cause of an event		Unsafe acts committed by people who are in direct contact with the patient or system, i.e. any behaviour, omission or deficiency that if corrected, eliminated or avoided, probably would have prevented the event. Active failure can also be sudden equipment failure.
Latent condition, latent cause of an event (contributing factor)		Inevitable “resident pathogens” within the system; i.e., any behaviour, omission, or deficiency that increases the probability or severity of the event. These may arise from decisions made by designers, builders, procedure writers, and top level management. They may (1) translate into error-provoking conditions within the local workplace and (2) create long lasting holes or weaknesses in the defences.

LIST OF ABBREVIATIONS

AAPM	American Association of Medical Physicists
ALARM	Association of Litigation And Risk Management
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
ASN	Autorité de Sûreté Nucléaire (The French Nuclear Safety Authority)
ASTRO	American Society for Therapeutic Radiation Oncology
BSS	Basic Safety Standard
CTA	Causal Tree Analysis
CTCAE	Common Terminology Criteria for Adverse Events
EC	European Commission
EN	European Norm
ETA	Event Tree Analysis
EU	European Union
EU BSS	European Basic Safety Standards, Council Directive 2013/59/Euratom
FAO	Food and Agriculture Organization of the United Nations
FMEA	Failure Mode and Effects Analysis
FMECA	Failure Mode, Effects and Criticality Analysis
FORO	Ibero-American Forum of Radiological and Nuclear Regulatory Agencies
FTA	Fault Tree Analysis
HFACS	Human Factor Analysis and Classification System
HSE	Health and Safety Executive
IAEA	International Atomic Energy Agency
ICPS	International Classification for Patient Safety
ICRP	International Commission on Radiation Protection
ICRU	International Commission on Radiation Units and Measurements
ILO	International Labour Organization
INSAG	International Consultative Group on Nuclear Safety Group
IMO	International Maritime Organization
ISO	International Standards Organization
IT	Information Transfer
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
MED	Medical Exposure Directive, Council Directive 97/43/Euratom
NHS	National Health Service
NPSA	National Patient Safety Agency
NRC	Nuclear Regulatory Commission
NRLS	National Reporting and Learning System
OECD	Organisation for Economic Cooperation and Development

ORION®	ORION® is a registered method for reactive analysis of events
PAHO	Pan American Health Organization
PC	Personal Computer
PRA, PHA	Preliminary Hazard and Risk Analysis
QA	Quality Assurance
QC	Quality Control
QM	Quality Management
RCA	Root Cause Analysis
RCR	Royal College of Radiologists
RM	Risk Management
ROSIS	Radiation Oncology Safety Information System
RPN	Risk Priority Number
RTOG	Radiation Therapy Oncology Group
SAFRON	Safety in Radiation Oncology
SEVRRA	Sistema de Evaluación del Riesgo en Radioterapia
SFPM	French society of medical physics
SFRO	French society of radiation oncology
SIMPATIE	Safety Improvement for Patients in Europe
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiations
UNEP	United Nations Environmental Program
WHO	World Health Organization

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1 INTRODUCTION

Radiotherapy is one of the primary treatment options in cancer management. According to the best available practices (Delaney, 2005; Lievens and Grau, 2012), more than 50% of patients should receive radiotherapy at least once during their cancer treatment. Together with other treatment modalities, such as surgery and chemotherapy, radiotherapy plays an important role in the treatment of patients whose cancer is ultimately cured (SBU, 2003). Radiotherapy is also a highly effective treatment option for palliation and symptom control in cases of advanced or recurrent cancer. Thus, radiotherapy effectively saves lives, prolongs lives, and allows patients to preserve quality of life.

Radiotherapy is widely recognised to be one of the safest areas of modern medicine and errors in radiotherapy are very rare. However, when errors do occur, the consequences can be significant for the patient, or the consequences may involve large numbers of patients, bringing harm and even death in the worst case. The safety of radiotherapy is supported by the fact that very few severe radiotherapy accidents have occurred in recent years. A review of the literature (WHO, 2008a) showed that from 1976 to the year 2007, a total of 3125 patients were reported to be involved in radiotherapy events that resulted in an adverse event. Only a small percentage (about 1%; N=38) of the affected patients died due to radiation overdose toxicity. To provide more context for these figures, it is important to highlight the large number of treatments administered in this same period. Although the WHO (WHO, 2008a) does not provide these figures, the number of radiotherapy treatments performed annually is > 500,000/year (UNSCEAR, 2008) and based on these figures, the percentage of treatments resulting in a reported adverse error-event seems extremely low (< 0.1%). Further, it is important to contextualize the radiotherapy-related error rate, which compares favourably with the rate of other types of medical errors (WHO, 2008a).

The risk for adverse effects and near misses in radiotherapy is real and should be studied because radiotherapy is a highly-complex, multi-step process, which requires the input of many different professional groups in the planning and delivery of the treatment. This complexity arises from the wide range of conditions treated, the number of professionals involved, the technologies used, and high degree of professional expertise needed to plan and deliver treatments. This complexity is compounded by the multiple steps involved and the fact that processes are continually changing in response to new research and the introduction of new technologies. Over the last decade, the rapid development of new technology has significantly changed the way in which radiotherapy is planned and delivered, with the emergence of a variety of new technologies and approaches: three-dimensional computed tomography-based planning; new imaging modalities such as magnetic resonance imaging (MRI) and positron emission tomography (PET); multi-leaf collimation; intensity modulation; flattening filter free beams; improved immobilization techniques; and more sophisticated planning and data management software—all of these new developments now permit complex treatment plans to be prepared individually for many patients (Huang, 2005; ICRP, 2009). Modern radiotherapy departments are multisystem-dependent environments that rely heavily on transfer of patient data between different units, systems, and staff from different disciplines.

Understanding the complex process of radiotherapy requires many different kinds of expertise: it involves understanding principles of medical physics, radiobiology, radiation safety, dose measurement and calculation, radiotherapy planning and simulation, and the interaction of radiotherapy with other treatment modalities, among others. Several different professional groups are needed to plan and deliver radiotherapy. The main professionals involved are radiation oncologists, radiation therapists[3], and medical physicists. Each of these disciplines must work together through an integrated process to plan and deliver radiotherapy to patients.

[3] Also called therapeutic radiographers (EFRS, 2013).

Every step in the radiotherapy process must be performed to a high degree of accuracy to ensure the greatest likelihood of achieving maximum tumour control with minimal risk to normal tissue. The radiation dose should be delivered and reported within acceptable tolerances as discussed in the relevant ICRU Reports (ICRU, 1993; 1999; 2010).

It is imperative that proper quality assurance (QA) measures are in place to achieve and maintain the required degree of accuracy, to reduce the likelihood of adverse error-events and other errors, and to increase the probability that any errors that do occur will be recognized and rectified. Studies in radiotherapy practice have shown that development of a comprehensive QA system, including an explicit and uniform protocol for implementation and timely assessment of errors, may reduce the frequency and severity of events (Huang, 2005; Yeung, 2005; Lawrence, 2007). QA guidelines specific to radiation treatment have been issued by a number of worldwide organizations, including the World Health Organization (WHO, 1988), the International Atomic Energy Agency (IAEA, 2007a; 2008), and the International Commission on Radiological Protection (ICRP, 1996).

There is a long history of documenting events and examining adverse error-events in radiotherapy, and several international and national systems of classification, recording and reporting of the events have been developed. However, while there have been efforts to unify the terminology (Ford et al., 2012), a worldwide consensus is still lacking in terms of both the basic terminology of adverse error-events and near misses, and in how to classify and report these events. The existing systems are also highly variable in terms of their purpose, sponsorship, participation, function, and feedback. While some of these differences can be justified by the different purposes of the systems, there is a need to harmonize, at the least, those systems that have similar aims. The existing international systems for reporting of events (SAFRON, ROSIS) merit greater attention due to the huge benefits of reporting to, and learning from, them.

Reducing the error rate to zero is an unrealistic goal in most fields, and radiotherapy is no exception. However, every effort should be taken to keep error rates as low as possible. International safety guidelines have been developed and are regularly updated to deal with radiotherapy errors related to equipment and dose measurement and calculation. However, there is no consensus yet as to how best to deal with errors not covered by regular system QA checks. Recently, several organizations have addressed the need for proactive risk assessment in radiotherapy in order to supplement the more common reactive analysis of adverse error-events and near misses. By studying such events and the factors underlying them, researchers have been able to map the risks (WHO, 2008a). Risk model researchers (Duffey, 2003) generally claim that errors can always be reduced to the minimum possible consistent with the accumulated experience by effective error management systems and tracking progress in error reduction down the learning curve. This can also lead to identification of events earlier in the process with less serious consequences.

The importance of risk management is evidenced in several other human activities where a high level of safety is required, such as civil aviation and the nuclear industry, but also in the manufacture of medical devices that emit ionising radiation. A proactive risk assessment is particularly necessary in the field of radiotherapy because event detection is more difficult: the consequences of events are not always immediately evident to the patient or physician and can emerge long after treatment has ended. Risk management, including both proactive risk assessment and reactive analysis of adverse events and near misses, is undoubtedly a high priority in efforts to prevent adverse error-events in radiotherapy.

Several methods of risk assessment, either generic or tailored to the needs of external beam radiotherapy, are available and have been in a pilot use or in some cases been applied routinely. The study of the available systems would be of value to help identify which approach(es) should be recommended. Conceivably, a basic method might be first recommended, and then a more complex, optimized approach could be recommended once sufficient experience and resources are available.

2 PURPOSE AND SCOPE

Article 11 of the Medical Exposure Directive (MED; EC, 1997) requires that "Member States shall ensure that all reasonable steps to reduce the probability and the magnitude of accidental or unintended doses of patients from radiological practices are taken (...)" and stipulates that "the main emphasis in accident prevention should be on the equipment and procedures in radiotherapy (...)". As shown in Section 3, these requirements have been reinforced in the recently updated EU BSS (EC, 2013).

The objective of these guidelines—the risk assessment and analysis of events, or the assessment of accidental and unintended exposures in external beam radiotherapy—is to support Member States in implementing the legislative requirement derived from the provision of Article 11 of MED (and the EU BSS) (EC, 2013). The aim of these requirements is to reduce the probability and the magnitude of adverse error-events in radiotherapy. It should be noted that the patient safety is the main concern of the risk assessment and analysis of adverse error-events in external beam radiotherapy, as discussed in these guidelines.

The target audience for these guidelines include the management team and the various professional groups who work at radiotherapy institutions, in addition to risk managers and other people who are directly involved with risk management within the radiotherapy institutions. Other users include radiation protection and regulatory authorities responsible for ensuring that the BSS requirements are integrated into national legislation and for managing the implementation of regulatory requirements. These guidelines will also be of value to the organisations charged with establishing and promoting the use of reporting and learning systems for adverse error-events in radiotherapy, and also for manufacturers, who have an important role related to the impact of equipment design on proactive risk assessment and reporting and learning from events.

The guidelines aim to provide basic information (section 4) and recommendations (section 5) for an overall risk management in radiotherapy, as highlighted in the introduction. The guidelines introduce the main concepts and present a short general review of proactive risk assessment, reactive analysis of events, event classification, reporting and learning systems, and other preventive measures or risk reduction interventions. The general review is intended to provide key concepts in risk management, which, in turn, leads to the recommendations given in the guidelines. Detailed information on the legislative and normative basis of the relevant regulatory requirements, various methods for proactive risk assessment and reactive analysis of events, event classification, reporting and learning systems, and the preventive measures, together with summaries of the results of the two questionnaires, is presented in the Technical Supplement to these guidelines.

The guidelines presented here support the links between risk assessment and the principle of defence in depth and user experience feedback, and stress the benefits of promoting an exchange of risk assessment results between equipment manufacturers and users.

While the scope of the guidelines is, by definition, limited to external beam radiotherapy, many of the general principles of proactive risk assessment, reactive analysis of events, event classification and reporting, and other preventive measures are also applicable to other modalities of radiotherapy, such as brachytherapy.

3 REGULATORY AND NORMATIVE BASIS

Risk assessment and analysis of events relative to accidental and unintended medical exposures have been addressed in both European and international safety standards.

The new EU BSS (EC, 2013) lays down the basic requirements for the risk assessment and analysis of events, including timely dissemination of information to the authorities, referrers, practitioners and patients or their representatives. Article 63 of the EU BSS entitled “accidental and unintended medical exposures”, introduces new specific requirements for QA and events reporting. Article 63 stipulates that Member States shall ensure that

- all reasonable measures are taken to minimise the probability and magnitude of accidental or unintended medical exposures of individuals subject to medical exposure from all medical radiological procedures;
- for radiotherapeutic practices the quality assurance programme includes a study of the risk of accidental or unintended exposures;
- for all medical exposures the undertaking implements an appropriate system for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures;
- arrangements are made to inform the referrer and the practitioner, and the patient, or their representative, about clinically significant unintended or accidental exposures and the results of the analysis;
- the undertaking declares as soon as possible to the competent authority the occurrence of significant events as defined by the competent authority; the results of the investigation and the corrective measures to avoid such events are reported to the competent authority within the time period specified by the Member State;
- mechanisms are in place for timely dissemination of information regarding lessons learned from events.

In addition, article 78 on “information on equipment” specifies that any undertaking acquiring medical radiological equipment shall be provided with adequate information on the risk assessment for patients (as required by the Medical Devices Directive).

The European Medical Device Directive 93/42/EEC (EC, 1993) sets some requirements which are specific to medical devices that emit ionising radiation, such as the medical devices used in external beam radiotherapy. Specifically, the directive requires manufacturers to produce technical documentation, including documentation that describes the results of the manufacturer's risk assessment. An additional requirement is to share information on post-marketing incidents.

The Council Directive on the application of patients' rights in cross-border healthcare (2011/24/EU) (EC, 2011) calls for “increased cooperation and sharing of knowledge” in areas related to cross-border health. Cooperative efforts to assess health technologies within the framework of the Directive will support improved communication among national authorities and will also contribute to preventing the duplication of efforts, both of which are also applicable in the field of risk management.

The Council of the European Union has issued a Council Recommendation (2009/C151/01) on patient safety (EC, 2009a) which includes suggestions on the prevention and control of healthcare-associated infections. The recommendations on general patient safety issues include the importance of disseminating information to patients about the risks of treatment and on safety measures which are in place to reduce or prevent errors and harm. Furthermore, the Council Recommendation supports the establishment or strengthening of comprehensive reporting and learning systems for adverse events.

The Safety Fundamentals, issued as part of the IAEA Safety Standard Series (IAEA, 2006), defines ten Fundamental Safety Principles including the principle of prevention of accidents

that could occur in the use of ionizing radiation for medical (or industrial or research) purposes. The international BSS, issued by the IAEA (IAEA, 2014) and jointly sponsored by the EC, FAO, IAEA, ILO, OECD/NEA, PAHO, UNEP and WHO, defines specific requirements for medical exposures, including the requirement that registrants and licensees promptly investigate any unintended or accidental medical exposures. Although the basis for events registration and notification, as well as safety assessments, are included in this BSS, risk assessment is not explicitly specified as a part of QA procedures.

The best reference for a Quality Management System in healthcare is an international standard, EN ISO 9001: 2000 (ISO, 2000). Some specific requirements of interest from this standard concern those that describe analysis, improvement, and preventive and corrective actions. An example of the implementation of the ISO standard in radiotherapy is available on the ASN website (ASN, 2008a).

In conclusion, with respect to the management of accidental and unintended medical exposure, the European regulatory framework is consistent with the international BSS and provides a firm basis for appropriate risk management. The reporting and learning of events is amply covered in both the European requirements and the international standards. Although the need for safety assessments that include a proactive risk assessment has been considered in the international BSS, currently no specific safety guidelines or reports on this matter for radiotherapy are available; as a result, there is a clear need for the present guidelines.

The legislative and normative basis is presented with additional details in the Technical Supplement to these guidelines.

4 RISK MANAGEMENT

4.1 Basic concepts

In this section a few basic concepts and their definitions, as adopted in these Guidelines, are presented. The terminology related to events is further discussed in Section 4.5.2 and in the Technical Supplement. Equivalencies between the terms used here and those used in the revised Euratom BSS (EC, 2013) are shown in Table 4.1 (also shown in the List of definitions and in Table 5.9). Although the relationships between the main procedural concepts are complicated, a simplified illustration is shown in Fig. 4.1.

Table 4.1. Equivalence of terms between the present Guidelines and the revised Euratom BSS (EC, 2013)

Present Guidelines (ACCIRAD)	Revised Euratom BSS (EC, 2013)
Proactive risk assessment, risk assessment	Study of risk
Analysis of events	Analysis of events
Adverse error-event & No harm or minor event	Event involving accidental or unintended medical exposures
Near miss	Event potentially involving accidental or unintended medical exposures
Significant event	Significant event

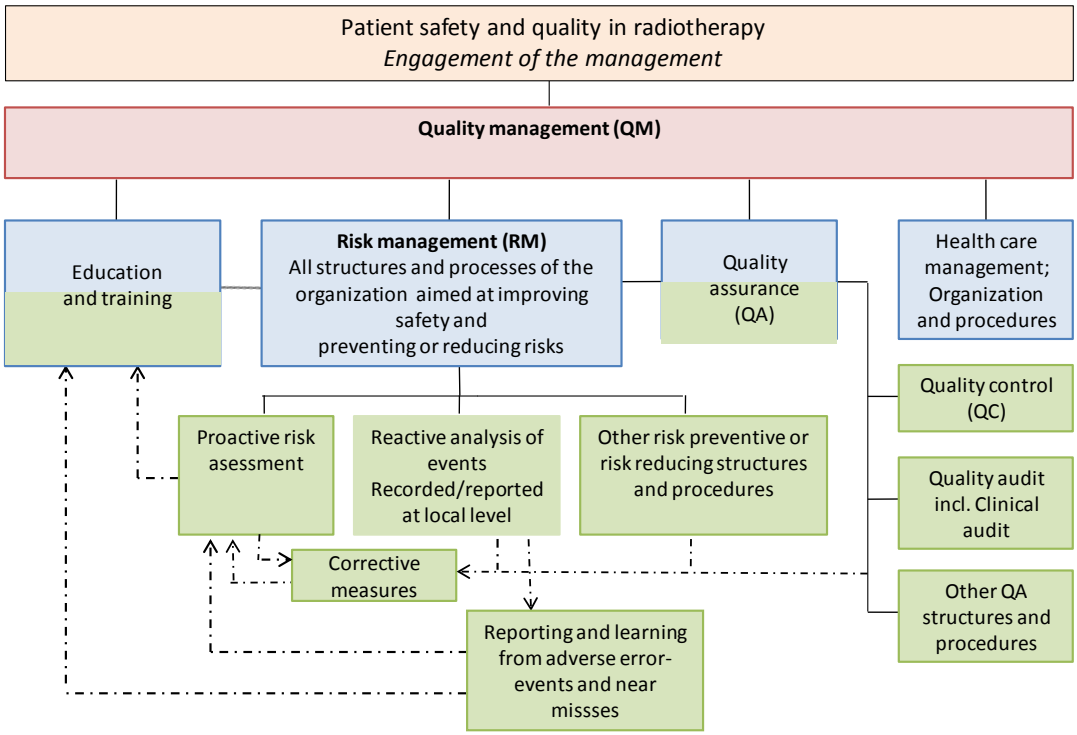

Figure 4.1. Simplified illustration of the relationships of the main procedural concepts discussed in these Guidelines. Blue boxes represent the main tools for QM, while the green boxes describe the main tools for RM (depicted here as QM "sub-tools"). Education and training and QA are tools for both QM and RM, hence the boxes are bi-coloured. Dotted lines with arrows indicate the main feedback lines, e.g., proactive risk assessment should benefit from learning of events.

General information on risk management is available also from the standards dealing with risk (ISO, 2009a; 2009b; 2009c).

4.1.1 Risk

In the terminology used in these guidelines risk means “radiation risk”—that is, risk of all the various ways in which a patient could be harmed in the context of using radiation for the treatment, which is considered to be an adverse error-event (Section 4.1.3). This includes the risk of administering a radiation overdose (higher than intended) or an underdose (lower than intended; reducing cure rate) or the risk of delivering the right dose to the wrong site (geographical miss). The concept of risk covers many details of the radiotherapy procedure, such as incorrect patient positioning or poorly-managed unscheduled interruptions, both of which can negatively impact treatment outcomes.

According to the definition given above, "risk" as used in these guidelines is limited to adverse error-events; in contrast, the side effects of radiotherapy (adverse reactions, see Section 4.1.3)—regardless of their severity—that may occur in a treatment performed under normal operating conditions are excluded from the definition used here. It is important to highlight the more limited concept of risk used in these guidelines, as risk in radiotherapy has a much wider scope. While the risks for treatment-related side effects are undoubtedly important, this wider concept is not included here because it is unrelated to any treatment errors. Furthermore, the radiation risk discussed in these guidelines does not include medication errors and other types of errors not directly related to the use of radiation.

The magnitude of the risk is estimated based on the likelihood of failures and hazards and the severity of their consequence (see Section 4.3).

4.1.2 Risk management

For the purpose of these guidelines, the following definition has been adopted:

> ***Risk management*** for patient safety in external beam radiotherapy: identifying, assessing, analyzing, understanding, and acting on risk issues in order to reach an optimal balance of risk, benefits and costs (NPSA, 2004). Only risks related to the use of radiation are considered.

In other words, risk management refers to all structures and processes of the organization intended to improve safety and to prevent or reduce risks or to limit the consequences of said risks (see Fig. 4.1)—that is, all risk prevention measures. Risk management is part of the overall quality management, requires appropriate education and training to be properly implemented, and is closely linked to important tools of quality assurance such as quality control and quality audits. Risk management involves two primary activities (“tools”): proactive risk assessment (study of risk) and reactive analysis of events. The reporting and analysis of adverse error-events and near misses, whose main purpose is to learn from such incidents in order to improve safety and avoid recurrence, are also a part of risk management.

It should be understood that risk management is just one “dimension” of the many dimensions that make up overall quality of care. The multiple dimensions in the general concept known as "quality of care" include: appropriateness (relevance), security (safety), acceptability, accessibility, timely delivery, continuity, effectiveness (achievement of objectives), and efficiency (achievement of the best cost). Despite the emphasis given in these guidelines on one particular dimension of care quality (safety of care and the procedures to assure safety through risk management), it is important that the other dimensions not be overlooked.

4.1.3 Adverse error-event

For the purpose of these guidelines, the following definition has been adapted:

> ***Adverse error-event***: An event that results in unintended harm—either minor or serious—to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient. All treatment-related side effects are excluded.

Due to the reasons described in Section 4.5.2 of these Guidelines, it is recommended that the term “accident” be replaced by the term “adverse error-event”. Moreover, although this new term is based on “adverse event”, the use of "adverse error-event" precludes any misunderstanding of the term.

In medicine, the term “adverse event” might include all *adverse effects* to the patient, regardless of their origin. Thus, the general use of "adverse event" also includes the side effects of radiotherapy. However, side effects in radiotherapy are considered adverse *effects*, which the treating radiation oncologist is required to inform patients about before treatment is initiated. These side-effects are usually observed during normal treatment and patients, by an explicit agreement (informed consent), acknowledge and accept such risks. Given that the normal side effects of radiotherapy are not included in the concept of risk as defined above, nor in the proactive risk assessment and reactive analysis of events defined below, nor in the reporting of events discussed in Section 4.5, only *adverse events caused by errors* should be considered. Therefore, to avoid confusion with the general use of the term “adverse event”, the term “adverse error-event” is defined. In addition, for the purposes of these guidelines, it is recommended that "adverse error-event" be used to replace the term “accident”.

4.1.4 Significant event

Significant event (or notifiable event) is defined as an event that should be notified to authorities according to national criteria defined by regulation. Due to the wide variety of proposed thresholds (see Section 4.5.3) and the difficulty of obtaining international consensus, no further discussion on recommendations for significant events is provided in these Guidelines.

4.1.5 Risk assessment and analysis of events

For the purpose of these guidelines, the following definitions have been adopted:

> ***Risk assessment (Study of risk)***: Proactive (prospective, a priori) assessment of risk is a process that helps organizations to understand the range of risks (both internal and external) that they face, their capacity to control those risks, the likelihood (probability) of the risk occurring and the potential impact thereof. This involves quantifying risks and using judgment, assessing and balancing risks and benefits and weighing these against cost.
>
> ***Analysis of events***: Reactive (retrospective, a posteriori) analysis (or assessment) of adverse error-events and near misses to determine causes and to prevent their recurrence.

The aim of proactive risk assessment is to identify potential hazards and to identify measures that can be implemented to avoid, prevent, detect, or control the potential occurrence of adverse error-events and to mitigate the consequences of such errors when they do occur.

Proactive risk assessment and reactive analysis of events should be used in parallel to provide optimum results for risk management. This means that results from the analysis of

events should be used to enhance the proactive risk assessment performed prior to the events analysis. Fig. 4.2 emphasizes this relationship and presents the different targets of risk management for these two tools. The figure also shows the available methods that can be used to the assessment or analysis. The final aim is to obtain a continuous cycle of improvement. For this reason, results should be monitored and evaluated regularly, using the feedback obtained from all the steps of the process.

In more detail, the five targets of Fig.4.2 are:

1. to identify potential hazards and/or failures,
2. to evaluate the consequences of a hazard or failure on the system or on patients and other persons involved, taking into account all available barriers and their efficiency,
3. to define the likelihood and severity of these hazards or failures in order to calculate the associated risks and to prioritise prevention efforts,
4. to establish how to decide (i.e., a method or criteria) which risk reduction actions should be undertaken and to check the efficiency of the implementation of said actions,
5. to use feedback from analysis and reporting of events as appropriate.

Targets 1 to 4 correspond to the proactive risk assessment steps discussed in section 4.3.2. None of the currently-available proactive risk assessment methods are capable of achieving all four targets; therefore, to perform a complete assessment, it is necessary to combine different methods. Furthermore, in order to take into account failures of the barriers to comply with the defence in depth approach (See Sections 4.1.7 and 4.3.2), a more comprehensive assessment is needed in which combinations of failures and probabilistic assessment are considered (Fault Tree and Event Tree Analysis methods). For step 5, feedback from reporting is added because, in addition to analysis of local events, feedback from reports published elsewhere (e.g., in SAFRON, see section 4.5) could also benefit risk assessment.

The criteria to initiate a proactive risk assessment and the sequence of procedures are presented briefly in Section 4.3. In addition, that same section includes two examples of radiotherapy-specific methods and a comparison of six methods: four general methods and the two aforementioned radiotherapy-specific methods. The principles and methods of reactive analysis of events are presented briefly in Section 4.4 along with a comparison of said methods. In the Technical Supplement to these guidelines, the various methods shown in Fig. 4.2 are described in detail along with a description of current practices in Europe—identified through the questionnaires—with proactive risk assessment and reactive analysis of events.

The reporting and learning systems, together with the basic terminology for classification and reporting of adverse error-events and near miss events (near misses), are discussed in Section 4.5, while a more detailed review is presented in the Technical Supplement.

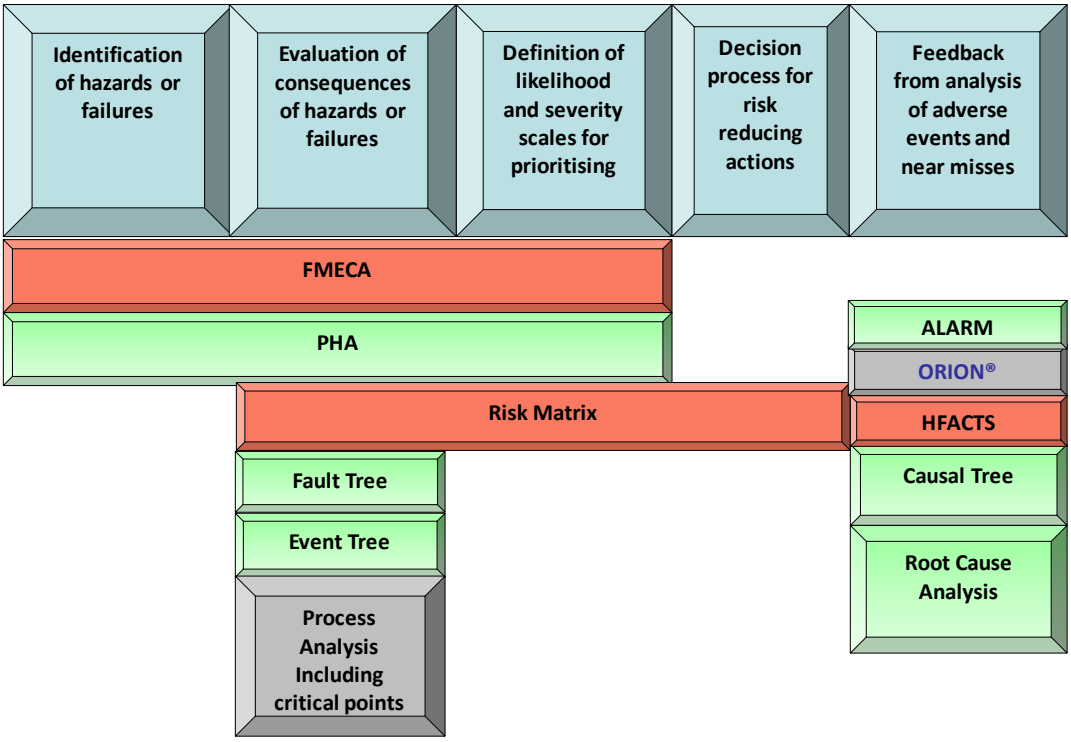

Figure 4.2. Risk management targets within proactive risk assessment and reactive analysis of events (the upmost blue boxes). The applicability of available assessment or analysis methods (the rectangles below the upmost boxes) is shown by the position and length of the rectangle (e.g., FMECA and PHA [PRA] can be applied for the first three targets). The green colour indicates a generic method, red indicates a generic method specifically adapted for external beam radiotherapy, and the gray colour indicates an approach rather than a method.

4.1.6 Safety assessment

The new EU BSS (EC, 2013) introduces the concept of safety assessment of both the activities and the radiotherapy facility, as a part of the information which the Member States shall require from the licensee for the licence application. As defined in the BSS, the safety assessment focuses on potential exposures, the probability and magnitude of such exposures, and the relevant protection and safety provisions that have been implemented. In addition, this safety assessment also requires the identification of the ways in which accidental and unintended medical exposures could occur. Thus, the safety assessment includes elements of proactive risk assessment. Since this assessment forms part of a licensing procedure, it will require proactive risk assessment from the moment operations commence, thus further strengthening BSS requirements related to the QA program for the lifetime of the facility.

4.1.7 Defence in depth

The defence in depth-approach systematically accounts for technical, human and organizational failures in order to implement successive layers of barriers—two or more barriers for the same function—which are sufficiently independent of each other such that these failures will be prevented. These defence layers can be tangible barriers such as alarms and redundant controls, or intangible ones, such as regulations, training, procedures and supervision. The defence in depth will thus provide added value by improving system safety against tolerant malfunctions and errors.

The defence in depth approach can be applied to all proactive risk assessment systems and to systems for reactive analysis of events. For the latter, this entails identifying deep origins of failures, the weaknesses of all the barriers currently in place in an effort to uncover more general problems such as those linked to particular equipment (dysfunction or concern of use) or deficiencies in a specific care protocol or insufficient training.

Risk management reinforces the application of the defence in depth-approach. Its implementation is based on the expertise of professionals.

4.1.8 Other concepts

4.1.8.1 Hazard

According to the WHO International Classification of Patient Safety (WHO, 2009b), a hazard is a circumstance, agent or action with the potential to cause harm, and risk is the probability that an incident will occur. A hazard is thus likely to cause harm or damage if not controlled. For example, insufficient training on new equipment or lack of user instructions represents a hazard which introduces the risk of causing an error in the dose delivered to the patient due to incorrect usage of this new equipment. Most hazards are potential, with only a theoretical risk; however, once a hazard becomes "active", it can lead to an adverse error-event.

In proactive risk assessments, the types of generic hazards are often classified as human, equipment or material, organizational, and environmental factors. In the process of risk assessment, these generic hazards have to be specified as in the following examples:

- Human (H): foreign patient (communication difficulties)
- Equipment or Material (M): an incorrect beam adjustment
- Organizational (OR): lack of training
- Environmental (E): missing laboratory results

Hazards are often identified with peers' experience and with event reporting. Check-lists of potential hazards exist and can be used, although they should first be adapted to fully meet the specific requirements of radiotherapy.

4.1.8.2 Failure and failure mode

Failure is the state or condition of not meeting a desirable or intended objective, and may be viewed as the opposite of success. A failure mode represents the various ways that failure can occur in a piece of equipment, a function or a process, or in a human (i.e., human error).

For example, for a linear accelerator, a failure mode could be a total power loss (due to an electricity failure), or an incorrect beam adjustment (due to a configuration error during maintenance). An example of a process failure mode could be an error in patient identification.

4.1.8.3 Severity and likelihood scales

The consequences derived from the failure modes, or hazards, on the system, must be specified in terms of events and provide details in relation with the severity scale defined. Severity (S) scale is used to define the level of potential consequences of hazards or failures, or real consequences of an event, in order to distinguish a minor or no harm event from an adverse error-event. The severity level increases from a near miss event (the lowest level) to a minor or no harm event and finally to an adverse error-event, which represents the highest level of severity.

The likelihood (L) scale is used as a qualitative estimate of the probability or frequency of events when precise data are not available for quantification. Likelihood is expressed in a qualitative form ranging from 1, 2 etc., or A, B, C etc., to the last step of the scale, whereas probability is expressed as a number ranging from 0 to 1. Likelihood is more subjective but easier to use when precise probabilities are not known.

These two scales are necessary to make a decision about whether a given situation is acceptable or not: the higher the severity is, the lower the likelihood should be (see also Fig. 4.3). The scales and the application thereof should be a consensus decision made by a working group or by adopting of international or national agreements on these scales.

4.1.8.4 Barrier

The term “safety barrier”, or more briefly “barrier”, as used in proactive risk assessments and reactive analysis of events, describes all measures that can:

- limit the probability of event occurrence. For example asking for the identity card for patient registration reduces the probability of identification error. Such barriers are called preventive barriers or probability reducers.
- limit the severity level of the consequences of the event. In radiotherapy, this could mean all measures designed to stop error propagation. For example, in vivo dosimetry performed at the first treatment session detects errors and rectifies the situation before the wrong treatment can be administered. Similarly, the periodic medical examination of a patient performed by the radiation oncologists (e.g., once a week) may detect errors and thereby reduce the consequences (e.g., by identifying unexpected clinical signs/symptoms). However, such barriers merely mitigate the severity of the adverse error-event and may not prevent the occurrence of a certain degree of damage. Those barriers are called protective or corrective barriers or consequence reducers.

The aim of barriers is to place all events in the area of acceptable risk (i.e., below the Farmer Curve in Fig 4.3).

Barriers can also be procedural, e.g., re-verification (double check) of arrangements to avoid giving an appointment in the same time slot to different patients with the same name, or physical, e.g., barcodes needed to identify the patient or to allow an action to be performed.

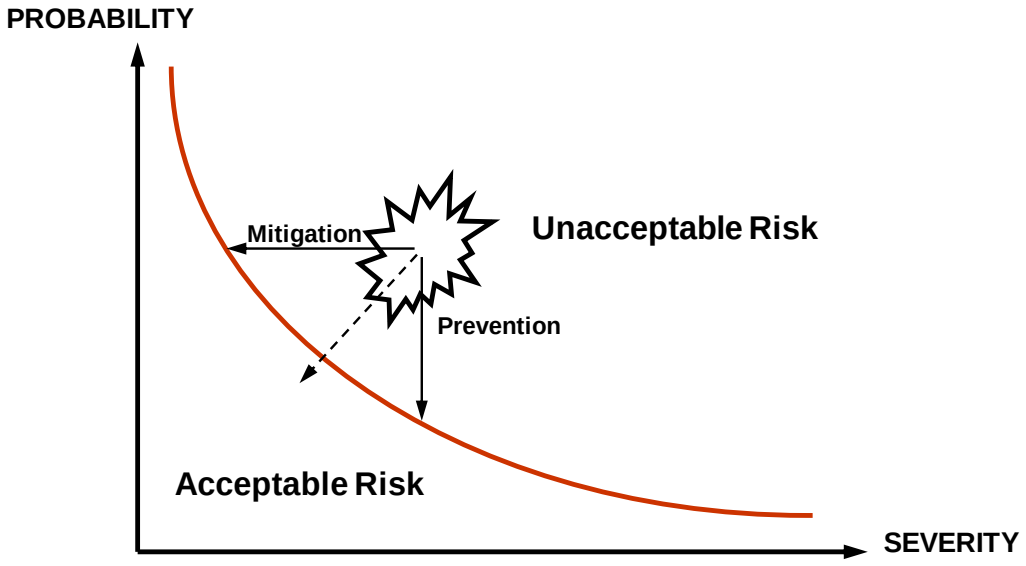

Figure 4.3. Relationship between severity and probability (Farmer Curve) indicating how to reach (via mitigation and prevention) the acceptable risk area.

The barriers can be further classified according to their robustness (likelihood of success) as shown by the following examples:

- Interlock type: These barriers are the most robust. They require no human intervention to work (e.g., the interlock for beam symmetry or flatness on radiotherapy equipment).
- Alarm type: These barriers warn the operator to take action, although human actions are required to fulfil the function of this type of barrier.
- Instruction or procedure type. These barriers depend wholly on human actions that are governed by instructions or procedures. They are less robust.

4.2 Organisation and resources

Before a risk management program can be implemented, it is first necessary to address the particular concerns of the organization and to allocate the necessary resources. These steps are necessary before any practical work is undertaken and prior to selecting the methodology to be used. However, there is no need to create a specific new structure for risk management; rather, what must be done instead is to complete the quality management structure by adding a risk management approach.

To build a risk management program focused on risk assessment and analysis and reporting of events, several provisions are needed. The extent of these provisions needs to be adapted to patient volumes and the size of the radiotherapy institution. The following represent the minimum provisions necessary:

- *Engagement of the management and allocation of specific resources, including training in risk management*. This could be formalized by an engagement letter as it is often done for quality assurance. Management support is essential to assuring the provision of sufficient resources, especially sufficient staffing in accordance with the size of the radiotherapy institution, and staff with the requisite knowledge of risk management. This support is particularly important when new safety measures requiring a change in the organization are implemented. The resources should include all skills needed and contributions by the key professional groups.
- *Quality management and safety culture*. Successful quality and risk management requires development of a culture of safety in the institution. A feature of a good safety culture is that there is a high awareness of risks, and that error reporting is considered positive, constructive and responsive—a culture that seeks solutions not culprits. The importance of a safety culture has been stressed in several recent contexts, notably in the IAEA publication INSAG-4[4] . This publication recognises that the behaviour of the individuals is the predominant factor in controlling safety, and concludes that priority should be given to safety over and above any other concern (deadlines, costs, technique). The IAEA has developed training programs that could be adapted for radiotherapy.
- *A risk management committee*. This arrangement is needed to define the risk management process, to allocate resources, to supervise the risk assessment and reactive analysis of events, to analyse the outcomes, to select the actions to be taken, and to follow-up on those actions. This committee could be dedicated to radiotherapy or form part of a more general structure that handles quality or risk management. In any case, whatever approach is taken, the committee must have the authority to make decisions about resources (financial, human). The committee should ensure that all staff is aware of the role of proactive risk assessment or analysis of events—that is, these are tools that leaders can use to help them make improve the care process.

[4] INSAG = International Consultative Group on Nuclear Safety Group (INSAG) established with the Director General of the International Atomic Energy Agency.

Several different bodies promote and support risk management programs: ASTRO (2012), NHS (2012) or WHO (2008b). As an example, ASTRO gives the following description:

> *"A dedicated formal QA committee should consist of a multidisciplinary team (e.g., physicians, medical physicists, medical dosimetrists, nurses, radiation therapists and IT support) that meets regularly and serves as liaison with leadership and hospital-wide safety committees. This committee should develop initiatives related to patient safety, which are feasible and work best for the individual institution. This committee should ensure that a mechanism for reporting and monitoring errors and near-misses is in place, that leadership is aware of trends, and that a process exists for implementing change when needed."*

- *Risk manager and a multidisciplinary team at the radiotherapy department.* For practical implementation of proactive risk assessment and analysis and reporting of events, a multidisciplinary team (e.g., radiation oncologists, radiation therapists, medical physicists, nurses, technicians, dosimetrists, medical secretary) at the radiotherapy department is needed. The support of a highly experienced risk manager, who could also be the team leader, is needed in order to select and implement the most appropriate method(s) and to train the team members in those methods.
- *Training and promotion of results.* Radiotherapy is one of the first medical disciplines to recognize the need for safety training, a fact that does not imply that radiotherapy is any less safe than other disciplines. Staff member who work daily in the radiotherapy unit are in the best position to identify areas of weakness and risk. However, these personnel require educational training in risk management to acquire sufficient knowledge and the skills necessary to carry out adequate risk assessment or analysis of events. Similarly, training is necessary to change attitudes about errors (e.g., a learning experience) and to raise awareness of patient safety issues.

A basic knowledge of the following topics is needed. These topics could be included in the education and training curricula for all professions involved in the radiotherapy process:

- Proactive risk assessment. Different methods and their limitations.
- Main risks present in each step of the radiotherapy process. Risk awareness.
- Risk prevention. Moral, legal and economic considerations. Human factors and human-technology interaction. Techniques for preventing events or reducing their consequences.
- Analysis and reporting of events in radiotherapy, lessons learnt from reported events.
- Individual and collective attitudes and behaviour in the case of adverse error-events (communication to the patient, communication to public, medical, ethical, legal and financial aspects).

For the local implementation of risk assessment and analysis and reporting of events, specific training efforts are needed to supplement and/or refresh the education and training delivered through the basic curricula of radiotherapy professionals. The recommended amount and contents of such training programs are presented in Section 5.1.3.

4.3 Proactive risk assessment

4.3.1 Criteria for implementation

A comprehensive understanding of the risks related to radiological hazards and the management of those risks in radiotherapy should be available before a new treatment technique or technology is initiated and before commencing routine use of any new equipment (hardware or software) in any part of the radiotherapy process (e.g., treatment planning, patient identification and preparation for treatment, treatment delivery). In most

cases, a good starting point to convey this information is through the risk assessment related to radiological hazards performed by manufacturers during the pre-market phase. According to the EU BSS (article 78) manufacturers should share this information with users. Because the radiotherapy process typically includes several different products of different manufacturers, the risk assessments of several manufacturers need to be addressed.

Other issues that could prompt a new or revised risk assessment include changes in patient pathways, updating of hardware and/or software, PC and IT related issues, or an action review performed when a near miss or adverse-error event has been identified and analysed.

The criteria for performing proactive risk assessment is thus typically due to changes in practice, equipment, or procedures in order to assess the impact of such changes on the broader processes across all the disciplines. Changes might be minor (e.g., changes to the quality control schedule) or major (e.g., implementation of new treatment technique or a new treatment equipment), and may only impact small work groups or, conversely, may be systemic or departmental wide (e.g., 'going paper-free/paper-light' or introduction of a new clinical service). Although traditionally the radiation oncology community has had a largely device-centric perspective to risk, any assessment of risk must take into account the fact that many of the safety and quality issues involve significant human and organizational factors.

Event analysis and reporting is another important source of information to initiate a focused risk assessment. This assessment can be prompted by local events or from events reported elsewhere (e.g., through international reporting and learning systems). Analysis and study of such reports can make institutions aware of the need to re-evaluate local preventive measures, barriers, etc. and to update and improve previously-performed risk assessments. This situation represents an important user-experience feedback model for implementation of risk assessments.

As evident from the above, the volume of risk assessment depends largely on the status of the processes, techniques, and equipment and the level of experiences in their use; new and modified systems require greater attention than standard systems with long experience. In addition to these factors, the volume of the risk assessment depends on the amount of local radiotherapy activities, the scope of the radiotherapy institution in cancer therapy, and the size of the unit. The larger the unit and the wider its scope (e.g., several different types of treatment techniques including also treatment of the most demanding cancer types), the more extensive the risk assessment must be.

Risk assessment should be a regular activity, within the above criteria, but its scope or vision can vary according to need and may include all or only some of the following fields:

- Equipment (e.g., accelerator, treatment planning software)
- Process (e.g., the various stages, set up controls)
- Human and organizational factors (e.g., staff and responsibilities, training, available documentation, relationships)
- External environment (e.g., patient transportation, interaction with a medical laboratory)

A risk assessment that considers all these fields is called a systemic approach study.

Taking into account that the comprehensive identification of all risks in the entire external beam radiotherapy process is a large and expensive project that could take many months and ultimately become unmanageable, decisions have to be made whether the goal of the assessment should be a complete or gradual assessment. In the gradual approach, risk assessments are focused on smaller part of the process or some specifics treatment techniques, and realised iteratively on risks which are “reasonably foreseeable” and sub-processes that appear most important for professionals. The scope of the assessment might be limited to risks related to failures observed (proven risk), or also include potential risks. One solution might be to analyse the failures which do not ensure delivering "the right dose at the right place for the right patient", thus setting the dose delivery to the patient on the

highest priority among the spread of the failures. Further, classifying risks by levels of robustness required for preventive measures (e.g., simple, enhanced or ultra-safe barrier), evaluated following feedback, could be an approach to achieve more easily this goal.

The level of detail in the risk assessment should be appropriate to the challenges identified, while the methods should not become unnecessarily cumbersome and ultimately ineffective. A balance has to be found between a specific analysis related only to the institution and a more comprehensive and pooled one carried out within the framework of a discipline or a region sharing their experience.

In the gradual approach, before going on with new targets of risk assessment, it is important that the improvement actions imposed by the results of the assessments are implemented. The feedback from events previously detected and analysed should be taken into consideration. All the decisions on gradual approach should be documents likewise the risk assessment methodology.

4.3.2 Sequence of procedures

As described in Section 4.2, proactive risk assessment is carried out in practice by a multidisciplinary working group managed by a team leader (risk manager or other). The composition of this working group should include all necessary skills, with members trained in the particular risk assessment method used.

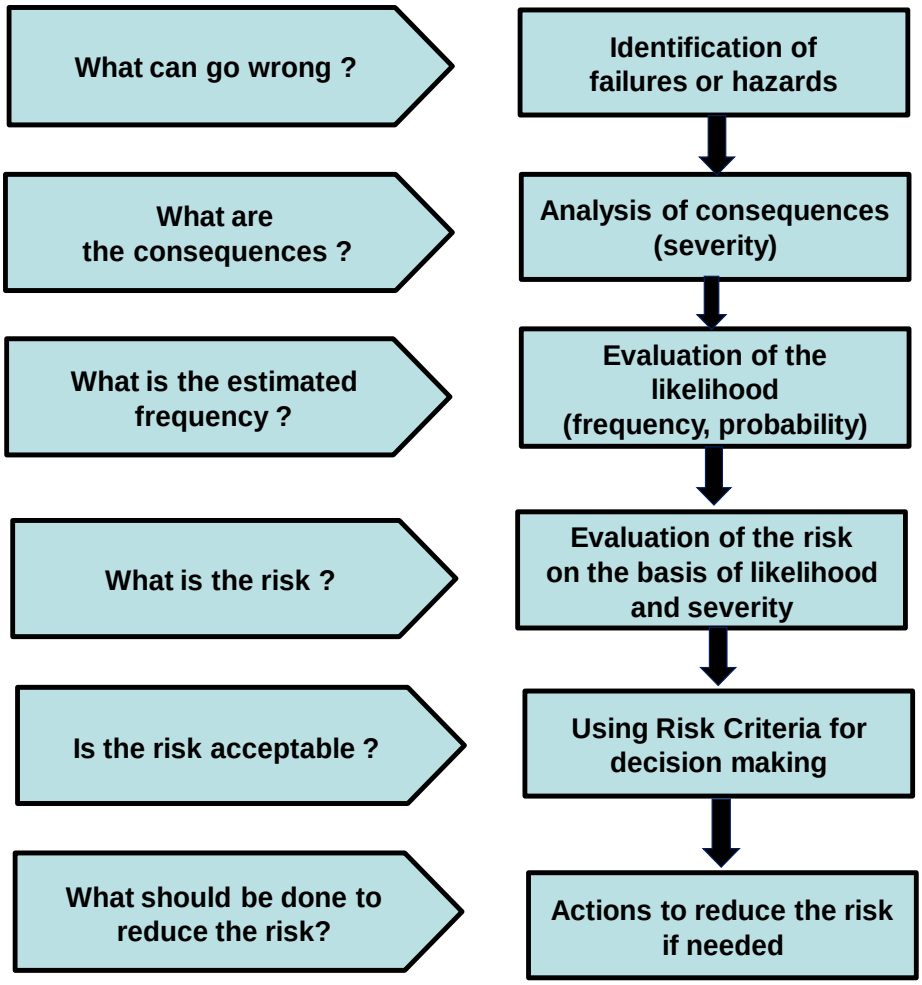

Figure 4.4. The various steps involved in proactive risk assessment (left side, questions; on the right, actions)

The steps in the process of a risk assessment are presented in Fig. 4.4. The first two steps correspond to the first two targets of Fig. 4.2, the next two steps correspond to the third target, and the last two steps to the fourth target.

The first step in a proactive risk assessment is to qualitatively identify (through staff experience, analysis of events, pre-established check lists) all potential failures or hazards which can affect the system (material, human, organisational) within the pre-established scope of the assessment. Check lists of potential hazards exist and can be used to perform this step, although they need to be adapted to account for specific aspects of the particular radiotherapy service. Performing this first step enables the working group to identify a list of initiating events (e.g., human error or equipment failure) that can potentially lead to an adverse error-event.

The second step of the process involves determining the impact (consequences) of potential failures or hazards on the system in terms of adverse events.

To identify potential failures or hazards (step one) and their impact on the system (step two), two inductive (bottom up approach) and qualitative methods exist: Failure Mode and Effect Analysis (FMEA or FMECA [C= criticality]) and Preliminary Hazard and Risk Analysis (PHA or PRA).

The FMEA method permits identification of single failures (basic events), preventive, corrective and detective measures (barriers) and prioritization, if a criticality evaluation is included. For each component of the system under study, the following must be identified:

- possible failure modes and their causes
- consequences of the failure mode on the system
- existing preventive, corrective and detective measures

PHA/PRA allows for the identification of the scenario which describes (i) how the system, from a process-based point of view, handles each hazard, (ii) what existing measures are in place to limit the likelihood (probability) of the scenario and/or (iii) the criticality of the consequences. Propagation of hazard through the process can also be performed, but implementation of this technique is onerous and complex.

The third step aims to evaluate how often the failure or hazard is likely to appear as an initiating event for an adverse error-event (i.e., its frequency [likelihood or probability]).

The fourth step then aims to estimate, either quantitatively or qualitatively, the risk (R) of the event, also called a Risk Criteria (Risk Priority Number [RPN] or Criticality [C]). It is estimated by using the following formula:

$$R = L \times S \times D$$

where

- L is the probability or likelihood for the initiating event to become a postulated adverse error-event (see Section 4.1.8.3).
- S is the severity of consequences—i.e., the magnitude of the impact evaluated in the second step.
- D is the detectability—i.e., the probability or likelihood that the failure will not be detected.

High R (RPN, C) values indicate the weakest areas of the process and should be addressed first.

This step requires that scales for likelihood (frequency or probability; Table 4.2), severity (Table 4.3), and detectability (if considered) have been established. The scales and their application should be the result of a consensus reached by the working group charged with managing the risk assessment.

Table 4.2. Example of a likelihood scale

Likelihood index (Frequency Index)	Level	Criteria
L1	Very infrequent	Once every ten years
L2	Infrequent	Once every five years
L3	Not very frequent	Once a year
L4	Frequent	Once a month
L5	Very frequent	Once a day

Table 4.3. Example of a severity scale

Severity Index	Level	Criteria: Consequences for the patient
S1	Minor	No obvious harm
S2	Significant	Temporary harm (less than a month)
S3	Critical	Harm that does not affect daily life
S4	Severe	Harm that affects daily life
S5	Catastrophic	Death of the patient

To provide a more comprehensive risk assessment that takes into account combinations of failures and probabilistic assessment, two methods are available: Fault Tree (FTA) and Event Tree (ETA) analysis. These methods represent the so-called “defence in depth approach” where failures of the barriers (reactive or corrective measures) are also considered. FTA is a deductive method, that is, a top down approach for qualitative assessment to what extent a fault or a basic event can propagate in the sequence leading up to the ultimate event. ETA, in contrast, is an inductive method for identifying the propagation of an initiator (failure, incident, etc.) and its possible consequences on the system (potential undesirable event); ETA is also known as the "barrier assessment method".

The fifth step compares the risk estimated in the fourth step to acceptable risk criteria, taking into account economic and social conditions. Many risk assessment techniques include proposed risk acceptance criteria that can be considered.

A standard way to display and add visibility to this process is to create a criticality matrix or risk matrix that shows how the various levels of risk result from the combination of the likelihood and severity categories: in this matrix, likelihood is depicted along one axis and severity along the other, and the corresponding risk level is displayed for each matrix position as shown in Table 4.4.

The colours in Table 4.4 signify the following:

- The red zone: unacceptable situation, risk reduction actions are needed,

- The yellow zone: acceptable with control, no risk reduction action needed yet, but there is a need to control this situation (for example, to verify the real efficiency of preventive or corrective measures considered when the probability was initially assessed),
- The green zone: acceptable situation.

The sixth and the last step consists of evaluating the actions that should be taken to reduce the risk of the adverse error-events that do not comply with the risk acceptance criteria. As illustrated in Fig 4.3, to reduce the risk to acceptable levels, implementation of preventive or corrective barriers is needed. When implementing a new barrier, its feasibility should be fully evaluated, as some barriers may be inappropriate given existing barriers.

Once the actions to reduce the risk have been decided, a new evaluation of the criticality value should be performed. The resulting new criticality values are known as "residual criticality".

Table 4.4. Criticality matrix (risk matrix, criticality table)

	SEVERITY SCALE →			
LIKELIHOOD	**S1**	**S2**	**S3**	**S4**
L4	**C2**	**C3**	**C3**	**C3**
L3	**C1**	**C2**	**C3**	**C3**
L2	**C1**	**C1**	**C2**	**C3**
L1	**C1**	**C1**	**C1**	**C2**

4.3.3 Examples specific to radiotherapy

Two specific methods of risk assessment applicable to external radiotherapy are available: a specific FMEA developed by ASN (ASN, 2008b) in France and a “Risk Matrix” approach used in Spain that was developed by the Ibero-American Forum of Radiological and Nuclear Regulatory Agencies (FORO) (IAEA-FORO, 2013a; 2013b). A brief introduction to these methods is presented in the following paragraphs. A comprehensive review of the available methods for proactive risk assessment, both generic and radiotherapy-specific methods (along with bibliographic references for practical examples of their application) is provided in the Technical Supplement.

The specific FMEA developed by ASN (ASN, 2008b) in France requires the application of FMEA on three main lines: patient pathways, equipment, and human and organizational. This model thus approaches a single failure mode from various viewpoints and enables a systemic approach. The method provides severity and probability scales to evaluate criticality. However, detectability is not considered. The consequences of failures are evaluated by a conservative approach: the propagation of a failure is considered through all the steps in the radiotherapy process. For example, an error in patient identification will lead to harmful consequences (the highest severity level) because it is assumed that it will not be detected before treatment.

A guide to apply this methodology was drawn up and published with the support of the SFRO (French Society of Radiation Oncology) and the SFPM (French Society of Medical Physics). The guide is specifically oriented to radiotherapy departments in France as a methodological support to carry out their own risk assessment. It includes complete tables of failure modes that can be adapted to each department. For more details, see the Technical Supplement.

The Risk Matrix approach developed by the Ibero-American Forum of Radiological and Nuclear Regulatory Agencies (FORO) (IAEA-FORO, 2013a; 2013b) and promulgated in

Spain, is a semi-quantitative method of evaluating the likelihood and the severity of events by means of a scale, and for defining risk acceptability criteria on the basis of the combination of likelihood and severity. Based on the observation that simple failure does not necessarily lead to a harmful health effect, this risk matrix seeks to assess how a barrier's reliability could be taken into account. The methodology consists of a progressive approach that includes the following steps:

- identification of hazards and the barriers in place to avoid an accidental exposure to the patient (FMEA or PRA);
- application of an initial simple conservative screening to sort events according to their risk by means of a previously constructed risk-matrix;
- finally, application of a second screening to the initiating events identified as high risk on the first screening; the analysis concentrates its focus on a carrying out a deeper, more realistic safety assessment of those high risk cases.

The risk matrix is a method that accounts for the number of barriers in the various steps of the process in order to interrupt propagation of the initiating event; additional, it provides a method to evaluate the reliability of these barriers when the second screening is needed. Finally, this approach makes it possible to define the area where the risk is acceptable and to develop a strategy of adding more barriers or increasing their reliability to bring any unacceptable scenario into the area of acceptability. For more details, see the Technical Supplement.

4.3.4 Comparison of methods

Proactive methods of risk assessment are compared in Table 4.5. The colours indicate the ease of implementation of the method in terms of the amount of time and complexity for implementation and training needed (green indicates the easiest methods; yellow, more difficult; orange, the most difficult).

As described earlier (Section 4.3.2), FMEA or FMECA and PRA (PHA) can be used to identify potential failures or hazards and their impact on the system (the first and second steps of the proactive risk assessment, Fig. 4.4.). To perform a more in-depth assessment that takes into account combinations of failures, failures of barriers, and probabilistic assessment (if needed), FTA and ETA can be used.

In terms of the identification of failures and hazards, FMEA and PRA are both exhaustive methods. The FMEA method is widely used in the field of external radiotherapy, and the specific FMEA developed in France by ASN (ASN, 2008b) allows a systemic approach by including different points of view in the same assessment (Process, Equipment, Human Factor and Organisation). Although PRA could be considered better suited to a systemic approach because it considers generic hazards such as organisation and environment, the fact that it requires concept integration (such as contact cause, initiate cause) make it more difficult to use.

In terms of evaluation of consequences of failures or hazards, FMEA is limited to single failures and does not permit identification of multiple failures or common cause scenarios. The scenario description available with PRA allows for identification of failure combinations, but in external beam radiotherapy, this method generates a quantity of scenarios that is not realistic to construct when all propagation of hazards are taken into account. FTA and ETA can consider event combinations that may ultimately lead to the adverse error-event. However, they both require a previous FMEA or PRA assessment to identify which basic events to combine. In addition, a software application is available to quantify probabilities for FTA or ETA, but it requires data on the probabilities of hazards and failures. Performing FTA to assess a particular event and its application to an entire system may prove tedious. In the same way, one event tree is created for one initiator only. In conclusion, if failure combination

modelling is excessively time-consuming, scenarios may be of greater interest for proactive risk assessment in radiotherapy.

Table 4.5. Comparison of six proactive methods of risk assessment

	Advantages	Disadvantages
Dedicated FMECA (ASN, 2008b)	All of FMECA plus: • Systemic approach • Guidelines and completed adaptable tables available • Severity and Likelihood scales provided	• Takes into account only single failures • No evaluation of the reliability of barriers
Dedicated Risk Matrix (FORO (IAEA-FORO, 2013a; 2013b))	• Barrier evaluation • Guidelines and completed adaptable tables available, software available • Scales and Risk Matrix to evaluate acceptability are available • Includes strategy recommendation for improvement • Quite easy to use	• Requires a previous FMEA or Hazard assessment (the FORO Risk Matrix includes FMEA results that are easy to adapt) • Takes into account only single failures
FTA	• Combinations of failures • Top-down approach • Concept quite easy to learn • Quantitative evaluation software available	• Requires a previous FMEA or Hazard assessment • Needs to be constructed for each particular adverse error-event to be evaluated • Difficult to account for common modes
FMECA	• Identification of failures • Evaluation of consequences using severity and probability scales • Quite easy to use	• Not a systemic approach • Only single failures • Conservative approach
PRA	• Systemic approach • Identification of hazards • Identification of scenarios • Evaluation of consequences using severity and probability scales	• Concept difficult to learn • Non-realistic number of scenarios to describe for a complete application to external beam radiotherapy
ETA	• Barrier failures • Concept quite easy to learn • Quantitative evaluation software available	• Requires a previous FMEA or Hazard assessment • Needs to be constructed for each particular adverse error-event to be evaluated • Difficult to account for common modes

In terms of prioritization, both the FMECA and PRA integrate the use of severity and probability scales.

Like FMECA and PRA, the Probabilistic Risk Matrix method developed by the FORO (IAEA-FORO, 2013a; 2013b) focuses solely on single failures; however, it offers a way to complete a FMECA or PRA assessment by taking into account the evaluation of existing barriers and the nature of those barriers (e.g., interlock, procedure) and also by defining the area of acceptable risk and the strategy to increase barrier reliability.

4.4 Reactive analysis of events

4.4.1 Principles and methods

The reactive (retrospective, a posterior) analysis of events is directly associated with the recording and reporting of the events (see Section 4.5.4). This can be illustrated with a typical sequence of procedures, which is initiated when an error in the treatment process is detected:

1. Initial recording and reporting—that is, an internal/local report inside the radiotherapy department, with a description of what happened. The initial reporting triggers, or is accompanied by a quick analysis of the causes, evaluation of consequences, and implementation of "immediate" corrective actions designed to achieve the planned treatment goals or to limit the consequences of an event with "high potential consequences".
2. *Detailed analysis* of the event, including its underlying causes and a proposal for steps to be taken to avoid reoccurrence of the same type of event. Here the methods of reactive analysis of events are called for.
3. Final reporting, complementing the initial local report when needed, and forwarding information to external reporting and learning systems.

Whatever method is used to perform the reactive analysis of an adverse error-event or near miss event, the following general principles should be considered:

- Only relevant events need to be fully analysed (step 2 in sequence described above): this could include all adverse error-events based on certain criteria (e.g., severity) and a list of predetermined events ("sentinel events");
- A multidisciplinary investigation team trained in event analysis is needed to collect documents and information and to carry out structured interviews with witnesses and relevant stakeholders (in particular, for step 2 above). This could be same team as established for proactive risk assessment (Section 4.2); however, the team must be independent of the persons responsible for, or directly involved in the event, and when necessary, an independent expert should be called in to manage all conflicts between the different participants;
- Active participation of relevant professionals is necessary as early as possible in the review process, while the situation is still fresh;
- Protection of staff members involved in the event from sanction must be considered.

The choice of the methodology depends on the type of results to be achieved.

The first step of a reactive analysis of events is to collect facts and data. This step is performed through interviews and by collecting documents. Some standard questionnaires (or templates) could be useful depending on what type of cause is expected to be identified.

The second step is to identify the causes of the event, which may be root causes. The objective of root cause identification during an event analysis is to identify the deeper (latent) causes behind the immediate (direct) causes observed on the event. These causes are all the more important as they could represent common causes of events.

The above principles are often used in global methods such as Root Cause Analysis (RCA; including 5 Whys and Ishikawa or 5M diagram), Causal Tree Analysis (CTA), ALARM, and ORION® , or in a method dedicated to radiotherapy, HFACS (Human Factor Analysis and Classification System). For all these methods, see more details in the Technical Supplement.

Identification of the root causes is based on the principle that a series of factors that provide favourable conditions for the event are present at the event origin. This is shown in the Reason diagram (Fig. 4.5). When conclusions about the contributing factors can be made,

preventive measures can be undertaken to decrease the probability or the consequences of the event and avoid its future occurrence.

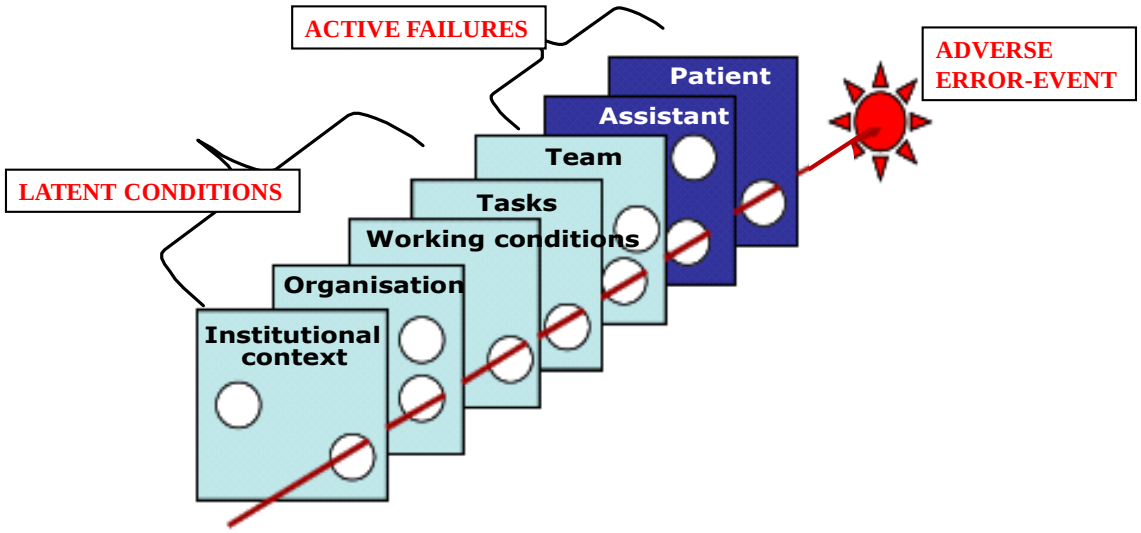

Figure 4.5. Reason diagram (active failures and latent conditions)

The "Swiss Cheese" model of accident causation was originally proposed by James Reason and compares defence systems to a series of slices of Swiss Cheese arranged vertically and parallel to each other with gaps between each slice. This model (Fig. 4.6) , as it name implies, has many holes, although unlike the cheese, these holes are continually opening, shutting, and shifting their location. The presence of holes in any one “slice” (or layer) does not normally cause a bad outcome. Rather, poor outcomes can happen only when the holes in many layers momentarily line up to permit a trajectory of adverse error-event / opportunity in which potential hazards can harm victims. The "holes" in the layers arise for two reasons: active failures and latent conditions, concepts originally defined by Reason and later adopted by other authors. Nearly all adverse error-events involve a combination of these two sets of factors.

Active *failures* are usually unsafe acts or omissions committed by people who are in direct contact with the patient or system. They are the result of an interaction between an individual and a larger part of the system (such as a linear accelerator or a patient) and it is immediately apparent. Active failures can also be sudden, unexpected equipment failures.

Latent conditions are the inevitable “resident pathogens” within the system. They arise from decisions made by designers, builders, procedure writers, and top level management. They can be related to the equipment (hardware or software) or the procedures. Latent conditions have two kinds of adverse effects: they can result in conditions that cause errors based on local working conditions (for example, time pressure, understaffing, inadequate equipment, fatigue, and inexperience) and they can create long-lasting holes or weaknesses in the layers (unreliable alarms and indicators, unworkable procedures, design and construction deficiencies, etc). Latent conditions—as the term suggests—may lie dormant (undetected) within the system for long time before they combine with active failures and local triggers to create an opportunity for the occurrence of an adverse error-event.

As an example, the improper commissioning of electrons on a linear accelerator or a poor dose calculation algorithm is a latent failure; a technologist’s failure to engage the gating system prior to treating a breath-hold patient is an active failure.

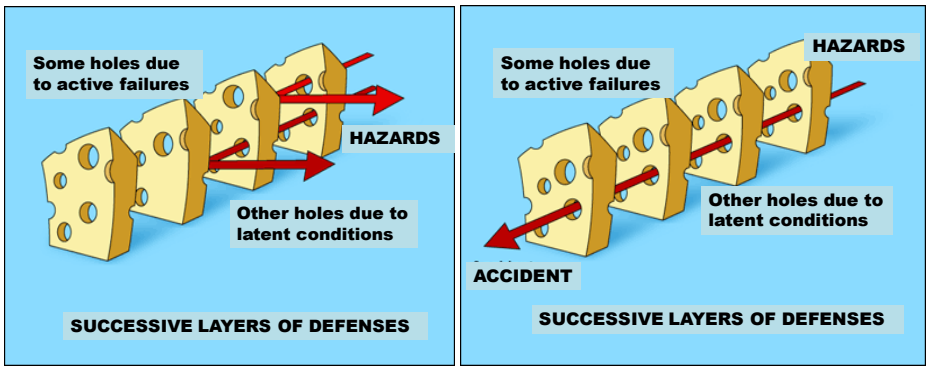

Figure 4.6. The Swiss "Cheese Model" described by James Reason

Whatever the method used, the chronology of the facts must first be reconstructed precisely to identify the causal relations. Before corrective actions can be taken, the specific failures and the lines of defence that have worked or not must both be identified; the causes must likewise be prioritised.

4.4.2 Comparison of methods

Differences between the various methods for reactive analysis of events are mainly related to the nature of causes identified and the practical support provided to carry out the analysis.

Root cause identification is allowed by using RCA (including 5 whys and Ishikawa diagram), ALARM, HFACS and ORION®. Tables and/or check list to support the analysis are available for ALARM, HFACS and ORION®.

HFACS describes failure levels and adds identifications of the root causes (e.g., unsafe acts, preconditions for unsafe acts, organizational influences, unsafe supervision); a specific and detailed version of HFACS has been developed in Italy for use in radiotherapy (Portaluri, 2009). The causal tree, which is provided in both CTA and ORION®, adds real value by allowing for identification of causal relationships between observed events. On the other hand, these methods are not suited to identifying overall system faults, or influencing factors.

Methods for the reactive analysis of events are compared in Table 4.6. The colours indicate how easy the method is (green = the easiest; yellow, more difficult; orange, the most difficult) to implement in terms of the amount of time required. It usually takes an investigation team in the radiotherapy department around two hours to analyse an event.

Table 4.6. Comparison of methods for reactive analysis of events

	Advantages	Disadvantages
Root Cause Analysis (RCA) 5 Whys? methods	• Method based on systematic questioning to identify the main cause • Schematic description • Easy to implement	• Generally used as a complement to a cause and effect diagram • Partial analysis due to the focus on identifying links between the event's causes • No chronology
Root Cause Analysis (RCA) Ishikawa diagram	• Questions focus on five to seven aspects: materials, method, manpower, environment, etc. • Graphic representation of causes • Cause and effect relationships	• No representation of logical relationships • No chronology

	Advantages	Disadvantages
	and ranking of causes	
Root Cause Analysis (RCA) HFACTS	• Method based on systematic questioning to identify the main cause • Includes supervision failures • Grid available	• No representation of logical relationships • No chronology
ALARM	• The analysis is steered towards finding latent errors in organisation and governance • Questions focus on six factors: environment, team, individual, institution, organisation, management of patients, tasks to be performed • Reconstruction of the chronology of the facts and consideration of multiple causes • Understanding of the complexity of the causes.	• Method designed for a hospital's clinical activities • The actions to be taken are more complicated (addressing latent errors) • Factors not ranked • No schematic description
Causal Tree Analysis (CTA)	• Schematic description • Reconstruction of the chronology of the facts • Consideration of multiple causes: linking of causes to their effects • Accessible method (a few hours of training)	• Factors not ranked • Schematic description is not easy to understand for those who did not create it
ORION®	• Systemic method of analysis • Recreates the context surrounding the event • Factual analysis of the chronology of the event • Identification of contributing factors: system errors, failure of barriers, etc.	• Initial analysis require support • No schematic description

4.5 Classification and reporting of adverse error-events and near misses

4.5.1 Introduction

Errors in radiotherapy need to be addressed promptly and appropriately to avoid future repetition and to diminish the expected effects; moreover, such errors tend to receive significant attention by the media and the public (Kirby, 2007; Oved, 2007; Poling, 2007; Bogdanich, 2010a; 2010b, Williams, 2007). Proper management of reported events and classification of adverse error-events, and near misses in radiotherapy are fundamental tools for learning from errors. The best way to analyze such data is first to organize them into categories and then study the details to understand the processes leading to the near misses, minor or no harm events or adverse error-events. How an organization learns from its experience is a safety-critical feature and an expression of its safety culture (Wilpert, 2001). The challenge is to strengthen a culture of reporting events by promoting a culture in which learning from events becomes routine in daily practice.

4.5.2 Terminology

Among the various recommendations for risk management and reporting systems, the definitions are highly variable: there is much ambiguity and little uniformity in terminology usage (Weingart, 2005). To date, no general agreement has been reached on the terminology and the meaning of the terms used in risk management; as a result, the same term can have different meanings to different people. The present situation is untenable and the terminology used to describe radiotherapy events should be intuitive, non-intimidating, and consistent with the terminology used in other areas of healthcare. Common terminology facilitates (or perhaps better said, "enables") the analysis and comparison of reported data from different sources. In short, common terminology is essential to compare the risk of radiotherapy with other health care areas.

The different terms defined and used by different institutions and agencies are discussed in detail in the Technical Supplement. Here, a few considerations leading to the present recommendations (Sections 4.1 and 5.4) are presented.

In the new EU BSS (EC, 2013) the following terms are defined:

- "Accidental exposure means an exposure of individuals, other than emergency workers, as a result of an accident". Notably, however, the term "accident" included in the definition remains undefined.
- "Unintended exposure means medical exposure that is significantly different from the medical exposure intended for a given purpose".

In addition, other terms, notably the words "incident" and "significant event", used in the EU BSS are not defined. The EU BSS assigns the task of defining "significant event" to the national competent authorities.

Many health authorities, including the Expert Group on Safe Medication Practices of the Council of Europe (EC, 2006), the World Health Organization (WHO, 2005), the Canadian Patient Safety Dictionary (Royal College, 2003) and the British Medical Journal (Davis, 2001), caution against the use of the term "accident" or do not consider this word in the list of preferred terms (AHRQ, 2013; WHO, 2009b; Kristensen, 2007). The word "accident" is more commonly used in the nuclear or radiation protection fields (ARPANSA, 2013a,b; IAEA, 2007b; ASN-SFRO, 2009; IAEA, 2002). One problem is that the word accident is sometimes not clearly distinguished from the word incident, or is only distinguished in classifications that describe adverse events vs. accidents.

There are two main problems with the use of the word "*accident*" in the field of radiotherapy:

- An *accident* is defined in the English dictionary (OXFORD, 2013) as "an unfortunate incident that happens unexpectedly and unintentionally, typically resulting in damage or injury" or "an event that happens by chance or that is without apparent or deliberate cause", so it can be understood to be unpredictable and unavoidable. In contrast, events usually are predictable and preventable.
- Radiotherapy adverse error-events are more visible (Kirby, 2007; Oved, 2007; Poling, 2007; Bogdanich, 2010a; 2010b) and are often presented by the media to general public in more dramatic way than adverse error-events in other health care areas, probably because of the social connotations that everything associated with "radiation" has for other professionals, the general public and the mass media. Use of the word "accident" in radiotherapy, given that this term is not used in other areas of health care, does not help to eliminate the negative connotations associated with the use of radiation. Perception of an event will vary according to the words used.

For the reasons given above, these Guidelines recommend replacing the term "accident" with "adverse error-event" (Sections 4.1.3 and 5.3.1).

In the conceptual framework for the international classification of patient safety (WHO, 2009a) the WHO distinguishes between near miss (an incident which did not reach the

patient), no harm incident (one in which an event reached a patient but no apparent harm resulted) and harmful incident or adverse event (incident that results in harm to a patient). These Guidelines largely adapt the WHO definitions but with a slight modification: the WHO term “no harm incident” is expressed in these guidelines as "no harm or minor event" while the WHO term “harmful incident or adverse event” is expressed as "adverse error-event".

4.5.3 Classification or taxonomy of events

An important aspect of patient safety is event classification, also called taxonomy (Ekaette et al., 2006; Dunscombe et al., 2008; Sherman, 2009; Tamuz et al., 2004; Elder and Dovey, 2002). A classification system provides a structure for organizing information, facilitates event analysis and reporting, thus constituting the first step required to extract useful data from events. In practice, the class of a new event within a given classification system is previously assigned by the experts who will subsequently analyse the event; in other words, classification is carried out before the event is finally reported (section 4.5.4.2).

Several classification systems have been created, often as part of the event reporting and learning systems (Table. 4.7) when the classification scheme depends on the objectives of the reporting and learning system. Some of these systems are general in nature while others are specific to radiotherapy; some are international and others national. The purpose of the existing systems can vary, with some designed to report events to an authority while others are intended to provide communication between peers or communication to the public. In the Technical Supplement, these systems are reviewed in detail. Unfortunately, event classification varies from system to system—even among systems that have the same purpose. In fact, event classification is as variable as the aforementioned terminology variation and the data fields used to categorize reports in different classification systems are also widely disparate. As a result, it is nearly impossible to aggregate or compare data between different reporting and learning systems.

Table 4.7. Existing reporting and learning systems including classification of events

	General systems	RT specific systems
International systems	ICPS (WHO) AIMS (Int., Australia)	ROSIS RT risk profile (WHO) SAFRON (IAEA)
National or other systems	Portailuri et al. (HFACS, US Navy) ARIR (Australia) AHRQ WebM&M (USA) JCAHO-PSET (USA) NRC (USA) DPSD (DK) ICHT/NRLS (UK) SiNASP (ES)	ASN-ANSM (FR) Ekaette et al. Towards safer RT (RCR, UK) AHFRM HTA ILS (Canada) PRISMA-RT (NL) Swiss ROSIS (CH) AAPM (USA; Ford et al., 2013)

In terms of the *classification criteria*, severity of consequences is used as the main criterion in many reporting and learning systems. Qualitative descriptors of harm such as light, minor, moderate, high, etc, are often used, and the number of subjective severity levels varies in the different systems. For example, several systems propose five levels of severity: Toward Safer Radiotherapy (RCR, 2008), in the conceptual framework for international classification for patient safety of the WHO (WHO, 2009a), in the Common Terminology Criteria for

Adverse Events (CTCAE) (NCI, 2013) and in the acute radiation morbidity scoring criteria of the RTOG (RTOG, 2013). In comparison, the SAFRON (IAEA, 2012) and ROSIS (ROSIS, 2013) systems use 6 levels, while the ASN-SFRO scale (ASN-SFRO, 2009) has 8 levels and the AAPM (Ford et al., 2012) has 10 levels for dosimetric deviation and 11 levels for medical severity. An international project, based on the ASN-SFRO and INES scales, to develop international criteria to communicate the severity of a medical event to the public is currently in progress.

Significant event has been defined as an event that should be notified to authorities according to national criteria defined by regulation (Sections 4.1.4 and 5.3.1). The thresholds at which a significant event (significant adverse error-event) occurs depend on factors such as the clinical situation, the part of the body treated, individual radiobiological factors, among others. While it is difficult to establish consistent criteria to track significant exposures, some organizations have defined a specific threshold for reporting, as follows:

- NRC (NRC, 2013) (total dose delivered differs from the prescribed dose by 20 percent or more)
- AAPM (Purdy et al., 1993) (>25% overdosage for one session)
- JCAHO (JCAHO, 2002) (>25% above the planned radiotherapy dose)
- HSE (HSE, 2006) (10% above the intended dose in the whole course or 20% in any fraction)
- ARPANSA (ARPANSA, 2008) (unintended variations in total dose greater than 10%)
- ASN-ANSM (ASN, 2013) (compliance with the total prescribed dose with a tolerance margin of ±5%)
- STUK (STUK, 2011) (25% over or underdosage, or overdose less than 25% if it can cause serious complications, or 5%-25% deviation if it is caused by a systematic error).

Besides severity, some other factors that have been used to classify events include equipment and stage in the process, error type, detection, personnel involved, equipment failure, causes and contributing factors, and preventive and corrective strategies. In particular, the cause is an important parameter as the correct identification of the cause(s) is of paramount importance to avoid similar failures. Both “direct” or active causes, as well as latent causes (latent conditions, contributing factors) (RCR, 2008), should be considered. The concept of hindsight bias is important in this discussion. This type of bias means that things that were not seen or understood at the time of the event seem obvious in retrospect (Committee on Quality of Health Care, 2000). Hindsight bias may cause an investigator to oversimplify the causes of an adverse error-event by emphasizing a single element as the cause while overlooking multiple (less evident) contributing factors or latent failures. Contributing factors that are remote in space and time are difficult to identify and this situation can lead investigators to assign too much weight to direct causes and/or direct contributing factors (Wilpert, 2001).

It is common in some of the systems to consider the effects of overdosing but not the effects of underdosing. Like overdosing, underdosing can also be catastrophic for the patient, but it is more difficult to detect clinically and may manifest as poor tumour control (ICRP, 2000). To check for possible underdosing errors, it is necessary to perform adequate patient follow up that includes evaluations of local control and toxicity as a part of recommended clinical practice.

Errors in radiotherapy need to be described and classified in similar ways to those that occur in other clinical disciplines. To promote harmonization among all medical disciplines existing general classification systems and general structures recommended by international bodies, such as the conceptual framework of the WHO (WHO, 2009a), should be used for radiotherapy as much as possible. The implementation of radiotherapy event reports in the NRLS (NPSA, 2013; NHS, 2010) is an example of how radiotherapy events can be reported to a general health care reporting system yet remaining easily accessible for separate

analysis if necessary. However, it must be recognized that a general event classification scheme is not completely practical for the highly specialized field of radiotherapy. For this reason, general systems should be supplemented with details and codes specific to the field of radiotherapy. The ROSIS (ROSIS, 2013) and SAFRON (IAEA, 2012) systems provide examples on how the necessary specificity for radiotherapy can be obtained.

Classification systems must also have sufficient flexibility to permit the incorporation of new evidence, such as new events that do not fit into existing classes, and to incorporate improvements that facilitate analysis and learning. A mechanism to receive comments and questions about the classification system should be implemented in order to resolve doubts and to evolve through user input.

In conclusion, adverse-error event classification systems may be improved by integrating and adapting, as appropriate, existing general classification schemes with radiotherapy-specific details. Wherever possible, individual radiotherapy facilities should use definitions and adopt classification schemes developed by national or international agencies in their internal reports and databases so that data can be easily shared, compared and aggregated to external reporting and learning systems.

4.5.4 Event Reporting and Learning

4.5.4.1 Purpose

One component of risk management is to record and report all near misses and adverse error-events, and to develop and implement an event reporting system for this purpose (Williams, 2007; Committee on Quality of Health Care, 2000; David et al., 2006; WHO, 2005; Ford et al., 2012; RCR, 2008; NHS, 2000; Battles and Stevens, 2009; ASN, 2009; SIMPATIE, 2013). The primary purpose of the reporting should be to learn from experience, that is, from previous errors; for this reason, these reporting systems should more appropriately be called reporting and learning systems. These reactive systems not only help to identify risks and system weaknesses (early warning, identification and analysis of new risks, and contributing factors to adverse error-events), but they are also a useful tool to evaluate the effectiveness of current measures to reduce the risks.

A fully developed reporting and learning system should include a detailed description of the event (date, stage in the process, sequence of events leading to the event, etc), its causes, categories of the contributing factors, categories for a description of how the event was discovered, severity of consequences, probability of recurrence, management of the event, corrective actions implemented, and recommendations to avoid future repetition.

4.5.4.2 Initial and final reporting

When something goes wrong in any stage of the radiotherapy process and the result is an adverse error-event or a near miss, an initial recording and reporting of the event takes place. This initial response is an internal/local report within the radiotherapy department and involves a description of what happened. All events previously defined by management are recorded and reported at the local level. This initial report triggers, or is accompanied by, a rapid preliminary analysis of the causes of the event, evaluation of its consequences, and “immediate” corrective actions necessary to achieve the planned treatment aims or to limit the consequences in case of event with “high potential consequences”. If the event is considered to be a significant event (according to national criteria established by the relevant authority), notification to authorities is made as soon as possible. The initial rapid analysis of the event for the initial reporting does not usually provide a comprehensive understanding of the event and its causes, nor does it give the comprehensive information requested by the reporting and learning systems. Consequently, a more detailed analysis of the event is necessary.

The detailed event analysis is carried out according to the guidelines given in Section 4.4, including an investigation into the root causes of the event and action proposals designed to avoid reoccurrence of the same type of event. In case of significant events, the results of analysis and corrective actions are notified to authorities (as required by EU BSS at Art. 63-e (EC, 2013). Corrective actions are implemented and if relevant, procedures and proactive risk assessment are updated.

After the detailed analysis has been completed, the final reporting of the event is implemented through local and/or external reporting systems, such as the PRISMA-RT national systems used in the Netherlands (PRISMA-RT, 2013) or the Swiss-ROSIS system, and/or an international system such as SAFRON and ROSIS (for more details, see the following two sub-sections, Section 4.5.3, and the Technical Supplement). This will complement the initial local report when needed, and forward information to external reporting and learning system(s). The primarily purpose of reporting is to share the lessons learned with other professionals.

4.5.4.3 Characteristics of the reporting and learning systems

Existing reporting and learning systems are highly variable in terms of sponsorship, participation, function, and feedback. Some of the features of reporting and learning systems are discussed briefly in the present section of these guidelines, while a more detailed discussion is presented in the Technical Supplement.

Reporting and learning from events should be fully supported and encouraged by top management because this is an integral part of an effective quality management system and an essential feature of a good safety culture.

A reporting and learning system can be *local* (used internally by the radiotherapy centre) and/or *external*, used for reporting to outside parties. Both systems are complementary and therefore should be designed—as occur with some of the existing systems (DPSD, 2013; André et al., 2004; Health, 2013)—for internal use but with the capability of exporting the data to external databases such as the ROSIS (ROSIS, 2013) or SAFRON (IAEA, 2012). The benefit of external reporting is that it enables events to be identified and analysed on a larger scale than would be possible with only locally-generated data. This permits learning from rare events and makes it possible for all radiotherapy departments to benefit from the experience of others. Manufacturers have a particularly important role in promoting external reporting and learning because any lack of adequate response from a manufacturer can undermine the motivation of healthcare professionals to make additional reports.

General reporting and learning systems that are non-specific to radiotherapy are valuable because they make use of established mechanisms and resources for reporting, analyzing and disseminating information. However, due to the specific risks and an important complexity of radiotherapy, radiotherapy staff are usually less likely to use general reporting and learning systems. One way to overcome this difficulty is to use the general system as the basis for reporting but with specific codes to filter data and account for the specific features of radiotherapy, as in the case of the NRLS (NPSA, 2013).

In many countries reporting is *mandatory*, primarily to ensure public accountability, although the specific requirements vary in terms of the types of events that must be reported and the follow-up actions taken by regulators. Additionally, there are voluntary systems that form part of collaborative efforts to enhance patient safety at different levels: departmental, institutional, regional, national and international. The most common failure of mandatory reporting systems is to require reporting but without providing adequate resources to analyse the reports and share the learning obtained through this analysis. Ideally, information from the mandatory and voluntary reporting and learning systems should be combined into a central reporting system to ensure effective sharing of lessons learnt.

The reporting and learning system should clearly state which events are reportable. A particular group of reportable events are the significant (notifiable) events, which have to be reported to authorities according to national requirements; mandatory reporting and learning systems usually include a threshold or classification for significant events.

Institutions should have a supportive environment for event reporting that seeks to avoid a policy of assigning blame and that protects the privacy of the person who reports the event. A major issue here is *confidentiality*. A report is considered *confidential* when identifying data are kept secret or private. In contrast, a report is *anonymous* when the reporter does not reveal his or her identity. A reporting and learning system may benefit from the advantages of both options: a confidential option is best when additional information may be required from the reporter and specific recommendations are given. The report can become fully anonymous afterwards in order to publicly disseminate the information about the event and the lessons learnt. It is important to note that in the context of encouraging reporting and avoiding assigning blame, the event report should avoid any semblance of "covering up" inappropriate behaviour: error identification can prompt a variety of actions ranging from changes in practice, reminders of good practices, and reinforcement of training of staff, to disciplinary action in extreme circumstances if duly justified.

An effective reporting and learning system should be available in a *design* that allows information to be recorded accurately, quickly, and in a way that facilitates coding. *Data entry* should be user-friendly because cumbersome forms are less likely to be used. Standard fields from agreed classification schemes should be used whenever possible. To facilitate an *information search*, anonymous databases of reporting systems should have a search engine that allows search by key words and filtering by fields or combination of fields. These databases should contain not only information on the reports and results of the investigation, but also links to online resources and comments on publications related to patient safety. Ideally, a departmental reporting and learning system should be a module within radiotherapy information systems. It would be highly beneficial also if the reporting and learning system could communicate with one of the international reporting and learning systems such as ROSIS (ROSIS, 2013) or SAFRON (IAEA, 2012).

In many reporting and learning systems, the database is accessible only to specific users. However, unrestricted reporting by all staff members should be encouraged. Furthermore, access to anonymous data could help to disseminate the lessons learnt among professionals and could also answer the public's right to know about events in radiotherapy; in such cases, however, access might be provided with the support by relevant national bodies to prevent generating unnecessary concerns amongst the general public with insufficient knowledge of radiotherapy.

The data from reporting and learning systems *should be interpreted carefully*. Mandatory reports usual address events with consequences above a certain magnitude, known as "sentinel" events or simply adverse error-events. Voluntary event reports, in contrast, are subject to selection bias due to the fact that the reporter may have legitimate concerns about the effects of reporting. Thus, voluntary reporting captures only a fraction of events, may focus on sporadic near misses and minor events (ROSIS, 2013; Ekaette et al., 2007), and might not reliably identify serious events. As a result, underreporting is probably the norm (Cooke, 2007; Farley et al., 2008; Menendez et al., 2010; Levinson, 2012) and therefore, the data collected through a reporting and learning system should not be considered a reliable indicator of the rate of adverse error-events. Using a minimum *number of event reports*, or preferably, the number of events above a certain grade of severity divided by the total number of reported events, as a quality index, can help to decrease the problem of underreporting. However, even small changes in reporting practices can produce a large change in the apparent number of real events (Shojania, 2008). When harmonized classification schemes are used, including the use of similar definitions for event reporting, too few reports as well as too many should trigger questions about safety.

For a successful reporting and learning system, reports should lead to a constructive and timely response (Benn et al., 2009). A structured mechanism must be established to direct how reports will be reviewed, and how action plans and follow-up the implementation of those actions should be undertaken. Reports must be evaluated by experts who understand the clinical and technical circumstances under which the events occur and who are trained to recognize underlying systemic causes and to propose solutions. The conclusions from the investigations of events should lead to remedial actions to improve safety. The conclusions and actions should be fed into staff training programmes and to professional accreditation schemes so that all staff members are thoroughly educated in the types of potential events that might happen. Effective communication about adverse error-events to the patients involved can improve patient understanding (confidence, emotional status) (Rozovsky and Woods, 2005), particularly in the difficult circumstances when the event results in unintended harm to the patient. Dissemination of summaries of reported events in a timely fashion is of utmost importance for the educational purpose of the system, to encourage professionals to report events, and to develop a safety culture. It is essential to have a pre-designed communication strategy to assure that all communication efforts are well-organized.

4.5.4.4 SAFRON

Among the existing reporting and learning systems, the Safety in Radiation Oncology (SAFRON) medical event database (IAEA, 2012) deserves special mention. This is a voluntary, confidential (no identifiable data is revealed to any governmental authority or other third party), non-punitive reporting and learning system for radiation oncology centres. The system allows registered facilities to review cases submitted to SAFRON and contribute cases to the system. If equipment failures were a factor in the event, the event reporter can provide information about the manufacturer, type and model of the equipment. The system also offers the ability to provide information on actions that contributed (caused) to the event and what steps the facility took to prevent a repetition of this type of event. There is a feature to toggle between your own event reports and all event reports, which allows the system to be used as a local database of events and actions, as well as a global system for sharing and learning from events. The system also has a feature (links to abstracts) that correlates the process steps to scientific publications on event prevention and quality assurance in radiation therapy.

The vision is that SAFRON will, through collaboration with other organizations and bodies, provide information not only on what has been directly reported into the system, but also information on events reported through other systems/information channels. The system has already been “pre-seeded” with event descriptions from previous IAEA records, as well as more than a thousand reported events from the earlier ROSIS efforts. The list of collaborators is likely to grow in the future.

4.5.4.5 Conclusions

Both initial and final reporting of adverse error-events and near misses is important in order to document all findings and actions relevant to implementing corrective actions, preventing their re-occurrence, and their occurrence elsewhere (by disseminating the lessons learned). Successful reporting and learning systems are non-punitive, confidential, and their main aim is to provide learning opportunities via information and action feedback. Organizations must move on from asking: “Whose fault was this?”, to asking: “Why did this error occur and what can we do to prevent it from occurring again?”. Analysis of event reports allows professionals to evaluate processes, systems, protocols, and practices that give rise to such events. Efforts to mitigate the consequences can then be targeted and focused on areas where events have been frequent or the consequences severe.

The “ten golden rules” of reporting presented in Table 4.8 summarize the reporting principles considered most important to encourage reporting. More details about these rules are described in the Technical Supplement.

Table 4.8. Ten golden rules to encourage reporting

1. Active support of leadership.
2. Respect to the reporter - avoid blame policy.
3. Confidential or anonymous systems.
4. Minimum number of reports as a Quality Indicator.
5. Educate on safety.
6. Simplicity.
7. Easy access.
8. Feedback of information and lessons learnt.
9. Look for solutions, not for culprits.
10. Follow-up of the implementation of the corrective actions.

4.6 Other preventive measures/risk reduction interventions

Besides the proactive risk assessments and reactive analysis of events discussed in Sections 4.3 and 4.4, and the related need for proper classification and reporting/ learning systems discussed in Section 4.5, there are a number of other measures or interventions which are likely to be effective for reducing risks and preventing adverse error-events and near misses in radiotherapy. In general, delivering and maintaining good quality radiotherapy also implies strong efforts to reduce risks and to prevent adverse error-events; in other words, quality management. Quality management, with its traditional tools such as quality assurance, quality control and quality audit, is therefore a corner stone for all preventive measures.

The other preventive measures presented here are well-covered by a number of national and international documents, regulations, recommendations, and/or guidelines. In the following paragraphs, the hierarchy of the effectiveness of practical preventive measures is briefly discussed. More details about how this hierarchy was developed, along with a few important examples (quality assurance, quality control and clinical audit), are presented in the Technical Supplement.

The existence of a safety culture within the institution is essential to ensure that preventive measures are effectively implemented. This can be taught, but to be effective it needs to be adopted by everyone and effectively monitored.

In general, when a hazard is identified, the safest approach is to perform a redesign which removes the hazard. If redesign is not feasible, then the next best approach is to employ a guard or barrier to separate the patient from the hazard. If the guard is not feasible, then the next step is to increase awareness and strengthen verification, training, and procedures. There is a tendency to create new procedures as the way to prevent an error, but when possible, it is better to devise measures that make things simpler and safer "by default" (so that even if an error occurs, the system prevents the process from proceeding using an appropriate forcing function). The hierarchy of the effectiveness of preventive measures is summarized in Fig. 4.7, which has been adapted from the Institute for Safe Medication Practices (Hendee, 2011).

Figure 4.7. Hierarchy of the effectiveness of preventive measures

The higher up a tool is in this hierarchy, the more powerful it is as a preventive measure. However, the various steps are not entirely independent, the classification is not strict, and the exact order of these items is somewhat situation-dependent; for this reason, the hierarchy should be used as a useful rule-of-thumb; effective error prevention requires a well-rounded approach and it is likely that actions at all levels of the hierarchy are needed.

The three top items are “system oriented”, that is, they try to fix the system by re-designing it to make it safer. The next items are “human oriented” measures that rely on human vigilance and memory, and though fundamental and necessary, they are less effective. We cannot change the human condition, but we can change the conditions under which humans work.

5 RECOMMENDATIONS ON RISK ASSESSMENT AND ANALYSIS AND REPORTING OF EVENTS

Based on the reviews, questionnaires, and critical analysis carried out in the context of this EC project (ACCIRAD), including the Workshop and critical reviews by several international organizations, the following recommendations are given. In accordance with the scope of these Guidelines, these recommendations are related to the specific topics of risk management: risk assessment and analysis and reporting of adverse error-events and near misses in external beam radiotherapy.

Risk management should be established first at a local level and then this experience can be used to contribute to a national arena. Analogously, within the present guide, two levels of recommendations are proposed:

- Recommendations to institutions that provide radiotherapy services, whose main responsibility is patient safety;
- Recommendations to national authorities, underlining the need of a strong support at national or regional level for the promotion of risk management and safety culture.

Finally, recommendations are given on the requisite features of reporting and learning systems and on how to report adverse error-events and near miss events using consistent terminology, to encourage reporting and to improve learning from such events in support of overall risk management.

5.1 Recommendations to institutions providing radiotherapy services

5.1.1 Organization for risk assessment and analysis and reporting of events

- The organization of proactive risk assessment, reactive analysis of events, and reporting of events should be led by the top management of the radiotherapy institution. Sufficient resources, in terms of staff levels and time, should be allocated for the assessment, analysis, and reporting, and should include appropriate training of the staff (see section 5.1.3). The commitment of management to these obligations should be formalized by an engagement letter either devoted to these specific topics of risk management or as a part of another engagement letter such as for quality and healthcare safety.
- The institution providing radiotherapy services should have a dedicated quality management system that incorporates national recommendations (if available) and international standards. This should cover all steps of treatment for both external beam radiotherapy and brachytherapy, and should include, among other things, clearly-defined staff responsibilities, methods to manage the records, internal and external audits, and continuous improvement of patient safety based on risk assessment, with corrective actions and steps to prevent adverse error-events. ISO standard 9001 (ISO, 2000) is the internationally recognised reference for a quality management system when used in conjunction with the highest professional standards.
- The institution providing radiotherapy services should develop a safety culture that encourages proactive risk assessment and reactive analysis of events, and reporting of events and near misses. To successfully develop such a culture, specialized training of the staff on the issues of safety culture is needed. This means that staff members learn about how risk assessment benefits patient safety, the situations which are critical for patient safety and, how analysis and reporting of events is important for learning purposes.

- A risk management committee (ASTRO, 2012; NHS, 2007; 2012a,b)—focused solely on radiotherapy or as part of a more general structure dealing with risk or quality assurance—should be established. This committee should be granted decision-making capabilities with regards to the following essential aspects: resource allocation (financial, human); actions to be undertaken; definition of the risk management process; risk assessment; selection of reporting practices; supervision of the reactive analysis of events; the outcomes to be analysed; and finally, follow up actions. Whatever organisational structure is chosen (e.g., a dedicated committee or not), people with the power to allocate resources needed to implement the committee's decision should be involved. Everyone should be aware that proactive risk assessment, reactive analysis of events and reporting of events (both initial and final reporting) are tools that help leaders make the decisions necessary to improve safety in the care process.
- Before any risk management program is initiated, it is strongly recommended that institutions identify an experienced risk manager to assist in choosing the optimal methodologies and to help implement the chosen methods (by describing the various steps in the process and defining the work process itself), and to assist in training the staff who will be involved in the process. The support of the risk manager is particularly important for proactive risk assessment, which can be more challenging than the reactive analysis of events.
- A multidisciplinary working group led by a team leader (risk manager or other) should be established to implement the selected methods of proactive risk assessment and reactive analysis of events. The working group should include individuals such that all the necessary skills and knowledge are covered, and should involve key professionals (e.g., radiation oncologists, radiation therapists, medical physicists, nurses, technicians, dosimetrists, medical secretary). Moreover, these staff members should undergo training in the methods that will be used. Given that it could be difficult to find individuals that possess all the skills needed for every aspect of the risk assessment, dedicated sessions requiring specific skills may be organised.

As a conclusion, the following key points on practical actions in risk management are summarized in Table 5.1.

Table 5.1. Five key, practical actions to successfully organize risk assessment and analysis and reporting of events for risk management

Key point	Action
1	Ensure leadership and commitment of the top management and allocation of specific resources
2	Ensure establishment of general provisions: quality management system, promotion of safety culture, process descriptions
3	Establish risk management committee and define the process of risk management, including methods to be used
4	Ensure involvement of an experienced risk manager
5	Establish a multidisciplinary working group with the requisite skills and radiotherapy professionals needed to implement the methods

5.1.2 Methods for risk assessment and for analysis and reporting of events

- Risk management should include both proactive risk assessment and reactive analysis of events (a complete or integrated approach). For both activities, a systemic approach is needed. This approach should include considerations related to equipment failure, human error, and organizational factors. For each method (proactive or reactive), the operational objectives should be specified to all users involved in the process:

- Proactive risk assessment is well suited to the study of possible organisational and equipment failures and human errors, and also useful for identifying barriers that can be implemented to limit the consequences of the aforementioned failures and errors.
- Reactive analysis of events focuses on the study of a specific event, and involves the investigation of causes, identification of barriers that failed, and the corrective measures required. This type of analysis should be used to update proactive risk assessments.

- The availability of process descriptions for the main activities should be ensured to avoid the time-consuming extra work that is often required of the staff who perform the proactive risk assessment when such descriptions are missing. However, for the risk assessment and reactive analysis of events, staff members must describe their real practice, even if it differs from the process description.

5.1.2.1 Proactive risk assessment

When should it be done?

- A proactive risk assessment should be started when the quality management process is being implemented. Considering that a comprehensive proactive risk assessment is difficult, time-consuming, and expensive, it should focus first on the main steps of the process that have been previously identified to have the highest risk.
- Until all the main procedures and functions of radiotherapy have been covered, a reasonable objective might be to perform one proactive risk assessment per month to evaluate one hazard or failure that could lead to a possible adverse error-event.
- After the institution has at least one year of experience working on the processes and protocols, the proactive risk assessment should be updated; in other words, the impact of this experience and changes in the existing risk assessment needs to be analysed.
- A new risk assessment, or an update of an earlier one, is recommended whenever there are significant changes in the treatment techniques, equipment or procedures, or if the results of the analysis of events suggest a need. Special attention should be given to new radiotherapy technologies and to software or hardware updates.
- The volume of risk assessment should be adapted to the status and scope of the radiotherapy processes, techniques and equipment and the level of experience in their use; new and modified systems deserve the greatest attention; similarly, the wider the scope of radiotherapy activities, the more extensive the risk assessment needs to be.

How should it be done?

- For proactive risk assessment, as the minimum approach to get started, the following sequence of procedures is recommended:
  - Identify potential failures or hazards (which might or might not lead to adverse error-events) through peer experts' advice, analysis of events and operational experience, or by making use of checklists available in published risk assessment studies; the existing checklists usually need to be adapted to account for the specificity of local practices.
  - Identify the impact of potential failures or hazards on the system (i.e. the evaluation of consequences) by deductive (bottom up approach) and qualitative methods, either Failure Mode and Effect Analysis (FMEA or FMECA) or Preliminary Hazard and Risk Analysis (PRA) (see Section 4.3 and the Technical Supplement). Available assessment guides (e.g., ASN, 2008a,b; IAEA-FORO,

2013), with completed, adaptable tables, as well as supporting tools such as excel sheets or specific programs (i.e. SEVRRA (SEVRRA, 2013)) could prove highly useful for the first application.

  - Prioritize efforts (in both the FMECA and PRA methods) by using a criticality matrix (see Section 4.3.2). The severity scales should be developed by consensus in the working group or adopted from international or national agreements on these scales. The criticality data is then used to assess, on each item in the FMECA or PRA table, if the situation is acceptable or not.

- A comprehensive understanding of the risks and the associated risk management should be available before commencing routine use of equipment with patients. The first step in this case may involve using the risk assessment analysis performed by manufacturers during the pre-market phases. Manufacturers should share the results of this assessment with users, as far as radiological hazards are concerned. This data, together with acceptance testing and commissioning, seems to be useful to enhance device-related risk assessment.
- Proactive methods are more difficult to learn than reactive ones, and it is more difficult for the team to apprehend events that did not occur. Therefore, the multidisciplinary working group for the study of risk needs appropriate guidance by the risk manager to focus on risk assessment using the selected method and to avoid confusion with methodological issues.
- As an additional, initial step when a quality assurance system is being developed, the lessons learned from published reports of events should be applied to the system. This should serve to test whether a newly developed quality programme is robust enough to withstand events known to have caused major or catastrophic consequences and to assure a very low probability of these major events occurring (IAEA, 2000; ICRP, 2009).
- After experience has been gained through the initial, basic approach to proactive risk assessment, a deeper assessment (a defence in depth approach) is recommended in order to take into account the possibility of combinations of failures and probabilistic assessment and also barrier failures (reactive or corrective measures). For this deeper assessment, either the Fault Tree or Event Tree method, or the Probabilistic Risk Matrix method, can be used (see section 4.3 and the Technical Supplement), and this could be focused on some specific situations considered to be especially critical.

How to use the results?

- The results of the proactive risk assessment should be used to implement necessary changes and improvements in practices, particularly in preventive measures (such as barriers) to strengthen treatment safety. Furthermore, the changes and improvements carried out should be integrated into the internal quality documentation used to support the various steps of the treatment process.
- The results of proactive risk assessment should be included in the staff training program. The professional training of all staff, particularly new members, should clearly identify the most dangerous situations in the treatment process and the barriers that are in place to reduce the risk for adverse error-events.

5.1.2.2 Reactive analysis of events

When should it be done?

- The reactive analysis of events should be performed for all adverse error-events and near misses that are considered significant by the radiotherapy institution.

- The reactive analysis of events should be performed as soon as possible after an event has been detected and should include all people involved in the event.

How should it be done?

- When a proactive risk assessment has been carried out, the defined criticality matrix should be used to prioritize the events that require in depth analysis.
- The reactive analysis of events should identify the scenario, barriers (successful or failed) and both direct and latent causes. Several useful methods are available (section 4.4).
    - Often initial perceptions are found to be incorrect after a more thorough analysis is completed.
    - Although some direct causes seem obvious, seldom are all the causes and contributing factors immediately known.
    - Contributing factors may not trigger the error, but contribute to creating an environment prone to error.
- The reactive analysis of events should be positive, constructive and sensitive and look for solutions not for culprits. A policy of blame should be avoided.

How to use the results?

- The results of the reactive analysis of events should be used to implement necessary changes and improvements in radiotherapy practices, particularly with regards to the preventive measures taken to avoid a re-occurrence (such as newly-identified barriers). The need to update the relevant proactive risk assessment should also be considered. Implementation of changes and improvements should be monitored to close the cycle of learning. These changes should eventually be integrated into the internal quality documentation that supports the various steps in the treatment process.
- The results of the reactive analysis of events should be included in the staff training program. The professional training of all staff, particularly new members, should include information on significant past errors and the improvement actions taken to remedy those errors.

5.1.2.3 Reporting of adverse error-events and near misses

When should it be done?

- All adverse error-events with significant consequences should be reported to internal and/or external (national or international) reporting and learning systems as soon as sufficient information, based on the analysis of the event, is available, unless local QA documents or national regulations impose more urgent and stringent reporting procedures. Near misses that offer a significant learning opportunity should also be reported, at the very least, to voluntary reporting and learning systems.

How should it be done?

- Institutions should have a supportive, encouraging environment for event reporting and learning that protects the privacy of the reporter.
    - All staff members and even patients should be encouraged to initiate reporting actions

  - The confidentiality policy of the reporting should be clearly stated in the supporting documents

- In their internal report databases, institutions should adhere to definitions and classification schemes developed by national or international agencies, so that data can be easily shared, compared and aggregated to external reporting and learning systems (see also section 5.3).
- *Reporting to the international system of SAFRON is encouraged*, to promote worldwide learning of events and improvement of safety.
- Reporting should be completed in accordance with the rules and instructions provided by the internal or external reporting and learning systems.
- Adverse events leading to both underdosing and overdosing of the patient should be reported. Near-misses with potentially significant consequences if not prevented should also be reported as they can reveal weaknesses, lead to improvement actions, and enhance learning related to risks and safety.
- Ideally, the department's event reporting and learning should be included as a module in radiotherapy information systems.

How to use the results?

- Reports of adverse error-events should be communicated to the patient to improve patient understanding (confidence, emotional status).
- The reports of adverse error-events and near misses should be used to implement improvement of practices and to raise awareness amongst professionals, and be incorporated into the staff training program.
- In cooperation with relevant authorities, all of the following should be used to inform and assure the public that errors are tracked and solutions implemented to improve the safety of radiotherapy: reports including summaries and statistical data on the events, actions taken, follow-up of these actions, and trends related to issues of radiotherapy safety.

As a conclusion, the following key points on practical actions in risk management are summarized in Table 5.2.

Table 5.2. Five key, practical actions to successfully implement risk assessment and analysis and reporting of events for risk management

Key point	Action
1	Implement risk assessment according to the minimum approach and apply lessons learned from published reports of events to the system
2	Implement risk assessment according to the defence in depth approach
3	Implement analysis of events and prepare and send reports to internal and/or external reporting systems for all events considered significant
4	Use the results of proactive risk assessment and reactive analysis of events to implement improvements to working practices (e.g. new barriers)
5	Include the results of proactive risk assessment and reactive analysis of events in the internal quality documentation and in staff training programs

5.1.3 Resources and training

- The personnel resources needed will depend primarily on the method(s) selected and on the existing knowledge and practices of the staff with regards to risk assessments and analysis and reporting of events. While it is difficult to give definitive recommendations

on the resources needed, Table 5.3 shows some illustrative figures. Because both risk assessment and analysis of events are not one-off activities, resources are also needed on a continuous basis as shown in Table 5.3.

- Based on experience, three types of training for risk management should be organized as shown in Table 5.4. The amount of training needed depends on the methods selected and on the existing knowledge and practices of the staff; illustrative values for minimum training are given in Table 5.4. The recommended contents of the training programs are given in more detail in Tables 5.5 to 5.7.

Table 5.3. Illustration of personnel resources needed

Task	Minimum resources	Includes contributions from
Initial work for *risk assessment* (creating the resources and selecting methods, organizing training, carrying out a process description, defining scales etc)	6 man-months	Risk manager All key professional groups
First proactive *risk assessment based on the minimum approach* (see section 5.1.2.1)	3 man-months	All key professional groups, multidisciplinary working group
Continuous development and updating of the *risk assessments*	2 man-months/year	All key professional groups, multidisciplinary working group
Analysis of events with reporting and feedback actions	One day/month	One day from each person of the multidisciplinary working group (investigation team)

Table 5.4. Three types of training needed for risk management, including risk assessment and analysis and reporting of events

Group to be trained	Minimum training	Topic of training and/or comments
Management staff	1 day	Risk management and safety culture (main concepts, traps to avoid etc)
Risk managers	2 days to complete general training with practical work. 1 day for each method chosen (proactive and reactive). 1 day to learn how to use the reporting and learning systems.	All key principles and concepts of quality and risk management (a priori and a posterior methods, barriers, latent conditions, reporting etc). Operating results and their relationship with regulations. Competence to train those selected to carry out risk assessments and analysis and reporting of events. Ideally this training can be carried out collaboratively among institutions that encourage risk managers to share their experiences.
Multidisciplinary working group	1 day for proactive risk assessment: 0.5 day theoretical training + 0.5 day to implement the selected methods. 1 day for a reactive analysis and reporting of events: 0.5 day theoretical training + 0.5 day implementation of chosen methods.	To be implemented once the risk manager has been trained and the processes for the risk assessment and analysis and reporting of events have been defined. In situ work should ideally be implemented with the support of the initial trainer, to overcome difficulties, to adapt materials, and to help identify improvement actions.

Group to be trained	Minimum training	Topic of training and/or comments
	0.5-1 day/month for 3-6 months: in situ practical work on own local processes	

- Contents of the training could be developed and adapted to radiotherapy by using available schemes published by WHO (2011) and EUNetPaS (2011).

Table 5.5. Recommended training program for risk managers

1. General summary of risk management concepts and issues.
   - The lessons of history, state of the art-regulation, current state of practice.
2. Overview of a risk assessment process and reporting and analysis of events
   - Basic concepts: risk, adverse error-events, near misses, severity, likelihood, criticality, acceptability, barriers to prevention / protection etc
     - How to identify, assess and prevent risks
     - Proactive risk assessment , initial reporting of events, reactive analysis of events, final reporting of events
3. Practical program for risk assessment and reporting and analysis of events
   - Contents, organization, decision-making, methods and management indicators, conditions for implementation, traps to avoid.
4. Safety Culture and experiences
   - Definition, how to implement, experiences.

Table 5.6. Recommended training program for proactive risk assessment in radiotherapy

1. Risk management concepts and requirements.
   - Radiation risks, lessons of history, state of the art-regulation, current state of practice.
   - General concepts of risk management: risk, adverse error-events, near misses, severity, likelihood, criticality, acceptability, barriers to prevention / protection etc
2. Overview of the methods for proactive risk assessment
   - How to identify, assess and prevent risks
   - Introduction of assessment guides (e.g. ASN, 2009)
3. Workshop: Implementation of the assessment guide
   - Debriefing
   - Practical exercise
4. Conclusions
   - Traps to avoid
   - A proposed program for the implementation.

Table 5.7. Recommended training program for reactive analysis and reporting of events

1. Introduction - Concepts and definitions
   - Radiation risks, lessons of history, state of the art-regulation, current state of practice.
   - General concepts of risk management: risk, adverse error-events, near misses, severity, likelihood, criticality, acceptability, barriers to prevention / protection etc
2. Overview of the methods for reactive analysis of events and the reporting of events
   - Life of an adverse error-event (latent conditions, active failures)
   - Analytical methods (CTA, ALARM, ORION®)
   - Initial and final reporting, reporting and learning systems
   - Example of event report
3. Workshop: Implementation of selected methods
   - Debriefing
   - Practical exercise
4. Conclusions
   - Traps to avoid

5.2 Recommendations to national authorities

The novel ideas presented in the revised EU BSS (EC, 2013) regarding quality and risk management are significant and offer Member States the opportunity to establish a comprehensive strategy to develop or update an improved safety culture in radiotherapy.

The requirements established in the new EU BSS respond to the needs evidenced in recent years in several countries: major adverse error-events that have occurred in various countries have prompted healthcare and radiation protection authorities in those countries to initiate a national strategy, as seen in the United Kingdom (multidisciplinary working party Towards Safer Radiotherapy), France (National action plan following the Epinal accident; the safety plan was integrated as a second step in the national cancer plan), in Spain (following the Zaragoza accident), and in Poland (after the Bialystok accident). In all these cases, the plan strategies were defined by a national committee whose focus was either specifically on radiotherapy or on patient safety in healthcare, and discussions and planning involved the national responsible authorities, professional societies, and other relevant bodies such as representatives of hospital administrators and patient organisations.

Based on the practical experiences of the countries described above, the following recommendation is directed to national authorities:

A national strategy on quality and risk management in radiotherapy that promotes the implementation of improved safety culture should be established and should involve national authorities responsible for radiation protection and healthcare and medical devices, as well as other stakeholders, decision-makers, and health care professionals. The involvement of patient organisations is also recommended to assure confidence in the safety of healthcare delivery. The main components of the recommended strategy are summarized in Table 5.8. Countries with an existing strategy are encouraged to consider updating the strategy.

The recommended strategy is crucial to promote the application of risk assessment and analysis and reporting of events and to make sure that appropriate resources are allocated.

In order to develop and implement the recommended strategy, two particular aspects of collaboration are stressed:

- *A close collaboration between national authorities and professional medical societies is recommended*

- *A dialogue between national authorities, professional medical societies, medical users of radiation, and manufacturers should be encouraged and promoted*

It is of paramount importance that the dialogue with manufacturers be improved, and this should be enforced by national authorities, particularly because direct connections between users and large multinational companies are often lacking. The dialogue with manufacturers should focus on:

- The exchange of information about the results of risk assessments carried out by users and manufacturers; the studies carried out by the manufacturer should indicate how risks related to radiological hazards have been accounted for in the design of the equipment or software.
- The role of manufacturers in reporting and learning from events; manufacturers should encourage users to report any events related to deficiencies of new equipment or technology (hardware and software), and for all such reports the manufacturer should promptly respond or give feedback to the sender, including suggesting remedial actions when needed. Similarly, the manufacturer should alert all other users of the same equipment or technology if there is a risk that the same event could occur elsewhere.
- National assessment or accreditation of the programs established by manufacturers to provide a platform to exchange information with users. These programs may include any of the following: procedures for handling reported safety problems with hardware, software or interaction with equipment or programs from other companies for which a declaration of compatibility has been delivered by the manufacturer; systems to manage user proposals to improve hardware and software safety; regular reports of reported safety problems and safety improvement proposals; manufacturer responses to reported problems; user mailing lists, groups, periodic meetings between users and manufacturers, or any other method designed to facilitate information exchange.

Table 5.8. The main components of the recommended strategy for quality and risk management in radiotherapy

No	Aim	Details
1	Updated legislation	• National legislation and/or regulation should be updated to implement the new BSS requirements on accidental and unexpected exposure. • Technical criteria to notify national authorities about significant events should be established.
2	Methodology for quality and risk management	• A reference methodology for quality management (e.g., ISO standard 9001 (ISO, 2000)) and a radiotherapy-specific risk management system should be selected and integrated into the accreditation/certification processes of healthcare organizations. • General methodologies of proactive risk assessment and reactive analysis of events should be promoted, including pedagogical examples. • A radiotherapy-specific methodology should be created jointly by professional societies and national authorities responsible for healthcare and radiation protection. • A harmonized event classification system that uses, to the extent possible, a general healthcare classification reporting system, should be promoted.
3	Dissemination of information on risk management	• Information on risk management should be effectively disseminated to promote awareness of the importance of risk management in a quality management system and as a part of a good safety culture. • Guidance should be issued to facilitate implementation of risk management at the institutional level, particularly with regards to its impact on the working process itself, on the “relevant time” to start a

No	Aim	Details
		proactive risk assessment, and on how relevant events are selected for reactive analysis. • Feedback and experience in proactive risk assessment and reactive analysis of events should be collected from radiotherapy centres to identify and promote good practices. • Internal recording of all events, including near misses, should be developed. External reporting to national/international reporting and learning systems should be encouraged.
4	Training in risk management and safety culture	• Training in risk management and safety culture should be undertaken by professional societies, in collaboration with national authorities, to provide both initial and continuing training to staff member at radiotherapy institutions. • Risk management should be incorporated into both under- and postgraduate educational programmes for all professions involved in the radiotherapy process, including managers. Such training should also for part of continuing education programs.
5	Informing patients and the public to increase trust in the health care system	• The *practitioner* should inform the patient in case of adverse error-events. • At the *hospital level*, the management and the responsible practitioner should be involved. A proactive communication strategy should be defined, particularly when there are adverse consequences for a cohort of patients or serious adverse effects to one patient. The strategy to inform the public should be worked out in collaboration with the authorities. • At the *national level*, information to the public may be periodically provided by authorities, primarily statistical analysis of reported events. In case of a serious event, national authorities should—in collaboration with the medical (radiotherapy) society—provide specific details about the event and the risk. • For the purposes of communication to the public, a specific scale of events may be useful (e.g., ASN/SFRO scale (ASN-SFRO, 2009)).
6	Clinical audit	• Implementation of quality and risk management systems in radiotherapy should be regularly verified by clinical audit (EC, 2013; 2009b). A clinical audit is the most appropriate method of assessing in detail the impact of proactive risk assessment and reactive analysis of events on overall improvement in radiotherapy safety at an institution.
7	Regulatory inspections	• Regulatory inspections by national authorities should focus on the local organisations and systems for quality and risk management, with a specific emphasis on the events reporting and learning systems. • The main findings of the inspection program should be made available to the public (EC, 2013; Article 104(4)).

5.3 Recommendations on reporting and learning systems

5.3.1 Terminology and classification of events

- The basic terminology recommended for use in radiotherapy is presented in Table 5.9 and Fig. 5.1. Common terminology facilitates (or enables) the analysis and comparison of reported data from different sources and is essential to permit comparisons between the risks of radiotherapy and other areas of health care.
    - In particular, use of the term “adverse error-event” is recommended to replace the word “accident”. The word “error-“ has been added to this term because in medicine, “adverse event” might include any event that produces adverse effects in the patient; for the purposes of these guidelines only adverse events caused by

errors are considered. The term “accident” has been widely used in the fields of radiation protection and nuclear energy, but it is neither used nor recommended for use in health care.

- Events that do not reach the patient are “near-misses” and any event that does reach the patient should be considered either a “minor event” (or “a no harm event”) or an “adverse error-event”. From the point of view of treatment safety, there is an important difference between an event that reaches the patient and one in which the error was detected before treatment delivery.

- Common classification systems, based on existing general healthcare classification systems, should be used to the extent possible. Specificity can be achieved by introducing details and codes specific to the field of radiotherapy to enable easy filtering and extraction of relevant data.
- Classification systems should be flexible and evolve as new evidence emerges to show that new events are not classifiable under existing systems. A mechanism to receive comments and questions from the users about the proposed classification should be implemented.

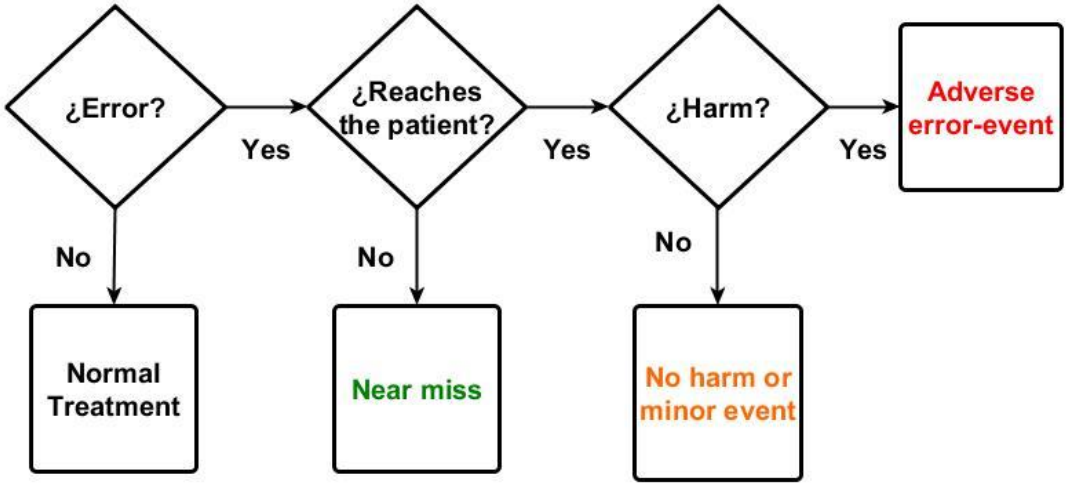

Figure 5.1. Scheme for the recommended basic definitions

Table 5.9. Definition of terms for patient safety in radiotherapy

Term	Equivalent term in EU BSS	Definition and references	Notes
Adverse error-event	Event involving accidental or unintended medical exposures	An event that results in unintended harm—either minor or serious—to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient. All treatment-related side effects are excluded[5].	To be used instead of the term "accident".
Event		Something that happens to or involves a patient (WHO, 2009). A circumstance that could have resulted, or did result, in unnecessary harm to a patient.	General term that may include near misses, no harm or minor events and adverse error-events.
Near miss event (Near miss)	Event potentially involving accidental or unintended medical exposures	An event which could have resulted in unintended harm to the patient but which did not reach the patient (i.e., without consequences for the patient).	
Minor or no harm event	Event involving accidental or unintended medical exposures	An event that reaches the patient but cause no harm to the patient.	
Significant event (Notifiable event)	Significant event	An event that should be notified to authorities according to national criteria as defined by regulation.	
Error		A failure to carry out a planned action as intended or application of an incorrect plan. Errors may manifest by doing the wrong thing (commission) or by failing to do the right thing (omission), at either the planning or execution phase (WHO, 2009)	This includes operating errors and equipment failures.

5.3.2 General features

- The term "event reporting system" should be replaced by the term "event reporting and learning system", to stress the importance of learning from the events.
- Local and external reporting and learning systems are complementary and therefore, the local systems should be designed with the capacity to send data to external databases.
- The reporting process should be easy, with user-friendly report forms to maximise feedback from reports.
    - The forms should contain check boxes, lists of option, and a limited number of fields for narrative descriptions (free-text is harder to analyze).
    - It should be possible to attach files in order to provide a more complete description.
    - It should be possible as well to enter the data in several sessions, rather than having to start over from the beginning if any data are missing or if there is a shortage of time.

[5] WHO defines a side effect as a known effect, other than that primarily intended.

5.3.3 Dissemination of information

- Reporting and learning systems should provide systematic and timely dissemination of information.
- Easy access to anonymous data should be provided to help to disseminate the lessons learnt to other professionals. Specific reports should be provided to respond to the public's right to know about events in radiotherapy. Public access should be planned with the support of relevant national bodies to avoid generating or fuelling unnecessary concerns amongst the general public.
- Data from reporting and learning systems must be interpreted carefully due to underreporting and selection bias (see section 4.5).

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