

Technical supplement to Radiation Protection n° 181

**General guidelines on risk management in external beam
radiotherapy**

FOREWORD

This document provides complementary information for the application of the “General guidelines on risk assessment and analysis of adverse error-events and near misses (accidental and unintended exposures)”. It is part of the outcome of an 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 a risk analysis of accidental and unintended exposures in external beam radiotherapy.

The document provides more detailed, technical and background information on the topics presented in the Guidelines, i.e. the regulatory and normative basis, the various methods of proactive risk assessment and reactive analysis of events, event classification, reporting and learning systems, and on other preventive measures or risk reduction interventions. Further, the status of the implementation of risk management and the reporting and learning systems in Europe is summarized, based on the results of the two questionnaires of the ACCIRAD project.

The information in this document has been derived from literature surveys, from the results of the questionnaires to European countries, from the previous work of the partners and from various discussions in the context of the project.

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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 ¹ .
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.

¹ WHO defines a side effect as a known effect, other than that primarily intended.

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	Qualiti Assurance
QC	Quality Control
QM	Quality Management
RCA	Root Cause Analysis
RCR	Royal College of Radiologists
RM	Risk Management
ROSI	Radiation Oncology Safety Information System
RPN	Risk Priority Number
RTOG	Radiation Therapy Oncology Group
SAFRON	Safety in Radiation Oncology
SEVRRRA	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 Effects of Atomic Radiations
UNEP	United Nations Environmental Program
WHO	World Health Organization

1. Introduction

In the ACCIRAD project, a lot of information was collected and prepared as a background material for the preparation of the General guidelines on risk assessment and analysis of adverse error-events and near misses. The information was derived from literature surveys, from the results of the questionnaires to European countries, from the previous work of the partners and from propositions made by the consortium in the context of the project. This information has been considered to be useful complementary information for the application of the General guidelines and is published in this document.

2. Purpose and Scope

This Technical Supplement aims to supplement the concise information presented in the General guidelines on risk assessment and analysis of adverse error-events and near misses, to

provide wider background information and to facilitate the implementation of the guidelines. More detailed information is presented on

- the regulatory and normative basis
- the methods of proactive risk assessment and reactive analysis of events
- classification and reporting of adverse error-events and near misses, including terminology
- other preventive measures or risk reduction interventions.

Further, the status of the implementation of risk management and the reporting and learning systems in Europe is summarized, based on the results of the two questionnaires of the ACCIRAD project.

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. In the following, a review of these standards is presented. A short summary is presented in the General guidelines. The status of the implementation of risk management in Europe, based on the results of the ACCIRAD questionnaire, is presented in Annex 4.

3.1 EU Basic Safety Standards (BSS)

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).

3.2 European Medical Device directive

The placing on the market of medical devices (MD) in Europe is based on a European regulatory framework, governed by so-called "new approach" Directives. They require manufacturers of medical devices to affix CE marking to their product before it is placed on the market. This CE marking symbolises the conformity of their devices with essential requirements described in Appendix I of Directive 93/42/EEC (EC, 1993). Some requirements, summarized in Annex 1, are specific to medical devices emitting ionising radiation, in particular medical devices used in external beam radiotherapy, such as linear accelerator, treatment planning system or recording and verifying system.

Technical documentation has to be produced by the manufacturer in the frame of the EC declaration of conformity, provided by this directive (Annex 1). Particularly, a documentation presenting the results of the risk assessment achieved by the manufactures and the list of standards in reference must be produced. Harmonised Standard EN ISO 14971 (ISO, EN ISO 14971) on the application of risk management to medical devices is a major reference used by manufacturers for the assessment of radiation-related risks.

In addition, the article 10 of Directive 93/42/EEC stipulates the exchange of information on post-marketing incidents and EN 14971 states that information acquired while using medical devices is to be considered in terms of the appearance of a new risk or the discovery of a new consequence.

3.3 Council Directive on the application of patients rights in cross-borderhealthcare

In Europe, the Council Directive on the application of patients rights in cross-borderhealthcare (2011/24/EU) (EC, 2011) calls for "increased cooperation and sharing of knowledge" in areas related to cross-border health. In this context, e.g. the development of "European reference networks" on guidelines set by the European Commission, will be advantageous for developing professional expertise in an international setting. In a similar vein, cooperation on health technology assessments within the framework of the Directive will support more communication between national authorities and contribute to avoiding the duplication of efforts.

3.4 Council recommendation on patient safety

The Council of the European Union has issued a Council recommendation (2009/C151/01) on patient safety (EC, 2009a), including the prevention and control of healthcare associated infections. The recommendations on the general patient safety issues include the following:

- 2 (b) disseminating information to patients on
 - (ii) risk, safety measures which are in place to reduce or prevent errors and harm, including best practices, and the right in informed consent to treatment, to facilitate patient choice and decision-making;
3. Support the establishment or strengthen blame-free reporting and learning systems on adverse events² that

² The term "adverse event" is used here instead of "adverse error-event" as this is a direct citation of the reference.

- (a) provide information on the extent, types and causes of errors, adverse events and near misses;
- (b) encourage healthcare workers to actively report through the establishment of a reporting environment which is open, fair and not punitive; this reporting should be differentiated from Member States' disciplinary systems and procedures for healthcare workers, and, where necessary, the legal issues surrounding the healthcare workers' liability should be clarified.

These Council recommendations provide a firm basis to establish a blame-free reporting and learning system also for adverse error-events and near misses in radiotherapy.

3.5 International Basic Safety Standards

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, 2011) to be 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.

In the following, the safety requirements in the international BSS are reviewed in more detail.

(i) Prime responsibility in protection and safety

The prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risks (IAEA, 2006). Other parties also bear certain responsibilities (manufactures and suppliers of radiation generators for instance). In the case of medical exposures, primary responsibility for protection and safety for patients lies with the health professional responsible for administration of the radiation dose, so called "the radiological medical practitioner", taking into account that other types of health professionals (medical physicist and medical radiation technologist) may be involved in the conduct of radiological procedures.

(ii) Management for protection and safety

Under the requirement dedicated to management for protection and safety, the international BSS develops the specific concept of "safety culture", encouraging the participation of workers in the development and implementation of rules and procedures, the accountability of the organization and open communication. The need to take into account "Human factors" is particularly underlined. In the case of medical exposures, it is stated that the radiological medical practitioner "shall take into account human factors and shall support good performance and good practices to prevent human and organizational failures", by ensuring that procedural requirements and "provisions are made:

- to reduce, as far as practicable, the possibility that human error or inadvertent action could give rise to accidents or other incidents leading to the exposure of any person;

- to provide means for detecting human errors and for correcting them or compensating for them;
- to facilitate protective actions and corrective actions in the event of failures of safety systems or failures of protective measures”.

(iii) Responsibility of registrant and licensees

Another requirement of the international BSS points out the responsibility of registrants and licensees in the development of procedures for reporting and learning from accidents and other incidents, and in arrangements for the periodic review of the overall effectiveness measures for protection and safety.

(iv) Safety assessment and prevention and mitigation of accidents

Safety assessment specifications are well developed in the BSS. Safety assessment focuses on the facilities, the sources and radiation generators, taking into account the protection of workers and population, but not specifically patient exposed for medical purposes. Patient protection has not been specifically addressed for the prevention and the mitigation of accidents, even if the concepts of “defence in depth” and “investigation and feedback” may be applied for medical exposures.

The general safety guide, concerning the safety of radiation generators (RS-G-1.10), deals with safety issues in relation with the use of accelerators but not with the treatment safety. However, for the use of radiations generators, the need for organising exchange of information on the condition of use and operating experience, between the supplier and the user but also between users, is stressed.

(v) Specific requirements on medical exposures

In addition of general requirements, specific requirements on medical exposures have to be considered. The most important of these requirements in the international BSS are the following:

Design considerations: registrants and licensees, in cooperation with suppliers, shall ensure that medical radiological equipment, and software that could influence the delivery of medical exposure, complies with applicable international standards.

Quality assurance: Registrants and licensees shall establish a comprehensive programme of quality assurance for medical exposures with the active participation of medical physicists, radiological medical practitioners and medical radiation technologists but risk analysis in relation with the treatment procedure is not considered.

Unintended and accidental exposures: Registrants and licensees shall promptly investigate any unintended or accidental medical exposures due to any medical treatment delivered to the wrong individual or to the wrong tissue of the patient, or a dose or dose fractionation differing substantially from the values prescribed by the radiological medical practitioner, or that could lead to unduly severe secondary effects.

Investigation: registrants and licensees shall, with regard to any unintended or accidental medical exposure, calculate or estimate the doses received and the dose distribution within the patient, indicate the corrective actions required to prevent the recurrence of such exposure, implement all the corrective actions and produce and keep a written record that states the cause of the event and submit it, as soon as possible, to the regulatory body.

Review: Registrants and licensees shall ensure that radiological reviews are performed periodically.

3.6 ISO 9001: 2000 standard for healthcare

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).

3.7 Conclusions

From the above review the following conclusions can be drawn:

For 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 General guidelines and the complementary information presented in this document.

International standards and European regulatory requirements stress the need to share information between manufacturer and users on risk analysis.

4. Status of risk management in radiotherapy in Europe

One of the objectives of the ACCIRAD 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; EC, 1997). For this objective, the implementation of risk management in Europe was reviewed by two questionnaires: (1) the overall status and the legal and practical arrangements in EU Member States regarding the implementation of Article 11 of MED, and (2) more detailed information on the systems and guidelines from those countries which had this information available.

The first questionnaire revealed that in most of the countries (62 %), *legislative requirements* for risk management were given but these were in most cases (53 %) part of a more general document (a law, decree etc concerning e.g. the health care in general); in only about 9 % of the countries these requirement were dedicated to radiotherapy (Fig. 4.1). In two countries (6 %), a legislation or regulation was in preparation. In most of the countries, *recommendations* on risk management had not been given, while in many of these countries legislative requirements existed.

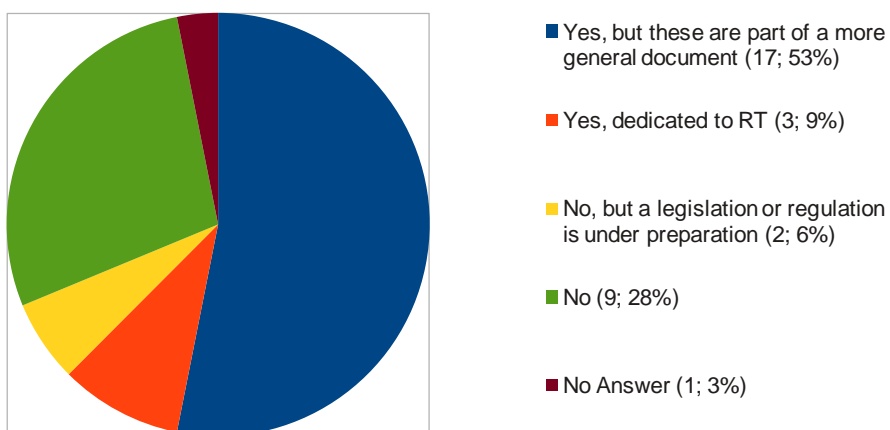


Fig. 4.1. Existence of *legislation or regulations* for risk management in Europe (percentage values from 38 countries who received the questionnaire).

Short summaries of the national regulatory frameworks and guidelines for *proactive risk assessment, reactive analysis of events* and *event reporting and learning systems*, as indicated by the second questionnaires are given in the respective sections (5.4., 6.5 and 7.5). Examples of local practices are presented in sections 5.5. and 6.6. More detailed summaries of all results of the questionnaires are given in Annex 4.

5. Proactive risk assessment

This section gives a comprehensive review of the available methods for proactive risk assessment, both generic methods and methods particularly developed and dedicated to radiotherapy. A bibliography for practical examples on their application is given in Annex 2. Further, the status of proactive risk assessment in Europe is briefly summarized, based on the results of the ACCIRAD detailed questionnaire; more detailed summary is presented in Annex 4.

5.1 Generic methods

To identify potential failures or hazards and their impact on the system (the first and second steps of the proactive risk assessment, see Fig. 4.4 of the General guidelines), 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**). To go deeper in the assessment and take into account combinations of failures and probabilistic assessment if needed, Fault Tree Analysis (**FTA**) and Event Tree Analysis (**ETA**) methods can be used. In this “defence in depth approach” failures of barriers (reactive or corrective measures) are taken into account. Another approach, not an actual method but a way to implement the risk assessment and/or to present outcomes, is **Process Analysis including critical points**.

5.1.1 Failure Mode and Effect Analysis (FMEA or FMECA)

Failure Mode and Effect Analysis, FMEA or FMECA (C= criticality), was developed in the United States in 1949 for a military application. It is an “inductive” method, that means a bottom up approach, where it is necessary to identify potential failures of “components” of system and then to evaluate the potential consequences. It is now used in industry, where it has become customary to speak of FME(C)A for equipment, process, product, etc.

The analysis 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.

This method allows the identification of *single failures (basic events)*, preventive, corrective and detective measures (barriers) and prioritization if the criticality evaluation is included. For its implementation, the method consists of methodical examination, in a working group, of potential failures of the system under study. A system can represent a physical system (equipment), an organisation, a process, a product, or a project.

For each component of the system under study, the following items must be identified (Table 5.1):

- possible failure modes, i.e. how the component will deviate from expected operation
- possible causes of each failure mode
- consequences of each failure mode on the system, most often expressed in terms of adverse error-event (e.g., overdose, radiation of a wrong area)
- existing preventive measures for limiting the appearance of the mode (e.g., backup of the electrical power of the accelerator)

- existing corrective measures for limiting consequences (e.g., have a backup accelerator),
- existing detective measures (e.g., alarm in case of the loss of electrical power).

For example, if the system represents “equipment”, a component could be the accelerator, and 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. When the system represents “a process”, a component could be patient identification and a failure mode an error in patient identification.

The results of the assessment are given in tables such as the example shown in Table 5.1. These tables are used to select the possible consequences (“undesirable outcomes”) that are to be controlled. The tables can then be used to identify qualitatively the “simple” malfunctions resulting in these outcomes, especially before the use of another method to combine failures (for example FTA or ETA).

Table 5.1. Example of a FMEA table.

Equipment	Failure mode	Possible causes	Preventive Measures	Corrective Measures	Consequences
Accelerator	Beam flatness change from baseline.	Deviation in the device setup. Incorrect adjustment of flatness control during maintenance.	Preventive maintenance of device. Systematic quality check of beams after any maintenance work.	Re-maintenance to adjust beam flatness correctly.	Incorrect dose planning and dose delivery to the patient or patients, depending on how long the failure remains undetected.

For prioritization a target, an additional step (the third and fourth steps from Fig. 4.4 of the General Guidelines) is taken to evaluate the criticality of each failure mode. The method is then known as FMECA. Criticality index (C) or risk (R) or (also called risk priority number, RPN) is defined as $C = L \times S$ or $C = L \times S \times D$ if detectability is included; here L is the likelihood of failure, D is the undetectability, i.e. the probability that the failure will not be detected, and S is the severity of the effect resulting from the failure if it is not detected and corrected. These steps require that a scale for likelihood (frequency or probability; Table 5.2), to rank the failure modes, and a scale for severity (Table 5.3), to rank the consequences, have been established. The scales and their application should be the result of consensus of the working group.

The assignment of a criticality level will take into account existing preventive, corrective and detective measures. This level will determine the “components and failure modes” to be treated according to their position in an acceptable area. The initial FMEA table is then completed to FMECA table as shown in Table 5.4.

Table 5.2. 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 5.3. 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

Table 5.4. FMECA table.

Equipment	Failure mode	Possible causes	Preventive Measures	Corrective Measures	Consequences	S	L	C
Accelerator	Beam flatness change from baseline.	Deviation in the device setup. Incorrect adjustment of flatness control during maintenance.	Preventive maintenance of device. Systematic quality check of beams after any maintenance work.	Re-maintenance to adjust beam flatness correctly.	Incorrect dose planning and dose delivery to the patient or patients, depending on how long the failure remains undetected.	5	1	5

The last step of FMECA is to use the FMECA table to evaluate for each line of the table if the situation is acceptable or not, i.e., the risk assessment is carried out resulting in the criticality table (also known as Risk Matrix) as shown in Table 5.5. The meaning of the colours is as follows:

- The red zone: unacceptable situation, risk reduction actions have to be implemented,
- The yellow zone: acceptable on control, no risk reduction action yet but there is a need to control this situation (for example, to check what is the real efficiency of

preventive or corrective measures which were considered when evaluating the probability),

- The green zone: acceptable situation.

Table 5.5. Criticality table.

	SEVERITY SCALE				
LIKELIHOOD	S1	S2	S3	S4	S5
P5	C2	C2	C3	C3	C3
P4	C1	C2	C2	C3	C3
P3	C1	C1	C2	C2	C3
P2	C1	C1	C1	C2	C3
P1	C1	C1	C1	C1	C2

A new evaluation of criticality value is performed taking into account the risk reduction actions decided. Those new values are named residual criticality.

5.1.2 Preliminary Hazard and Risk Analysis (PRA)

The Preliminary Hazard and Risk Analysis (PRA or PHA) was developed in US in 1949 for military application. It is an inductive approach which is now widespread in industrial field. In practice the analysis is managed by a team leader (risk manager or other) who will drive a working group. The working group has to cover all necessary skills, and the members have been trained to this method. The approach leads the working group to determine the impact of potential hazards on the system.

PRA allows to identify the scenario which describes how the system (with a process point of view) face with *each hazard* and what are the existing measures to limit the likelihood (probability) of the scenario and/or the criticality of the consequences. Propagation of a hazard through the process can also be taken into account but it is quite heavy and complex to implement. The results are presented in a PRA scenario table (Table 5.6) analogous to the FMEA table.

The implementation of the method requires different steps to perform (Fig. 5.1). The first step is to identify (with peers' experience and feedback data) all potential hazards which can affect the system.

The roots of hazards considered could be for example:

- Human (**H**): foreign patient (communication difficulties),
- Equipment, Material (**M**): wrong set up of accelerator,
- Organisationnal (**OR**): lack of training,
- Environmental (**E**): laboratory results missing.

Some check lists of potential hazards exist and can be used to perform this step. In fact they need to be adapted, completed to take into account the specificity of the field.



Fig. 5.1. The different steps of PRA

The cartography of dangerous situations leads to identify, in a table (Table 5.6), which function or process step is affected by each hazard and at which level it is affected: no consequences (0), low consequences (1) or high consequences (2) on the function or process step. At this phase of the assessment the consequences of the dangerous situations on the patient are not considered.

Table 5.6. Dangerous situation cartography table.

Hazard		Dangerous situation		
General hazard	Specific hazard	Patient reception	Contouring	Dose evaluation
H	Foreign patient	2	0	0
	Input error	2	2	2
M	Accelerator deviation	0	0	0
E	Laboratory results missing	0	0	2
OR	Lack of training	1	2	2

Next, PRA scenario is developed in tables (Table 5.7). It consists of evaluating the consequences of each hazard on each situation affected (level 2 in the dangerous situation table).

Table 5.7. PRA scenario table

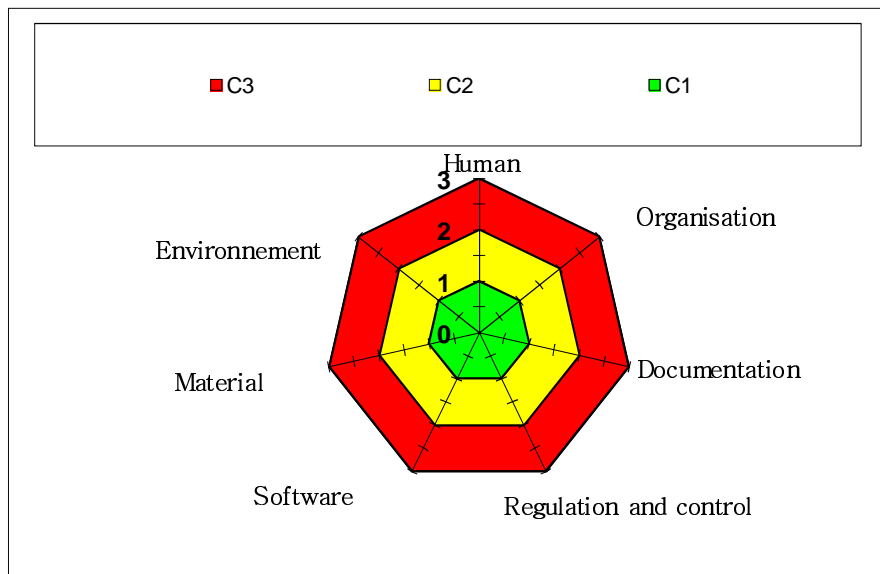
General Hazard	Specific Hazard	Dangerous situation	Contact cause	Initiate cause	Undesirable event	Existing measures	S	L	C
OR	Lack of training	Dosimetrist without training on new program	Work-station failure	Wrong input to the dose evaluation program	Wrong dose evaluation	Double check			

Two types of causes need to be identified:

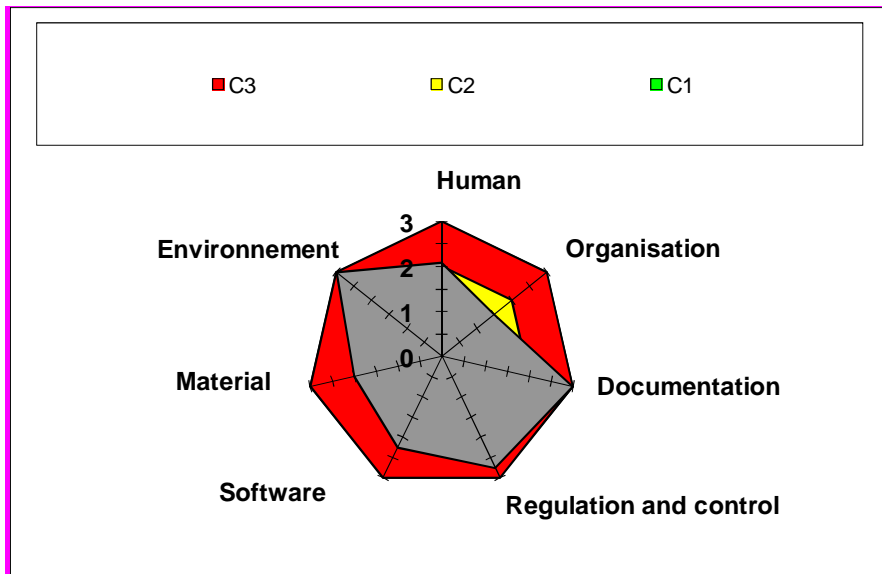
- *The contact cause* represents how the hazard will come in contact with the system, what creates the dangerous situation (“contact cause” is a specific term used in PRA but is similar to “latent cause” defined previously). In the example it will be the moment when the dosimetrist will need to use the new program without any training before.
- *The initiate cause* represents the event which leads to the undesirable event (“initiate cause” is a specific term used in PRA but is similar to “direct cause” defined previously). In the example it is the wrong data input in the program.

For prioritization, severity (S) and likelihood (L) scales are used in the same way as in a FMECA. Also a criticality (C) matrix similar to Table 5.5 is defined and used to determine acceptable and unacceptable areas.

A new evaluation of criticality value is performed taking into account the risk reduction actions decided. Those new values are named residual criticality. The results are then synthesized and represented as a cartography. The following example (Fig. 5.2) illustrates a cartography where the mean criticality value for each type of danger is indicated. The same thing can be represented considering the different step of the process activity studied. The mean value is evaluated taking into account the number of scenario involved.



(a)



(b)

Fig. 5.2. Risk cartography: (a) initial criticality, (b) residual criticality after risk reduction measures.

5.1.3 Fault Tree Analysis (FTA)

Fault Tree Analysis (FTA) was created in the early 1960s for military applications. It is now widely used in many fields as part of an a priori analysis to determine the sequence and combinations of events that may lead to an undesirable outcome that serves as a reference.

FTA is a deductive method, i.e., a top down approach. It leads to describe all events (failures) using logical combinations (conjunction or disjunction) that can lead to the undesirable outcome (potential undesirable event). Use of the tree for qualitative assessment concerns examining to what extent a fault or a basic event can propagate in the sequence leading up to the ultimate event.

Implementation of the method requires learning the symbols used in the tree, in addition to:

- knowing the undesirable outcomes for which to identify combination faults,
- having a solid knowledge of the simple failure in the system (e.g., through a PRA or a FMEA) to consider the combinations.

The method is carried out in three or four steps (Fig. 5.3), depending on whether there will be a quantitative analysis of the tree.

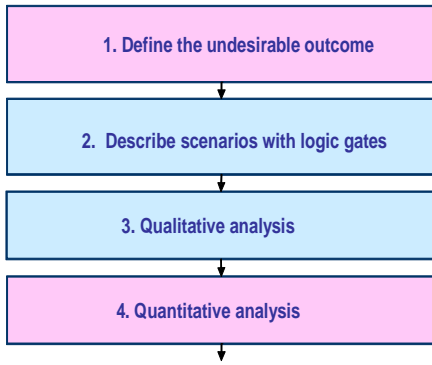


Fig. 5.3. Steps in fault tree analysis

The initial step consists of defining the top event, or undesirable outcome, for which the scenarios that produce it are sought. Analysis includes a fault tree for each undesirable outcome (e.g., radiation treatment of the wrong area).

The second step consists of describing all events using logical combinations (conjunction or disjunction) that can lead to the undesirable outcome (Fig. 5.4). Intermediate events, which are less global than the top event, will appear, and a logical connector that relates them to the top event (e.g., for the radiation treatment of a healthy organ, wrong patient file or incorrect patient positioning). The next steps consist of describing all of the lines to explain the top lines (by events and logical connectors) until all known causes are included. The second step is repeated to include all basic events, i.e., events that cannot be broken down further.

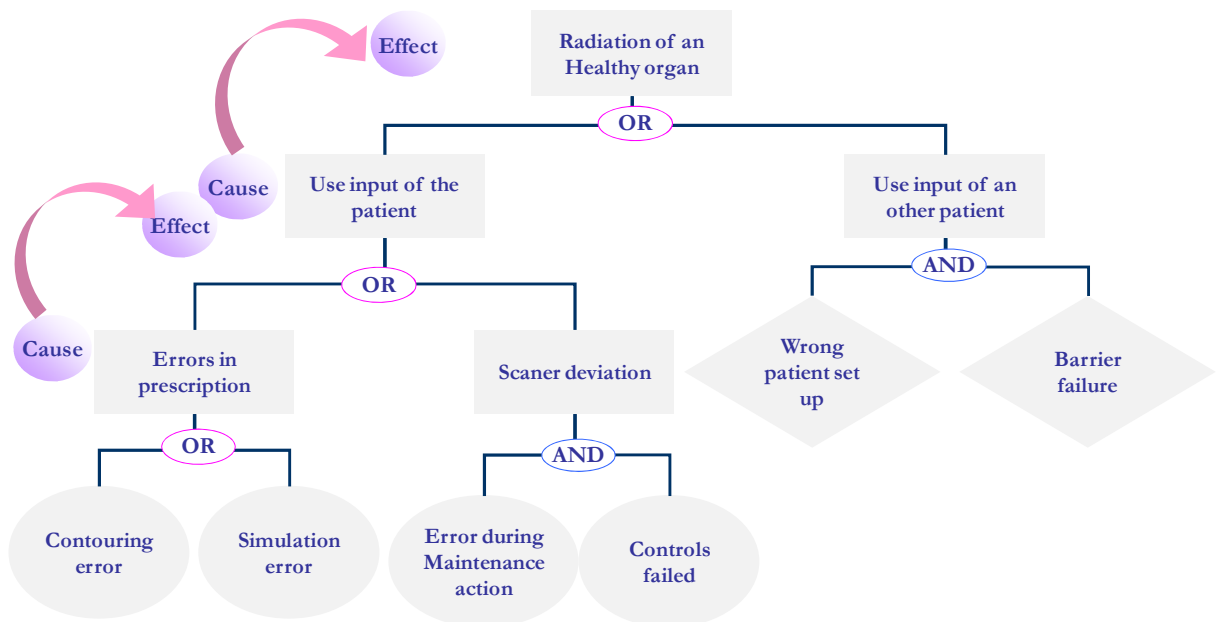


Fig. 5.4. Example of Fault Tree description.

Use of the tree for qualitative analysis concerns examining to what extent a fault or a basic event can propagate in the sequence leading up to the ultimate event. In this regard, an equal probability is assumed for all basic events. Intuitively, a fault propagating through a system encountering only OR gates is likely to result in the ultimate event very quickly. Inversely, a path that leads exclusively through AND gates indicates that occurrence of the ultimate event

beginning from the event or the combination of basic events is less likely and thus demonstrates better prevention of the ultimate event. A “minimum cut set” designates the shortest path, i.e., the most critical scenario.

This qualitative approach is nevertheless based on the relatively strong assumption that the basic events have an equal probability. It may also be supplemented by a quantitative approach which requires attributing occurrence probabilities to the basic events in order to evaluate the probability of the ultimate event as well as that of the intermediary events. As basic events in FTA have to be regarded as independent, it is difficult to take into account actions defined as common modes that lead to different failures at the same time; for example, misidentification can be a common cause for different failures such as wrong dose, wrong treated area and wrong fractionation. In practice, it is often difficult to obtain accurate probability values for basic events but theoretically they may be estimated using databases of reporting and learning systems and expert opinions.

This assessment should be considered as a means for prioritising the various possible causes in order to be able to concentrate prevention efforts on the most likely causes.

5.1.4 Event Tree Analysis (ETA)

Event Tree Analysis (ETA) provides an inductive method for identifying the propagation of an initiator (failure, incident, etc.) and its possible consequences on the system (potential undesirable event). It is used particularly in the nuclear field to evaluate accident sequences. It is also known as the barrier analysis method. Due to the specific objective of ETA, it requires identification in advance of the triggering events whose propagation will be studied. Building the event tree requires knowledge of all barriers that exist throughout the process to stop the propagation of an initiator. A specific training in the formal preparation of the tree is necessary, especially for quantification.

The initiator is the event from which the tree will develop through a propagation process with the system “barriers” that can stop it. A tree is created for each initiator (Fig. 5.5). To limit the analysis, it is first necessary to limit the initiators to those that may lead to unacceptable consequences (an undesirable outcome such as overdose, error in treatment area, etc.). This preliminary identification may be the product of a failure mode and effect analysis (FMEA) or operating experience feedback and expert statements.

For each step in the process, existing barriers must be identified. These barriers may be:

- equipment (software warning),
- human (double control and validation),
- organisational (recovery procedure, etc.), etc.

Barriers may be specific or shared by several initiators. The tree is then built by following sequentially the propagation of the initiator and by creating two branches for each “barrier” encountered:

- barrier does function, and the consequences on the system are evaluated,
- barrier does not function and propagation continues to the next barrier, if it exists.

INITIATOR	Soft interlock	Hard interlock	Hard interlock 2	Dosimetric tests QA			Patient medical follow-up	# Sec	Likelihood	Severity
				DAILY	MONTHLY	ANNUAL				
								1		1
								2		2
								3		3
								4		4
								5		5
								6		5
								7		5
								8		

Fig. 5.5. Example of Event Tree

Each branch in an event tree represents a separate sequence that might or might not lead to the undesirable outcome (in red in Fig. 5.5). This sequence thus represents a multiple failure scenario that includes barrier failures.

Qualitative use of the event tree will determine the shortest sequences (lowest number of failures) that may lead to undesirable outcomes. As with fault trees, this is the “minimum cut set”. The sequences defined in an event tree are joined with the word AND for logical event combinations. As a result, these event sequences may be assembled to create a fault tree for additional qualitative analysis for the same undesirable event and various initiators.

This qualitative approach is nevertheless based on the assumption that the envisaged faults have an equal probability. Like for FTA, it can then be supplemented by a quantitative approach that requires attributing occurrence probabilities to each branch of the tree. As branches of the tree in ETA have to be regarded as independent, it is difficult to take into account actions, defined as common modes that lead to different failures at the same time.

In practice, it is often difficult to obtain accurate probability values. They may be estimated using databases and expert opinions, which may involve the entire sequence.

5.1.5. Process Analysis including critical points

Process Analysis including critical points consists of identifying the level of safety for each step of the process by verifying its “robustness” in situations of risk by demonstrating that each step is monitored and inspected. This approach is one of the methods recommended by the Haute Autorité de Santé (HAS) in France. It requires a detailed description of the various steps of the process under study.

The method consists of scanning the description in processes of the activity under various aspects. Graphic representation, e.g., mapping tools, is used to facilitate this work. The description shall specify for each step in the process:

- input data,
- necessary internal resources (human and equipment), e.g., radiation oncologist, CT-scanner, dosimetry software, etc.
- support resources (external), e.g. laboratory analysis results, etc.
- output data.

For each step of the process, the risk situations and malfunctions associated with the process are then identified. These situations will be the results of preliminary studies (such as a FMEA or PRA) or determined using expert statements (e.g., feedback from operating experience).

Next, for each risk situation, it is necessary to determine possible causes, to identify existing safety barriers and to evaluate consequences. All the results can then be presented in tables that closely looks like those used in FMEA. An initial assessment will identify the safety level of each step in the process using the degree of coverage of all risk situations identified by the existing barriers without considering the severity of consequences. Then a Table (Table 5.8) synthesizes the results for situations with high level of severity.

Table 5.8. Outcomes table

Phase 1				Phase 2	Phase 3	Phase 4
Description of steps process				Risk situations, malfunctions	Causes	Barriers
N°	What	Who	With what			
1						
2						

The critical points are represented by those uncovered situations leading to high severity level of consequences.

The use of these results to determine which improvement actions are to be taken requires performing an analysis such as an FMEA in advance.

5.2 Methods dedicated to external radiotherapy

Two methods of risk assessment are available which have been specifically developed and dedicated for radiotherapy application: a **Specific FMEA** developed in France (ASN, 2008b) , and a **Risk Matrix** approach developed by the Ibero-American Forum of Radiological and Nuclear Regulatory Agencies (FORO) (IAEA-FORO, 2013a; 2013b). The basic characteristics and information on the outcomes of these methods are presented in the following.

5.2.1. Specific FMEA (ASN, France)

Following the first events reported in 2005, the ASN drew up a guide to the assessment of risks in radiotherapy: identification of failure modes, quantification of the consequences, proposition of preventive measures, and evaluation of risk reduction measures.

The method requires the application of FMEA on three mainlines: patient pathway, equipment, human and organization, thus approaching a single failure mode from various viewpoints and enabling a systemic approach. It provides severity and probability scales to evaluate criticality. The consequences of failures are evaluated by a conservative approach: their propagations are considered through all the activities of the radiotherapy process. For example, an error in patient identification will lead to harmful consequences (highest severity level) without considering that it could be detected before treatment.

A guide to apply this methodology was drawn and published (ASN, 2008) with the support of the SFRO (French Society of Radiation Oncology) and the SFPM (French Society of Medical Physics). The guide is specifically intended to every radiotherapy department in France as a methodological support to carry out their own risk assessment. Its purpose is educational but not mandatory. Radiotherapy centres are free to choose another means of assessing these risks. It offers fulfilled tables of failure modes to be adapted (see below).

5.2.1.1 Method development

A multidisciplinary working group, including experts from the Nuclear Safety Authority, was established to investigate the risks deriving from abnormalities in the treatment planning and delivery phases. The work was based on the FMECA method. This method was selected because of its many advantages: it is easy to understand and implement, and preventive measures can be prioritized.

The severity assessment of the failure modes was inspired from the "Common Terminology Criteria for Adverse Events (CTCAE)" issued by the National Cancer Institute (USA) and the "Toxicity Criteria" issued by the Radiation Therapy Oncology Group. However, it differs from these criteria in the following respects:

- unlike the CTCAE and the "Toxicity Criteria", which are defined for each specific location, the severity assessment table is generic for all organs;
- the severity assessment table (Table 5.9) uses 4 levels of severity (unlike the CTCAE, which uses 5), in order to prevent "median" effects.

The system shown in Table 5.10 was used to score the probability of events.

The method developed leads the application of failure mode analysis on three mainlines:

- patient pathway;
- equipment, i.e. technical devices used throughout treatment;
- human and organizational factors, i.e., the set of components of a working situation which affects the human performance, and furthermore the system performance.

Table 5.9. Specific severity scale

Determining the severity of an event		
Level	Criterion	Score
Not very critical	Temporary discomfort, malaise, unpleasantness	1
Critical	Prolonged discomfort Reversible damage or impairment Medical treatment required Temporary handicap	2
Very critical	Delayed consequences, but marked for the patient Irreversible damage or impairment Permanent handicap Not life threatening	3
Serious	Short-term fatal outcome for the patient Life threatening	4

Table 5.10. Specific probability scale

Determining the probability of an event		
Level	Criterion	Score
Very rare	Once every 5 years	1
Rare	Once a year	2
Frequent	Once a month	3
Very frequent	Once a session	4

Because of the structure adopted, a single failure mode can be approached from various points of view. When the final risk assessment tables are drawn up, any failure modes appearing for a second time under a different theme are removed: hence, if an event appears both in the "patient pathway" table and another table, it is erased from the second table. The "equipment" and "human and organizational factors" tables contain mainly cross-discipline failure modes.

5.2.1.2 Outcomes

82 generic failure modes were identified (32 related to the patient itinerary, 26 to the equipment, and 24 to the human and organizational factors). Extracts of the FMECA tables are provided below in Tables 5.11 to 5.13.

32 failure modes were identified related to the patient itinerary. An example on morphological data acquisition is shown in Table 5.11. The higher criticality after correctives measures were found in: incorrect identification, simulation, imaging and volume determination, and failure in patient positioning.

26 failure modes were identified related to the equipment. An example on dose planning is shown in Table 5.12. The higher criticality after correctives measures were found in: ergonomics of man-machine interface, lack of training of users leading to misunderstandings, errors related to data transfer between devices, and computer bugs.

24 failure modes were identified related to the human and organizational factors. An example on Identification of discrepancies/feedback is shown in Table 5.13. The higher criticality after correctives measures were found in: failure to change management (treatment, equipment, organization), failure to protocolized treatment by type of organs within service, failure to inform operators, unavailability of medical physicists and lack of technologists.

The success of this self-assessment relies in particular on the participation of the entire radiotherapy team. Therefore, radiotherapy centres were required to set up a multidisciplinary group in order to identify all the failures likely to be generated by each phase of the clinical process (from treatment to post- treatment follow-up), and to propose measures to improve the safety of patients during treatment.

Table 5.11. Patient pathway (PP). S: Severity; P: Probability, C: Criticality, iC initial, fC final after corrective actions.

Patient pathway	Failure mode	Potential effects	Causes	S	P	iC	Possible corrective actions	S	P	fC	Optimisation
3 morphological data acquisition	PP-8 error in the acquisition of "patient" parameters (for each imaging system [CT scanner, MRI, PET scanner])	Patient integrity is significantly jeopardized (treatment error)	Coding direction, magnification of images differ (emitter vs. Receptor), particularly if external images	4	3	12	Check the standards for coding and transmission between the emitter and receptor	4	2	8	Check the direction accuracy of the laser movement
							Conduct the quality controls				
			Error in laser movement direction (reverse direction)				New imaging system/new software : -check that slice orientation has not changed -check laser and scanner zero concordance				Conduct validation imaging of the position of the selected isocentre
			Inconsistency between the laser system indication and the actual position of the slice plane				Train staff on new equipment or software				

Table 5.12. Equipment (E). S: Severity; P: Probability, C: Criticality, iC initial, fC final after corrective actions.

Equipment	Failure mode	Potential effects	Causes	S	P	iC	Possible corrective actions	S	P	fC	Optimisation
9 Dose planification TPS (Treatment Planning System)	E-1 Incorrect data input Incorrect interpretation of some parameters Confusion between two data input parameters	Inappropriate treatment The patient is endangered	Inadequate training of staff The data input interfaces used in dose planning are not user-friendly Text in a foreign language unfamiliar to the operator Units not indicated for some parameters Operator fatigue	4	3	12	Draw up a procedure to indicate the units used for each measurable parameter (dosimetric or non-dosimetric) Use the French version of the software, if available Keep a translated glossary of the parameters within the reach of users	4	2	8	Make data input and treatment delivery interfaces more user-friendly; Indicate the units used for each measurable parameter (dosimetric or non-dosimetric) Clarify the designation of certain parameters Install a French version of the software
	E-2 Computer bugs (occurrence of adverse effects due to the software)	The patient is endangered Uncontrollable effect on the distribution of the delivered dose	Software/hardware No record of possible errors (rarely catalogued)	4	2	8	Keep an up-to-date record of the bugs encountered Keep this record within the reach of operators Introduce a system for alerting an expert if a new bug is encountered Suspend treatment until the situation is resolved	4	1	4	Set up a procedure for dealing with new bugs
	E-3 No procedure to verify the dose delivered per measurement in complex treatment plans	The patient is endangered Over- or underdose of the tumour and/or the adjacent critical organs Short-term, medium-term or long-term side effects of the treatment	Failure to take into consideration: Regions where electronic equilibrium is not established Dose under shields Penumbra regions Tangential beams Heterogeneity Techniques using intensity modulation (IMRT) Techniques based on dynamic arc therapy, using stereotactic positioning	4	3	12	Introduce a procedure for verifying the dose delivered per measurement	4	2	8	Periodically review the procedure

Table 5.13. Human and organizational factors (HOF). S: Severity; P: Probability, C: Criticality, iC initial, fC final after corrective actions.

General organisation	Failure mode	Possible effects	Causes	S	P	iC	Possible corrective actions	S	P	fC	Optimisation
18 Identification of discrepancies / Feedback	HOF-15 Inadequate preparation of changes (to the treatment, equipment or organisational set-up)	Occurrence of unexpected events due to the incorrect implementation of the treatment process Failure to take a change (and all its consequences) into account	No risk assessment No change implementation and management procedure Failure to comply with IAEA requirements No procedure for tracking the changes implemented	4	3	12	Conduct a risk assessment before making a change Set up a change management procedure Make sure that changes are being applied by staff Conduct implementation tests Organise change traceability procedures, and the information and training of staff	4	2	8	Conduct risk assessments for each piece of equipment, in collaboration with the manufacturers Allocate staff time to coordinating quality in the radiotherapy department Verify compliance with IAEA requirements
	HOF-16 Failure to inform users when equipment is changed (software upgrades, etc.)	Failure to take the change into account Treatment planning or delivery errors	Isolated decision Poor communication within the department	4	3	12	Set up a system for informing all users when equipment or software is changed Make sure that changes are traceable	4	2	8	Allocate staff time to coordinating quality in the radiotherapy department
	HOF-17 Failure to inform concerned parties when a treatment variable is changed	Failure to take the change into account Treatment planning or delivery errors	Isolated decision Poor communication within the department	4	3	12	Set up a system for informing all concerned parties when a treatment parameter is changed Make sure that changes are traceable	4	2	8	Allocate staff time to coordinating quality in the radiotherapy department

5.2.2 Risk Matrix Methodology (Spain – FORO³)

A **Risk Matrix** approach has been developed by the Ibero-American Forum of Radiological and Nuclear Regulatory Agencies (FORO) (IAEA-FORO, 2013a; 2013b; Vilaragut et al., 2013) and promoted in Spain. It is a semi-quantitative method of evaluating the likelihood and the severity of events by means of a scale, and it defines risk acceptability criteria on the basis of the combination of likelihood and severity.

Based on the observation that simple failure does not lead to harmful health effect, the specific development aimed at considering how the barrier's reliability could be taken into account. The method thus offers a way to take into account the number of barriers in the different steps of the process to stop the propagation of the initiating event, and to evaluate their reliability level when the second screening is needed. It makes possible to define a strategy of adding more barriers or making barriers more reliable to bring any unacceptable scenario into the area of acceptability.

³ Foro Iberoamericano de Organismos Reguladores en seguridad nuclear, radiológica y física

The methodology consists of a progressive approach with the following steps:

- (1) identifying, by means of a proven methodology (e.g., FMEA or PRA), the hazards and the barriers provided to avoid an accidental exposure to the patient;
- (2) applying an initial, simple conservative screening to sort events according to their risk by means of a previously constructed risk matrix;
- (3) finally applying the second screening to those initiating events that resulted in high risk after the first screening and by focusing efforts on a deeper, more realistic safety assessment of those cases.

This process needs to be preceded by the development of the risk-matrix, which links the probabilities of the events and severity of the possible outcomes with a risk measure that will allow practitioners to perform the screening of important events. Both the risk matrix itself and a comprehensive list of hazards and barriers are readily available for use, including a software tool (SEVRRRA; Beltrán et al., 2012), thus simplifying the adoption of this method.

5.2.2.1 Concepts and definitions

In common language, risk is the probability of harm. In a more precise and quantitative way, risk may be defined as:

$$R = f \times P \times C$$

where

- *f* is the frequency (or annual frequency of occurrence) of the hazard (initiating event) that challenges the process. Table 5.14 shows the frequency criteria and ranges adopted.
- *P* is the probability of failure of the barriers provided, discussed in detail below.
- *C* is the severity of the potential harm (consequences). Table 5.15 shows the scale for the consequences used in this study adapted from the definitions in ICRP-86 (ICRP 2002).

The accident process starts with an “initiating event:” an equipment failure or a human error that triggers a sequence of events that might lead to an undesired consequence should the safety measures, foreseen to detect the error and stop the sequence, fail to work. Consequences represent the patient outcome derived from the initiating event. The scale of consequences should take account of the severity and the number of patients affected. It ranges from the death of the irradiated patient to a simple loss of defence in depth with no health effect.

Safety measures or barriers can be defined as the measures in place to avoid, prevent, detect, and stop an accidental exposure or to mitigate its consequences. Safety measures may be of a technological (such as interlocks) or organizational nature (such as procedures or double checks to avoid or detect an error.) All of them are part of the defence in depth principle. Barriers that do not stop the incident from progressing but that can reduce the probability of the initiating event or the severity of the consequences are called “frequency reducers” and “consequence reducers”, respectively.

Thus an “accidental sequence” is a chain of events starting with the initiating events and possibly ending up in an undesired consequence, including adverse error-event. It includes the initiating event, the success or failure of the safety measures, and the potential appearance of the consequences in the form of an adverse error-event.

One example of an initiating event might be a mistake made in the calibration of a radiation beam, which could lead to a wrong value of the absorbed dose rate at the reference point. For this initiating event, an example of a frequency reducer is the physicist’s qualification and training to perform this task; an example of a direct barrier would be an independent absorbed dose determination; an example of a consequence reducer would be the daily patient observation by the technologist and the weekly patient follow-up made by the radiation oncologist that could identify harm at an early stage. Finally the potential consequences would be an over- or underdosage to patients treated with the miscalibrated beam.

Table 5.14. Frequency levels for initiating events

Annual frequency (for 500 patients/year)	Frequency level	Acronym	Qualitative
More than 50 y ⁻¹	High	<i>F_H</i>	The event occurs frequently
Between 1 and 50 y ⁻¹	Medium	<i>F_M</i>	The event occurs occasionally
Between 1 y ⁻¹ and 1 every 100 y	Low	<i>F_L</i>	It is unusual or rare, although it is assumed that it has occurred
Less than 1 every 100 y	Very low	<i>F_{VL}</i>	It is very unusual, and it is not known to have occurred but there is a remote possibility

Table 5.15. Severity levels for the consequences

Severity level	Acronym	Description
Very high, catastrophic	C_{VH}	Causing multiple deaths or limiting damage to multiple patients (roughly more than 25% under- or overdosage can cause this effect).
High	C_H	Causing single death or limiting damage to several patients. Also dose deviation of 10 and 25 % to multiple patients that does not threat their lives are included in this level.
Medium or moderate	C_M	No risk to patient's life, only recoverable deviation affecting one or a few sessions.
Low	C_L	Reduction of defense in depth with no dose deviation.

5.2.2.2 Risk matrix development

The risk matrix could be constructed as a table that links the combination of several categories of frequency (f) and probability (P), corresponding to the likelihood of a given scenario, and the severity of its consequences (C) to a level of risk. The application of the risk matrix requires the evaluation of every sequence triggered by each initiating event. However, a first step, prior to identifying the initiating events and categorizing them, is to construct the matrix itself.

Four levels could be used for each of the independent variables, f, P, and C, as well as for the dependent variable, the risk, R. The levels are assigned, with a given set of rules and numerical criteria, by a multidisciplinary group of experts: radiation oncologists, medical physicists, dosimetrists, radiotherapy technologists, maintenance engineers and experts in risk tools. Participation of various specialists along with written quantitative criteria provides for an additional degree of objectivity.

5.2.2.3 Failure probability of the set of barriers.

The failure probability of the set of barriers is given by the product of the failure probability of each individual barrier ($P=p_1*p_2*p_3$), provided that these probabilities are independent from each other. An important simplification can be made for the initial conservative screening: the reliability and effectiveness of the barriers are ignored, and an equal probability is assumed for each barrier, namely p. The different probability levels for the total failure of a set of barriers are shown in Table 5.16.

Table 5.16. Probability levels for total failure of a set of barriers

Probability level	Acronym	Number of barriers
High	P_H	No barrier at all
Medium	P_M	One or two barriers
Low	P_L	Three barriers
Very low	P_{VL}	Four or more barriers

5.2.2.4 Risk level.

Once the available levels have been assigned to the variables f, P, and C, the corresponding level of risk (Table 5.17) can be obtained by combining the values of the variables (Table 5.18). Four levels of risk are considered in this methodology.

To develop the relationship between the levels of the variables and the levels of the risk, the following procedure is used: The first step implies the combination of the first two variables (f and P), and then the result is combined with the third variable, C, to provide the risk level, R. Figure 5.6 graphically shows clearly the relationship of the different levels of Risk with the 3 variables in the form of a multi-dimensional matrix.

Table 5.17. The four risk levels

Risk level	Acronym
Very high	R_{VH}
High	R_H
Medium	R_M
Low	R_L

Table 5.18. Risk matrix linking f, P and C with risk.

PH	CVH	CH	CM	CL
FH	RVH	RVH	RH	RM
FM	RVH	RH	RH	RM
FL	RH	RH	RM	RM
FVL	RH	RH	RM	RM

PH	CL	CM	CH	CVH
FH	RM	RH	RVH	RVH
FM	RM	RH	RH	RVH
FL	RM	RM	RH	RH
FVL	RM	RM	RH	RH

PM	CVH	CH	CM	CL
FH	RVH	RH	RH	RM
FM	RH	RH	RM	RM
FL	RH	RH	RM	RL
FVL	RH	RM	RM	RL

PM	CL	CM	CH	CVH
FH	RM	RH	RH	RVH
FM	RM	RM	RH	RH
FL	RL	RM	RH	RH
FVL	RL	RM	RM	RH

PL	CVH	CH	CM	CL
FH	RH	RH	RM	RL
FM	RH	RH	RM	RL
FL	RM	RM	RM	RL
FVL	RM	RM	RM	RL

PL	CL	CM	CH	CVH
FH	RL	RM	RH	RH
FM	RL	RM	RH	RH
FL	RL	RM	RM	RM
FVL	RL	RM	RM	RM

PVL	CVH	CH	CM	CL
FH	RH	RM	RM	RL
FM	RM	RM	RM	RL
FL	RM	RL	RL	RL
FVL	RM	RL	RL	RL

PVL	CL	CM	CH	CVH
FH	RL	RM	RM	RH
FM	RL	RM	RM	RM
FL	RL	RL	RL	RM
FVL	RL	RL	RL	RM

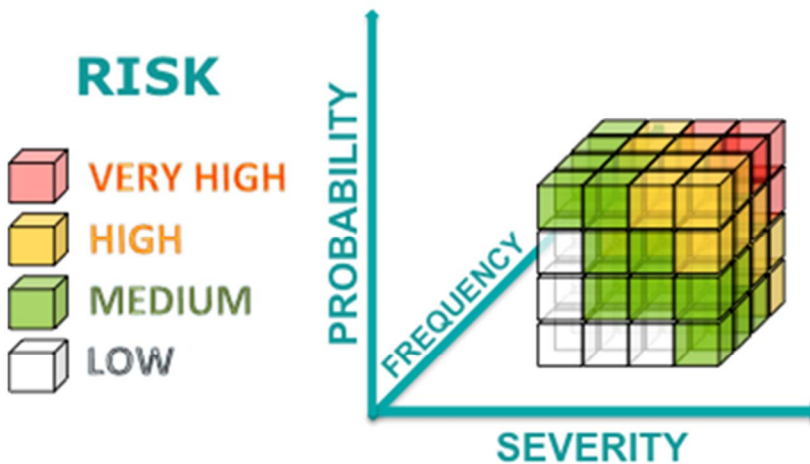


Fig. 5.6. Relationship between Risk and the three independent variables (Frequency, Probability and Severity of the Consequences) as defined by the FORO Risk Matrix.

5.2.2.5 Application of the Risk Matrix method

The application of the Risk Matrix method follows the first typical steps of most risk assessment tools and then departs from that traditional approach to implement the two screening steps based on the specific barriers analysis.

The first step requires defining the process that is going to be analysed.

Next, following a systematic procedure, the potential failures and causes of potential harm are identified, resulting in a list of initiating events. The identification of all possible initiating events is critical, because any event escaping the identification will remain unaddressed. Among a variety of methods developed to identify the dangers associated with a practice, FMEA is frequently used.

For each initiating event identified, its potential harm is analysed, and the barriers existing in the radiotherapy department to avoid it are recorded. Then the expert team defines the corresponding levels for the initiating event frequency for the total failure probability of all barriers and for the severity of the consequences. These values are used as entry data into the risk-matrix to obtain the level of overall risk for each accidental sequence. These risk levels are used to carry out the first screening of events in the process: Accidental sequences with a risk assignment of “medium” or “low” do not require further analysis, so that attention can be focused on the fewer remaining sequences of “high” and “very high” risk.

Once these events (sequences of “high” and “very high” risk) have been selected, other elements that are not specifically included in the first screening have to be taken into account. The first screening is conservative because it assumes that:

- the probability of failure is based on the number of barriers only, thus ignoring their efficiency, which might result in an actual lower risk level;
- the option chosen when combining levels of the three variables lies on the pessimistic side;
- the radiotherapy department may have elements that enable to reduce the frequency of the initiating events or mitigate the consequences. This moderately conservative approach used up to this point is meant to avoid assigning a low level of risk to event sequences that may deserve further attention.

The second screening addresses these conservative assumptions by reassessing the remaining events in a systematic way, choosing a few standardized questions, called “key questions for risk reduction.” The key questions are:

- Are the barriers robust enough to assign a level of barrier failure probability lower than that assigned by the risk matrix?
- Are the frequency and severity reducers robust enough to assign a level to the frequency or to the severity lower than those assigned by the risk matrix?

By answering these questions, the levels of f , P , or C might be reduced, and a new risk level might be reassigned, possibly resulting in a lower number of events with “high” or “very high” levels that would require risk management.

In the final analysis phase, consisting of risk management and reduction, criteria are needed to decide where priorities are to be assigned. These criteria are outlined in Table 5.19.

For the remaining events in which the elements considered in the second screening do not provide confidence to warrant a reclassification to a lower risk level, there would be a need for strengthening some of these elements or for additional safety measures. These elements are identified with the help of a new set of “key questions”:

- Is it possible to introduce additional barriers or reducers?
- Which measures can be proposed to globally reduce the risk?

Measures to reduce the frequency of initiating events considered are related to strategies for maintenance and for reducing human error (e.g., staff qualification, moderate workload, working environment prone to concentration, discouraging distraction and bad practices, as well as a program of quality management). Measures to reduce barrier failure probability are directed to increasing barrier efficiency and reliability; e.g., by testing or monitoring them. When additional barriers are needed, harmonization with the existing system will be also needed.

Table 5.19. Risk acceptability criteria and corrective actions.

Risk level	Risk acceptability	Actions
R _{VH}	Unacceptable	Risk for the patients is so high that implementing safety measures becomes the very first priority, even if this leads to temporary interruption of radiotherapy treatments.
R _H	Unacceptable, if the severity of the consequences is high or very high.	Measures are required to reduce risk or the practice will have to be stopped.
R _M	Unacceptable, but tolerable temporarily under some conditions if the consequences are medium or low.	Measures for risk reduction should be taken in an appropriate time frame.
R _L	Tolerable under risk-benefit criteria Negligible	Measures for risk reduction should be chosen under risk-benefit criteria. No action is required.

Table 5.20. Example of provisional risk estimation.

Initiating event	f	C	Safety barriers	P	Risk	Frequency reducers	Consequences reducers
To introduce erroneous dose data for the calculation of the monitor units.	F _M	C _H	<p>Joint evaluation of the dosimetric plan by the radio-oncologist and the medical physicist. Independent verification of the resulting calculations of the dosimetric plan for patient treatment by a medical physicist different from who made the original plan.</p> <p>In vivo dosimetry in the initial session of the treatment to verify the correspondence of the administered doses with the planned ones, which allows detection of errors in the dose administration.</p>	P _L	R _H	Moderate workload	<p>Daily patient positioning, during which the radiotherapy technologist can detect geometry or dose errors by visual signs (erythema, etc.)</p> <p>Weekly patient follow-up by the radio-oncologist, who can detect errors in the administration of the treatment or in the previous stages.</p> <p>Weekly in vivo dosimetry, which allows detection of errors in the dose administration.</p>

Finally, an assessment of the barriers for the outstanding events is performed as a complementary sensitivity analysis. This sensitivity study allows identifying which barriers have a

larger impact in risk due to their participation in many accidental sequences or in those with a higher risk level. This information proves very useful when defining risk management strategies and optimization.

An example of provisional risk estimation is shown in Table 5.20.

5.2.2.6 Outcomes

The method was applied as described above to a generic hypothetical radiotherapy department. The number of events and barriers assessed with the methodology are presented in Table 5.21.

Table 5.21 - Global results

Number of Initiating Events Analyzed	142
With Very High Risk	0
With High Risk	27
With Medium Risk	105
With Low Risk	10
Number of barriers analyzed	100
Number of frequency reducers analyzed	37
Number of consequences reducers analyzed	26

An example of the added value of this method to analyze the existing barriers is shown in Table 5.22.

Table 5.22. Analysis of existing barriers.

Barrier name	Sequences in which the barrier participates	
	Number	%
In vivo dosimetry in the initial session of the treatment to verify the correspondence of the doses administered with the planned ones, which allows detection of errors in the dose administrations.	36	25
Portal images in the initial session of the treatment, evaluated by the radio-oncologist and the medical physicist, with which errors of geometry of the treatment are detected.	36	25
Positioning and immobilization of the patient in the treatment position for the initial session, in the presence of the radio-oncologist, the medical physicist, and the x-ray technicians.	27	19
Daily tests of constancy of the reference dose and evaluation of the beam quality within the framework of the QA controls.	23	16
Joint evaluation of the dosimetry plan by the radio-oncologist and of the medical physicist.	23	16

5.3 Comparison of the different proactive methods

Proactive methods for risk assessment are compared in Table 5.23. 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).

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.

In terms of prioritization, both 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.

Table 5.23. Comparison of six proactive methods of risk assessment

	Advantages	Disadvantages
Dedicated FMECA (ASN, 2008b)	<p>All of FMECA plus:</p> <ul style="list-style-type: none"> • Systemic approach • Guidelines and completed adaptable tables available • Severity and Likelihood scales provided 	<ul style="list-style-type: none"> • Takes into account only single failures • No evaluation of the reliability of barriers
Dedicated Risk Matrix (FORO (IAEA-FORO, 2013a; 2013b))	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Combinations of failures • Top-down approach • Concept quite easy to learn • Quantitative evaluation software available 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Identification of failures • Evaluation of consequences using severity and probability scales • Quite easy to use 	<ul style="list-style-type: none"> • Not a systemic approach • Only single failures • Conservative approach
PRA	<ul style="list-style-type: none"> • Systemic approach • Identification of hazards • Identification of scenarios • Evaluation of consequences using severity and probability scales 	<ul style="list-style-type: none"> • Concept difficult to learn • Non-realistic number of scenarios to describe for a complete application to external beam radiotherapy
ETA	<ul style="list-style-type: none"> • Barrier failures • Concept quite easy to learn • Quantitative evaluation software available 	<ul style="list-style-type: none"> • 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

5.4 National regulations or recommendations

The general questionnaire about the basic legal provisions (national regulations; see Annex 4) revealed that proactive risk assessment are not widely performed in Europe and is without a systematic methodology support, except in a few countries where a dedicated method is available and/or it is a safety requirement. When a method is used it is often a FMEA method

(HFMEA, SAFER, FMEA-ASN (ASN, 2008) or Risk Matrix (FORO (IAEA-FORO, 2013a; 2013b)), and it is often limited to evaluate impact of a modification: new equipment, process evolution etc.

Following the general questionnaire sent to national contact point from 38 countries, the analysis of the 32 answers was used to identify 10 countries having defined “requirements” for proactive risk assessment and/or reactive analysis of events. These “requirements” issued to radiotherapy centres might either be defined by the national authorities by regulations and sometimes by associated guidelines, or be recommended by national professional societies. The aim of the subsequent detailed questionnaire was to get information of the main features of the proactive risk assessment and the system for analysis of events used in these 10 countries.

The detailed questionnaire was sent to national contact points from Denmark (DK), Ireland (IE), Spain (ES), Finland (FI), France (FR), Italy (IT), Netherlands (NL), Poland (PL), Slovakia (SK) and United Kingdom (UK).

In most of the countries having answered to the detailed questionnaire, the regulation in radiation protection implemented in accordance with European directives clearly defines requirements on a priori assessments of risks for workers. However, for patients, the implementation of proactive risk assessment is mandatory in few countries (FR, NL, IE, UK), according to either national healthcare regulation (FR, NL) or general radiation protection regulation (IE, UK), or is specific to radiotherapy (FR). In the others countries, risk assessment is recommended.

In countries where proactive risk assessment is mandatory, no methodology is defined but some general methodologies are recommended by either authorities or by professional societies who have provided guidelines to radiotherapy centres (Table 5.24). Spain and France proposed special examples dedicated to radiotherapy while only Slovakia mentioned the WHO patient safety radiotherapy risk profile (WHO, 2008).

The requirements for this risk assessment are closely linked to quality assurance management. As an example, in Finland, even if the proactive risk assessment is not explicitly stated in the guide published by STUK, principles for preventing errors are included in the requirements on quality assurance programme.

The lack of sufficient staff and time to implement the risk assessments is a common problem encountered by all countries. The difficulties to evaluate hazards or previous failures, and to make an agreement for their rate evaluation are also underlined. As for the benefits, risk analysis was reported to improve the knowledge of the team and the awareness on how to manage the residual risk.

The detailed results of the questionnaire on risk management are summarized in Annex 4 (section A4.2).

Table 5.24. The methods used for proactive risk assessment.

Method	FR	NL	SK	ES	UK
FMEA	X	X		X	
PRA		X	X	X	
FTA					X
ETA					X
Risk Matrix				X	X
Other			WHO (WHO, 2008)	Money value Barrier analysis	Dosimetry audit Peer review

5.5 Examples of local practice

The local proactive risk assessment was reviewed by a specific questionnaire (see Annex 4, section A4.3) to a few radiotherapy centres, selected by the help of the national contact points. Twelve questionnaires were completed by 1 to 3 radiotherapy centres in 7 countries as shown in Table 5.25. The detailed answers to this questionnaire by each radiotherapy centre are presented in Annex 4.

Table 5.25. Summary of the replies to the questionnaire on the methods locally used for proactive risk assessment (in 1-3 centres of the given countries; see more details in Annex 4).

Method	DK	FR	IT	NL	PL	ES	UK
FMEA		Yes	Yes	Yes (SAFER)	Yes		
PRA							Yes
FTA							
ETA				Yes			Yes
Risk Matrix				Yes	Yes	Yes	Yes

6. Reactive analysis of events

This section gives a comprehensive review of the available methods for reactive analysis of events, both generic methods and a method particularly developed and dedicated to radiotherapy. A bibliography for practical examples on their application is given in Annex 2. Further, the status of reactive analysis of events in Europe is briefly summarized, based on the results of the ACCIRAD detailed questionnaire; more detailed summary is presented in Annex 4.

6.1 General principles

The internal reasons that lead a potential reporter to not make a report are largely psychological and the way the analysis or investigation is made is psychologically very important. The analysis could be emotionally demanding and sometimes it could be an uncomfortable experience and therefore it should be carried out carefully. The objective of the analysis is to determine solutions by learning from the event and make the staff involved feel that they are part of the solution. The objective should not be to identify and punish the individual staff members involved in patient-safety in the event.

Whenever possible, the contribution of risk management experts in the analysis of events is of importance because:

- They are trained in risk analysis methodologies leading to not get to premature hypotheses that lead to restricted information and restricted causal search.
- They have experience in previous and similar events, which helps them to fully decompose the causes and to make proposals about actions to avoid repetition.
- They know how important the psychology is in the process of investigation. It is important to instigate a culture of openness, not individual blame, and reflective learning to get to a cooperative environment in the event under investigation (specially in stressful episodes) and in future events that might happen.

However, the unavailability of a risk management expert should not impede the internal analysis made by frontline personnel. In any case, training in risk management of all the personnel involved in the radiotherapy process is needed.

The analysis must be systematic and detailed to ascertain what can be learnt. It should answer to the following questions:

What happened? Detailed account using all sources of information: interviews, electronic or paper records, simulation, etc. The impact (or potential impact) of the event to the patient, professionals involved and to the organization should be determined, the timeline of the event, how (and by whom) it was discovered, as well as the information given to the patient and to the organization.

Why did it happen? Establish the main and underlying causes that contributed to the event happening. Direct causes may hide less evident contributing causes that should be determined. Whilst it is important to get the view of all involved team members, large groups tend to

function less well than small groups to determine the causes. Therefore individual interviews are recommended with a review in group of the conclusions.

What can we learn from what happened? What needs to change? As the aim is changing to reduce the likelihood that a similar event happens again, the proposals of change have to be determined. The design and prioritizing of new barriers may imply changes in the equipment, procedures, communication, training of staff, adaptation of material and human resources to the safety needs, etc. A contribution with the results of the analysis to national and/or international reporting and learning systems should be made.

How do we know that lessons are not only good intentions? Proper implementation of actions to avoid future repetition must be demonstrated at an individual, team and organizational level. Follow-up and responsibilities in the implementation of remedial actions must be considered.

6.2 Generic methods

Any event analysis begins with an initial step of collecting the facts. This first step must be carried out so the causes can be identified. Identification is based on the principle that at the origin of the adverse error-event (accident, incident, or the undesirable outcome), the following can be found (see Fig. 6.1):

- active faults (active failures, direct causes) representing the direct observable causes (software bug, etc.),
- latent faults (latent conditions, latent causes) that are not direct causes but favoured them (expired maintenance contract, failure to update software, etc.).

The active faults are all the more important because they will represent common causes of failures. They may render the existing system of “barriers” deficient as shown in the Swiss Cheese model of Reason (Fig. 6.2).

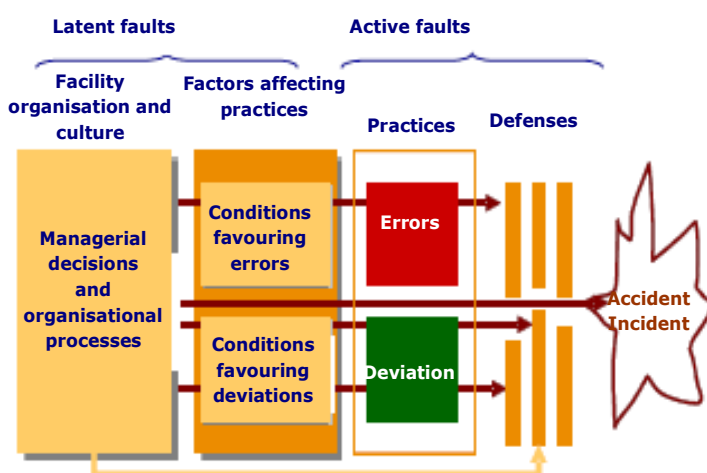


Fig. 6.1. Latent and active faults

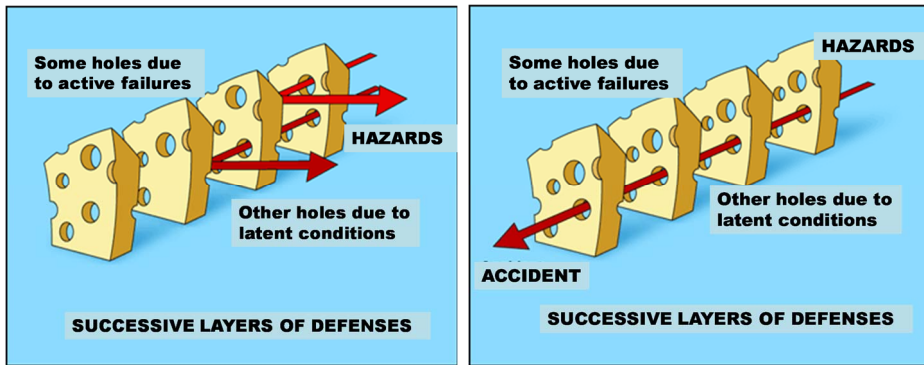


Fig. 6.2. The swiss cheese model of Reason

The Swiss cheese model of Reason has many holes—though unlike in the cheese, these holes are continually opening, shutting, and shifting their location. The presence of holes in any one “slice” does not normally cause a bad outcome. Usually, this can happen only when the holes in many layers momentarily line up to permit a trajectory of opportunity for an adverse error-event—bringing hazards into damaging contact with victims.

In the following, several generic methods for reactive analysis of events, applicable to but not dedicated to radiotherapy, are introduced: Root Cause Analysis (RCA), ALARM, Causal Tree Analysis (CTA) and ORION.

6.2.1 Root cause analysis (RCA)

The objective of root cause analysis (RCA) during event analysis is to identify the root causes (deeper causes, latent conditions, latent causes, latent factors, contributing factors) behind the immediate causes (direct causes, active failures) observed on the event. These principles are often also used in more global methods (ALARM, ORION[®], etc.).

The simplest method that help to implement this analysis is the “five whys technique”. Following the first identified cause, the question why is asked five times in succession. This technique thus leads to the root causes. It then remains to analyse them to deduce actions for improvement. It leads to identify the one root cause for each event. An example of “five whys technique” is shown in Fig. 6.3.

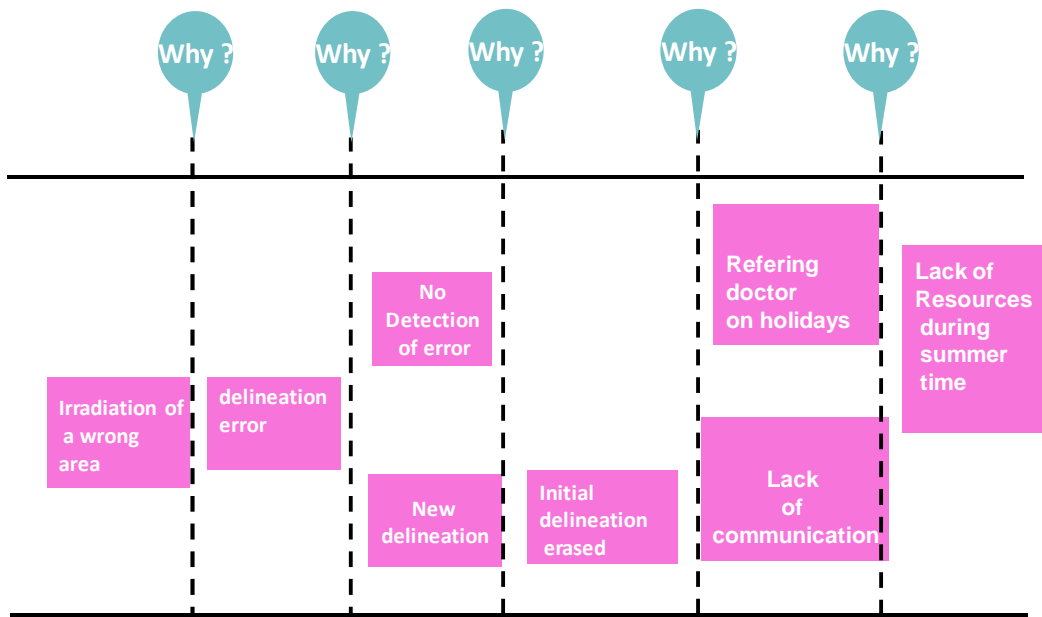


Fig. 6.3. Example of the “five whys technique”.

In addition, an Ishikawa or 5M diagram may be used to show the various types of causes (Fig. 6.4):

- Mother Nature (Environment),
- Manpower (Staff),
- Methods,
- Material,
- Machine (Equipment).

Two other categories can be added: Money Power and Management (7M). Preparation of the diagram may thus serve as an aid in leading the working group in charge of the analysis.

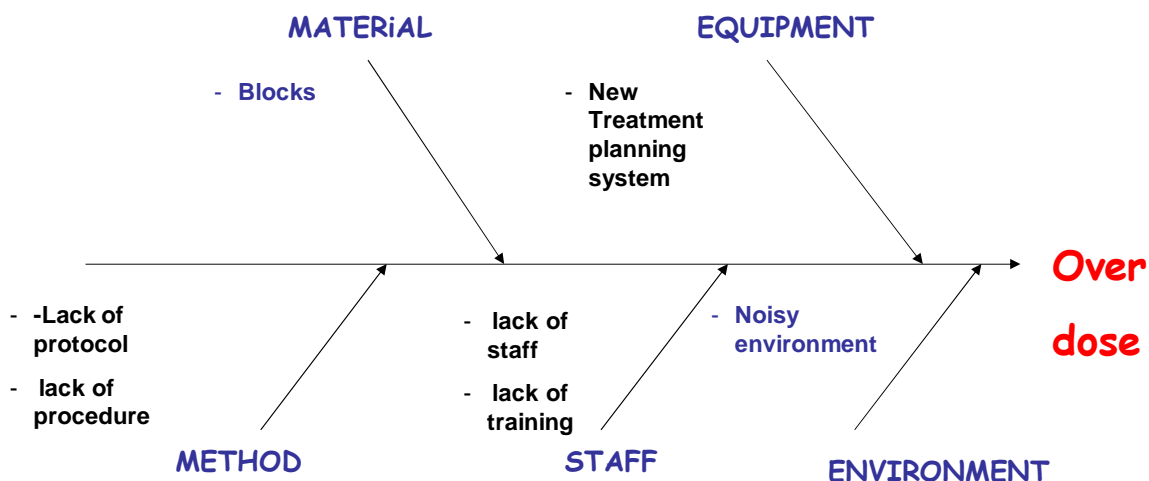


Fig. 6.4. Example of Ishikawa fishbone diagram.

Possible root causes can be related, e.g., to the following:

- patient (aggressiveness, communication issues, etc.);
- tasks performed (lack of protocol, lack of planning, etc.);
- staff (tiredness, lack of skills, etc.);
- team (lack of cooperation, patient file not readily accessible, etc.);
- work environment (unsuitable work areas, inadequate equipment, noise, etc.);
- organisation (lack of training plan, etc.);
- institutional context (regulatory constraints etc.).

Standard lists for setting aside a significant number of possible root causes are available; an example is shown in Table 6.1. The characterisation of root causes is often in relationship with a system reporting and learning software or a visual representation.

Table 6.1. Examples of possible root causes.

Type of the root cause	Examples
Institutional	<ul style="list-style-type: none"> • A hospital with 60 different buildings had to be rebuilt • Lack of continuous improvement (through auditing etc)
Environmental	<ul style="list-style-type: none"> • Tension between staff and management
Resource related	<ul style="list-style-type: none"> • Radiotherapy department has only one medical physicist, with responsibilities also in another institution
Individual shortcomings	<ul style="list-style-type: none"> • Poor knowledge of the QA procedures by person in charge • Poor knowledge of the long term complications of radiotherapy
Protocol related	<ul style="list-style-type: none"> • Poor preparation of the change of protocol: follow-up of the procedures before introducing the new protocol and the subsequent adoption of the new protocol not performed
Organisational	<ul style="list-style-type: none"> • Unclear assignment of responsibilities for management and for informing to authorities • User's guide in local language are missing • No proper training for modifications made • Late informing of the hospital's director about an overdose event
Patient related	<ul style="list-style-type: none"> • Complex health problems • Emergency situation

6.2.2 ALARM

The ALARM (Association of Litigation And Risk Management) method was developed by Charles Vincent in 1998, based on the Reason Diagram (Fig. 4.5 of the Guidelines). The ALARM method does not attempt to identify only root causes (latent causes) as the Root Cause Analysis (RCA). The objective of the analysis is precisely to understand the complexity of causes. The analysis identifies errors in health care (Fig. 6.5) and requires an accurate knowledge of standard processes and procedures related to each career in order to identify deviations during analysis.

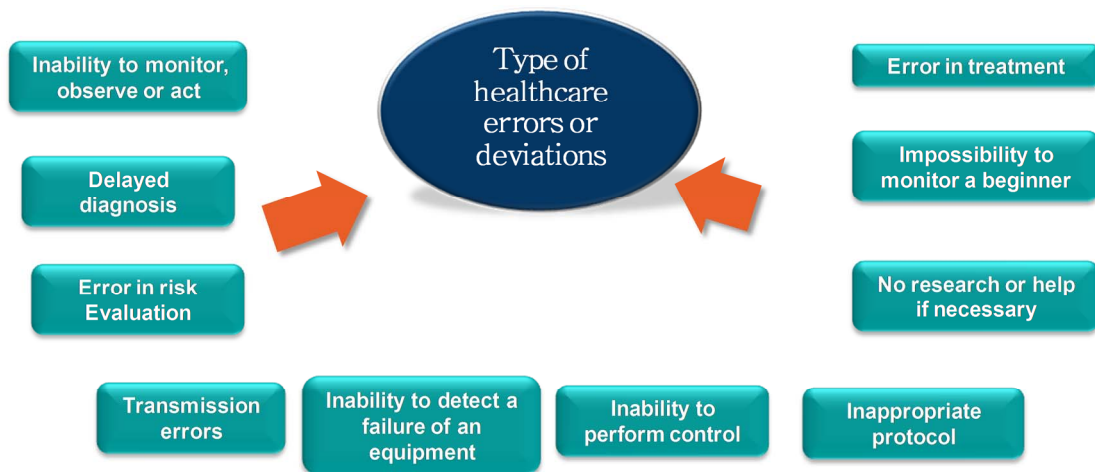


Fig 6.5. Example of healthcare errors considered by ALARM

The method involves seven steps (see Fig. 6.6), where steps 1-4 are found in all types of a posteriori analyses, regardless of methodology.

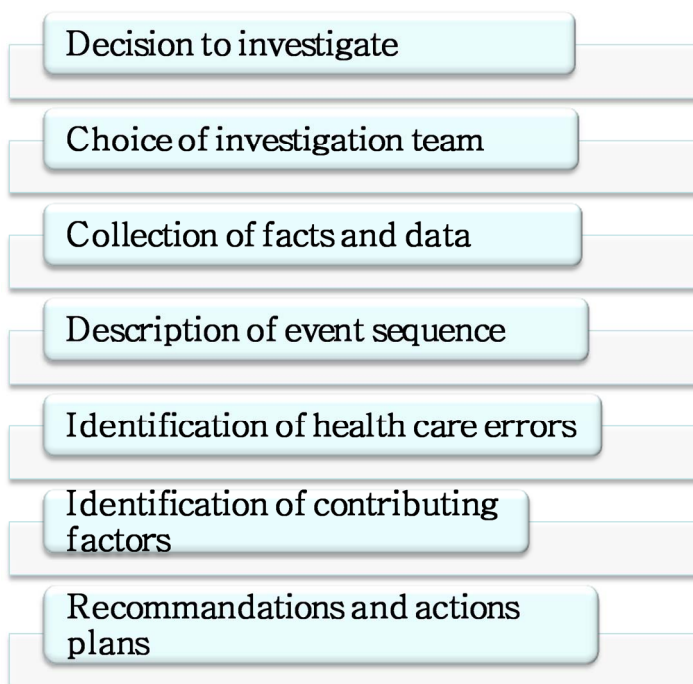


Fig. 6.6. The different steps of ALARM.

Steps 5 and 6 are performed simultaneously using interviews. Questionnaires are provided in order to identify actions and oversights that occurred during care, e.g.:

- wording confusion or error in judgement;
- incorrect or incomplete implementation of a procedure;
- deliberate negligence in safety practices, procedures or standards.

Possible root causes (Step 6) can be related to the same list as shown above for RCA, i.e., patient, tasks performed etc.

Standard lists presenting a significant number of possible root causes to be taken into consideration are integrated in the questionnaires supplied during interviews.

Finally, deviations and influential factors that have been identified are analysed to determine actions for improvement.

6.2.3. Causal tree analysis (CTA)

Causal Tree Analysis (CTA) was developed by the Institut National de Recherche et de Sécurité (French national institute for occupational health and safety research, INRS) to investigate and research accident factors in the area of workplace accidents and professional risks. Specific training is necessary for the person preparing the causal tree to acquire the formal elements for presenting information and constructing the tree.

Like in all approaches to the analysis of events, the first step is to collect the events. The objective is to identify the sequences and combinations of events that played a role in bringing about the undesirable outcome (adverse error-event or near miss), to obtain an objective description and demonstrate the causal relationship between events; this is achieved by:

- limiting the search for proven and observed events leading up to the outcome,
- excluding judgments and opinions,
- not seeking a possible guilty party (notion of individual fault),
- not blaming those involved,
- avoiding the simplest interpretation that relies on the single cause model.

CTA relies on the standard method of identifying root causes but does not offer a practical questionnaire grid. The way to construct the Causal tree is:

- Starting from the earliest events, will go back as far as possible in time,
- Replying to the questions: “What must have been the case for this to happen?” “Was it necessary?” and “Was it sufficient to cause the event?”, and then verifying the received information.

Repeating this interrogation process several times will identify the root causes behind the event.

The information that is collected is then expressed graphically in the causal tree. The objective is then to:

- depict all identified events without consideration for their importance;
- specify if they concern habitual or unusual acts (such as a current practice, etc.);
- show cause and effect relationships between observed events, given that these relationships may be explicit and verified, or hypothetical and to be verified.

Building the tree begins with the earliest observed event and follows the events using the symbols given in Fig. 6.7. It can be used as an aid for leading a working group of those involved, particularly to characterise events that have been identified (both habitual and unusual) and the link of causality between them. An example of causal tree is shown in Fig. 6.8.

Finally, deviations and influential factors that have been identified are analysed to determine actions for improvement.

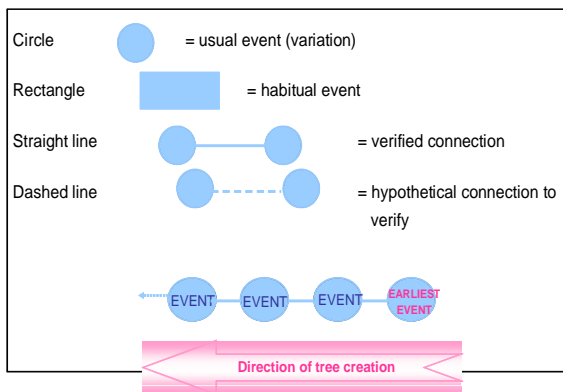


Fig. 6.7. Causal tree symbols

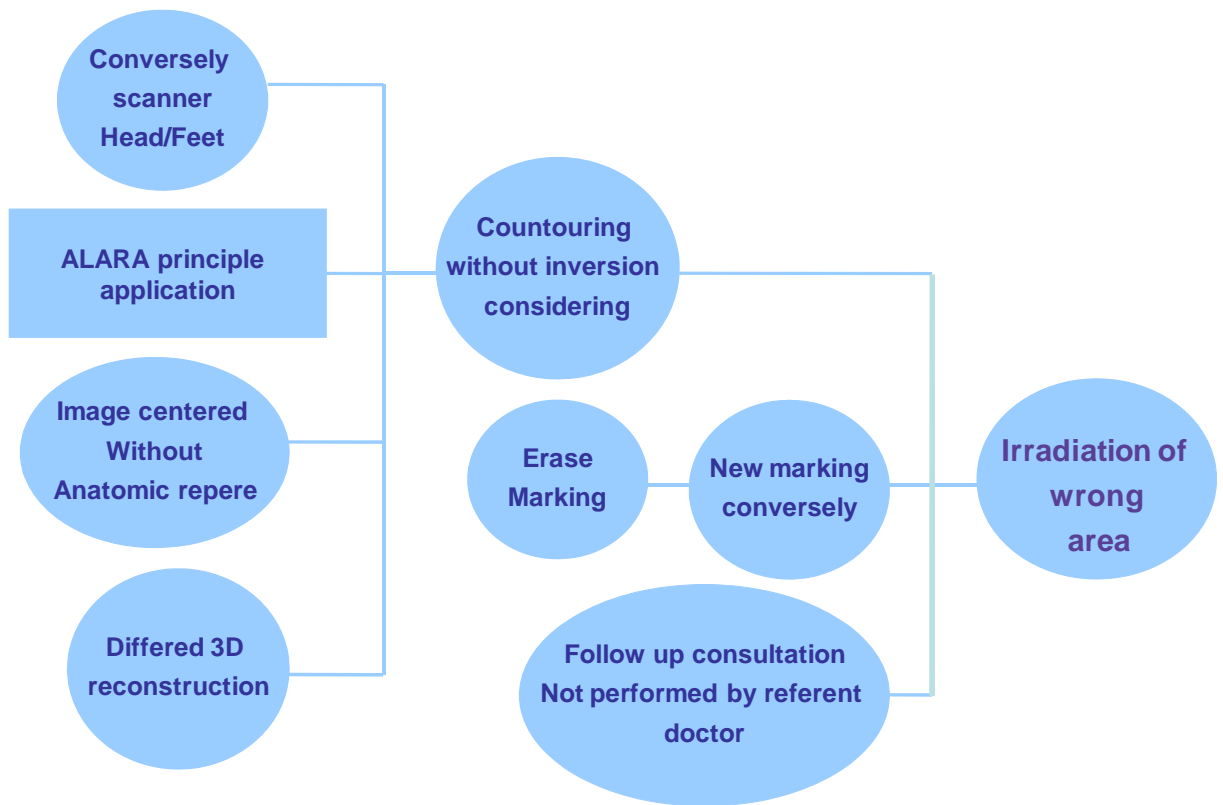


Fig. 6.8. Causal tree example.

6.2.4 ORION®

The ORION® method was developed in the aeronautics industry for performing detailed event analysis. It has been implemented in hospitals in France. It implies active participation by workers as early as possible while the situation (event) is still fresh.

More than a method, the ORION[®] is an overall approach for performing the analysis that, depending on the step, relies on existing methods. Implementing the ORION[®] approach requires integrating the ALARM and CTA methods. It provides check lists to identify latent factors but no specific support to the description of the chronology of events. The approach involves five steps (see Fig. 6.9), where steps 1-4 are found in all types of a posteriori analyses, regardless of methodology.

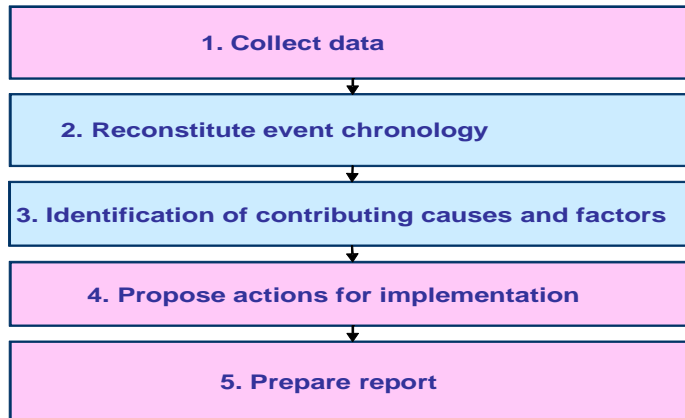


Fig. 6.9. Steps of the ORION[®] method

From the initial step, ORION[®] offers a form for characterising the event (vision declaration) and collecting a description of causes from interviews, by:

- selecting two cases (processes, practices, etc.);
- collection of data from all participants in the process.

The form, modelled on the radiation oncology safety information system (ROSIS), integrates a descriptive part of the event chronology (Step 2). In step 3, the cause-effect relationships between the facts are explained (causal tree analysis) and the influential factors are located (ALARM method) that may explain the following facts:

- defective conditions,
- inappropriate actions,
- deviations from expectations.

The formal elements and aids from the ALARM and causal tree analysis can be used in this step.

To guide steps 4 and 5, the ORION[®] approach includes in the results:

- the list of explained causes,
- cause tree,
- lines of defence that did not perform their role while explaining why.

All that remains is to deduce actions for improvement.

6.3 A method dedicated to external radiotherapy (HFACS)

HFACS (Human Factor Analysis and Classification System) (Portaluri et al., 2009) is a method of detailed event analysis for the identification of latent and active failures. It provides a practical framework for identifying failures.

The method can be used for a posteriori analysis of an undesirable outcome, or a set of events that have already been reported and analysed. For analysis when an undesirable outcome is still fresh, creation of an investigation team, requirement of independence, protection from sanction etc. are the usual prerequisites for this type of approach. It also requires the knowledge of the concepts of latent and active failures found in the Reason diagram (Fig. 4.5 of the Guidelines).

The method is based on the observation that while the Reason diagram is a good representation of the mechanism that results in the undesirable outcome, in practice it is not easy to identify the failures, the “holes” in the diagram. Therefore, it proposes a framework to break the Reason diagram down into four levels and associated sublevels (see Fig. 6.10):

- organisational influences (resources, process);
- latent failures related to supervision (inappropriate supervision, failure in supervision, lack of corrective measures, etc.);
- conditions favouring error (substandard practice, particular working conditions);
- unsafe acts (errors or violations).

A questionnaire is provided for each level and sublevel to facilitate identification.

This questionnaire was adapted as part of a specific application for radiotherapy (see the footnote) and leads to the subsequent framework (not exhaustive) shown in Tables 6.2 to 6.5.

Finally, deviations and influential factors that have been identified are analysed to determine actions for improvement.

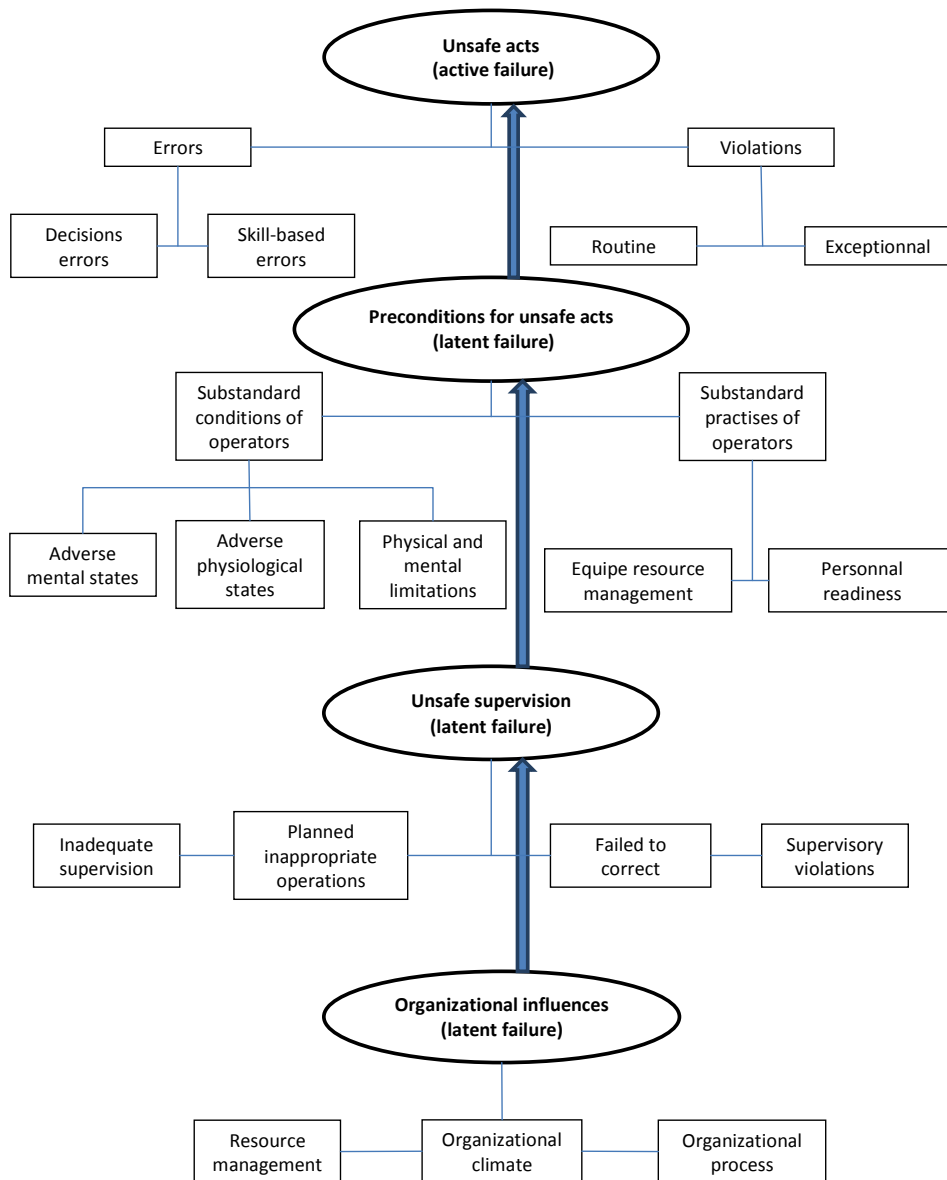


Fig. 6.10. Structure of interrogation framework

Table 6.2. Framework for operator errors (*Note : this is not a complete list*)

HFACS adapted framework
Skill based errors (SBE)
<i>Attention failures (AE)</i>
Wrong patient set-up (e.g tattoos exchange)
Wrong schedule of treatment
Wrong data input in RVS (both patient registry data and chose prescription)
Patient exchange at the treatment check in
<i>Memory failures (MF)</i>
Organ at risk dose out of limits (lack of dose volume histogram evaluation)
Decision errors (DE)
<i>Improper procedural execution (IPE)</i>
Wrong treatment fields size (wrong simulation)
Wrong planning target volume contouring
Wrong TC volume acquisition for a given target
Wrong treatment fields junction
Wrong multi leaves collimator placement
Wrong dose normalization in presence of an asymmetrical treatment field

Table 6.3. Framework for conditions favouring errors (*Note : this is not a complete list*)

Unsafe supervision
Inadequate supervision (IS)
Failed to provide operationnal protocol
Failed to provide oversight
Failed to provide training
Failed to track qualification
Failed to track performance
Planned inappropriate operations (PIO)
Failed to provide correct data
Failed to provide adequate brief time
Failed to correct a known problem (FKP)
Failed to correct document in error
Failed to initiate corrective action
Failed to report unsafe tendencies

Table 6.4. Framework for (latent) supervision failures

Preconditions for unsafe acts
Substandard conditions of operators (SCO)
<i>Adverse mental state (AMS)</i>
Channelized attention
Complacency
Distracted
Overconfidence
Mental fatigue (sleep loss or other stressors)
Get-home-it-is
Haste
Life stress
Loss of situational awareness
Misplaced motivation
Task saturation
<i>Adverse physiological states (APS)</i>
Impaired physiological state
Medical illness
Physical fatigue

Table 6.5. Framework for organisational factors

Organizational influences
Resource/acquisition management (R/AM)
Human resources (selection, staffing/manning, training)
Monetary/budget resources (excessive cost cutting, lack of funding)
Equipment/facility resources (poor design, purchasing of unsuitable equipment)
Organizational climate (OC)
Chain of command
Delegation of authority
Communication
Norms and rules
Values and beliefs
Organizational process (OP)
Time pressure
Production quotas
Schedules
Deficient planning
Clearly defined objectives
Risk management
Safety programs
Quality assurance programs

6.4 Comparison of different methods for reactive analysis of events

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 6.6. 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 6.6. Comparison of reactive methods for the analysis of events.

Method	Advantages	Disadvantages
Root Cause Analysis (RCA) 5 Whys? methods	<ul style="list-style-type: none"> • Method based on systematic questioning to identify the main cause • Schematic description • Easy to implement 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Questions focus on five to seven aspects: materials, method, manpower, environment, etc. • Graphic representation of causes • Cause and effect relationships and ranking of causes 	<ul style="list-style-type: none"> • No representation of logical relationships • No chronology
Root Cause Analysis (RCA) HFACTS	<ul style="list-style-type: none"> • Method based on systematic questioning to identify the main cause • Includes supervision failures • Grid available 	<ul style="list-style-type: none"> • No representation of logical relationships • No chronology
ALARM	<ul style="list-style-type: none"> • 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. 	<ul style="list-style-type: none"> • 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)	<ul style="list-style-type: none"> • 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) 	<ul style="list-style-type: none"> • Factors not ranked • Schematic description is not easy to understand for those who did not create it
ORION®	<ul style="list-style-type: none"> • 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. 	<ul style="list-style-type: none"> • Initial analysis require support • No schematic description

6.5 National regulations or recommendations

The results of the general and detailed questionnaires (Annex 4) revealed that for most of the countries, a reactive analysis of events is mandatory and closely related to quality assurance management but also to mandatory recording at hospital level and/or to mandatory reporting at local and national level. The provision for this analysis is related to radiation protection regulation (NL, FR, UK) with specific requirements in radiotherapy (ES, FI, FR), or to healthcare regulation with specific requirements on medical devices regulation (FI, FR, IE). A guide specific to radiotherapy but not binding have been developed in particular in the United Kingdom and Ireland.

In countries where reactive analysis of events is mandatory, no methodology is defined but some general methodologies are recommended by either authorities or by professional societies who have provided guidelines to radiotherapy centres (Table 6.7).

Table 6.7. Methodologies recommended for reactive analysis of events.

Method	DK	FR	IE	NL	SK	ES	UK
ALARM					x		
CTA				x	x	x	
RCA	x		x	x		x	
ORION [®]		x ¹					
Others		HAS ²	TSRT ³ Alberta ⁴		TSRT ³	5 why's Ishikawa	TSRT ³

1. MeaH 2008: "Improve the safety of care organizations " promoted to French radiotherapy centres

2. HAS Guideline 2012: "Implement risk management associated with care in health facilities"

3. (RCR, 2008)

4. Alberta Canada guidelines ("A reference guide for learning from incidents in radiation treatment" AHFMR –HTA initiative #22 <http://www.ihe.ca/documents/HTA-FR22.pdf>)

The detailed results of the questionnaire on the methods for the analysis of events are summarized in Annex 4 (section A4.2).

6.6 Examples of local practice

The local practices in reactive analysis of events were reviewed by a specific questionnaire to a few radiotherapy centres, selected by the help of the national contact points. Twelve questionnaires were completed by 1 to 3 radiotherapy centres in 7 countries (Table 6.8). The detailed answers to this questionnaire by each radiotherapy centre are presented in Annex 4 (section A4.3).

Table 6.8. Summary of the replies to the questionnaire on the methods locally used for reactive analysis of events (in 1-3 centres of the given countries; see more details in Annex 4).

Method	DK	FR	IT	NL	PL	ES	UK
RCA	Yes		Yes	Yes	Yes		Yes
CTA							Yes
ORION		Yes					

7. Classification and reporting of adverse error-events and near misses in radiotherapy

This section gives a comprehensive review of the reporting and learning systems for adverse error-events and near misses in radiotherapy, including the relevant terminology and classification of events. A summary of this section is presented in the Guidelines. Detailed characteristics of some existing, national and international, reporting and learning systems is presented in Annex 3 and the status of the systems used in European countries in Annex 4 (section A4.4); the latter is based on the results of the questionnaire of the ACCIRAD project.

7.1 General Introduction

Following the Hippocratic Oath of "primum non nocere" or "first do no harm", a fundamental principle in health care is patient safety. Radiotherapy is a quite safe area in medicine (Munro, 2007), despite having an important technical and organizational complexity. However, errors in medicine in general and in radiotherapy in particular may occur and, sometimes, patients are harmed as a consequence. The medical therapeutic application of ionising radiation is irreversible, may cause significant morbidity and is potentially lethal. There is a high expectation of safety in radiotherapy and the aim should be to reduce risks (Hendee, 2011) to limit error rates to a level similar to that in the airline and nuclear industries (Ford, 2010).

Errors in radiotherapy need to be addressed promptly and appropriately to try to avoid future repetition and to try to diminish the expected effects; moreover, they have a significant media and public attention (Kirby, 2007; Oved, 2007; Poling, 2007; Bogdanich, 2010a; 2010b) because radiotherapy is sometimes seen as a mysterious procedure by patients and the public alike. Because radiation is involved and because it can neither be seen nor felt, there is an air of mystery that adds to the perception of danger (Williams, 2007).

Correct managing of reported events and classification of adverse error-events and near misses in radiotherapy are fundamental tools for learning from errors. Tracking reported near misses is useful to aim organizational improvement efforts at preventing adverse error-events, rather than waiting until a major event occurs before action is taken. From near miss and adverse error-events valuable lessons can also be learnt to avoid repetition. 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, incidents or the adverse error-events. Monitoring of events also enables the organization to measure the improvements. How an organization learns from its experience is a safety-critical feature and an expression of its safety culture (Wilpert, 2001).

Nevertheless looking backward for past errors is not enough. Now the challenge is trying to look forward in anticipation of future risks, search for patterns of error and move from a culture of reporting events to a culture of learning from events.

7.2 Terminology

The definitions vary among recommendations and reporting systems, and there is ambiguity and little uniformity in terminology (Weingart, 2005). There is no general agreement on the language and the meaning of words in risk management. The terms can have different

meanings to different people, e.g. “error” might, or might not, be understood as “incident” or “adverse error-event”, and a “near miss” may be understood as an event that does not reach the patient or an event that does not produce patient injury.

Iatrogenic injury has its own terminology. Iatrogenic injury means injury originated from or caused by a physician (iatros, Greek for “physician”). However, the term has come to have a broader meaning and is now generally considered to include unintended or unnecessary harm or suffering arising from any aspect of health care management. Problems arising from acts of omission as well as from acts of commission are included. Confusion and ambiguity in communication can occur because there is a wide range of terms in use, the same term is used with different meanings and the same circumstances may be described using different terms.

7.2.1 Terms and definitions in generic use

Among others, the following terms have been defined and used by different institutions and agencies:

- *accident* (ARPANSA, 2013a,b; EC, 2013; Committee on Quality of Health Care, 2000; IAEA, 2007b; ASN-SFRO, 2009; IAEA, 2002; NPSF, 2013; Senders, 1994; MEDSTAT, 2002)
- *adverse event* (Committee on Quality of Health Care, 2000; NPSF, 2013; MEDSTAT, 2002; David et al., 2006; AHRQ, 2013a,b; Runciman and Moller, 2001; NCI, 2013; Committee on Data Standards for Patient Safety, 2003; WHO, 2005; 2009; NCI, 2012; CMPA, 2008; Kristensen, 2007; Ford et al., 2012)
- *radiation incident* (RCR, 2008; ARPANSA, 2008)
- *error* (NPSF, 2013; MEDSTAT, 2002; David et al., 2006; AHRQ 2013a,b; Committee on Data Standards for Patient Safety, 2003; WHO 2005; 2009; CMPA, 2008; Kristensen, 2007; Ford et al., 2012; RCR, 2008)
- *event* (IAEA, 2007b; MEDSTAT, 2002; WHO, 2005; 2009; CMPA, 2008)
- *incident (or adverse incident or critical incident)* (ASN-SFRO, 2009; NPSF, 2013; David et al, 2006; Runciman and Moller, 2001; WHO, 2005; 2009; Kristensen, 2007; Ford et al., 2012; RCR, 2008; AHRQ, 2013a,b; Cooke, 2007; IAEA, 2013b; NPSA, 2013)
- *near miss (or close call or potential adverse event)* (IAEA, 2007b; NPSF, 2013; MEDSTAT, 2002; AHRQ, 2013a,b; Committee on Data Standards for Patient Safety, 2003; WHO, 2005; 2009; Kristensen, 2007; Ford et al., 2012; RCR, 2008)
- *preventable adverse event* (WHO, 2005)
- *sentinel event* (NPSF, 2013; MEDSTAT, 2002; AHRQ, 2013a,b; Kristensen, 2007; JCAHO, 2002)
- *significant event* (Pringle, 1995)
- *unintended exposure* (EC, 2013)

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”. Nevertheless, the term accident that is included in the definition is not defined.

- “Unintended exposure means medical exposure that is significantly different from the medical exposure intended for a given purpose”. Nevertheless, the meaning of “significantly different” is not defined.

Finally, the words “*incident*” and “*significant event*” are used in the EU BSS but are not defined.

In Table 7.1 examples of terms and definitions given by different institutions and agencies are presented in detail. In Fig. 7.1, the differences of the concept “near miss”, as used by a few key organizations, are illustrated.

Table 7.1. Examples of terms and definitions for event classification and reporting.

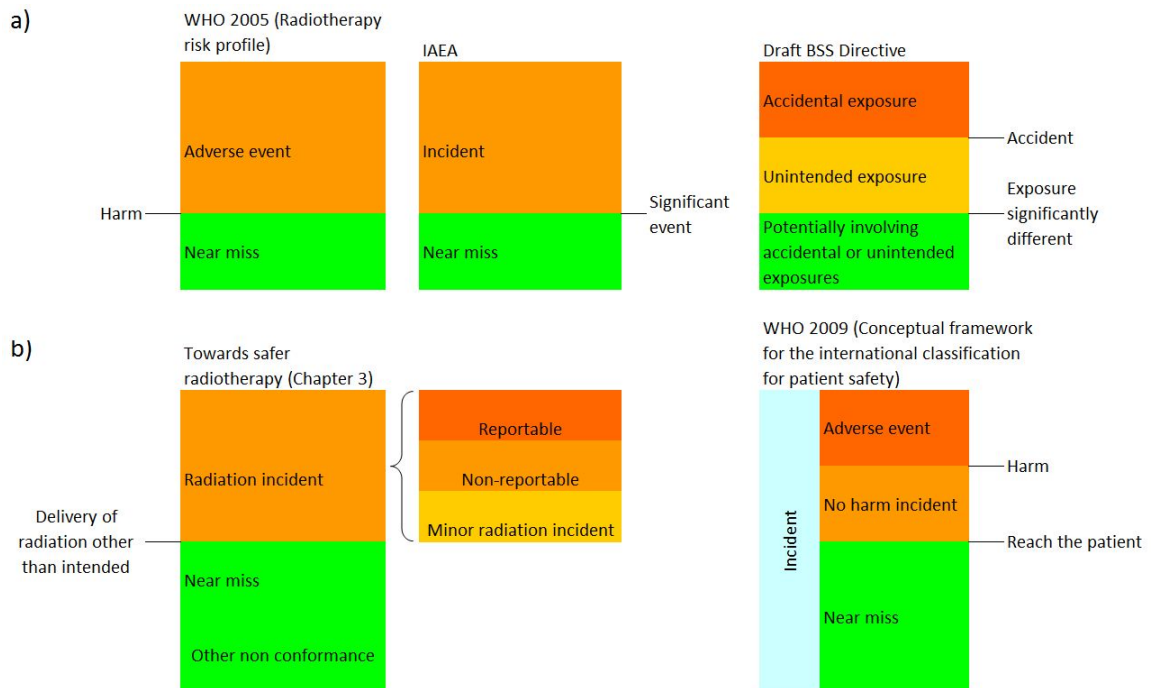
Term	Definition	Defined by
Accident	Any occurrence, associated with controlled apparatus, controlled materials or a controlled facility, which results in, or has the potential to result in, exposure to radiation, such as to cause injury, damage or harm to any person or the environment. This includes occurrences involving or resulting from acts or omissions that were deliberate, reckless or negligent.	ARPANSA, 2013
	Any unintended event, including operating errors, equipment failures and other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection or safety	IAEA, 2012b
	An event that involves damage to a defined system that disrupts the ongoing or future output of the system <ul style="list-style-type: none"> This definition is extracted from a book devoted to accidents not related to the health care, such as Bhopal, Chernobyl, and the Challenger disaster. 	IOM 2000, Perrow, 1984
Accidental exposure	An exposure of individuals, other than emergency workers, as a result of an accident.	EC, 2013 (EU BSS)
Adverse event	An incident that occurs during the process of providing health care and results in sub-optimal clinical outcome including unintended injury or complication leading to disability, death or prolonged hospital stay for the patient.	Cooke et al., 2006 (AHFMR)
	Any injury caused by medical care. <ul style="list-style-type: none"> Identifying something as an adverse event does not imply ‘error’, ‘negligence’, or poor quality care. It simply indicates that an undesirable clinical outcome resulted from some aspect of diagnosis or therapy, not an underlying disease process. 	AHRQ, 2013a,b
	Any event or circumstances leading to unintended harm or suffering which results in admission to hospital, prolonged hospital stay, significant disability at discharge or death.	Runciman and Moller, 2001
	Any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical treatment or procedure that may or may not be considered related to the medical treatment or procedure.	NCI, 2013 (CTCAE)
	An event that results in unintended harm to the patient	IOM, 2004

	by an act of commission or omission rather than by the underlying disease or condition of the patient.	
	An injury resulting from a medical intervention.	IOM, 2000
	An injury related to medical management, in contrast to complications of disease. <ul style="list-style-type: none"> • Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. • Adverse events may be preventable or non-preventable. 	WHO, 2005
	An incident that results in harm to a patient.	WHO, 2009
Event	In the context of the reporting and analysis of events, an event is any occurrence unintended by the operator, including operating error, equipment failure or other mishap, and deliberate action on the part of others, the consequences or potential consequences of which are not negligible from the point of view of protection or safety.	IAEA, 2012c IAEA, 2007b
	Any deviation from usual medical care that causes an injury to the patient or poses a risk of harm. Includes errors, preventable adverse events, and hazards.	WHO, 2005
	Something that happens to or involves a patient.	WHO, 2009
Preventable adverse event	An adverse event caused by an error or other type of systems or equipment failure.	WHO, 2005
Sentinel event	An adverse event in which death or serious harm to a patient has occurred; usually used to refer to events that are not at all expected or acceptable. <ul style="list-style-type: none"> • The choice of the word sentinel reflects the egregiousness of the injury (e.g., amputation of the wrong leg) and the likelihood that investigation of such events will reveal serious problems in current policies or procedures. 	AHRQ, 2013a,b
	An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase, 'or the risk thereof' includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called 'sentinel' because they signal the need for immediate investigation and response.	JCAHO, 2002
Incident (or adverse incident)	An unwanted or unexpected change from a normal system behaviour, which causes or has a potential to cause an adverse effect to persons or equipment.	Cooke et al. , 2006 AHFMR
	A patient safety event that reached the patient, whether or not there was harm.	AHRQ, 2013a
	Any event or circumstance which could have or did harm anyone or results in a complaint, loss or damage.	Runciman and Moller, 2001
	An unwanted or unexpected event or condition that	Cooke et al.,

	<p>represents changes from what you would normally expect.</p> <ul style="list-style-type: none"> • These are changes that cause, or have the potential to cause, an adverse outcome that could affect a patient, a colleague or you; or could impair quality, efficiency or effectiveness of the patient care system. 	2007
	Any unintended event, including operating errors, equipment failures, initiating events, accident precursors, near misses or other mishaps, or unauthorized act, malicious or non-malicious, the consequences or potential consequences of which are not negligible from the point of view of protection or safety.	IAEA, 2012c IAEA, 2007b
	Any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving NHS-funded healthcare.	NPSA, 2013
	A radiotherapy error where the delivery of radiation during a course of radiotherapy is other than that which was intended by the prescribing practitioner as defined in IR(ME)R and which therefore could have resulted, or did result, in unnecessary harm to the patient.	RCR, 2008
	Any deviation from usual medical care that causes an injury to the patient or poses a risk of harm. Includes errors, preventable adverse events, and hazards.	WHO, 2005
	An event or circumstance that could have resulted, or did result, in unnecessary harm to a patient.	WHO, 2009
Correctable radiation incident	A radiation incident that can be compensated for, such that radiobiologically the final outcome is no different in terms of clinical significance from that which was intended.	RCR, 2008
Unintended exposure	Medical exposure that is significantly different from the medical exposure intended for a given purpose.	EC, 2013 (EU BSS)
Error	A failure to complete a planned action as it was intended or a situation in which an incorrect plan is used in an attempt to achieve a given aim.	Cooke et al. , 2006 AHFMR
	<p>An act of commission (doing something wrong) or omission (failing to do the right thing) that leads to an undesirable outcome or significant potential for such an outcome.</p> <ul style="list-style-type: none"> • Errors of omission are more difficult to recognize than errors of commission but likely represent a larger problem. In other words, there are likely many more instances in which the provision of additional diagnostic, therapeutic, or preventive modalities would have improved care than there are instances in which the care provided quite literally should not have been provided. • In many ways, this point echoes the generally agreed-upon view in the health care quality literature that 	AHRQ, 2013a,b

	underuse far exceeds overuse, even though the latter historically received greater attention.	
	The failure of a planned action to be completed as intended (i.e., error of execution) and the use of a wrong plan to achieve an aim (i.e., error of planning). It also includes failure of an unplanned action that should have been completed (omission).	IOM, 2004
	A non-conformance where there is an unintended divergence between a radiotherapy treatment delivered or a radiotherapy process followed and that defined as correct by local protocol. Following an incorrect radiotherapy protocol is also a radiotherapy error.	RCR, 2008
	The failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning). Errors may be errors of commission or omission, and usually reflect deficiencies in the systems of care.	WHO, 2005
	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
Near miss or close call or potential adverse event	An event or situation that did not produce patient injury, but only because of chance. This good fortune might reflect robustness of the patient or a fortuitous, timely intervention.	AHRQ, 2013a,b
	A patient safety event that did not reach the patient.	AHRQ, 2013a
	A potential significant event that could have occurred as the consequence of a sequence of actual occurrences but did not occur owing to the plant conditions prevailing at the time.	IAEA, 2012c IAEA, 2007b
	An error of commission or omission that could have harmed the patient, but serious harm did not occur as a result of chance, prevention or mitigation.	IOM, 2004
	A potential incident that was detected and prevented before treatment delivery. <ul style="list-style-type: none"> • However, mistakes in plans, calculations etc do not constitute near misses if they were detected and corrected as part of the checking procedure before authorising for clinical use. 	RCR, 2008
	A serious error or mishap that has the potential to cause an adverse event but fails to do so because of chance or because it is intercepted. <ul style="list-style-type: none"> • Also called potential adverse event. 	WHO, 2005
	An incident which did not reach the patient.	WHO, 2005

Figure 7.1. Different definitions of near miss: (a) an event that does not produce harm and (b) an event that does not reach the patient



7.2.2 The use of word “accident” in the field of radiotherapy

Many health authorities caution against the use of the term “*accident*”, such as 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), or do not consider this word in the list of preferred terms (AHRQ, 2013a,b; WHO, 2009; Kristensen, 2007). The word “*accident*” is more used in the nuclear or in the radiation protection field (ARPANSA, 2013; IAEA, 2007; ASN-SFRO, 2009; IAEA, 2002) and is defined by the IAEA (IAEA, 2007b; 2002) as:

“Any unintended event, including operating errors, equipment failures or other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection or safety”.

This definition given by the IAEA is basically the same as the definition of *incident* (IAEA, 2007b): “any unintended event, including operating errors, equipment failures, initiating events, accident precursors, near misses or other mishaps, or unauthorized act, malicious or non-malicious, the consequences or potential consequences of which are not negligible from the point of view of protection or safety”. The ARPANSA uses the words *accident* and *incident* interchangeably, and for example gives a definition for the word *accident* (ARPANSA, 2013a) that has to be reported to the Australian Radiation *Incident* Register (ARIR) (ARPANSA, 2013b). In the ASN-SFRO scale (ASN-SFRO, 2009) there is a difference between *accident* and *incident* depending on the consequences of the event and the criteria of severity is based on the clinical consequences defined in the Common Terminology Criteria for *Adverse Events* (CTCAE grades) (NCI, 2013).

So, the word *accident* is sometimes not clearly distinguished from the word *incident* or it is distinguished based in a classification that talks about Adverse Events instead of 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. However, *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. Using the word “*accident*” in radiotherapy, taking into account that this term is not used in other health care areas, does not help to eliminate the bad connotations associated with the use of radiation. The perception of the same event is different depending on the words used.

7.2.3 What are “near misses”?

In the conceptual framework for the international classification for patient safety (WHO, 2009) 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 discernable harm resulted) and *harmful incident* or *adverse event* (incident that results in harm to a patient). Different systems use different definitions of near misses:

a) an event that does not produce patient injury (EC, 2013; IAEA, 2007; AHRQ, 2013a,b; WHO, 2005) or

b) an event that does not reach the patient (WHO, 2009; RCR, 2008; AHRQ, 2013a,b).

In the Guidelines it is proposed to use the second definition and therefore considered that any event that reach the patient should be considered as a minor *event* even though it produces no harm to the patient. From the point of view of safety in the treatments it is very different whether the event has reached the patient or, on the other hand, it has been possible to detect the error before the actual treatment. The possibility of an event to produce injury, or not to produce it, depends on factors related to the safety of treatments (how fast the error is caught for example), treatment factors (radiobiology of the organs or tissues exposed and planned dosage), patient factors (patient condition or individual radiosensitivity), etc.

7.2.4 Definition of terms for patient safety in radiotherapy

Table 7.2 and Figure 7.2 summarizes the definitions proposed in the Guidelines for the field of patient safety in radiotherapy. It is recommended, in particular, not to use term “accident”.

Table 7.2. 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 ⁴ .	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.

Most of the *errors* result in *near misses* and only a few result in *adverse error-events*. Therefore, not all *errors* result in *adverse error-events*.

⁴ WHO defines a side effect as a known effect, other than that primarily intended.

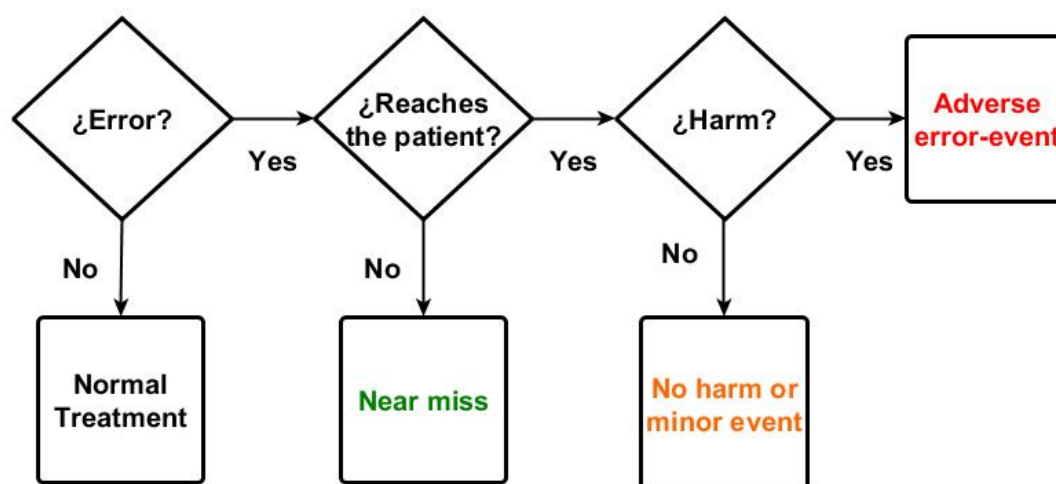


Fig. 7.2. Scheme with the definitions proposed in the Guidelines.

There is a particular concern of using the term “adverse event”. In medicine, this term might include all events leading to *adverse effects* to the patient, i.e. within the general use of adverse event, also the side effects of radiotherapy should be included. *Adverse effects* have to be described by the Radiation Oncologist before starting the treatment. They are usually observed during normal treatment and accepted by an agreement between the patient and the practitioner (informed consent). However, because the side effects of radiotherapy are not included in the concept of proactive risk assessment, reactive analysis of events and the reporting of events, as defined for the Guidelines (See section 4.1 of the Guidelines), only *adverse events caused by errors* will be considered. Therefore, to avoid confusion with the general use of the term “adverse event”, a term “adverse error-event” is defined and used for the purposes of the Guidelines (Table 7.2).

7.2.5 Conclusions

Terminology used in the description of radiotherapy events should be intuitive, non-intimidating and consistent with the terminology used in other healthcare areas. Nevertheless, there is a lot of confusion in the terminology related to patient safety. The confusion and ambiguity is even greater in the field of radiotherapy, where terms widely used in radiation protection of nuclear field are also used in this medical area. This is the case of the word “*accident*”, widely used in the radiation protection of nuclear field, but that is not used and has even been disrecommended in health care areas. There is a negative social perception of everything associated with radiation, and the word “*accident*”, not used in risk management in other healthcare areas, does not help to reduce this feeling.

Common terminology facilitates (or perhaps makes possible) the analysis and comparison of reported data from different sources and is the key to compare the risk of radiotherapy with other health care areas. A proposal of the basic terminology to be used in radiotherapy has been made in the Guidelines (shown here as Table 7.2 and Fig. 7.2).

7.3 Classification

7.3.1 Purpose of classification

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 provides a structure for organizing information and constitutes the first step to get useful data from events. A direct link exists between the type and complexity of the event classification scheme, and the level of analysis that is possible. That is, the analysis plan of events should determine the classification scheme, not the reverse.

Summing up, the purposes of the classification of event reports are: organising reports, facilitating analysis and finally improving safety through this analysis.

Nevertheless the classification of events varies as much as the terminology and there are disparate data fields to categorize reports in different classification systems. This makes it nearly impossible to aggregate or compare data between different reporting systems.

7.3.2 Classification criteria

The classification of events according to the consequences on the patient is commonly used, but some other factors have been used to classify events such as: equipment and stage in the process, error type, detection, personnel involved, equipment failure, causes and contributing factors, preventive and corrective strategies, etc. Radiotherapy is a field so specialized that a general event classification scheme is not completely practical. A radiotherapy-specific development based on general event classification schemes is likely to be more useful.

7.3.2.1 Severity of consequences

Severity of consequences is used as the main classification criterion in many reporting and learning systems. The main reason is that when there are limited resources it is important to direct them to prevent and avoid those events with major effects. A deeper analysis of an event, monitoring of remedial actions and, in general, a prioritization of safety initiatives is normally based on the consequences of the event.

The consequences can be considered together with the expected likelihood that the event occurs again, as for example, in the Severity Assessment Code (SAC) Matrix (United States Veterans Health Administration, 2013). Theoretically, with adequate data, a reporting and learning system can offer valuable information about risk. With a large number of reports, estimations of the probability of recurrence of a specific type of error can be calculated. Analysis of reported outcomes can also produce an estimate of the average severity of harm caused by the event. The Safety Assessment Code of the United States Veterans Health Administration (United States Veterans Health Administration, 2013) uses these two factors, probability of recurrence and severity, to calculate a score for prioritizing events for safety initiatives.

If the management of an event depends on the harm associated with the event, it is necessary to quantify the injury to a patient. Injury to a patient can be of two different types:

- 1) Harm due to overdosing of sensitive normal structures and tissues.
- 2) Harm due to under-dosing the cancer cells and therefore not curing the patient.

Nevertheless, the definition of harm is also a problem, especially so for underdosage. On the one hand, harm depends on patient factors and on the other hand the adverse effects of the event may take time to manifest and, in the meantime, the disease may progress making it hard to separate the harm due to the event and the harm due to the disease. Additionally, severity will likely depend on whether one is considering late or early toxicities. Finally, minor overdoses theoretically may lead to stochastic effects with potential serious effects.

Qualitative descriptors of harm such as light, minor, moderate, high, etc, are often used, although a quantitative measure of severity using “equivalent uniform dose” has also been proposed (Dunscombe et al., 2007). Although assigning severities may be partly based on observation, estimation is always needed. Different number of subjective severity levels are used by different systems, for example in Toward Safer Radiotherapy (RCR, 2008) five levels of severity are proposed, like in the conceptual framework for international classification for patient safety of the WHO (WHO, 2009), the Common Terminology Criteria for Adverse Events (CTCAE) (NCI, 2013) and the acute radiation morbidity scoring criteria of the RTOG (RTOG, 2013). The SAFRON (IAEA, 2012) and ROSIS (ROSI, 2013) systems use 6 levels, as well as the RTOG/EORTC late radiation morbidity scoring schema (RTOG/EORTC, 2013) and the report form of the Tom Baker Cancer Centre in Calgary (Canada) (David et al., 2006). The ASN-SFRO scale (ASN-SFRO, 2009) has 8 levels, the JCAHO has 9 levels (Chang et al., 2005) and the AAPM (Ford et al., 2012) 10 levels for the dosimetric deviation and 11 levels for the medical severity.

The CTCAE of the National Cancer Institute (NCI) (NCI, 2013) is widely accepted throughout the oncology community as the standard classification and severity grading scale for adverse error-events in cancer therapy clinical trials and other oncology settings. The ASN-SFRO scale is based on the CTCAE classification but introduces the number of patients affected as an additional criterion to grade the severity of the event. The goal of the ASN-SFRO scale is to inform the public about events in radiotherapy, having different levels and methods of communication depending on the classification of the event. Based on the ASN-SFRO scale and the INES scale an international project to develop international criteria to communicate the severity of a medical event to the public is currently in progress.

The thresholds at which significant adverse error-events occur depend on factors like the clinical situation, the part of the body treated, individual radiobiological factors, etc. However, in order to track significant exposures, some organizations have defined a specific threshold for reporting, like

- NRC (NRC, 2013a,b)
- AAPM (Purdy et al., 1993) (>25% overdosage)
- 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 (ANSM, 2013) (compliance with the total prescribed dose with a tolerance margin of $\pm 5\%$)
- 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).

The AAPM presented (Ford et al., 2012) two complementary severity scales, a medical severity scale with scores from 0 to 10 and a dosimetric scales with scores from 1 to 10. These

scales are complementary and should be used to assign severity to both actual and near miss events.

It is common in some of the systems to consider the effects of overdosage but not the effects of underdosage. Underdosage can also be catastrophic for the patient, but it is difficult to detect clinically and may only be manifested as poor tumour control (ICRP, 2000). Departments should consider the collection of outcomes assessments (treatment related toxicity and control rates) in databases linked to national or international registries as an essential part of the Quality Assurance Program (ASTRO, 2012). These data may enable checking also for possible underdose errors by comparing the outcomes of the department to others' results, and to monitor variations with the introduction of new techniques, protocols, etc. An adequate follow up of the patients, including evaluations of local control and toxicities should be implemented as a recommended clinical practice.

7.3.2.2 Other systems and criteria of classification

The Safety in Radiation Oncology (**SAFRON**) (IAEA, 2012) counts with a clinical incident severity with 6 levels (see Table 7.3). Additionally, the number of adversely affected patients is also determined to rate the severity of the event and, if relevant, an estimation of the dose deviation from the prescribed dose per fraction in these groups can be provided: 0-5%, 5-10%, 10-20%, 20-50% or >50%.

Table 7.3 Classification of severity in SAFRON

Minor Incident

- Dose variation from prescribed total dose of <5%
- Near miss or unsafe condition which could potentially cause a treatment error
- Patient complaint

Potential Serious Incident

- A near miss that could have been a serious incident

Serious Incident

- Dose variation from prescribed total dose of 5 - 10%
- Radiation dose or medication error causing side effects requiring minor treatment or ongoing monitoring and assessment
- Set up variation > 1cm - no critical structures included

Potential Major Incident

- A near miss that could have been a major incident

Major Incident

- Dose variation from prescribed total dose of 10 - 20%
- Radiation dose or medication error causing side effects requiring major treatment and intervention or hospitalization
- Set up variation that will/could impact on normal tissue (e.g. heart, lung, eyes, kidney etc.)

Critical Incident

- Radiation dose or medication error causing death or disability
- Dose variation from prescribed total dose of >20%
- Completely incorrect volume

SAFRON also uses a classification of process steps in External Beam Radiotherapy to determine to what phase in the process the event is associated and where in the process the event was discovered. There are 3 main phases: non-clinical phase, pre-treatment phase and treatment phase. Each phase is categorized with additional items classified up to 3 levels (see the details of this classification in Table 7.4). The list of process steps is based on the World Health Organization's "Radiotherapy Risk Profile" (WHO, 2008), and the radiotherapy pathway outlined in "Towards Safer Radiotherapy" (UK) (RCR, 2008). If any event does not fit into any of the process steps, it is always possible to use the last item in any group: "Other".

At the time of writing this Complementary Information to the Guidelines, a similar classification for brachytherapy is not available.

Table 7.4. Classification of external beam radiotherapy steps in SAFRON

	<p>Equipment and software specific activities</p> <ul style="list-style-type: none"> • New equipment • Installation • Acceptance tests • Customization and configuration of equipment • Commissioning • Data recording • Preparation of data files for planning computers • Other
	<p>Routine machine QA</p> <ul style="list-style-type: none"> • Daily consistency checks • Planned QA programme checks • Regular preventive maintenance and repair programme • Handover of radiotherapy equipment • Routine radiation safety checks • Other
Non-clinical phase	<p>Other</p> <ul style="list-style-type: none"> • Room design <ul style="list-style-type: none"> ○ Patient safety ○ Staff and public safety ○ Environmental controls ○ Access control ○ Other • Scientific infrastructure <ul style="list-style-type: none"> ○ Implementation of codes of practice for radiation dosimetry ○ Development of dosimetry algorithms for local application ○ Development of treatment planning algorithms for local application ○ Other • Booking process (pre-treatment and treatment) <ul style="list-style-type: none"> ○ Booking of appointment ○ Recording of booked appointment ○ Communication of appointment to patient ○ Other • Processes prior to first appointment <ul style="list-style-type: none"> ○ New patient registration process ○ Old patient location of details ○ Availability of reports/imaging required by protocol for treatment ○ Availability of consent documentation

- Other

Pre-treatment phase

Assessment of patient

- Identification of patient
- Verification of diagnosis/extent/stage
- Other

Decision to treat

- Completion of required information
- Recording of patient ID
- Recording of previous treatment details
- Recording of patient's specific requirements
- Recording of non-standard information/protocol variations
- Other

Prescribing treatment protocol

- Choice of dose
- Choice of modality
- Choice of energy
- Choice of fractionation
- Choice of start date
- Consideration of patient condition/co-morbidities
- Choice of other interventions and their sequencing
- Consent process
- Other

Positioning and immobilization (mould room/workshop activities)

- Confirmation of ID
- Production of immobilization devices
- Production of other accessories/personalized beam shaping device
- Recording of information in patient record
- Instructions to patient
- Other

Simulation, imaging and volume determination

- Confirmation of ID
- Positioning of patient
- Localization of intended volume
- Production of images
- Labelling of images
- Saving and recording of data
- Other

Treatment planning

- Verification of patient ID
- Importing of data from external data sources
- Choice of technique
- Target and organ at risk delineation
- Generation of plan for approval
- Authorization of plan
- Recording of definitive treatment prescription
- Calculation for non-planned treatments
- Other

Treatment phase	Treatment information transfer
	<ul style="list-style-type: none"> • Choice of data entry method (input vs transcription) • Use of correct data • Other
	Pre-treatment patient preparation
	<ul style="list-style-type: none"> • Confirmation of ID • Confirmation of consent • Confirmation of fertility/pregnancy status • Advice on procedure • Other
	Other
	Treatment setup
	<ul style="list-style-type: none"> • Patient setup <ul style="list-style-type: none"> ○ Patient ID process ○ Patient data ID process ○ Explanation/instructions to patient ○ Patient positioning ○ Use of reference marks ○ Other • Treatment unit setup <ul style="list-style-type: none"> ○ Setting of treatment machine parameters ○ Setting of collimator angle ○ Setting of jaw position ○ Setting of asymmetry ○ Setting of couch position/angle ○ Setting of energy ○ Setting of monitor units ○ Other • Use of treatment accessories <ul style="list-style-type: none"> ○ Use of immobilization devices ○ Use of beam shaping devices ○ Use of beam direction aids/applicators ○ Use of compensators ○ Use of wedges ○ Availability of treatment accessories ○ Other
	Treatment delivery
	<ul style="list-style-type: none"> • Treatment • Other
	Treatment verification
	<ul style="list-style-type: none"> • On-set imaging process • Recording of data • Other
	Treatment monitoring
Other	

The information on actions that contributed to (or caused) the event are classified in 4 main groups: Job factors, Systemic/Management factors, Personal factors and Natural factors. Each type of factor is sub-divided in 2 levels of causes, as can be seen from Table 7.5.

Table 7.5. Classification of causes of the event in SAFRON

Job Factors	Standards/Procedures/Practices
	<ul style="list-style-type: none"> • Not developed • Inadequate standard/procedure/practice • Standard/Procedure/Practice not followed • Inadequate communication of procedure • Inadequate assessment of risk • Not implemented
	Materials/Tools/Equipment
Systemic/Management Factors	<ul style="list-style-type: none"> • Availability • Defective • Inadequate maintenance • Inspection • Used incorrectly • Inadequate assessment of materials/tools/equipment for task
	Design
	<ul style="list-style-type: none"> • Inadequate hazard assessment • Inadequate design specification • Design process not followed • Inadequate assessment of ergonomic impact • Inadequate assessment of operational capabilities • Inadequate programming
Systemic/Management Factors	Planning
	<ul style="list-style-type: none"> • Inadequate work planning • Inadequate management of change • Conflicting priorities/planning/programming • Inadequate assessment of needs & risks • Inadequate documentation • Personnel availability
	Communication
	<ul style="list-style-type: none"> • Unclear roles, responsibilities, and accountabilities • Lack of communications • Inadequate direction/information • Misunderstood communications
Systemic/Management Factors	Knowledge/Skills
	<ul style="list-style-type: none"> • Inadequate training/orientation • Training needs not identified

- Lack of coaching
- Failure to recognize hazard
- Inadequate assessment of needs and risks

- Personal Factors**
- Capabilities**
- Physical capabilities (height, strength, weight, etc.)
 - Sensory deficiencies (sight, sound, sense of smell, balance, etc.)
 - Substance sensitivities/allergies
- Judgment**
- Failure to address recognized hazard
 - Conflicting demands/priorities
 - Emotional stress
 - Fatigue
 - Criminal intent
 - Extreme judgment demands
 - Substance abuse

- Natural Factors**
- Fires
 - Flood
 - Earthquake
 - Extreme weather
 - Other

There is also a classification of safety barriers and verifications that failed to identify, identified or might have identified the event (see details in Table 7.6).

Table 7.6. Classification of barriers and verifications important in the identification of event according to SAFRON

What safety barrier/Verification	failed to identify the event?	identified the event?	might have identified it?
Patient ID			
Verification that pretreatment condition have been taken into account			
Verification of imaging data for planning (CT scan, fusion, imaging modality, correct data set)			
Verification reference points			
Physician peer review			
Review of treatment plan			
Independent confirmation of dose			
Time out			
Use of record and verifying system			
Verification of treatment accessories			
Image based position verification			
In vivo dosimetry			
Intra-treatment monitoring			
Regular independent chart checks			
Regular clinic patient assessment			

Post treatment evaluations (evaluation of clinical and process)
Independent review of commissioning
Regular internal audit
Regular external audit
Regular equipment performance verification
Other, please specify

There are also additional criteria of classification, such as a classification of the professional who discovered the event, and a classification to determine how the incident was discovered (Table 7.7).

Table 7.7. Additional criteria of classification in SAFRON

Professional who discovered the event:

- Radiation oncologist (physician)
- Medical physicist
- Radiation therapist/Staff at treatment unit treating patients
- Radiation therapist/Staff at simulator and/or in-house CT
- Staff doing technical maintenance on the radiotherapy equipment
- Others

How was the incident discovered:

- Chart check
- In vivo dosimetry
- Portal imaging
- Clinical review of patient
- Quality control of equipment
- Found at the time of first patient treatment during regular checks
- Found at later stage during patient treatment
- External audit
- Others

The Radiation Oncology Safety Information System (**ROSIS**) (ROSIS, 2013) uses items categorized in four domains:

1. Event/Occurrence
2. Causes/Contributing factors
3. Detection
4. Severity

Each domain has additional items classified in up to 3 levels. This detailed classification system (Table 7.8 and Table 7.9) facilitates analysis. To make easier the filling of the event report form, answer options are suggested as well as dynamic options, where the next step depends on the answer to a previous question. Additionally, there are other questions that have empty text boxes for narrative answers.

The causes/contributing factors of the ROSIS system include the headings (but not the subcategories) of the Eindhoven Classification Model (Van Vuuren et al, 1997) (Technical factors / Organisational factors / Human factors / Patient factors / Other factors), as well as an option of "Don't know". The full Eindhoven Classification Model categories are used in Radiation Oncology in the Netherlands in the **PRISMA-RT system** (PRISMA-RT, 2013), that classifies reports

of “near misses” (near-incidents) based on causes and context variables to analyse the sources of errors.

Table 7.8. Items in the report form of ROSIS. Event/Occurrence

Intended treatment technique	Linac Photons	2-D RT, 2.5D RT, 3-D RT, 4D/Gating, IMRT, Stereotactic, TBI, HBI, Rotational Technique.
	Linac Electrons	TSEI, Skin apposition.
	Orthovoltage	
	Co-60	
	Brachytherapy	HDR, LDR, 2D, 3D, 4D.
	Intraoperative RT	
	Radioisotopes	
	Protons	
	Neutrons	
	Light ions	
	Gammaknife	
	Cyberknife	
	Others	
	Intended treatment site	Abdomen, brain, breast, extremity, HBI, head and neck, pelvis, TBI, thorax, others.
Hardware/Software make and model		
Description of the incident/near incident		
Process classification (activity where the error originates)	Imaging	Identifying the patient. Positioning the patient. Scanning the patient (volume scanned or use of contrast). Marking the patient. Documenting the procedure (patient position, position of origin). Others.
	Simulation	Identifying the patient. Positioning the patient. Localizing the target volume. Defining the RT setup (collimator angle, couch angle, couch height, field size, field name, gantry angle, object in beam path, FSD, treatment isocentre, other). Acquiring the simulation image (collimator angle, couch angle, couch height, field size, gantry angle, object in beam path, FSD, treatment isocentre). Marking the patient (conventional 2D simulation, cone-beam simulation, virtual(CT) simulation, other). Taking a patient contour. Documenting the procedure (patient position, RT set-up, details of any beam modification, patient separation, patient contour). Other.

Planning	<p>Retrieving & Preparing the image for planning (incorrect patient, incorrect image for correct patient, table height, position of origin/zero slice).</p> <p>Localising the target volume.</p> <p>RT set-up (collimator angle, couch angle, couch height, field name, field size, gantry angle, object in beam path, FSD, treatment isocentre).</p> <p>Plan-Miscellaneous (beam energy, beam weight, junction position, normalization point, plan feasibility –space, collision-).</p> <p>Beam modification (bolus, compensator, electron applicator, electron cutout, shielding-MLC, shielding-μMLC, shielding-Pb, TBI screen, wedge).</p> <p>Documenting the procedure (patient position, RT-setup, plan-miscellaneous, beam modification, verification films/DRRs, other).</p> <p>Other.</p>
Prescription	<p>Patient position.</p> <p>Target volume (treatment site –e.g. wrong side-, extent of target volume, other).</p> <p>Dose (fractionation, change not updated, method, total dose, tolerance dose, energy of beam, depth, other).</p> <p>Beam modification (bolus, compensator, electron applicator, electron cutout, shielding-MLC, shielding-μMLC, shielding-Pb, TBI screen, wedge, other).</p> <p>RT set-up (collimator angle, couch angle, couch height, field name, field size, gantry angle, object in beam path, FSD, treatment isocentre, other).</p> <p>Other.</p>
Dose calculation	<p>Calculation method.</p> <p>Arithmetic.</p> <p>Calculation (use of factors, dose per fraction, separation, energy, depth, misread calculator, wrong tables, other).</p> <p>Other.</p>
Treatment preparation	<p>Beam modification (bolus, wedge, compensator, other).</p> <p>Chart –paper/electronic- (patient position, RT set-up, plan-miscellaneous, beam modification, dose, other).</p> <p>Patient positioning device.</p> <p>Verification.</p> <p>Other.</p>
Treatment delivery	<p>Patient identification.</p> <p>Patient positioning (patient orientation relative to machine, positioning aid incorrectly used).</p> <p>RT set-up (collimator angle, couch angle, couch height, field name, field size, gantry angle, object in beam path, SSD/FSD, treatment isocentre).</p> <p>Plan-Miscellaneous (<i>beam energy</i>).</p> <p>Beam modification (bolus, compensator, electron applicator, electron cutout, shielding-MLC, shielding-μMLC, shielding-Pb, TBI screen, wedge).</p> <p>Dose (field was omitted, field was re-treated, fraction was missed, extra fraction was given, dose was incorrect).</p>

Further details on incident

Suggestions for future prevention

Table 7.9. Items in the report form of ROSIS. Causes, Detection and Severity

Causes	Contributing factors	Don't know		
		Human factors		
		Patient factors		
Phase in the process	Detection method	Organisational factors		
		Technical factors		
		Other		
Detection	Staff type	Dose calculation		
		Imaging		
		Planning		
Severity	Was any part of the treatment delivered incorrectly?	Yes	Prescription	
			Simulation	
			Treatment delivery	
Severity	Was any part of the treatment delivered incorrectly?	No	Treatment preparation	
			Chart-check during treatment	
			Chart-check pre-treatment	
Severity	Was any part of the treatment delivered incorrectly?	No	Clinical review of patient	
			External audit	
			Found at later stage during patient treatment	
Severity	Was any part of the treatment delivered incorrectly?	No	Found at time of 1st patient treatment during regular checks	
			In-vivo dosimetry	
			Quality control of equipment	
Severity	Was any part of the treatment delivered incorrectly?	No	Portal imaging	
			Volumetric imaging	
			Other	
Severity	Was any part of the treatment delivered incorrectly?	No	Medical physicist	
			Radiation oncologist	
			Radiation therapist at simulator and/or in-house CT	
Severity	Was any part of the treatment delivered incorrectly?	No	Radiation therapist at treatment unit	
			Staff doing dosimetry	
			Nº of affected patients, staff or visitors	
Severity	Was any part of the treatment delivered incorrectly?	No	How many fractions were delivered incorrectly?/Fractions prescribed?	
			Outcome:	
			None: Event without consequences.	
Severity	Was any part of the treatment delivered incorrectly?	No	Light (grade 1): Event with dosimetric consequences but no expected clinical consequences - No expected symptom.	
			Moderate (grade 2): Event leading to or liable to lead to a moderate impairment of an organ or function - Dose higher than recommended, doses liable to lead to unexpected but moderate complications.	
			High (grade 3): Event leading to a severe impairment of one or more organs or functions - Dose or irradiated volume higher than tolerable doses or volumes.	
Severity	Was any part of the treatment delivered incorrectly?	No	Severe (grade 4): Serious life-threatening event, disabling complication or sequelae - Dose or irradiated volume far higher than tolerable doses or volumes.	
			Death (grade 5): - Dose or irradiated volume far higher than normal leading to fatal complications or sequelae.	
			Comments regarding actual outcome	
Severity	Was any part of the treatment delivered incorrectly?	No	Potential outcome: None, Light (grade 1), Moderate (grade 2), High (grade 3), Severe (grade 4) or Death (grade 5).	
			Comments regarding potential outcome.	
			Potential outcome: None, Light (grade 1), Moderate (grade 2), High (grade 3), Severe (grade 4) or Death (grade 5).	
Severity	Was any part of the treatment delivered incorrectly?	No	Comments regarding potential outcome.	

The WHO (WHO, 2009) has worked in defining, harmonizing and grouping safety concepts into the **International Classification for Patient Safety (ICPS)**. It is not a complete classification yet, but a conceptual framework for an international classification which aims to provide understanding of the world of patient safety and patient concepts to which existing regional and national classifications can relate. The conceptual framework consists of 10 high level classes:

1. Event Type
2. Patient Outcomes
3. Patient Characteristics
4. Event Characteristics
5. Contributing Factors/Hazards
6. Organizational Outcomes
7. Detection
8. Mitigating Factors
9. Ameliorating Actions
10. Actions Taken to Reduce Risk

Each class has hierarchically arranged subdivisions. These concepts may be represented by a number of terms that allow for regional dialects, different languages, different clinical disciplines and/or provider or patient preferences.

The **radiotherapy risk profile of the WHO** (WHO, 2008) used the following items to collect information about radiotherapy errors for the report:

- Country & year
- Description
- Direct cause
- Contributing factors
- Stage at which error happened
- Outcome/impact
- Existing safety measures
- Safety measures proposed.

In **Towards safer radiotherapy** (RCR, 2008), a five-level classification of errors in radiotherapy shown in Fig. 7.3 is presented.

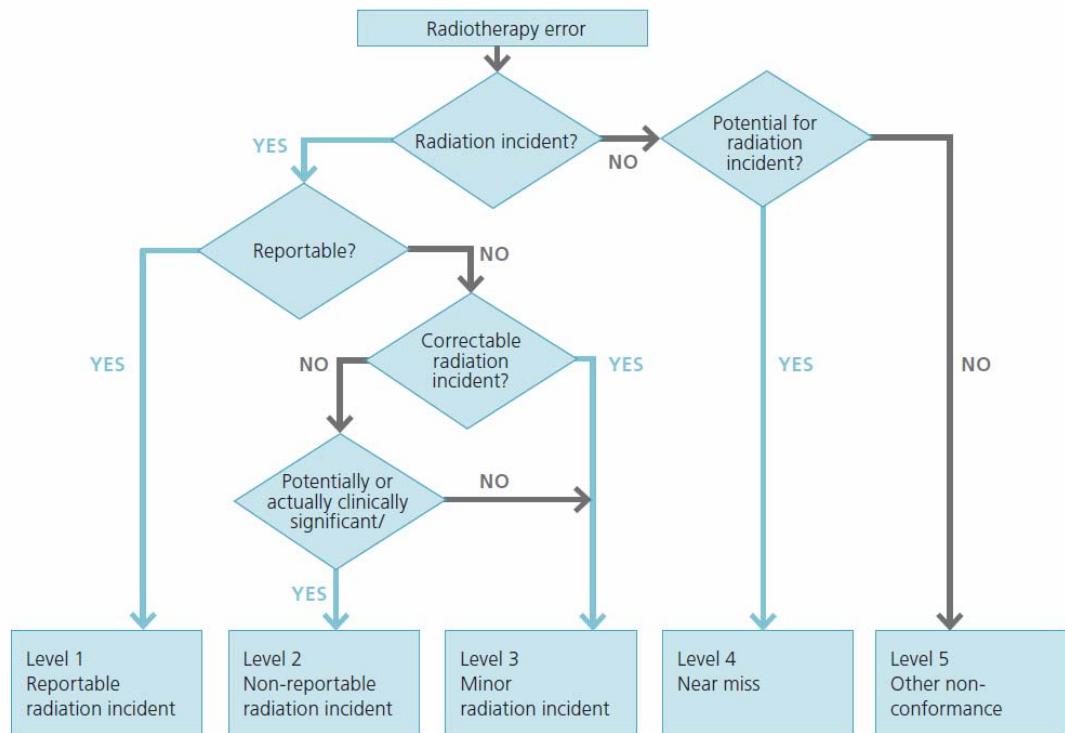


Fig. 7.3. Classification of errors in radiotherapy in “Towards safer radiotherapy” (RCR, 2008).

Table 7.10. Radiotherapy pathway coding. 21 main codes and 196 sub-codes. From “Towards safer radiotherapy” (RCR, 2008)

0. Scientific infrastructure
1. Room Design
2. New equipment
3. Routine Machine QA
4. Referral For treatment
5. Communication of Intent
6. Booking process
7. Processes prior to first appointment
8. Pre-treatment preparation of Patient
9. Mould room/workshop activities
10. Pre-treatment activities – Imaging
11. Pre-treatment planning process
12. Treatment data entry process
13. Treatment unit process
14. On treatment review process
15. Brachytherapy
16. End of treatment process
17. Follow up process
18. Timing
19. Document management
20. Staff management

They also developed a radiotherapy pathway coding system to identify where errors occur (Table 7.10). The RT pathway was broken down into constituent processes and described in terms of 21 codes and 196 sub-codes. This 'Radiotherapy Pathway Coding' describes where the error occurred. In this way each activity involved in the planning and delivery of radiotherapy could be described by a unique alphanumeric code.

This classification was implemented to report radiotherapy events to the National Reporting and Learning System (NRLS) (NPSA, 2013) within the structure of the NHS Commissioning Board, and it is a good example of how reporting events of the field of radiotherapy can be implemented with appropriate codes in the structure of a general healthcare reporting system (NHS, 2010).

The **ASN-ANSM** (ANSM, 2013) counts with one of the few systems with a classification specific for radiotherapy of how the error was detected. The following items are distinguished:

- During treatment: in vivo dosimetry, review of patient files, modification of treatment plan, record and verify, patient set up, control (imaging or visual).
- During patient follow up: during treatment, at the end, after treatment
- Outside treatment process: maintenance, quality checks, event analysis, external alert
- Fortuitous discovery

The classification system in Australian Incident Monitoring System (**AIMS**), developed by the Australian Patient Safety Foundation (see Annex 3), is perhaps the most highly developed of any known general reporting systems, comprising more than a million permutations of terms to describe an incident or adverse error-event. The system has components about contributing factors (environmental, organizational, human, subject of incident, agents), details of the event (type, component, person involved, timing of the incident, timing of detection, detection method, preventability), factors minimizing or aggravating outcomes or consequences, and consequences for the patient and organization. The system is implemented via a series of cascading (hierarchically based questions and answers) and it is designed to deconstruct an event into a very detailed dataset that defines the relationships between the component factors of the classification system. This facilitates subsequent analysis and learning.

The Joint Commission on Accreditation of Healthcare Organizations (**JCAHO**) (JCAHO, 2002) also has a general classification system called Patient Safety Event Taxonomy (PSET) (Chang et al., 2005), not specific of radiotherapy. The classification has five root nodes with additional sub-elements:

- Impact—the outcome or effects of medical errors and system failures, commonly referred to as harm to the patient.
- Type—the implied or visible processes that were faulty or failed.
- Domain—the characteristics of the setting in which an event occurred and the type of individuals involved.
- Cause—the factors and agents that led to an incident.
- Prevention and mitigation—the measures taken or proposed to reduce the incidence and effects of adverse occurrences.

The recommendation (NQF, 2006) is that PSET does not replace existing classification systems that are in use. Rather, the proposal is that existing systems should be mapped to PSET

and should evolve to align with it (as PSET should evolve to incorporate important elements of its classification system that are currently lacking).

The Agency for Healthcare Research and Quality (**AHRQ**) has developed what they call Common Formats (AHRQ, 2013a) for reporting patient safety events although none of them are specific for radiotherapy. The idea is to promote standardization of collected patient safety event information by specifying rules for data collection and submission, what will ensure that data collected have comparable clinical meaning and provide direction to software developers.

In a recent paper (Ford et al., 2012), the **AAPM** provide consensus recommendations for event reporting systems. This consensus includes very detailed process maps for external beam radiotherapy (91 process steps) and brachytherapy (88 process steps) with identification of safety barriers (35 for external beam radiotherapy and 32 for brachytherapy). Additionally, a casualty table and a severity metrics are presented. Key data elements organized into three levels (the reporter's form, the analyst's form and the reponder's or follow-up form) are also defined.

The **Radiation and Nuclear Safety Authority (STUK)** (STUK, 2011) has developed in cooperation with medical physics experts in radiotherapy a system to categorize events for reporting to STUK. There are three categories A, B and C.

- The category A concerns staff members and external persons. All abnormal events in category A has to be reported to STUK.
- Category B concerns patients and has two sub categories:
 - *B1 seriously harmful effect.* The category B1 includes a patient received (harmful event) or could have received (near miss event) an incorrect radiation dose that causes objective medical adversity to the patient in comparison with normal treatment, or may seriously compromise the success prospects of the treatment. When assessing the error, attention must be paid to the overdose applied to the target area or risk organ, because of which the patient could suffer serious complications. The incorrect dose may also be an underdose seriously compromising the prospects for the success of the treatment. The deviation from the planned total dose is more than 25%. This limit applies both to overdoses and underdoses, even though underdoses are often easier to correct. The limit should not be applied as an absolute, but as typical when considering the consequences of the incorrect dose. If an overdose of less than 25% can cause serious complications, then the abnormal event belongs to this class. In B1 all harmful events have to be reported to STUK and also all nearmiss incidents caused by a systematic error (an equipment fault or human error) or an incidental equipment fault.
 - *B2 mildly harmful effect.* The category B2 includes a patient received (harmful event) or could have received (a near miss event) a radiation dose on some area deviating 5–25% from the planned dose. These limits apply to both overdoses and underdoses. An overdose must not cause an increase in the risk of serious complications for the patient which differs clearly from general practice. In B2 all harmful events caused by a systematic error (an equipment fault or human error) have to be reported to STUK as well as nearmiss incidents caused by a systematic equipment fault.
- The category C concerns patients and includes abnormal events not pertaining to radiation safety, such as hazards arising from the mechanical characteristics or electrical safety of equipment. There is no need to report category C events to STUK.

Moreover, all kinds of events have to be reported and discussed according to quality systems in each hospital and this is inspected in every two years.

Ekaette et al. (Ekaette et al., 2006; Dunscombe et al., 2008) define five domains: assessment, prescription, preparation, treatment and follow-up. They only consider events reported in the prescription, preparation and treatment domains, leaving out the other two domains of radiotherapy clinical activity.

They developed a radiotherapy-specific classification system that classifies clinical events into three types:

- Prescription elements.
- Occurrence.
- Source.

In Table 7.11 a summary of this classification is shown.

Table 7.11. Radiotherapy event classification according to Ekaette et. al (Ekaette et al., 2006; Dunscombe et al., 2008)

Event type	Subtype	Comment
Prescription elements	Dose events	Administered dose differed from the prescribed Dose.
	Volume events	The irradiated volume differed from the prescribed volume.
Occurrence	Systematic event	It occurs predictably under similar circumstances because it is a consequence of the system design. It has the potential to affect multiple patients until discovered and corrected.
	Sporadic event	It occurs in an unpredictable fashion despite having suitable equipment, well designed work procedures and adequate quality control. Sporadic events at preparation may affect the whole course of the treatment for a particular patient.
Source	Process events	An activity for the definition and/or execution of a treatment plan for an identifiable patient. For each step in a process, errors may occur during execution of the step or selection, interpretation or transfer of treatment parameters.
	Infrastructure events	All that is set up or established for the treatment of multiple patients. This includes equipment, standard work procedures, protocols and data books. Infrastructure events result from errors during commissioning, maintenance, upgrade or repair of equipment, incomplete development of protocols for dosimetry, etc.

Volume events always imply an incorrect dose to a particular volume. Systematic events are more dangerous because they affect all treatments. However, they are consistent and can be detected more easily with, for example, independent verification by external audits. Sporadic events tend to have less impact, but are more difficult to detect. A sporadic event in an early domain can lead to systematic effects in a subsequent domain (e.g. an error during the treatment preparation that is not caught can lead to severe effects as the error propagates through the delivery domain).

Authors used this classification system for analysing data from the Nuclear Regulatory Commission (NRC) (NRC, 2013b), the Radiation Oncology Safety Information System (ROSIS)

(ROSI, 2013) and the International Atomic Energy Agency (IAEA) (IAEA, 2000) and concluded that:

- All three data sources reported fewer events in the Prescription domain than in the Preparation and Treatment domains.
- Infrastructure events are either very rare or underreported, and are more likely to be systematic than sporadic events.
- In the data sources more sporadic than systematic events can be found. Most sporadic events are also process events.
- There are inconsistencies when analyzing dose and volume events. The NRC database reports more dose than volume events in Preparation, but more volume than dose events in Treatment. The IAEA reports a more dose than volume events in both Preparation and Treatment. The ROSIS database reports more volume than dose events in both Preparation and Treatment.

Thomadsen et al. (Thomadsen et al., 2003) discussed three published error classification applied to brachytherapy and populated them with events reported to the U.S. Nuclear Regulatory Commission and the International Atomic Energy Agency to analyse the causes and the contributing factors of those events. They concluded that events have multiple causes. In many events one or several of the following causes were present: failure to consider human performance in the design of equipment, ineffectual verification procedures, failure to detect the abnormal situation, inappropriate response for the conditions of the event, few time available to take an action, lack of training and procedures for unusual conditions and new procedures or new persons joining a case in the middle.

Portaluri et al (Portaluri et al., 2009; 2010) analysed events in a radiotherapy department by means of human factor analysis and classification system (HFACS; see Section 6.2), a framework adapted from the one originally developed by the US Navy. The system describes four levels of failure:

- Unsafe acts (active failure)
- Preconditions for unsafe acts (latent failure)
- Unsafe supervision (latent failure)
- Organizational influences (latent failure).

7.3.3 General classification system vs Radiotherapy-specific classification system

The complexity associated with radiotherapy may imply a radiotherapy-specific classification system to be completely useful, but this option has also some drawbacks. Radiotherapy should be clearly understood by other professionals and radiotherapeutic errors should be placed in their correct perspective in relation to other clinical disciplines. Existing general classification systems should be used for radiotherapy as much as possible and introduce details and codes specific to the field of radiotherapy, but trying to keep as close as possible to agreed general classification systems. Starting a new specific classification system for radiotherapy from scratch would be probably more expensive, time consuming and probably make radiotherapy more different and misunderstood to the public and other health care areas. 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 and learning system and easily analysed separately whenever it is required.

7.3.4 Classification of causes

The causes of an event should be taken into account in the design of a classification system. A correct analysis of causes is of paramount importance to avoid similar failures. It is important not to fall into oversimplification; both “direct” or active, and latent causes⁵ (latent conditions, contributing factors) (RCR, 2008) should be considered. Events are not simply discrete and instantaneous activities, but processes that may be partially identified and predicted in advance (Caldwell, 2008). The complex set of hidden and unexpected coincidences that cause an event could rarely have been completely foreseen by the people involved. As a result, they are reviewed only in hindsight; however, knowing the outcome of an event influences how we assess past events. Hindsight 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 also misleads a reviewer into simplifying the causes of an adverse error-event, highlighting a unique element as the cause and overlooking multiple (less evident) contributing factors or latent failures. Hindsight bias makes it easy to arrive at a simple solution or to blame an individual, but makes it difficult to determine what really went wrong (latent causes like poor design, procedures, understaffing, lack of effective communication systems, interruptions, fatigue, shift change and other aspects of working environment, inadequate training, bad management decisions, lack of resources, etc, are often not considered). Contributing factors that are remote in space and time are not identified easily, which leads to giving too much weight to directly contributing factors (Wilpert, 2001).

7.3.5 Harmonization of classification systems

Although there are similarities between the different classification schemes developed, there are also differences and inconsistencies. Without harmonization it is not possible to aggregate data from different databases and to compare results.

The current problem is not the lack of definitions or classification systems, the problem is that there are too many. Evolution of the definitions and classification systems will probably improve them and allow the survival of only those best fit to the field of patient safety in general and radiotherapy in particular, what will probably simplify the current reality.

In previous sections, different approaches to general patient safety classification systems and others specific for radiotherapy have been outlined. General structures recommended by international bodies like the conceptual framework of the WHO (WHO, 2009) should be followed as much as possible to get homogeneity. Specific aspects of the radiotherapy field based on previous works like the one made in the ROSIS system (ROSI, 2013) can offer the necessary specificity for radiotherapy.

Harmonization allows also the integration of radiotherapy reporting and learning system in existing general healthcare reporting and learning systems with the incorporation of specific codes to filter data and with an important save of resources.

⁵ Latent causes are also direct causes, but they are more hidden and less evident if a thorough analysis is not made. They can keep unrecognized and have the capacity to be among the root causes of multiple errors.

Classification systems should also be flexible and evolve with the evidence that new events do not fit in existing systems and that there are improvements that facilitate analysis and learning. Standardization should not mean inflexibility and although existing local classification systems should be mapped to internationally recommended systems, in the same way, international systems should evolve to incorporate important elements that are currently lacking. A mechanism to receive comments and questions about the classification proposed should be implemented as a way to solve doubts and to evolve with the suggestions and the discussion with users.

7.3.6 Conclusion

The purposes of classification systems for event reports are: organising reports, facilitating analysis and finally improving safety through this analysis. These objectives may be facilitated adapting existing general classification systems with radiotherapy-specific details.

Efforts to develop common definitions and agreed-on classification systems (specific in some aspects of the radiotherapy process) will facilitate the comparison between reported data to different databases and make the aggregation of data possible. The information will be more rapidly accumulated if common classification systems and definitions are agreed.

Where 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.

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

7.4 Event Reporting and Learning Systems

One component of risk management programs is the development and implementation of reporting and learning system (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) being their *primary purpose to learn* from experience, that is, from previous errors. In fact, to stress this primary purpose of reporting, reporting systems should be called *reporting and learning* systems. These reactive systems not only help in identifying 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 when evaluating the effectiveness of current measures to reduce the risks through the study of tendencies in patient safety, reduce variations among centers and facilitate the sharing of best practices to reduce the patient risk. Therefore, reporting of events is not an endpoint in itself but one step in a method for improving safety of radiotherapy procedures. The complete process of notification and continuous improvement of safety management includes the processes shown in Fig. 7.4, but not necessarily in the order given in the figure.

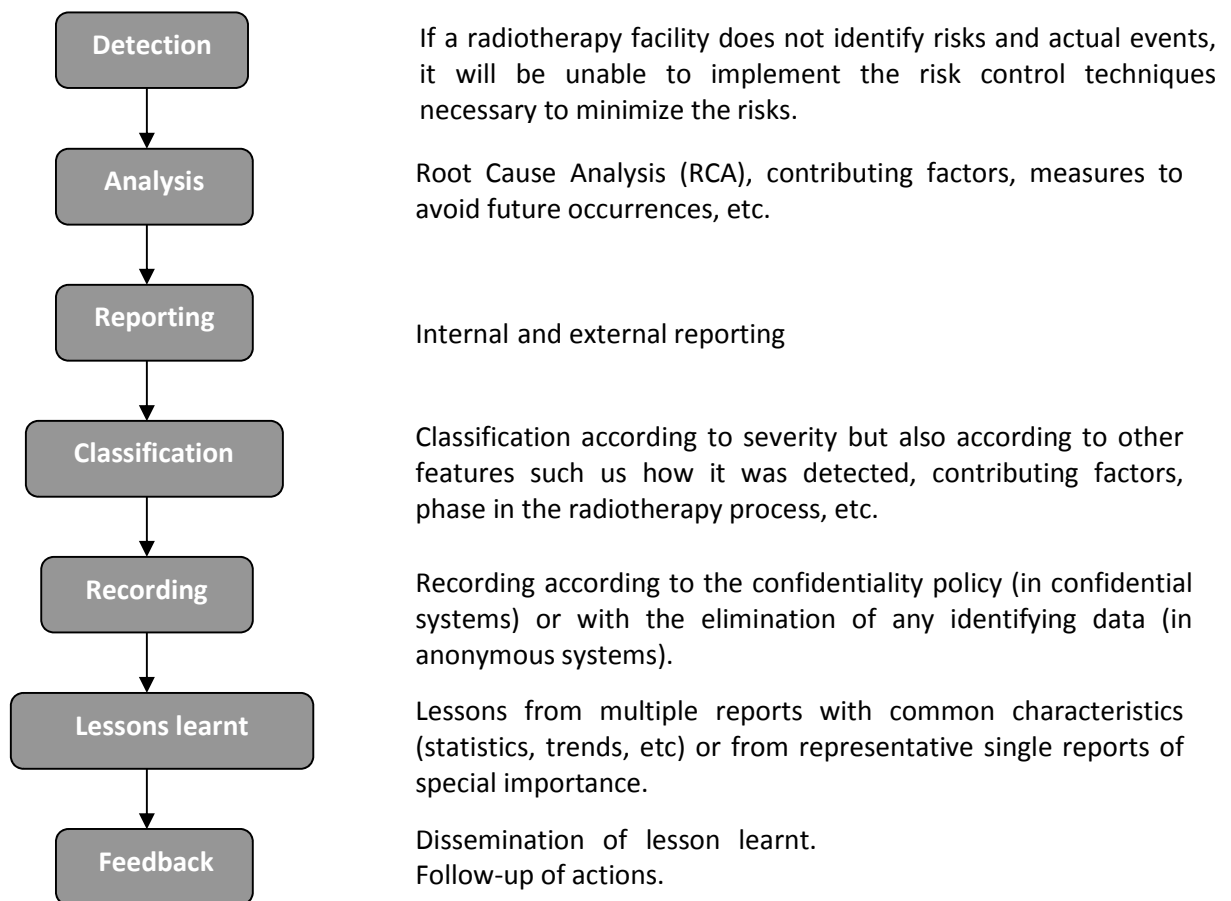


Fig. 7.4. Process of event management and continuous improvement of safety management.

Reporting and learning systems exhibit a great variation in sponsorship, participation, function and feedback. Many countries have a mandatory system, and the 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 at different levels: departmental, institutional, regional, national and international.

The Organization for Economic Co-operation and Development (OECD) produced a report (Millar et al., 2013) on patient-safety with 21 indicators that would best allow the assessment of hospital patient safety. One of these indicators is “medical equipment-related adverse events” because efforts to improve patient safety and quality healthcare delivery must take into account the omnipresence of medical technology. This is especially true in the case of radiotherapy. Manufacturers and software developers of systems integrated in the radiotherapy chain use reports not only because of legal requirements, but also to give notice to their customers of an event that might give rise to a claim.

Event reporting and learning systems raise awareness of harm or potential harm caused in the radiotherapy process. However, the data collected through a reporting and learning system may be perceived as a reliable indicator of the rate of adverse error-events, but in reality, underreporting is probably the norm (Cooke, 2007; Farley et al., 2008; Menendez et al., 2010; Levinson, 2012). Too often professionals do not advise others when a mishap occurs or they do not share the lessons learnt when an internal investigation has been carried out. Underreporting is a significant problem caused mainly by the negative perceptions of event reports and fear to disciplinary proceedings and adverse publicity. Underreporting increases the

likelihood that an error occurs repeatedly (more probability) and that an error go undetected for longer time (more consequences).

Together with reporting and learning systems, there are other complementary methods (WHO, 2005; ASTRO, 2012; NHS, 2000; SIMPATIE, 2013; Farley et al., 2008; Brundage et al., 1999; Olsen et al., 2007) of screening and detecting patient-safety problems such as risk assessment (cf. Section 5), stimulated voluntary reporting (e.g., confidentially contacting clinicians and asking them about the occurrence of critical events), departmental regular quality improvement meetings, random medical records audits, respectable peer institutions, data of routine records to retrospectively identify a possible adverse error-event, chart-based trigger tools, computerised surveillance, screening electronic records such as discharge summaries or patient complaints and claims analysis, safety walk rounds⁶ or real-time surveillance.

7.4.1 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 principles and methods described in Section 6, 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-ROSI system, and/or an international system such as SAFRON and ROSIS (for more details, see Annex 3). This will complement the initial local report when needed, and forward information to external reporting and learning system(s). The primary purpose of reporting is to share the lessons learned with other professionals.

⁶Safety walk round is a process whereby a group of senior leaders visit areas of a health-care organization and ask front-line staff about specific events, contributing factors, near misses, potential problems, and possible solutions

7.4.2 Characteristics of reporting and learning systems

There are distinctive features or options of the reporting and learning systems to play their role in patient risk management. The main features that characterize a reporting and learning system are:

1. Local or external reporting.
2. National or international (geographical area).
3. Language.
4. Specific of radiotherapy or general patient safety reporting and learning system.
5. Voluntary or mandatory.
6. Confidentiality policy.
7. Registration and accessibility.
8. Data entry: web-based or not, difficulty of filling the form.
9. Reportable events.
10. Classification and definitions.
11. Possibility to search information.
12. Number of reports in the database.
13. Feedback: summaries, statistics, recommendations, publications, presentations, courses, meetings, mailing lists, alerts, blogs, etc.
14. Links and publications. Links to additional resources of information on patient safety and reference to publications.
15. Notification managing process.
16. Items in the report form.

Some of these features are discussed more in the following sections. A summary of some existing reporting and learning systems for patient safety in radiotherapy is presented in Annex 3.

7.4.2.1 Local vs external reporting

Reporting and learning systems can be local (used internally by the radiotherapy centre) and external, used for reporting to outside parties. Both systems are complementary and therefore, like some of the existing systems (DPSD, 2013; André et al., 2004; Health, 2013) should be designed to be used internally with the possibility to send data to external databases.

Local reports can be used to design specific prevention activities or barriers, to support departmental review and implementation of risk control activities, for trending analysis (Arnold et al., 2010; Margalit et al., 2011). Some of the local systems (David et al., 2006) also include monitoring of the implementation of remedial actions. External reporting has the benefit of identifying and analyzing events on a larger scale than it is possible with data generated only locally. This allows learning from rarely occurring events and makes it possible that all the radiotherapy departments benefit from the experience of others. Both local and external data from outside databases can be used in the determination of initiating events for proactive assessment of risk.

Voluntary sharing of “lessons learnt” with other radiotherapy units through reporting to external organizations is important to raise awareness and therefore to reduce the risk of future event occurrences in other radiotherapy departments. This helps to develop a safety culture that eventually further reduce the global risk of radiotherapy practices.

Feeding of regional, national or international reporting and learning systems will be more effective if it does not depend on individual professionals but it is a natural consequence of a risk management culture in which reports are routinely used to reduce risks by identifying and analysing events and to address resources and efforts.

The WHO recommends (WHO, 2005) that “the reporting system must be independent of any authority with the power to punish the reporter or organization with a stake in the outcome. Maintaining a ‘firewall’ between the reporting agency and the disciplinary agency in a governmental system can be difficult, but it is essential if trust in reporting is to be maintained”.

7.4.2.2 Radiotherapy specific or general patient safety reporting and learning system

Radiotherapy is somewhere in between the legislation for radiation protection and the legislation for medicine and in fact it is covered by different bodies in different countries. Radiotherapy professionals are used to enormous scrutiny in their practice. In addition to a facility’s peer review and quality assurance committees, there might be audits by the healthcare system and inspections by the regulatory authority.

Events in radiation oncology have specific risks associated. There is an important complexity in the processes involved in delivering the dose because they imply many professionals, processes, complex calculations and systems where failures can occur and can result in errors. This uniqueness and complexity are the main reasons to develop specific systems to report, analyze, detect trends, and ultimately reduce even more the occurrence of events in the field of radiation oncology.

General reporting and learning systems usually have few (if any) reported events specific of the field of radiotherapy. Staff in radiotherapy is less prone to make reports to non-specific radiotherapy reporting and learning systems because they usually do not fit their requirements and expectations. For example, extracting radiotherapy-specific events can be time consuming and labour intensive in general reporting and learning systems because radiotherapy events represent a very small percentage in such databases. A solution is the use of a specific code for radiotherapy as in the case of the NRLS (NPSA, 2013).

Using a general system has the benefit of making use of the established mechanisms and resources for reporting, analyzing and spreading information on patient safety events. This can make the implementation easier and cheaper but to be successful they need codes to filter data and specific features for radiotherapy.

7.4.2.3 Voluntary vs. mandatory

Some reports are generated to comply with legal mandates primarily issued to ensure public accountability, while other information is reported voluntarily as part of collaborative efforts to enhance patient safety. Ideally, the mandatory and voluntary reporting and leaning systems should be combined into a central reporting and learning system to ensure most effective sharing of lessons learnt.

Mandatory reports are usually addressed to events with consequences above a certain magnitude also called “sentinel” events or simply adverse error-events. These events have

sometimes an important media attention (Kirby, 2007; Oved, 2007; Poling, 2007; Bogdanich, 2010a; 2010b) which affect the perceived risk of patients and the public in general.

Mandatory reporting and learning systems are meant to guarantee to the public that serious events are investigated and necessary actions are taken with the affected persons as well as to prevent future recurrence of such events through the dissemination of the lessons learnt. Lessons learnt provide incentive to the administration to improve patient safety and awareness to professionals about latent risks. Nevertheless, the mechanism for elaborating and disseminating information from mandatory systems is usually less developed than in voluntary systems. This, together with the fear to sanctions or penal responsibilities, make health-care organizations perceive reporting in mandatory systems as all risk and no gain (Rosenthal et al., 2001).

Voluntary event reports are subject to selection bias due to the fact that the reporter may have legitimate concerns about the effects of reporting. They capture only a fraction of events and may not reliably identify serious events. The rate of reported sporadic near misses and minor incidents (ROSI, 2013; Ekaette et al., 2007) (reports with no consequences or minor consequences) is likely higher than the actual rate. Sporadic near misses and minor incidents are very valuable to improve a safety environment but we should be conscious that any data collected are a biased sample not representative of the actual spectrum of events. Therefore, data from reporting and learning systems should be interpreted carefully.

7.4.2.4 Confidentiality policy

A major issue for all reporting and learning systems, general or specific, mandatory or voluntary, is confidentiality. Embarrassment feelings and medico-legal aspects make it quite difficult for anyone directly involved in an event to publicly release any information about the event.

A report is confidential when identifying data are kept secret or private. A report is anonymous when the reporter does not reveal its identity. Institutions must have a supportive environment for event reporting that protects the privacy of the reporter. It is not only a matter of getting as many reports as possible, but the recognition that when an unintended threat to patient safety happens we are facing in most of the occasions a symptom of a defective system, not the error of a particular member of staff.

In confidentiality systems:

- Prior to approval, complementary or missing information can be asked from the reporter. The dialog with the reporter is important to obtain elaborated information concerning the circumstances of the event that may have not been available in the initial report. Additionally this dialog gives the opportunity to suggest specific corrective actions and to motivate the reporter through the perception that the system works actively in the reports.
- With the appropriate legal information on the confidentiality policy, the system can be considered as quite safe for the reporter. The reporter should know what would happen if, in case of litigation, identifying data of a report are required.

In anonymous reporting systems:

- The identity of the reporter cannot be revealed even in a legal requirement because the identity is unknown. This way, the system can be regarded as safer in case of litigation.
- In the case that there is missing or ambiguous information or an inappropriate language is used, there is no connection with the reporter, so some reports may be incomplete or simply have to be rejected.

Despite the shortcomings of the anonymous system the trade-off may be in increased participation. Recognizing that several available reporting and learning systems have gaps in data collection, it would seem that this data would still have value and enhance the participation in reporting events.

Accountability systems intend to improve learning from mistakes, but also to satisfy the public interest in making sure that specific known mechanisms for risk reduction are being used and that new hazards are promptly addressed when they are uncovered. These systems cannot be anonymous but confidentiality and constructive response should be seriously considered for encouraging reporting.

Reporting and learning systems may benefit from the advantages of both options, being confidential while additional information may be required from the reporter and specific recommendations are given, and becoming fully anonymized afterwards to publicly spread the information from the event and the lessons learnt.

7.4.2.5 Registration and accessibility

Reporting and learning systems should be easily accessible to all staff. If it is necessary to register and enter into the system with a personal user and password to make a report, the reporter could be identified by the managers of the system, even though the reports are fully anonymised before publication. It would be necessary to state in the policy of the system if, after de-identification and publication of the report, data of the reporter are kept in complementary databases or are completely erased.

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

7.4.2.6 Data entry

While traditional reporting and learning systems were paper based, web-based systems are now the norm, making the reporting and analysis easier and faster. An effective reporting and learning system must be available through the internet in a design that allows information to be recorded accurately, quickly, and in a way that facilitates coding. This will ensure fast and accurate entry and swift retrieval of information. Emphasis should be made on making data entry user-friendly, because cumbersome forms are less likely to be used. It would highly

beneficial also if the reporting and learning system can communicate with one of the international reporting and learning systems such as ROSIS (ROSI, 2013) or SAFRON (IAEA, 2012).

The forms may have defined data elements or free-text reporting, but free-text is harder to analyze, so it is convenient that the forms contain check boxes, option lists and a limited number of fields for narrative descriptions. Some events may not fit completely into existing classification categories of a reporting and learning system or it may be convenient to add additional information that it is not specifically asked for in the report form. Therefore, text boxes are always needed in the report form.

It should be possible to attach files to give a complete description. It should be possible as well to make the data entry in several sessions, not having to start from the beginning if there are missing data or a shortage of time.

Ideally, department reporting and learning systems should be a module in radiotherapy information systems, so that all the information is integrated, making it easy the access and investigation of the event. It is important to ask software developers for this functionality in radiotherapy information systems.

7.4.2.7 Reportable events

The existing reporting systems do not share the same criteria for what constitutes a reportable event. The system should clearly state which kind of events are reportable in a radiotherapy department. In principle, any kind of event that can suppose a suboptimal treatment, taking into account the standards of care, should be reported. Therefore, besides adverse error-events also near-misses and the lost of barriers that could avoid the propagation of a failure, should be reported. Near-misses are of great value because they have no legal implications and there is no interest in hiding them. Additionally, best-practice examples and “success stories” should be collected and disseminated. We learn more from mistakes but we can also learn from successes.

The International Safety Standards (IAEA, 2002) requires that any error, mishap, or unusual occurrence with the potential to cause patient exposure that differs from the one intended should be investigated and that procedures should be developed for learning from events.

Reportable events can be, for example:

- Misdiagnoses or misinterpretation of the diagnosis that results in patient injury or a wrong treatment choice.
- Misidentification of the patient, wrong site or wrong delineation of PTV or organ at risk.
- Wrong technique, treatment or dose prescription.
- Treatment equipment malfunction, failure in the calculations of the TPS, error in the radiotherapy information system or in the transfer of data.
- Wrong acceptance or commissioning of the equipment involved in the radiotherapy treatment chain.
- Wrong acceptance of the plan.
- Wrong positioning of the patient.
- Procedure not performed as in the approved plan of treatment.
- Lack of adequate follow-up.
- Error in the communication between professionals.

- Any situation that could mean skipping steps in the procedures or not having all the barriers active and properly working, such as failure or temporal unavailability of equipment that control the radiotherapy process, overwork, fatigue, intimidation or time pressure.

Another question is what kind of events (significant events) have to be reported to the authorities; this should be decided by the national authorities.

7.4.2.8 Classification and definitions

Many of the forms for reporting events have insufficient contextual information due to a not fully developed classification system. Some free-text fields let the reporter decide about including this important information or not and how it is included. On the other hand, text is difficult to analyse and therefore the number of this kind of fields must be limited.

Efforts to develop common definitions and classification systems specific of the radiotherapy process (but with a common language to other health care reporting and learning systems) will facilitate comparison between data reported to different databases and the possibility of data aggregation.

7.4.2.9 Possibility to search information

Ideally, anonymised databases should be fully open for consultation by professionals, patients or the public in general. There should be a possibility to filter reports and to export them in standard formats so that the information can be freely analyzed and the data from different sources can be easily gathered and studied. It is important to offer the possibility to generate customized reports to support local quality-improvement activities.

The reporting and learning system should ideally have a search engine with key words and filtering for any field or combination of fields. The information that the reporting and learning system should be able to provide directly may be for example:

- Recent reported events.
- Events reported by geographical area.
- Events reported by date or interval of dates.
- Events reported by technique or equipment.
- Events reported by origin (direct cause and contributing factors).
- Events reported by stage in the process.
- Events reported by staff involved.
- Events reported by staff who discovered the error.
- Events reported by staff who acts as reporter.
- Events reported by consequences.
- Events reported by actions taken.
- Events reported since the last visit to the system.

7.4.2.10 Number of reports

Using a minimum number of event reports as a quality index can help in decreasing the problems of underreporting. A facility with more near misses reported does not necessarily mean a facility with more risks, but perhaps a facility more involved in risk analysis of their particular way of working. Changes in the number of event reports are difficult to explain because an increment can be seen as a reflection of an improved reporting culture, while others celebrate a reduction assuming that such a reduction is due to fewer events, that is, to an improved safety.

Analogous situation has been very well developed for evaluation of hospital safety based on a number of in-hospital caused infections. The hospitals that report a relatively low number may in some systems become a subject for screening for not having a reliable detection system in place. Similarly in radiotherapy too few reports as well as too many should trigger questions about safety. However, any serious consideration in this direction require a comparable classification system and definitions on which of the events are subject for reporting.

Event reporting and learning systems typically detect only a small number of the events produced, so even small changes in the reporting practices can produce a large change in the apparent number of real events (Shojania, 2008). A somewhat better indicator may be the value and trend of the number of events above a certain grade of severity divided by the total number of reported events.

The reporting and learning system of the Agency of Healthcare Research and Quality Web Morbidity & Mortality (AHRQ WebM&M) (AHRQ, 2013b) looks for particularly representative or interesting cases to learn lessons from them. The system does not intend to get a large number of cases (in fact only selected cases from those reported are published), nor large statistics, focusing on the educational conclusions that can be extracted from the selected cases. To encourage reporting, besides being an anonymous reporting system that requires no registration, a reward (\$300 paid anonymously through PayPal) is offered for cases of special interest from the patient safety point of view, emphasizing analysis and processes of improvement rather than number or reports. When a case is selected, the editors invite an expert author to write a comment based on the case.

7.4.2.11 Feedback

For a successful reporting and learning system, reports should lead to a constructive response (Benn et al., 2009). 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 systems causes and to propose solutions. While it seems obvious that collecting data and not analysing and widespreading the conclusions is of little value (Fraass, 2008) the most common failure of governmentally run reporting systems is to require reporting but not to provide the resources needed to analyse the reports and to extensively share the information (WHO, 2005). Huge numbers of reports may be collected only to end up in administrative boxes or in computers, especially in mandatory systems. In fact, it is more important to develop a response system than a reporting system. Using different sources of information, not necessarily a reporting and learning system, very useful responses to the patient safety aspects identified can be given.

Some reporting and learning systems issue results of investigations or summary reports (AHRQ, 2013a,b; NPSA, 2013; JCAHO, 2002; ARPANSA, 2013; ROSIS, 2013; ANSM, 2013; PRISMA-RT, 2013; DPSD, 2013; Health, 2013) while others only make the reports themselves available to the public or to registered professionals (NRC, 2013; André et al., 2004). One of the main stated barriers to reporting and a major contribution to perceive reporting as lack of value is no or inadequate feedback (Cooke, 2007; Farley & al., 2008; Evans et al., 2006; NBH, 2007).

The results of individual events and the statistical analysis of reported events databases should be distributed, discussed and conclusions disseminated, so that barriers are implemented to avoid or reduce the likelihood of a future occurrence of the same event. Some reporting and learning systems publish reports in the form of, for example, recommendations, alerts, newsletters or even podcasts or videos. Considerable variations exist in terms of frequency of feedback and level of detail of information outputs. Dissemination in a timely fashion of summaries of reported events is of utmost importance for the educational purpose of the system, to encourage professionals to report events and to develop a safety culture. Best practices established through review of event data should be fed into staff training programmes and to professional accreditation schemes. The confidentiality and anonymity of these reports should be a guarantee for the professionals that the reports will be used only for safety and educational purposes.

The role of the manufacturers in reporting and learning systems should be stressed, noting that a lack of adequate response of manufacturers often undermines the motivation of the healthcare professionals to further reported events.

Information feedback from external reporting and learning systems is insufficient on its own. Action feedback is also necessary through local investigation of events, implementation of remedial actions and follow-up of safety actions. Action feedback has to be made locally although external support of experts can be very helpful. If timely actions are not subsequently undertaken the reports lead to apathy and reluctance to report new events. Therefore, action feedback is not only important for the implementation of barriers that avoid future repetition of an event, but also to encourage future reporting of events by giving a personalised response the reporter.

The only way to check if the feedback is adequate is through monitor of the implementation and measuring effectiveness of recommendations in preventing recurrence.

7.4.2.12 Links, publications

The reporting and learning systems should be a source of information about safety. So, not only information about reports and results of the investigation are important, but also links to web resources and comments on publications related to patient safety are useful to access to additional information. Many reporting and learning systems include this kind of additional information with different levels of detail (AHRQ, 2013a,b; NPSA, 2013; JCAHO, 2002; DPSD, 2013).

7.4.2.13 Notification managing process

A structured mechanism must be working for reviewing local reports, developing action plans and follow-up the implementation of those actions. The data of the event should be peer-

reviewed to explain how it happened, what were the causes and to select those aspects that are prime candidates for improvement.

There is an obligation to act (just recording is useless) through action plans that may include new barriers to avoid future repetition of the event. A follow-up to monitor the correct implementation of the action plans is also recommended. Finally, after de-identification with regard to the patient identity and staff involved, the report should be sent to national or international reporting and learning system like ROSIS (ROSI, 2013) or SAFRON (IAEA, 2012).

7.4.2.14 Items in the report

There are different reporting formats and fields making it difficult to compare and aggregate data from different event reporting databases. Standard fields from agreed classification systems should be used whenever possible.

Although free text is necessary for some fields, the narrative format is difficult to analyse and an initial effort in the design of the event reporting forms can greatly facilitate analysis as well as an easy filling.

7.4.3 How to encourage reporting: Ten golden rules

Reporting should be encouraged by the ten golden rules shown in Table 7.12. In detail, the rules mean the following:

1. Minimizing the punitive aspects and legal actions associated with event reporting⁷. The system should generally not be used to blame someone or as evidence against the employee in a disciplinary procedure, it has to be used as an educational tool to avoid similar kinds of failure (Committee on Quality of Health Care, 2000). The principle is that the cause of adverse events is, in the vast majority of the cases, not bad people, it is bad systems, so the aim should be to avoid blame policy, encouraging staff to report events without fear. An example of protection to promote reporting is the Danish Act on Patient Safety (Danish ACT, 2003) that states that an individual who reports an adverse error-event cannot as a result of that report be subject to investigation or disciplinary action by the employer, the Board of Health, or the Court of Justice.
2. Actively supporting suggestions to improve safety by senior management and local clinical leadership, which is fundamental to motivate the staff to make event reports. All team members must be open to having any member of the team (whether in leadership positions or not) raise concerns about safety as well as suggesting and considering change (ASTRO, 2012). Leadership needs to make all staff feel comfortable to raise concerns about safety without fear of reprimand or reprisal.
3. Using confidential or anonymous systems. Some reporters may fear embarrassment or missuse of the report out of context by the media and others. Confidential or anonymous reporting helps to eliminate the punitive aspects. The preservation of confidentiality

⁷ Vast majority of reports contribute to safer treatment of the patients in the future, thus they should not initiate the action against the staff who reported. Cases where negligence is detected or other severe omittance of duty are extremely rare and should not deteriorate positive aspects of reporting errors by staff members. In these rare cases, which might impose legal investigation a decision should be left to competent authorities taking into account that on a long run safety may only be improved if reporters have feeling that will not be punished in exchange of their participating in reporting systems.

encourages accurate and frequent reporting and it should be kept by all the personnel in the radiotherapy department and in the reporting and learning system. Legal consults should be made to know the best way for keeping confidentiality in case of litigation, and whether there are cases in which confidentiality has to be broken taking into account the national legislation. The reporter has the right to know all the information on the confidentiality of the system and on the legal aspects related to this issue.

4. Setting a minimum number of reports as a quality control index of the department. As near-misses happen in all departments, a minimum level of reporting is a measure of how well the risk management system is endorsed by all members of the department.
5. Educating on a safety culture to make the staff be aware of the importance of reporting to learn from mistakes and to change attitudes when dealing with errors.
6. Showing simplicity. The information required and its structure should be simple. Reporting forms often consist of highly categorized fields using check boxes or drop-down menus that help in classification and in the future search for information. There should be no need to fill the report at once, having the possibility to resume the work without losing any data. Difficulties in the use of the reporting and learning system decrease the likelihood that users submit reports (Farley et al., 2008; NBH, 2007).
7. Having easy access to a reporting and learning system. Web-solutions are the best option for its implementation.
8. Letting risk management analysis and results be visible and available. Feedback through alerts and reports with conclusions, statistics, etc, highlights the usefulness of reporting and contributes to encourage the staff members to report new events. If there is a systematic identification of problems in patient safety and they are addressed without delay, staff will be more motivated to report events.
9. During the investigation it must be clearly shown that the system is being judged, not the person and that with the investigation the intention is to solve a problem not to determine who is guilty.
10. Effectiveness in the implementation of the proposed safety measures to motivate the staff. The analysis of an event is not finished after reporting and recording, not even after making a proposal of corrective actions, but once a survey of those actions determine that they are correctly implemented.

Table 7.12. Ten Golden rules to encourage reporting

1. Respect to the reporter - avoid blame policy
2. Active support of leadership.
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.

7.4.4 Training

Lack of educational objectives regarding reporting and patient safety during undergraduate training concerns not only radiotherapy. As mentioned in the introduction errors occur in some other medical specialities more often and with more severe consequences, while the safety issues associated with these events are also not present in undergraduate and postgraduate training. The radiotherapy is one of the first medical disciplines that highlights the *need* for safety training but not for the reason that radiotherapy would be less safe than other disciplines.

Despite recognizing the need, nowadays, there are little, if any, educational objectives on patient safety in the curricula of most of the professionals involved in the radiotherapy process. Misreporting is in part a consequence of considering reporting associated with potential punitive actions instead of having a pure educational purpose. No matter how good your bike is if you cannot ride and, similarly, no matter how good a reporting and learning system is if there is not a safety culture that contributes to its use. On the other hand, feedback from reporting and learning systems is one important point in developing a safety culture among professionals.

Staff working daily in the radiotherapy unit is in the best position to identify areas of weakness and risk and can offer meaningful and adequate solutions. They only need an educational program to get the knowledge on risk management and the skills for performing an adequate risk assessment, change attitudes to learn from errors and raise awareness of patient-safety issues.

It is important to support proactive learn from anticipated risks and from other's errors, instead of just reactively learn from our own errors. Reporting and learning systems are a fundamental source for learning, for generating teaching materials for the continuous training of professionals (radiation oncologists, medical physicists, dosimetrist, radiation therapist and nursing staff) and to raise awareness. The conclusions from the analysis of events 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. Promotion of a safety culture through training is fundamental.

Training activities should also include communication strategies and guidelines for patient communication. Involvement in an adverse error-event is in many cases a tough experience for patients, their families and healthcare professionals, but a good communication about the adverse error-event could lead to less frustration for all parties. The training of the communication skills and procedures should be addressed mainly to physicians, but also to other professionals who work directly with the patient in the radiotherapy treatment process.

A basic knowledge of the following topics should be included in the education and training curricula of all professions implied in the radiotherapy process:

- Lessons learnt from reported events. Risk awareness.
- Risk assessment. Different methods. Pros and cons. (see Section 5)
- Risk prevention. Moral, legal and economical considerations. Human factors. Human-technology interaction. Techniques for preventing events or their consequences. Main risks in every step of the radiotherapy process. (see Section 8)
- Reporting, analysing and following-up of events in radiotherapy (Sections 6 and 7).

- Individual and collective attitudes and behaviour in the case of adverse error-events (communication with the patient, medical, legal, financial and ethical aspects).

7.4.5 Communication strategies

Sometimes unanticipated outcomes related to the radiotherapy treatment occur. Radiotherapy professionals have ethical, professional and legal obligation to communicate to the patient any adverse error-event. Effective communication about adverse error-events that occurred 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.

As a general approach, a near-miss needs not be disclosed to the patient, except in those cases in which patient awareness can serve to avoid ongoing a similar safety risk along its treatment or in those cases in which an explanation will allay concern and promote trust.

Following an adverse error-event, patients have clinical needs, information needs, and emotional needs. They want (CMPA, 2008; Duclos et al., 2005):

- An acknowledgement that something has happened;
- The facts known about what happened;
- An understanding of the recommended next steps in clinical care – what is going to happen and how the clinical situation can be improved, if this is possible;
- A perception of caring, honesty, concern, responsibility and regret; and
- Assurance that appropriate steps are being taken to prevent a similar occurrence from happening again or to others.

The term error should be avoided in disclosure discussions (CPSI-ICSP, 2011), because it often misrepresents the reasons for the event, masking contributing factors, and because the word carries with it a sense of blame for an individual that is often inappropriate, especially before all the facts are known. The use of the term “error” may be misunderstood to mean the care provided was substandard or negligent in law. Errors may or may not be negligent.

The clinical facts (dosimetric estimation of under or overexposure, clinical effects observed or expected, information to the patient) surrounding an event should always be documented in the medical record. However, in the medical record there should be no mention of the fact that a formal report on the circumstances of the event has been completed or any data of the staff involved in the event. The medical record is not the place for including an event report, regardless of the consequences of the event.

Communication of the event and the results of the analysis to reporting and learning systems is also important as a way of communication with the public. Support from the organization to the health professionals is crucial to make disclosure of the adverse error-event possible and to enable keep learning from adverse error-events. Although accountability does not require release of all information, some form of public disclosure of adverse error-events seems indicated (WHO, 2005; CPSI, 2013). It is important to provide statistical information about events in radiotherapy and the actions taken so that the public know that there is an active track of errors and design of solutions and how is the big picture of errors in radiotherapy in comparison with other health care areas. The results from the analysis of adverse error-events

and large-scale adverse error-events (those affecting many patients) should also be accessible to the public. Institutions should assume that media coverage of large-scale adverse error-events is inevitable (Dudzinski et al., 2010). Responses to the media should demonstrate the institution's commitment to honesty and transparency to build public trust.

7.4.6 Conclusions

Radiation therapy occurrences should be reported and tracked in all radiotherapy units. Successful reporting and learning systems are non-punitive, confidential and have learning through information and action feedback as the main aim.

Today's event report forms vary in content and structure and from organization to organization. There are many countries with mandatory reporting and learning systems for events with severe consequences. However, it is usual that because of the lack of resources of the government agency in charge to investigating or to analysing reports and disseminating results, the opportunity for learning from those events is not fully seized. In addition, the risk of sanctions makes health-care organizations reluctant to report events. On the other hand, voluntary reports are seldom used to report severe events.

The analysis of event reports allows the professionals to evaluate processes, systems, protocols, and practices that give rise to such events. The analysis can be facilitated if department's reporting and learning systems are part of the radiotherapy information management systems. There might be hidden risks that are not the direct cause that triggers an error, but contributes to an environment prone to error. Efforts to mitigate the consequences can then be targeted and focused on areas where events have been frequent or with severe consequences. A proactive risk assessment (Section 5) is always necessary because using reported events as the only source of knowledge on potential problems in radiotherapy can miss some hidden errors that have never being reported.

Reporting and learning systems are one mechanism for reducing risks, but merely collecting data contributes little to patient safety improvement. It is important to create a culture in radiotherapy departments that promotes identifying errors, evaluating the causes and implementing remedial actions. Failure to report errors increases the likelihood that these errors will be repeated. Failure to give an adequate feedback after a report means losing a learning opportunity and increases the likelihood that future errors are not reported. Best practices established through review of event data should be fed into staff training programmes and to professional accreditation schemes.

Organizations must move from asking, "Whose fault was this?" to asking, "Why did this error occur and what can we do to prevent it from occurring again?". The occurrence of an event should trigger completion of a report used locally and sent to other parties, depending on the radiotherapy unit's policy and legal requirements, so that others can avoid similar problems.

Without confidential data, it is easy to fall in the problem of underreporting, and without feedback and an easy access to data it is easy to forget that the purpose of reporting and analyzing event data is the development and implementation of systems and processes to minimize the potential for errors and finally enhancing patient safety. The main limitation of reporting and learning systems are underreporting, biased reporting of the true frequency and type of events, lack of coordinated processes for analyzing and acting upon event reports and feedback of local and external reporting and learning systems.

Although reporting and learning systems are pivotal for improving patient safety, it is important to recognize both their strengths and their weaknesses. There are opportunities to improve existing reporting and learning systems, but there are very good systems nowadays and perhaps the main problem for their implementation and success is the lack of a safety culture among professionals who do not consider reporting and learning systems as an opportunity to learn and improve the safety in radiotherapy. There is not a real consciousness of the risks in a radiotherapy environment and how to address them, there are little, if any, educational objectives on patient safety in the curricula of the professionals and misreporting is in part a consequence of considering reporting associated with potential punitive actions instead of having a pure educational purpose. The inclusion of patient safety contents in the education of health professionals is fundamental to generate a safety culture that contributes to the use of reporting and learning systems. On the other hand, feedback from reporting and learning systems is one important point in developing a safety culture among professionals.

Being aware of the limitations of reporting methods, it is clear that they must be combined with both proactive risk assessment and reactive analysis of events.

7.5 National regulations and recommendations

The results of the ACCIRAD general questionnaire (Annex 4) revealed that, in most of the countries (56 %), no legislative requirements for the *classification* of adverse error-events and near misses were given. However, in about one third (35 %) of the countries such requirement existed and in most cases (22%) these were dedicated to radiotherapy. For the *reporting* of adverse error-events, in most of the countries (69 %), legislative requirements were given but these were in most cases (44 %) part of a more general document. However, in about 25 % of the countries such requirements dedicated to radiotherapy existed. As for reporting of near misses, less than half of the countries (44 %) had legislative requirements, and only 16 % of these were dedicated to radiotherapy.

For the second, detailed questionnaire on the reporting and learning systems, 20 replies were completed, coming from 9 countries and representing 18 different reporting and learning systems (Annex 4). The countries, the systems and organizations providing replies are reproduced in Table 7.13. The results indicate that there is a great variety of the national reporting and learning systems in Europe: from radiotherapy-specific to general health-care or general radiation protection systems, from those where only near misses are reported to those where only adverse error-events are reported, from voluntary to mandatory, with different levels of accessibility, feedback, classification of information and terminology.

Half of the 18 reporting and learning systems are specific for radiotherapy, 7 are general patient safety reporting and learning systems where events of radiotherapy can be reported, and 2 out of 18 are radiation protection reporting systems where data from radiotherapy can be reported. Most of the systems are reported to be voluntary, 4 are mandatory and 3 are both voluntary and mandatory. There are 6 systems that are local, 6 systems that are external (reports are made to a regional, national or international event database) and 6 that are both local and external (local with the possibility of sending information to external systems or external with the possibility of filtering data from an Institution so that the system can also be used locally). The confidentiality policy is also varying from system to system: 9 systems are confidential, 3 are anonymous, 2 are confidential while the analysis is being made and all the data are anonymised afterwards.

Table 7.13. Replies to the detailed questionnaire on event reporting and learning systems.

Country	Provided replies of Event Reporting and Learning Systems
Denmark	DPSD (National Agency for Patients' Rights and Complaints)
Finland	STUK (Radiation and Nuclear Safety Authority, Finland)
France	Vigie-Radiotherapie (ASN-ANSM, Autorité de sûreté Nucléaire-Agence Nationale de Sécurité du Médicament et des produits de santé)
Ireland	IIMS (Incident Information Management System). HSE (Health Service Executive) Starsweb (State Claims Agency)
Italy	Incident Reporting System of Radiotherapy Activity in medical Physics Dpt (Atienza Ospedaliero Universitaria Udine S. Maria della Misericordia) Hospital Incident Reporting System (AOUUD S. Maria della Misericordia)
Luxembourg	CFB (Centre François Baclesse)
Netherlands	PRISMA (Prevention Recovery Information System for Monitoring and Analyses for radiotherapy). Maastrro Clinic
Spain	Radiotherapy reporting system at Hospital Clínico San Carlos Local system for event notification and registration in radiotherapy (Hospital U. Puerta del Mar de Cádiz) ISO 9001:2008 (Institut Català d'Oncologia-Girona) Notification of Deficiencias, CSN (Consejo de Seguridad Nuclear) Registre d'incidències ANTARES (Hospital Sant Pau, Barcelona) ROSIH_HVH (Physics Department - Hospital de la Vall d'Hebron, Barcelona) SINASP (Sistema de Notificación y Aprendizaje para la Seguridad del Paciente), Spanish Ministry of Health
United Kingdom	NRLS (National Reporting and Learning System) Radiotherapy Reporting System. Health Protection Agency (HPA) Datix Web (University College London Hospital) Datix Web (Hull & East Yorkshire NHS Hospitals Trust)

One of the main problem in reporting and learning systems with unknown, few or no reports is that they are not specific for radiotherapy. Specificity for radiotherapy is working in local systems, but also in general patient safety reporting systems with the use of specific codes for radiotherapy. The main stated problems of the systems were underreporting, insufficient support of leaders (government or the head of hospitals or departments), lack of motivation and embarrassment or fear to possible sanctions.

A detailed summary of the results of the questionnaires is shown in Annex 4.

8. Preventive measures/ risk reduction interventions

Besides proactive risk assessments and reactive analysis of events discussed in Sections 5 and 6, and the associated need of good classification and reporting systems discussed in Section 7, 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 of the effectiveness of preventive measures, as presented in the Guidelines, is discussed in more detail here, followed by two important examples on concept which represent, or incorporate, a lot of preventive measures. The two examples (Sections 8.2 and 8.3) are only briefly discussed, because they are well covered by a number of national and international documents, regulations, recommendations or guidelines; some references are included for more information.

8.1 Hierarchy of effectiveness of preventive measures

The existence of a safety culture within the institution is essential to ensure that the 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 the 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 think about new procedures as the way to prevent an error, but when possible, it is better to think about measures that make things simpler and safer "by default" (even though someone makes an error, the system prevents the process from proceeding using an appropriate forcing function). Therefore, there is a hierarchy of the effectiveness of preventive measures that can be summarized as shown in Fig. 8.1, adapted from the Institute for Safe Medication Practices (Hendee, 2011).



Fig. 8.1. Hierarchy of effectiveness of preventive measures.

The different steps are not completely independent and the classification is not strict. Probably examples can be found of preventive measures in one step that, in a particular situation, are more or less effective than the position that they occupy in the figure. The exact order of these items is somewhat situation-dependent and the preventive measures hierarchy should not be considered as a scientific principle but as a useful rule-of-thumb that can help in defining the best strategy to prevent an error.

The higher in this hierarchy, the more powerful a tool is as a preventing measure. The three top items are “system oriented”, that is, they try to fix the system by re-designing it to make it safer. The following 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. People cannot be expected to consistently and effectively compensate for weak systems, so it is better to select preventive measures that are designed to fix the system, not just people, whenever possible.

It is not always feasible to implement measures of the two top items, but when designing strategies of error prevention the categories of effectiveness should be considered in descending order. However, effective error prevention requires a well-rounded approach and it is likely that actions in all levels of the hierarchy are needed.

Interlocks, forcing functions, constraints. Although there is no measure 100% effective, this group counts with the most powerful and effective error prevention tools. They rely on designing processes that make errors virtually impossible or difficult to happen.

Interlocks are used for example in a linear accelerator that prevent operation once a certain dose is reached, if flatness or symmetry is not adequate, if the vault door is open, etc. Very often, these interlocks rely on a double-check of a critical factor with two independent systems (different systems or calculation tools).

A good example on the use of forcing functions is the operation of a HDR equipment: the equipment does not allow the user to make incorrect connections, it does not allow the user to forward the radiation source if the connections are not all right, if the steps are not followed in the right order, if there is an obstruction in the source channel or if there is not enough energy in the battery etc.

Interlocks and forcing functions can be considered constraints but there are also other constraints that can be important for safety. Examples of these constraints are that every HDR source package has to include a calibration certificate to be verified and accepted, or fields or prescriptions in a Record & Verify system cannot be used for treatment if they are not previously approved by the professionals with the appropriate user profile and rights.

Automation and computerization. The use of automation can lessen human fallibility by limiting reliance on memory and concentration. This group often implies the use of computers. Examples include dose calculations in the TPS, default programming parameters for the TC depending on the area to be scanned or the use of networks and DICOM protocols to transfer the important amount of data needed for every treatment from the TPS to the linac.

Automation leads to lower probability of error because manual calculations, transcription of data and, in general, manual tasks are more prone to error. But less probability should not mean less control or blind faith on the results of computers, because then an error could go undetected for long. Computers behave more in a systematic way and systematic errors are perhaps more dangerous, although they are more easy to detect precisely because they are systematic. With computers we can do more and more precise calculations but we tend to blindly rely on their results and much more awareness on this aspect is needed. Further, there can also be fortuitous computer errors, e.g., due to file corruption after a power failure, and also the computer language can be an issue prone to errors. The weakness in Treatment machines, TPS and Radiotherapy Information Systems usually comes from the interaction with humans, through inappropriate commissioning (quality control is of utmost important at this stage as it has been reported in many major events), inappropriate training in the use of the system (training, communication should be reinforced and the case of Épinal could be a good example on this) or the inappropriate use of the software (the case of ION in Panama could be an example). Double and independent checks of software programs are then clearly necessary.

Simplification, standardization. Simplification of processes and standardization are very often not considered or disregarded when considering new preventive measures but these measures are very powerful to improve safety. Very often, new and theoretically safer procedures in radiotherapy are cumbersome or not straightforward and become ineffective. Examples of the use of standardization are the use of standard forms for dose prescription or quality controls, the use of standard prescriptions whenever possible as well as standard names and colours for the volumes or the isodoses, standard names for quality control files, etc. Examples of simplification are the use of bar codes or chips for patient identification, a software design that facilitates entering data or the calibration of ionization chambers in terms of absorbed dose to water instead of in terms of air kerma. A system for scheduling tasks is also a very important tool for simplifying the organization of the system.

Self-verification, double verification, independent verification. The likelihood that the same error is made in a verification is greatly reduced (the likelihood of error would be the product of the likelihood of error in the action and in the verification if the action and the verification are completely independent). Self-verification is the action of self-checking your own actions by repeating them twice or reviewing what you have done or are about to do. Double verification is an individual verification made by another professional. Finally independent verification is a completely different verification made by a different professional and using a different and independent system of verification. Among these redundancies, independent verification is more robust than double verification, which in turn, is more powerful than self-verification. A potential risk of verification tools is the so called “confirmation bias”, that leads one to “see” information that confirms our expectation rather than to see information that contradict our expectation.

There are tools that can help in the verification. Check-lists are for example important tools of verification, although they are useless if they are regarded as paperwork and they are not properly used for verification.

Reminders and automatic warning messages can also be used for verification. Nevertheless, there are factors which can promote or reduce warning effectiveness. Users learn to trust some warnings. Warnings are generally most effective when the user is new to the task and especially when the user already believes that risk exists. On the other hand, warnings are least effective when there is no perceived risk. With experience, the behaviour becomes automatic and the user cease noticing information in warning messages, losing the power for triggering verification. The above can be true especially if the warning message is written in a foreign language, which might be the case in many computerized systems in many countries.

Finally internal audits and external audits are very powerful tools for discovering errors and opportunities for improvement. Very often, audits are the only way to detect some knowledge-based errors (errors due to a lack of knowledge or training), rule based errors (bad rules or procedures, or good procedures not applied or misapplied) and technical errors (such as measuring equipment not working properly).

Although absolutely fundamental, we should be aware that the weakness of verification strategies is that they are designed to detect human error, not to prevent it.

Rules and policies. Very often the first and unique intervention in a system to prevent error is made by designing new rules and policies. Yet establishing new rules and enforcing old policies is often reactive and intended to control people, not necessarily fix the system and, as it has been pointed out previously, they often add system complexity unnecessarily. If a safety procedure causes a significant inconvenience, the user will almost certainly attempt to find a way to circumvent it and to increase efficiency. This is human nature and it is the main weakness of this kind of preventive measures.

While rules and policies are useful and necessary in organizations, they should be used primarily to support more effective error prevention strategies designed to fix the system.

Education and Training. Staff education can be an important error prevention strategy when combined with other strategies that strengthen the safety of the radiotherapy process. Education and training are a must. Lack of education and training may make all other

preventive measures useless or at least, less effective. However, they should not be used as the only strategy for reducing errors.

Education and training do not offer only a way of acquiring knowledge, but also (and perhaps even more important) raise awareness and can correct human performance. Education and training are particularly important in implementing a safety culture in the radiotherapy field.

Information. Information (user manuals, alerts, etc) without an initial and continuous education and training program can be of little use. Information requires an important effort of reading, understanding and practising that not always can be done or not always is prioritized.

Punishment. Punishment is sometimes the first and only preventive measure. The effort should be put in designing error-free systems and trying to get staff involved in a culture of continuous improvement of quality and safety. Punishment can easily make the system less safe by making the system less transparent and prone to hide errors, losing the opportunity to fix them. Therefore, punishment has no value as a preventive measure, and it should only be used in the very extremely unusual exceptions where malicious acts are proven. Even in those cases, a very important effort should be made to not affect negatively in the rest of the system.

There are two possible responses that organization, authorities and managers might make to the realities of human nature. Safety can be planned based on what people should do, paying close attention 100% of the time, consciously considering every risk, noticing and complying with every procedure, warning and piece of information provided. The problem is that there is often cognitive overload, high workload, multitasking, interruptions, environments that make concentration difficult, miscommunications and increasing complexity in technology. This response of organizations, authorities and managers allows the use of quite cheap preventive measures (basically warnings and procedures), which also shifts blame to the user when they are not followed.

Conversely, organizations, authorities and managers can promote a safety culture based on acknowledging that radiotherapy is a complex system and human nature is fallible. As a first option, preventive measures should not rely, whenever possible, on user behaviour and try to promote a design of inherently safer systems. The hierarchy of preventive measures exposed here can help in prioritizing the strategy of action against errors.

8.2 Quality management: quality assurance and quality control programs

Quality management is one of the basic concepts for preventive measures. It includes several components as tools: quality planning, quality assurance, quality control, quality improvement, quality audit (see also Fig. 4.1 of the Guidelines). In the following, only quality assurance and quality control are briefly discussed. Further, the focus is on equipment related QA, while also patient related QA is an important part of quality management in radiotherapy.

By definition (ISO, 2000), quality assurance means all those planned and systematic actions necessary to provide adequate confidence that a structure, system, component or procedure will perform satisfactorily complying with agreed standards. Quality control is part of quality assurance. It covers monitoring, evaluation and maintenance at required levels of all characteristics of equipment performance that can be defined, measured, and controlled. Appropriate quality assurance programmes including quality control measures and patient dose assessments have to be implemented by the holder of the radiological installation.

Quality assurance in radiotherapy is all procedures that ensure consistency of the medical prescription, and safe fulfillment of that radiotherapy related prescription. Written instructions should cover all stages of the radiotherapy process, as the planning and implementation of treatment requires many kinds of technically demanding apparatus and procedures, and effective collaboration by several vocational groups. The written instructions should also include practical directions for responding to and preventing adverse error-events.

A quality assurance programme shall include the principles for preventing errors and mishaps which may cause unintended radiation doses. Therapy equipment quality assurance programmes shall therefore include the inspection of the operating conditions of the warning and safety devices that are associated with the therapy equipment and the related premises.

Technical quality control begins from the acceptance testing and continues according to a written quality control programme. Before taking therapy equipment into use, the responsible medical physicist must measure or verify the characteristics of the therapy equipment that are required as input data for the dose planning system.

The quality control programme for radiotherapy equipment should specify:

- inspections and measurements to be performed and the purpose thereof
- methods of inspection and measurement
- apparatus and instruments to be used in inspections and measurements
- intervals for performing inspections and measurements
- action level (tolerance criteria) for inspection and measurement results
- measures to be taken when the approval criteria are exceeded.

The persons performing inspections and measurements (vocational group) should be specified and trained. The inspection and measurement methods should be described in sufficient detail for the inspections and measurements to be repeated on the basis of the quality assurance programme in the manner intended by the person who prepared the programme. The medical physicist has the major responsibility for performing or supervising dose measurements and other performance tests specified in a quality assurance program.

To ensure the quality of the treatment planning system, the system should be tested before any new system or modification is introduced and at regular intervals in order to detect any unintended or random changes in the apparatus or software. The purpose of commissioning testing is to ensure that the system calculates the dose and the dose distribution correctly in relation to the criteria set by the user, based on international recommendation. This is done by comparing the dose calculation result from the system to the best measurement and calculation data available. The quality assurance of treatment planning should include the inspection of each individual treatment plan using a procedure optimally independent of the treatment planning system (e.g. independent monitor unit calculation). The correct targeting of therapy should be ensured for every patient.

Self assessments, internal and external audits are part of quality assurance. A dosimetry audit is an essential part of these audits.

8.3 Clinical audit

By its definition (EC, 2009), for the medical use of radiation, clinical audit is a systematic examination or review of medical radiological procedures (radiological here including also radiotherapy). It seeks to improve the quality and the outcome of patient care through structured review whereby radiological practices, procedures, and results are examined against agreed standards for good medical radiological procedures. Modifications of the practices are implemented where indicated and new standards applied if necessary.

According to the EC guidelines (EC, 2009), clinical audit should

- Be a multi-disciplinary, multi-professional activity.
- Follow general accepted rules and standards which are based on international, national or local legal regulations, or on guidelines developed by international, national or local medical and clinical professional societies.
- Be a systematic and continuing activity, whereby the recommendations given in audit reports are implemented.
- Be carried out by auditors with extensive knowledge and experience of the radiological practices to be audited.
- Combine both internal and external assessments in order to achieve optimal outcomes. The internal and external audits should supplement each other.
- Aim at evaluating the current status of the radiological unit with respect to its radiological services and to identify areas for future improvement.
- NOT be research, quality system audit, accreditation or regulatory activity.

The EC guidelines also set some priorities of clinical auditing. In general, the structure, process and outcome should be audited, and the parts of the *process* which are among the list of priorities include:

- Procedures for dose delivery to the patient in radiotherapy (beam calibrations, accuracy of dosimetry and treatment planning)
- Quality assurance and quality control programmes
- Emergency procedures for incidents in use of radiation
- Reliability of information transfer systems

It is evident from these priorities that clinical audit should be a tool to promote good practices in several preventive measures, and subsequently also in risk assessments and reporting and analysis of adverse error-events and near misses in radiotherapy. Whether internal or external, clinical audit could address the local arrangements relevant to risk management, e.g. by using the present guidelines and the associated knowledge as the criteria of good practice for the audit. In particular, the audit could improve the decision making that will have flow-on effects throughout the treatment process.

The EC guidelines (EC, 2009) provide a general framework in order to establish sustainable national systems of clinical auditing. There are a few other international or national guidelines developed for clinical audits, e.g. the IAEA has developed comprehensive audit programmes under the term of clinical audit (IAEA, 2007a).

There are also several reports of clinical audits, indicating their benefit on point of view of preventive measures and risk management. An external audit of an oncology practice in Asia was able to identify 'areas of need' in terms of gaps in knowledge and skills of the staff involved (WHO, 2008; Shakespeare et al., 2006). The study found that about half (52%) of the patients audited received suboptimal radiation treatment, potentially resulting in compromised

cure/palliation or serious morbidity. Inadequate knowledge and skills and high workload of the radiation oncology staff were described as the reasons for poor quality of service. In another institution, real time audits of 3052 treatment plans for a period of eight years provided important direct and indirect patient benefits that went beyond normal physical QA procedures, and addressed issues related to physician prescriptions (Brundage et al., 1999). Another example is frequent audit and regular peer review of the specialist's protocols, processes, procedures and personnel involved (Shakespeare et al., 2004), which could lead to behavioural modification preventing radiotherapy errors in decision-making and poor, or incorrect, work practice. Shakespeare (Shakespeare et al., 2006) observed that their audit acted as an informal learning needs assessment for the radiation oncology staff of the audited centre.

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ANNEX 1. Safety issues in European medical device directive

ER	Description
11. Protection against radiation 11.1 <i>General</i>	
11.1.1	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.
11.2 Intended radiation	
11.2.1	Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.
11.3 Unintended radiation	
11.3.1	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible.
11.4 Instructions	
11.4.1	The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.
11.5 Ionizing radiation	
11.5.1	Devices intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended use.
11.5.3	Devices emitting ionizing radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of radiation
12. Requirements for medical devices connected to or equipped with an energy source 12.8 Protection against the risks posed to the patient by energy supplies or substances	
12.8.1	Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.
12.8.2	Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger. Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.
12.9	The function of the controls and indicators must be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate,

	the patient.
13. Information supplied by the manufacturer	
13.6 Where appropriate, the instructions for use must contain the following particulars:	
13.6.b	the performances referred to in Section 3 and any undesirable side-effects;
13.6.c	if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination.
13.6.d	all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times;
13.6.j	In the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.
13.6.k	Precautions to be taken in the event of changes in the performance of the device.

ANNEX 2. Bibliography on examples on risk management

A2.1 Proactive risk assessment

A2.1.1 FMECA

Application guide

ASN guide n°4 (ASN, 2008b). Guide of the French National Authority for Health (HAS). "Improvement in health care practices and safety: Patient safety. Implementing risk management for treatment in health care facilities – from concepts to practice." March 2012 (Support Sheet 26).

Examples

1. Marie Claire Cantone et al., Application of failure mode and effects analysis to treatment planning in scanned proton beam radiotherapy - Radiotherapy and Oncology 2013, 8:127 - doi:10.1186/1748-717X-8-127
2. Agnieszka Srobała - Risk assessment methods as one of the elements of the implementation of new technologies in radiation therapy – ACCIRAD workshop <http://accirad-workshop.eu/page/27/>
3. Applying failure mode effects and criticality analysis in radiotherapy: Lessons learned and perspectives of enhancement. Marta Scorsetti, Chiara Signori, Paola Lattuada, Gaetano Urso, Mario Bignardi, Pierina Navarra, Simona Castiglioni, Pietro Mancosu, Paolo Trucco - Radiotherapy and Oncology 94 (2010) 367–374
4. Application of failure mode and effects analysis to intraoperative radiation therapy using mobile electron linear accelerator. Ciocca M, Cantone MC, Veronese I, Cattani F, Pedrolì G, Molinelli S, Vitolo V, Orecchia R. Int J Radiat Oncol Biol Phys. 2012 Feb 1;82(2)
5. Analyse des risques a priori du processus de prise en charge des patients en radiothérapie : exemple d'utilisation de la méthode AMDEC C.Meyrieux, R.Garcia, N.Pourel, A.Mège, V.Bodez Cancer/Radiotherapie 16(2012) 613-618

Links

<http://www.asn.fr/index.php/S-informer/Publications/Guides-pour-les-professionnels/Activites-medicales/Guide-de-l-ASN-n-4-Guide-d-auto-evaluation-des-risques-encourus-par-les-patients-en-radiotherapie-externe>

<http://accirad-workshop.eu/page/27/>

http://www.qualitytrainingportal.com/resources/fmea/fmea_process.htm

http://www.qualitytrainingportal.com/resources/fmea/fmea_process.htm

<http://chapter.aapm.org/seaapm/meetings/2011/S1-T3-Mutic-FMEA.pdf>

<http://www.treatsafely.org/index.php>

<http://www.waqualitycenter.org/Portals/0/Tools%20to%20Use/Collecting%20Data%20and%20Information/HFMEA%20Steps.pdf>

https://www.rcr.ac.uk/docs/oncology/pdf/Towards_saferRT_final.pdf

A2.1.2 PRA

Examples

1. Alain Marre, Sylvie Biver, Mihaela Baies, Christophe Aventin - Gestion des risques en radiothérapie : intérêt d'une APR dans une démarche qualité. Expérience du service radiothérapie du centre hospitalier Jacques Puel de Rodez (France) – Techniques hospitalières 724 – 2010 - 55-61
2. Mireille Bulot - Improving risk analysis in radiotherapy using a scenario approach – ACCIRAD Workshop

Links

<http://accirad-workshop.eu/page/27/>

A2.1.3 FTA

Application guide

IEC standard 61025 (1990): Fault tree analysis (FTA).

Examples

1. Edidiong Ekaette, Robert C.Lee, David L.Cooke, Sandra Iftody and Peter Craighed (Canada) "Probability Fault Tree Analysis of a radiation Treatment system" - Risk Anal. 2007 Dec;27(6):1395-410.
2. T. Pawlicki, P Dunscombe, AJ Mundt, P Scalliet - Quality and Safety in Radiotherapy – Imaging in medical imaging and therapy, William R.Hendee, Series Editor (chapter 24).CRC Press 2011

A2.1.4 ETA

Examples

1. Maria Luisa Ramirez Vera, "Méthodes d'analyse de risque appliquée à la radiothérapie". Conférence internationale de radiothérapie - Versailles 2009 – <http://www.conference-radiotherapy-asn.com>

A2.1.5 Risk matrix

Application guide

Prevention of accidental exposure in radiotherapy: the risk matrix approach. J.J. Vilaragut, C. Duménigo, J.M. Delgado, J. Morales, J.D. McDonnell, R. Ferro, P. Ortiz López, M.L. Ramírez, A. Pérez Mulas, S. Papadopulos, M. Gonçalves, R. López Morones, C. Sánchez Cayuela, A. Cascajo Castresana, F. Somoano, C. Álvarez, A. Guillén, M. Rodríguez, P.P. Pereira, and A. Nader - Health Physics February 2013, Volume 104, Number 2

Examples

1. IAEA-TECDOC-1685/S: Aplicacion del Metodo de Analisis de Matriz de Riesgo a la Radioterapia -2012.

2. Carlos Prieto Martin - Discovering our risks. Application of the risk matrix in the Radiotherapy Service of Hospital Clinico San Carlos. ACCIRAD Workshop

Links

<http://accirad-workshop.eu/page/27/>
<http://www.foroiberam.org/web/index.php>
[http://www.foroiberam.org/web/UserFiles/File/MMaster_Matriz_de_riesgo_radioterapia_Volumen%201_version%205%20con%20riesgo%20medio%20\(3\).pdf](http://www.foroiberam.org/web/UserFiles/File/MMaster_Matriz_de_riesgo_radioterapia_Volumen%201_version%205%20con%20riesgo%20medio%20(3).pdf)
[http://www.foroiberam.org/web/UserFiles/File/MMaster_Matriz_de_riesgo_radioterapia_VOLUMEN_2_final_2_\(2\).pdf](http://www.foroiberam.org/web/UserFiles/File/MMaster_Matriz_de_riesgo_radioterapia_VOLUMEN_2_final_2_(2).pdf) xxx

A2.1.6 Process analysis including critical points

Application guide

Guide of the French National Authority for Health (HAS). "Improvement in health care practices and safety: Patient safety. Implementing risk management for treatment in health care facilities – from concepts to practice." March 2012 (Support Sheet 25)).

Links

http://www.has-sante.fr/portail/upload/docs/application/pdf/2012-04/okbat_guide_gdr_03_04_12.pdf

A2.2 Reactive analysis of events

A2.2.1 RCA (5Whys, Ishikawa Diagram)

Application guide

Vincent, C., Taylor-Adams, S., Chapman, EJ et al. "How to investigate and analyse clinical incidents: the clinical risk unit and association for litigation and risk management protocol," British Medical Journal. 320:777-781.

Links

[http://www.jointcommission.org/Framework for Conducting a Root Cause Analysis and Action Plan/](http://www.jointcommission.org/Framework%20for%20Conducting%20a%20Root%20Cause%20Analysis%20and%20Action%20Plan/)

A2.2.2 ALARM

Application guide

Guide of the French National Authority for Health (HAS). "Improvement in health care practices and safety: Patient safety. Implementing risk management for treatment in health care facilities – from concepts to practice." March 2012 (Support Sheet 23)).

Examples

1. M.Raux, M.Dupont, J.M.Devys "Systematic analysis of two consecutive anaesthesia incidents using the ALARM method", Ann Fr Anesth Reanim 26(9) (2007): 805-9.

Links

http://www.has-sante.fr/portail/upload/docs/application/pdf/2012-04/okbat_guide_gdr_03_04_12.pdf

A2.2.3 CTA

Application guide

Guide of the French National Authority for Health (HAS). "Improvement in health care practices and safety: Patient safety. Implementing risk management for treatment in health care facilities – from concepts to practice." March 2012 (Support Sheet 24).

Links

http://www.has-sante.fr/portail/upload/docs/application/pdf/2012-04/okbat_guide_gdr_03_04_12.pdf

A2.2.4 ORION

Application guide

French public national mission for hospital audit and expertise (MeaH), "Improving safety in healthcare organisations – using operating experience feedback". February 2008

Examples

1. F. Debouck, É. Rieger, H. Petit, G. Noël, L. Ravinet. "Orion method: simple and effective systemic analysis of clinical events and precursors occurring in hospital medical practice in Cancer/Radiothérapie (16:3), pp. 201-208.

A2.2.5 HFACS

Application guide

Diller T1, Helmrich G, Dunning S, Cox S, Buchanan A, Shappell S. The Human Factors Analysis and Classification System—HFACS - Am J Med Qual. 2014 May-Jun;29(3):181-90. doi: 10.1177/1062860613491623

Examples

1. Portaluri M, Fucilli FI, Bambace S, Castagna R, De Luca MC, Pili G, Didonna V, Tramacere F, Francavilla MC, Leone A, Leo MG. Incidents analysis in radiation therapy: application of the human factors analysis and classification system - Ann Ist Super Sanita. 2009;45(2):128-33.
2. G. Sands, W. van der Putten, P.O Connor, E.Fallon, and M.Galiere, "Using the HFACS to Examine Software-Human Interface Incidents in Radiotherapy"- ACCIRAD Workshop

Links

<http://hfacs.com/about-hfacs-framework>

ANNEX 3. Existing reporting and learning systems for patient safety in radiotherapy

A3.1 Introduction

A representative sampling of organizations with reporting and learning systems was studied including the AHRQ WebM&M, AIMS, ARIR, DPSD, JCAHO, NRC, NRLS, ROSIS, Swiss ROSIS and SAFRON reporting and learning systems. This illustrates the broad variation in how reporting and learning systems have played their role in patient risk management.

In the reporting and learning systems reviewed, several characteristics were analyzed:

1. Local or external reporting and learning system.
2. Geographical range.
3. Language.
4. Specific of radiotherapy or general patient safety reporting and learning system.
5. Voluntary or mandatory.
6. Confidentiality policy.
7. Registration and accessibility.
8. Data entry: web-based or not, difficulty of filling the form.
9. Reportable events.
10. Classification and definitions.
11. Possibility to search information.
12. Number of reports in the database.
13. Feedback: summaries, statistics, recommendations, publications, presentations, courses, meetings, mailing lists, alerts, blogs, etc.
14. Links, publications. Links to additional resources of information on patient safety and reference to publications.
15. Notification managing process.
16. Items in the report.

A3.2 Results

The Agency of Healthcare Research and Quality Web Morbidity & Mortality (**AHRQ WebM&M**) (Tables A3.1 and A3.2) (<http://www.webmm.ahrq.gov/>) is part of the U.S. Department of Health & Human Services.

Users of AHRQ WebM&M may anonymously submit through the web cases that highlight medical errors or other patient safety/quality issues. What is interesting about this system is that it looks for particularly representative or interesting cases to learn lessons from them. The system does not intend to get a large number of cases (in fact only selected cases from those reported are published), nor large statistics, focusing on the educational conclusions that can be extracted from the selected cases. To encourage reporting, besides being an anonymous reporting and learning system that requires no registration, a reward is offered for cases of special interest from the patient safety point of view, emphasizing analysis and processes of improvement rather than number of reports.

Submitters of cases that are selected because they are interesting or have an important educational value, receive \$300 paid anonymously through PayPal. When a case is selected, the editors invite an expert author to write a comment based on the case.

There are selected cases dealing with general safety aspects of patient care that can be applied to radiotherapy such as patient identification, communication slips, double dosing, wrong site, etc.

Table A3.1. Main features of the AHRQ WebM&M reporting and learning system.

Name (Organization), Reference	AHRQ WebM&M (US HHS) http://www.webmm.ahrq.gov/
Local/External	External
Geogr. range	National (USA)
Language	English
RT specific	No
Voluntary	Yes
Confidentiality	Anonymous
Registration & Accessibility	Registration not required. Open access.
Data entry	Web based, narrative format.
Reportable events	Any event interesting from the patient safety point of view.
Classification and definitions	Classification of cases according to safety target, error type, approach for improving safety, clinical area, target audience or setting of care. Glossary of terms (http://www.webmm.ahrq.gov/glossary.aspx).
Possibility to search information	Yes, word search and filtering using the classification of cases.
Number of reports in the database	248 cases & commentaries (March 2012) none of them directly related to radiotherapy
Feedback	<ul style="list-style-type: none"> • Perspectives: podcasts with excerpt of interviews on patient safety topics (http://www.webmm.ahrq.gov/perspectivesHome.aspx) • Continuing medical education by completing quizzes based on spotlight cases & comments (http://www.webmm.ahrq.gov/cme.aspx) • Patient Safety Primers. Each primer defines a topic, offers background information on its epidemiology and context, and highlights relevant content from both AHRQ PSNet and AHRQ WebM&M. (http://www.webmm.ahrq.gov/primerHome.aspx) • Revision and analysis of publications on patient safety. • Subscription to AHRQ PSNet newsletters (http://psnet.ahrq.gov)
Links, publications	Yes

Table A3.2 Items in the report form of the AHRQ WebM&M system.

Title	Max 75 words
Patient description	Max 250 words
Nature of error and contributing factors	Max 250 words
Impact of the error on the patient	Max 250 words
How the error was recognized	Max 250 words
Suggestions to prevent similar errors from happening in the future	Max 250 words
E-mail (only for contacting if the case is selected)	

The Australian Patient Safety Foundation Inc. (APSF) is a non-profit independent organisation dedicated to the improvement of patient safety (<http://www.apsf.net.au>). The APSF developed the **AIMS** (Advanced Incident Management System) software (Table A3.3), which helps to collect and analyze detailed information about healthcare incidents. The AIMS incident management software is used by over 400 Australian hospitals, as well as at sites in South Africa, New Zealand and the United States. For monitoring incidents, APSF collects data from the health units with all identifying information removed. This de-identified data is then keyed into an aggregated database that allows all health units to receive comparative information linking their performance with other 'like' organizations.

Table A3.3. Main features of the AIMS.

Name (Organization), Reference	AIMS (Advanced Incident Management System), Australian Patient Safety Foundation http://www.apsf.net.au
Local/External	External
Geogr. range	International (Commonwealth, mainly Australia)
Language	English
RT specific	No
Voluntary	Yes
Confidentiality	Data entered in the APSF software contains confidential information on those involved in the incident and is protected from legal discovery under Australian Commonwealth Quality Assurance legislation. For monitoring incidents, APSF collects data from the health units with all identifying information removed.
Registration & Accessibility	AIMS software, developed and supported by iSOFT Solutions http://www.isothealth.com/en/Solutions/HospitalsandClinics/AIMS.aspx
Data entry	Incident information is collected throughout the health unit on paper form and data are then entered and coded using the APSF software.
Reportable events	AIMS is designed to receive a wide range of events, including predefined "Sentinel" events, all adverse events, near misses, equipment failures, new hazards, and specific events such as suicide and abduction. AIMS can accept and classify incident information from any source including incident reports, sentinel events, root cause analysis, coroner's findings, consumer reports, and morbidity and mortality reviews.
Classification and definitions	Utilize a taxonomy that includes over 24,000 concepts organized into 18 incident types and with detailed information regarding contributing factors, outcomes, actions and consequences. It has taxonomies for different medical specialties, but radiotherapy is not included.
Possibility to search	The AIMS software transforms free-text incident descriptions into actionable data.

information	
Number of reports in the database	Unknown
Feedback	<ul style="list-style-type: none"> • Different views of the reports, filtering and analysis through the AIMS software. • APSF e-mails on patient safety (members only) • Alerts • E-newsletters: http://www.apsf.net.au/enewsletters.php
Links, publications	Yes, http://www.apsf.net.au/links.php http://www.apsf.net.au/articles.php

The mandatory Australian Radiation Incident Register (**ARIR**) (Table A3.4) is maintained by the ARPANSA, <http://www.arpansa.gov.au/radiationprotection/arir/index.cfm>. Radiation incident reports of the ARPANSA license holders are compiled to produce annual reports with summaries of the most frequent incident categories, description of all radiation incidents that occurred in the period and lessons learnt. The register includes reports of incidents classified in 31 categories one of which is Radiotherapy.

Table A3.4. Main features of the ARIR reporting and learning system.

Name (Organization), Reference	ARIR (Australian Radiation Protection and Nuclear Safety Agency- ARPANSA) http://www.arpansa.gov.au/radiationprotection/arir/index.cfm
Local/External	Local and External
Geogr. range	National (Australia)
Language	English
RT specific	No
Voluntary	No
Confidentiality	Not confidential
Registration & Accessibility	Registration not required. Only license holders can make reports. Open access to summary reports.
Data entry	Microsoft Word form with free text that has to be e-mailed or faxed. Items in the report: Date and time of accident, name of license holder, license number, description of controlled material, apparatus or facilities involved in the accident, description of the accident, description of steps taken to control the accident, description on any injury, damage or harm to persons or the environment, any other relevant information or comments, name and position of the person providing this information, signature and date of notice.
Reportable events	Incidents (called accidents) have to be reported. Near-misses can also be reported.
Classification and definitions	Definition of accident http://www.arpansa.gov.au/pubs/regulatory/guides/OS-COM-SUP-274A.pdf The word accident and incident are used interchangeably
Possibility to search information	No. Information can be found in pdf format in the annual summary reports. Additional information can be requested via e-mail (secretariat@arpansa.gov.au)
Number of reports in the	55 reports from radiotherapy units in the period 2004-2010

database	
Feedback	<ul style="list-style-type: none"> Annual summary reports: http://www.arpana.gov.au/radiationprotection/arir/arir_reports.cfm
Links, publications	No

One example of a radiotherapy-specific mandatory reporting and learning system is the online national French reporting and learning system of the **ASN-ANSM** for collecting and analyzing significant events affecting patients treated with radiotherapy (Table A3.5).

In order to enable radiotherapy professionals to simultaneously fulfill their notification obligations relating to radiation protection and equipment safety (materiovigilance), ASN and the French Health Products Safety Agency (Agence National de Sécurité du médicament et des Produits de Santé - ANSM) have provided a website (<http://vigie-radiotherapie.fr/>) to help them to notify these events. This portal, dedicated to radiotherapy professionals, allows communicating to the responsible authority:

- Significant Radiation Protection Events (SRPE) likely to affect human health by exposure to ionizing radiation
- A “materiovigilance” incident: any incident or accident involving a device that resulted or may have resulted in death or serious deterioration of health of a patient, a user or other person.
- An event relevant from the point of view of materiovigilance and radiation protection (mixed event).

Criterion 2.1 (ASN guide ASN/DEU/03) defines what can be considered significant events for notification in the field of radiation protection:

- Any adverse situation or any malfunction on an organizational, material or human level arising during the treatment of a patient in radiotherapy, having led to the realization of treatment that does not comply with the prescription in terms of the delivered dose(*);
- or any adverse situation or any malfunction on an organizational, material or human level arising during the treatment of a patient, having led to deterministic effects which were unforeseeable in view of the therapeutic strategy agreed upon with the patient.

(*) Conforming to the delivered dose implies:

1. in radiotherapy and brachytherapy: compliance with the total prescribed dose with a tolerance margin of $\pm 5\%$, and compliance with the planned overall treatment time and/or fractionation, taking into account the potential clinical or technical constraints involved in the treatment of a patient.
2. the absence of systematic dose errors for several patients, regardless of the value of this dose error.

Table A3.5. Main features of the ASN/ANSM reporting and learning system.

Name (Organization), Reference	Vigie radiothérapie (ASN/ANSM) http://vigie-radiotherapie.fr/
Local/External	External
Geogr. range	France, Monaco, Others
Language	French
RT specific	Yes
Voluntary	Mandatory (criterion 2.1.)
Confidentiality	Depending on the scale of the event the name of the Department and Hospital are revealed (events rated 2 and above).
Registration &Accessibility	All the radiotherapy departments are registered. Publications are accessible to the public.
Data Entry	Web based: www.vigie-radiotherapie.fr If you leave the form, all data are lost and must be reentered. Free text for circumstances, consequences, corrective actions and comments. There are notification guides (ASN guide 11 and 16).
Reportable events	Criterion 2.1 (ASN guide ASN/DEU/03)
Classification and definitions	Reporting criteria in the ASN Guide ASN/DEU/03. The criterion 2.1 is for radiotherapy. Events are rated on eight levels on the ASN-SFRO scale: - levels 0 and 1 are used to rate events with no clinical consequences for the patient(s) concerned; - levels 2 and 3 correspond to events categorized as "incidents"; - levels 4 and 7 correspond to events categorized as "accidents". The seriousness of the effects should be assessed by referring to the international clinical classification (CTCAE grades). For every significant event notified to ASN, the rating proposed by the individual responsible for the activity is written on the notification form. This rating is then validated by ASN after consulting the SFRO. This consultation is systematic when the event is initially rated level 2 or above, and in the event of uncertainty for all other levels of classification.
Possibility to search information	Summaries (Bilan)
Number of reports in the database	Almost 300 events reported in the period 2007-2008. In the annual report of the ASN of 2009 it is said that 131 events were reported, most of them rated 0 or 1 and 8 rated 2 in the ASN-SFRO scale.
Feedback	Publications (see next row in this table). Detailed analysis of the causes of Significant Event Reports (SER) and a description of the planned or implemented corrective action.
Links, publications	Publications: <ul style="list-style-type: none"> • events rated 0 on the ASN-SFRO scale are listed in the ASN annual report. • events rated 1, with the exception of those relating to a cohort of patients (serial events), are compiled in a quarterly report which does not mention the names of the notifying Centre and are

	<p>published on the website www.asn.fr.</p> <ul style="list-style-type: none"> • serial level 1 events (single cause in a cohort of patients) and those rated 2 or above are communicated via an 'Incident Notice' stating the place where the incident took place: http://www.asn.fr/index.php/Les-activites-controlees-par-l-ASN/Utilisations-medicales/Avis-d-incidents-affectant-un-patient-en-radiotherapie • level 3 events are systematically dealt with in a memo. They may, where appropriate, be communicated in a press release • level 4 and above, the events are communicated via press releases. <p>Reporting Guides (ASN guide 11 and 16) Summaries of reports (Bilan) Bulletins (patient identification, first treatment session).</p>
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Adverse events are reported to the Danish patient safety database (Danish Patient-Sikkerheds-Database **DPSD**, <http://www.dpsd.dk/>) electronically via web or via local reporting and learning systems (Table A3.6). In either case the hospital directors receive the reports, analyze them and take the necessary actions, for example by implementing changes in the working procedures. Finally, the reports are anonymized and sent to the National Board of Health.

The Act on Patient Safety in the Danish Health Care System came into force in January 2004. The Act obligates:

- Frontline personnel to report adverse events to a national reporting and learning system
- Hospital directors to act on these reports
- The National Board of Health to communicate the learning nationally

The purpose of the reporting and learning system is to learn, not punish. Therefore, the Act contains a paragraph protecting the health care personnel from sanctions: "A frontline person who reports an adverse event cannot as a result of that report be subject to investigation or disciplinary action from the employer, the Board of Health or the Court of Justice". The Act on Patient Safety was implemented into the Danish Health Care Act, January 1st 2007. The Act on Patient Safety was expanded in 2010 to the primary care sector as well as to patients and relatives.

Table A3.6. Main features of the DPSD reporting and learning system.

Name (Organization), Reference	DPSD (National Board of Health), http://www.dpsd.dk/
Local/External	Local and External
Geogr. range	National (Denmark)
Language	Danish
RT specific	No
Voluntary	Mandatory for adverse events. Act on Patient Safety in the Danish Health Care System.
Confidentiality	Confidential. It is not mandatory for a health care professional to state his/her name or other identifiable information when reporting, but it is

	recommended not to use anonymous reporting because it makes the collection of further information difficult for the analyzing team. Data are anonymized before they are sent to the National Board of Health.
Registration & Accessibility	Registration not required. Free access
Data entry	Web-based (https://dpsd.csc-scandihealth.com/Form/PublicSubmission.aspx?form=DPSD_Public) or via local reporting and learning systems. Items in the report: <ol style="list-style-type: none"> 1. Title, description of what happened. 2. Where did it happen? When (date and time) did it happen? 3. Description of the consequences, how serious was the incident? (no damage, mild, moderate, severe or lethal). 4. Proposals for prevention. 5. Information to the patient. 6. Where there other factors involved in the incident?. Drugs, medical equipment, Radiation equipment (X-ray, radioactive sources, radiotherapy). 7. Contact information (not compulsory). 8. Attach a file.
Reportable events	Adverse events: <ul style="list-style-type: none"> • Adverse events related to medication • Adverse events related to surgical or invasive procedures • Other serious adverse events, which are at risk of reoccurring
Classification and definitions	Definition of adverse event. Although there are no national requirements for analysis, there is a general use of the Safety Assessment Code (SAC) score. Adverse events with less serious SAC scores are acted upon locally, whereas serious adverse events (SAC score of three) prompt a root cause analysis.
Possibility to search information	Search for documents and publications on the DPSD website using keywords: http://www.dpsd.dk/S%C3%B8g.aspx
Number of reports in the database	Unknown
Feedback	Hospital directors are obligated by the Act on Patient Safety to take preventive actions on the basis of the reported adverse events, while the National Board of Health is in charge of disseminating the lessons learnt. The National Board of Health issues alerts in the form of regular Newsletters, Explanations (there is a report in Danish about patient safety in cancer treatment including radiotherapy, http://www.dpsd.dk/upload/temarap07_risikomed_dpsd_9nov07fin.pdf), Warnings, Patient stories (individual events with a full description of the causes, consequences and proposal of remedial actions), Information (about reporting), Manuals, Legislation and Annual reports.
Links, publications	Yes, different types of publications in Danish: http://www.dpsd.dk/Publikationer%20mv.aspx

The Health Technology Assessment (HTA) Unit of the Alberta Heritage Foundation for Medical Research (AHFMR) in Canada published in 2006 “A Reference Guide for Learning from incidents in Radiation Treatment”, which was originally developed by the Radiotherapy Quality Assurance Committee at the Tom Baker Cancer Centre, Calgary, Alberta in Canada (Table A3.7).

The framework proposed comprises not only the reporting and classification of adverse events and near misses, but also an in depth investigation of the root causes leading to those events as well as the adoption of corrective actions and learning lessons from the results of the complete process.

In the year 2007 the Radiation Oncology Quality Improvement Committee of the Ottawa Hospital implemented the Incident Learning System (ILS) developed at the Tom Baker Cancer Centre in Calgary. In this System, an incident is defined as “an unwanted or unexpected change from a normal system behaviour that causes or has the potential to cause an adverse effect to persons or equipment”. In this framework, the person who identifies the incident reports the incident using a paper form and submits to their manager. The manager enters the incident into the ILS spreadsheet. Each incident is delegated to the appropriate Radiation Oncology Quality Improvement Committee (ROQIC) member who then leads the investigation, causal analysis and follow up. Every incident is discussed at the weekly meeting of the ROQIC, where incidents are then considered from a multi-disciplinary perspective.

Even though this program is limited to the aforementioned hospitals, it has been included in this report because it successfully addresses all the fundamental features identified in more general programs. The program in order at the Ottawa Hospital has subsequently been improved adding features from others programs in the investigation and feedback phases.

Table A3.7. Main features of the AHFMR HTA ILS reporting and learning system.

Name (Organization), Reference	Incident Learning System – ILS (ALBERTA HERITAGE FOUNDATION FOR MEDICAL RESEARCH, HEALTH TECHNOLOGY ASSESMENT UNIT), as implemented at the Odette Cancer Center, Toronto. http://www.ahfmr.ab.ca/
Local/External	Local
Geographical range	Regional (Alberta, Canada)
Language	English
RT specific	Yes
Voluntary	Yes
Confidentiality	Not Confidential
Registration & Accessibility	Not Available (Hospital internal use)
Data entry	Hardcopy (being made electronic). Combination of check and narrative format. Management combines all reports in a spreadsheet.
Reportable events	Any incident affecting patients, public or staff, with special stress in reporting (and investigating) near misses.
Classification and definitions	Classification of cases according to (i) persons involved, (ii) process or system that failed (clinical, operational, environmental, security) and (iii) incident severity.
Possibility to search information	Not Available (Hospital internal use)
Number of reports in the database	2221 cases (2007-2010) reported, 315 actual incidents after investigation

Feedback	In the Ottawa Hospital implementation the events reported are investigated by a member of the Radiation Oncology Quality Improvement Committee, comprised by professionals from all the different areas involved in the treatment. The program itself has evolved from the original ILS adding elements from other approaches.
Links, publications	Yes http://www.ihe.ca/documents/HTA-FR22.pdf http://www.resilience-engineering-asso.org/ACTES/2011/Papers/14.pdf http://www.ncbi.nlm.nih.gov/pubmed/20400189

The Joint Commission on Accreditation of Healthcare Organizations (**JCAHO**) Sentinel Events reporting and learning system uses information from a variety of sources to improve the quality and safety of the more than 19,000 health care organizations that this institution accredits and certifies (Table A3.8). Some of these sources are complaints from patients, their families, government agencies, and the public, as well as from an organization's own staff and the media. The system is voluntary and confidential, it is addressed to serious events (sentinel events) and the accreditation status is not penalized for any organization that reports an error, applying processes to its future prevention. JCAHO requires organizations to conduct a Root Cause Analysis (RCA)⁸ accompanied by an action plan. JCAHO also requires access to review the organization's response to the sentinel event. Guidance on conducting RCA is offered by JCAHO on their website or upon request. Although reporting is voluntary, providing a RCA is required.

The JCAHO has performed the function of data analyses to propose and disseminate recommendations for implementing systems changes using a relatively small number of thoroughly investigated incidents reported to its sentinel events monitoring programme.

One of the occurrences that are subject to review by the JCAHO under the sentinel event policy is any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose.

Table A3.8. Main features of the JCAHO reporting and learning system.

Name (Organization), Reference	Joint Commission on Accreditation of Healthcare Organizations (JCAHO), http://www.jointcommission.org/
Local/External	External
Geogr. range	National (USA)
Language	English
RT specific	No
Voluntary	Voluntary reporting a sentinel event, or responding to The JCAHO's inquiry about a sentinel event.
Confidentiality	Confidential
Registration & Accessibility	Only accredited healthcare organization can submit reports. Complaints of patients about an accredited center http://jcwebnoc.icafo.org/QMSInternet/IncidentEntry.aspx
Data entry	Web form
Reportable	Sentinel events

⁸ A root cause analysis (RCA) is a structured analytical methodology used to examine the underlying contributors to an adverse event or condition. Because RCA is implemented after an event has occurred, it is considered a reactive risk management technique.

events	
Classification and definitions	Definition of sentinel events
Possibility to search information	Search engine
Number of reports in the database	Unknown
Feedback	Sentinel event alerts The individual organization's action plan is monitored by the JCAHO The JCAHO have instituted National Patient Safety Goals Statistics Videos and Podcasts, Blogs, Newsletters, Books, Manuals, Webinars, Conferences & Seminars, e-mail list, etc ...
Links, publications	JCAHO publications

The Nuclear Regulatory Commission (**NRC**, www.nrc.gov) regulates the activities with nuclear reactors and radioactive materials (Table A3.9). The reporting and learning system counts with many reports of the nuclear and industrial field, but some reports on the use of radioactive materials in radiotherapy (brachytherapy and Co-60 units) can be found in <http://www.nrc.gov/reading-rm/doc-collections/event-status/>. There is a good system for searching events reported by commercial nuclear reactor licensees (<https://lsearch.inl.gov/SearchCriteria.aspx>) but there is nothing similar for searching through medical events with radioactive sources. Reporting is mandatory when there is a substantial safety hazard, an event of true medical significance. Dissemination is made through Event Notification Reports (<http://www.nrc.gov/reading-rm/doc-collections/event-status/event/>) that only can be searched by date and Preliminary Notification Reports (<http://www.nrc.gov/reading-rm/doc-collections/event-status/prelim-notice/>) that constitute an early notice of events of possible safety or public interest significance (the information is as it was initially received without verification or evaluation).

For all medical uses of NRC-licensed radioactive materials, a "medical event" (<http://www.nrc.gov/reading-rm/doc-collections/fact-sheets/risks-assoc-medical-events.html>) occurs if *BOTH* of the following criteria are met:

(1) One or more of the following representative incidents occur:

- the dose administered to a patient differs from the prescribed dose by at least 20 percent, either too high or too low.
- the wrong radioactive drug is administered.
- the radioactive drug is administered by the wrong route.
- the dose is administered to the wrong individual.
- the patient receives a dose to a part of the body other than the intended treatment site, that exceeds by 50 percent or more the dose expected by proper administration of the prescription
- a sealed source used in the treatment leaks;

And

(2) The difference between the dose administered and the prescribed dose exceeds one of the reporting limits contained in the NRC's regulations at 10 CFR 35.3045, which correspond to the annual occupational dose limits at 10 CFR 20.1201.

The licensee shall notify by telephone the NRC Operations Center no later than the next calendar day after discovery of the medical event. The written report must include:

1. The licensee's name;
2. The name of the prescribing physician;
3. A brief description of the event;
4. Why the event occurred;
5. The effect, if any, on the individual(s) who received the misadministration;
6. What actions, if any, have been taken or are planned to prevent recurrence; and
7. Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

The report may not contain the individual's name or any other information that could lead to identification of the individual.

From the side of a radiotherapy facility, it seems strange that the NRC reports incidents involving isotopes, but not those equivalent involving linear accelerators.

Table A3.9. Main features of the NRC reporting and learning system.

Name (Organization), Reference	NRC (USA), www.nrc.gov
Local/External	External
Geographical range	National (USA)
Language	English
RT specific	No
Voluntary	Mandatory
Confidentiality	Not confidential
Registration & Accessibility	Facility registration required
Data entry	Communication by telephone in 24 h and written report in 15 days.
Reportable events	Medical events with radioactive sources
Classification and definitions	Definition of reportable medical events. Classification by date.
Possibility to search information	Yes, only by date of occurrence
Number of reports in the database	Unknown
Feedback	Event Notification Reports, Preliminary Notification Reports
Links, publications	Links to NRC documents.

The United Kingdom's National Patient Safety Agency (NPSA) maintains the National Reporting and Learning System (NRLS); a nationwide voluntary event reporting and learning system <http://www.nrls.npsa.nhs.uk/> that was established in 2003 (Tables A3.10 and A3.11). An agreement between NPSA and the Health Protection Agency (HPA) allows this agency to conduct regular analysis of the data transferred on a monthly basis from the NPSA data base to provide feedback to the radiotherapy departments. The data base is not specific for radiotherapy events, however a code has been defined to identify them and get them for further analysis. In April 2012 the NPSA was abolished. The work of the NRLS has moved from the NPSA and continues within the new proposed structure of the NHS Commissioning Board.

Table A3.10. Main feature of the ICHT/NRSL UK reporting and learning system

Name (Organization), Reference	ICHT/NRSL (Imperial College Healthcare NHS Trust /National Reporting and learning System) http://www.nrls.npsa.nhs.uk/
Local/External	External
Geographical range	United Kingdom
Language	English
RT specific	No, but radiotherapy incidents include a trigger code TSRT9 based on the report of "Toward Safety Radiotherapy" to classify them
Voluntary	Yes (However some adverse events are reportable under legislation to the appropriate authority under a separate scheme. Anonymised synopses of these events are also shared with the HPA for analysis).
Confidentiality	Confidential. No personal or staff information is required. All that information is encrypted and not shared outside the system. Each institution has been attributed a unique identifier so if necessary HPA staff can ask National Reporting and Learning System (NRLS) staff to contact institution with an enquiry whilst protecting the anonymity of the institution from the HPA.
Registration & Accessibility	Organizations, health care staff and patients can submit an electronic report. Data only accessible within NHS (National Health System) but third party may request access under strict conditions (Royal Colleges, Health Authorities) or under legal requirements. Every NHS RT Institution is registered and has reported through this system. In some institutions access to the NRLS is available within the radiotherapy department. In other institutions it is available in Risk Management departments within the institution.
Data entry	This varies and is dependent on the resources available in individual institutions. The initial report will be logged within the radiotherapy department on a paper form or an e-form and then uploaded to an electronic reporting system for forwarding to the NRLS. A trigger code is employed for a search of patient safety incidents to identify radiotherapy reports. This dataset is then forwarded to the HPA on a monthly basis for analysis. A guidance document was written to support the radiotherapy community

	<p>by explaining how to implement the classification and coding system from Towards Safer Radiotherapy and how to improve submission of RT events to the NRLS. In addition minimum criteria for data inclusion in reporting were defined within this document.</p> <p>The reporting form includes the following item in the report: incident information (date, incident category, incident description) patient information (general information, actual/potential harm) contributing factors staff and organization information</p>
Reportable events	All radiotherapy errors including Adverse events, Incidents and Near misses and others
Classification and definitions	<p>Terminology and Classification of the severity and type of incident according to what is defined in the document "Towards Safer Radiotherapy"</p> <p>https://www.rcr.ac.uk/docs/oncology/pdf/Towards_saferRT_final.pdf</p> <p>The RT pathway was broken down into constituent processes and described in terms of 21 codes and 196 sub-codes. This 'Radiotherapy Pathway Coding' describes where the error occurred. In this way each activity involved in the planning and delivery of RT could be described by a unique alphanumeric code.</p>
Possibility to search information	Search using the TSRT9 trigger code in the free text of the patient safety report
Number of reports in the database	4 million patient safety incident reports, 4,209 reports specific of radiotherapy (30th May 2012)
Feedback	<p>Analysis of the incident report carried out by HPA (Health Protection Agency)</p> <p>Information on safer radiotherapy at http://www.hpa.org.uk/radiotherapy</p> <p>2 yearly trend analyses undertaken by the HPA on all data received.</p> <p>Quarterly newsletters entitled 'Safer Radiotherapy' providing regular updates on the analysis of radiotherapy error (RTE) reports for professionals working in the radiotherapy community</p> <p>http://www.hpa.org.uk/ProductsServices/Radiation/Radiotherapy/RadioterapyNewsletters/</p> <p>Presentations and articles.</p> <p>Alerts are sent electronically to radiotherapy stakeholders (professional bodies, inspectorates for legislation, manufacturers etc) and every radiotherapy institution in the UK when a new document is released on the website.</p> <p>Guidance on reporting</p> <p>http://www.hpa.org.uk/ProductsServices/Radiation/Radiotherapy/RadioterapyGuidanceDocuments/</p>
Links, publications	Yes

Table A3.11. Items in the report form of the NPSA/NRSL UK reporting and learning system.

Trigger code/classification/code all defined in the document "Toward Safety Radiotherapy"	Trigger code	TSRT9 mentioned in the table identify the incident as a radiotherapy error
	Classification code determines the severity of the error	Five levels of error are defined : Level 1 reportable radiation incident as defined in the UK radiation protection regulations Level 2 non reportable radiation incident as above but with potential or actual clinical implications (e.g underdoses) Level 3, minor incidents and incident with no potential or actual significance Level 4, Near misses, a potential radiation incident that was detected before the delivery of treatment. Level 5, Other non-conformance, none of the above
	Code process	Step of the radiotherapy pathway where the error has occurred: eg 11d/11t : pre-treatment planning process, importing data from external imaging system/ end of process checks
Anatomical site		
Prescribed fractionation		
Dose administered or almost administered with indication of percentage of error (if appropriate)		
Magnitude of geographic misplacement (if appropriate)		
Information about random or systematic error		
circumstance surrounding the incident	Significant contributory factors	
	Implication for the patient	
	How the error was detected	
	Corrective/preventive action taken	

PRISMA-RT was established in 2008, as a cooperation of 17 of the 21 Dutch Radiotherapy organizations (Table A3.12). The name PRISMA-RT is an acronym for Prevention, Recovery and Information System for Monitoring and Analyses in RadioTherapy. These radiotherapy organizations developed a national database. By means of the national database system, 17 Radiotherapy departments are able to collect and analyze their (near) incidents and report these analyses to the organization. They use (near) incidents because they assume that the root causes that lead to errors are often identical to the root causes of (near) incidents.

The PRISMA process includes 7 steps: collect, select and research, incident description, classification, reporting, interpretation and training. Every (near) incident report is being analyzed by means of a tree structure (fault tree), in order to identify root causes. The primary objective of this initiative is to improve processes and increase patient safety within radiotherapy by comparing the root causes of incidents.

On a periodic basis, analyses on the root causes are undertaken to determine the risk trends within the organization.

Table A3.12. Main features of PRISMA-RT.

Name (Organization), Reference	Prevention, Recovery and Information System for Monitoring and Analyses in RadioTherapy (PRISMA-RT) http://www.prisma-rt.nl
Local/External	External
Geographical range	The Netherlands
Language	Dutch
RT specific	Yes
Voluntary	Yes
Confidentiality	
Registration & Accessibility	Accessible only for the Dutch departments involved in the cooperation
Data entry	Web based
Reportable events	Near incidents
Classification and definitions	For root cause classification the Eindhovens-Classification Model (ECM) is used. For this purpose, 21 different codes are defined each divided into 4 categories: human, technical, organization or patient related. In addition, context variables in which the incident occurred are determined. Besides general context variables, specific human, technical and organizational context variables are determined
Possibility to search information	Unknown
Number of reports in the database	Unknown
Feedback	Fault tree analysis of (near) incidents reported. Risk trends by analysis of the root causes. Educational meetings.
Links, publications	Yes

ROSIS is an acronym for "Radiation Oncology Safety Information System" and it is a voluntary web-based safety information database specific to radiation oncology (Table A3.13). Reporting is confidential in relation to the reporter, institution and country and anonymised in relation to the patient. The database is very structured (see table II and III) with a classification system consisting in four classes:

1. Event / Occurrence
2. Severity
3. Causes / Contributing Factors
4. Detection.

When possible, answer options are given, while others questions have free text for narrative answers. To make the form simple, there are dynamic options where the next question depends on the answer to a previous question.

The facility can be known by the ROSIS management personnel as the reporter makes use of a user and a password given after registration of the facility. Nevertheless, the reporter is encouraged not to give any information about institution, staff or patient that could identify them on the report form. The report's details are available on the website once they have been reviewed and are fully anonymised. No information about the institution is accessible.

The fully anonymised database can be provided to individual researchers or research organisations on request. The reports are used as a source of information by major international organisations (e.g. WHO, ICRP, IAEA, UNSCEAR, RCR).

All "old" ROSIS incident reports are available under the main menu heading "ROSI Safety Information" (<http://www.rosis.info/archive.php>). All "new" ROSIS incident reports are available in the member's area after logging-in to the system. You can search this online database under predefined headings.

The ROSIS working group has disseminated the information of the reports through several publications (Cunningham, Coffey et al. 2010; Cunningham 2011), an annual teaching course on Patient Safety in Radiation Oncology and Newsletters.

Table A3.13. Main features of ROSIS.

Name (Organization), Reference	ROSI (independent) http://www.rosis.info/
Local/External	External
Geographical range	International
Language	English (translation available using Google Translate toolbar). There is a plan to have the possibility to use languages other than English.
RT specific	Yes
Voluntary	Yes
Confidentiality	Confidential
Registration & Accessibility	Clinic registration required (registration form cannot be filled in online)
Data entry	Web based, dynamic options
Reportable events	Incidents Near misses
Classification and definitions	Classification system very structured to facilitate analysis. The form is easy to fill because dynamic options are used (not all options presented at once, options visible depending on the answer to previous questions).
Possibility to search information	Yes, only registered facilities. Filtering: incidents by discovery and incidents by origin
Number of reports in the database	1195 reports (March 2011)
Feedback	Spotlight cases (web and sent by e-mail) http://www.rosis.info/index.php?content=spotlightCases Publications http://www.rosis.info/index.php?content=publications Annual teaching course on Patient Safety in Radiation Oncology

	http://www.rosis.info/index.php?content=learnSafetyInRO Videos www.ecco-org.eu/oncoveideos/Radiation-Oncology.aspx
Links, publications	Yes

The **Swiss ROSIS** (www.rosis.ch) is an anonymous and voluntary radiotherapy event reporting and learning system (Table A3.14). A program named RO-CIRS was distributed to all Swiss radiotherapy institutions. This program can be used as a local IRS with the option to transfer data to the central database of ROSIS. An e-mail address is transferred with the data to give the ROSIS editor the opportunity to ask for complementary information, but to keep the report anonymous, a not identifying e-mail address can be used (e.g. unknown@hotmail.com).

Table A3.14. Main features of the Swiss ROSIS reporting and learning system.

Name (Organization), Reference	ROSIS (SGSMP, SASRO, BAG), www.rosis.ch
Local/External	Local and External
Geographical range	Switzerland
Language	German
RT specific	Yes
Voluntary	Yes (in case of serious events, the system informs that a non anonymous reports must be sent to the Federal Office of Public Health, as it is stated in the Swiss radiation protection legislation).
Confidentiality	Anonymous
Registration & Accessibility	No Through the program RO-CIRS distributed to all Swiss radiotherapy institutions.
Data entry	Form in the RO-CIRS program: Title, irradiation unit, discovered by, how was it discovered?, part in the process, number of affected persons (patients, staff), consequences, potential consequences, number of fractions/total number of fractions, description of the event, cause, proposed measures to avoid repetition, technical cause, dose exceeded?.
Reportable events	RO_CIRS informs the user if an incident should be transferred to www.ROSIS.ch because it fulfils the criteria from the working group and, in case of a relevant radiation accident, if a (not anonymous) report to the Federal Office of Public Health is necessary.
Classification and definitions	Not in the web site.
Possibility to search information	Only a list of the reported events
Number of reports in the database	31 reports in the web site (March 2012)
Feedback	Reported events
Links, publications	Not in the web site

The Safety in Radiation Oncology (**SAFRON**) medical event database is a voluntary, confidential (any identifiable data is not revealed to any governmental authority or other third party), non-punitive reporting and learning system for radiation oncology centres (Table A3.15). The system allows registered facilities to review cases submitted to SAFRON and contribute cases to the system. The reviewer will be able to identify the severity of the incident (number of adversely affected patients and dose variation), the person (by profession) who discovered the incident or near miss, and where in the process the incident happened. If equipment failures were a factor in the incident, the contributor of the incident can provide information about the manufacturer, make and model. Another feature is the ability to provide information on actions that contributed (that caused) the incident and what the facility changed to prevent a repetition of this type of incident. There is a feature to toggle between viewing only your own incident reports, and all incident 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 that correlates the process steps to scientific publications (links to abstracts) on event prevention and quality assurance in radiation therapy.

The SAFRON system is designed to educate radiation oncology professionals by sharing information on events (near misses included). SAFRON may be beneficial to facilities that are looking to initiate some of the newer technology. They may be interested in reviewing incidents and near misses associated with this new treatment method such as SBRT (an example) and corrective action that have been used to prevent reoccurrence of this type of error. The system allows the search of key words, what phase in the process is the event associated with, who discovered the event and how it was discovered.

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. Already now, the system has 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.

Currently SAFRON is only collecting external beam events. The list of process steps is based on the World Health Organization’s “Radiotherapy Risk Profile”, and the radiotherapy pathway outlined in “Towards Safer Radiotherapy” (UK). If any event does not fit into any of the process steps, it is always possible to use the last item in any group: “Other”. Selecting “Other” in the group that most closely describes the situation will open a text field, which can then be used to provide additional details.

Table A3.15. Main features of SAFRON (Safety in Radiation Oncology).

Name (Organization), Reference	SAFRON (IAEA) https://rpop.iaea.org/safron/
Local/External	Local and External. It can be used as local reporting system by selecting in the option Dataset “Own incident report” instead of “All incident reports”. Nevertheless, SAFRON can register only one contributor per facility
Geographical range	International
Language	English

RT specific	Yes
Voluntary	Yes
Confidentiality	Confidential. Any detail that may reveal the identity of the relevant facility, patient/s and persons submitting the report/s is considered to be confidential and will not be shared. Any detail that might reveal the identity of the patient should not be reported. IAEA treats identifying details as confidential information, and will not release these to regulatory officials, the media, other radiation facility, or any other 3rd party.
Registration & Accessibility	Registration required. Access with personal user and password for the local contact person. In the registration process details about the Radiotherapy Department are given. There can be only one contributor registered per facility.
Data entry	Web-based. Drop down options help to categorizing the incident. In the section Frequently Asked Questions, examples of process task, and additional written instructions can be found.
Reportable events	Any event, called generically incidents and divided into 6 levels of severity (minor, potential serious, serious, potential major, major or critical incident)
Classification and definitions	Process steps of External Beam Radiotherapy grouped in 4 levels. The list of process steps is based on the World Health Organization's "Radiotherapy Risk Profile", and the radiotherapy pathway outlined in "Towards Safer Radiotherapy" (UK). Additionally, there are other classification criteria: who discovered the incident, how was it discovered, causes of the incident, barriers and severity.
Possibility to search information	Yes, only registered facilities. Filtering: incidents by process step (at the moment only External Beam Radiotherapy, not Brachytherapy), who discovered the incident, how was the incident discovered, any word in the free text fields or a combination of these criteria.
Number of reports in the database	More than 1150 reports (Mach 2013).
Feedback	Featured incident reports and documents. Registered participant automatically receive summary reports and news alerts
Links, publications	Documents and links. You can search own/all documents and links by process step or by any word in document/link title.

The aim of **SiNASP** (the acronym stands for "Reporting and Learning System for Patient Safety" in Spanish) is to improve patients' safety by analysing situations, problems and incidents that produced, or could have produced, harm to patients (Table A3.16). The primary emphasis of the system is on learning for improvement.

Reporting is voluntary and confidential. Data are encrypted and only professionals involved in managing the system and the investigation of incidents have access to complete information on reported incidents. These professionals are committed to maintain and protect the data before accessing the information. Details about individual cases are not given to any person or organization, only aggregated data analysis and recommendations for improvement arising from the analysis of the cases are given.

Only hospital professionals registered in the system may notify incidents to SiNASP. All kind of incidents involving patient safety may be notified (events or circumstances that have caused or could have caused harm to a patient). These include adverse events, incidents without damage and safety-related incidents that did not reach the patient.

Table A3.16. Main features of SiNASP.

Name (Organization), Reference	SiNASP (Spanish ministry of health) www.sinasp.es
Local/External	Local (hospital) and external
Geographical range	National (Spain)
Language	Spanish
RT specific	No
Voluntary	Yes
Confidentiality	The information is always confidential (only SiNASP managers from each hospital can access the notifications in order to analyze them). The reporter can identify himself/herself (this information would be de-identified in 15 days) and anonymous reporting is also possible.
Registration & Accessibility	Registration required. Only professionals (with Center code)
Data entry	Web-based. Estimated time 7 minutes. Possibility to save and resume later.
Reportable events	Adverse events Incidents without damage Near misses
Classification and definitions	Classification based on the WHO's patient safety taxonomy. Adaptation of the Severity Assessment Code (SAC) Matrix
Possibility to search information	It is possible to search information by all the questions that have a closed list of response alternatives. The information is searched and analyzed by the SiNASP managers, and there is a manager in each hospital. There are also managers for the Region and the Ministry, but these 2 levels get aggregated data from all the hospitals.
Number of reports in the database	More than 5.700 reports (beginning of May 2012). No specific identification of radiotherapy events
Feedback	Feedback is mainly managed at organizational level: each hospital has a committee to analyze the events and provide feedback within the organization. Publication of Root Cause Analysis (RCA) of high and extreme risk reported events with recommendations and links.
Links, publications	Link to other notification systems in Spain. Links for further information in every RCA published.

The SiNASP notification managing process is outlined in the diagram of Fig. A3.1.

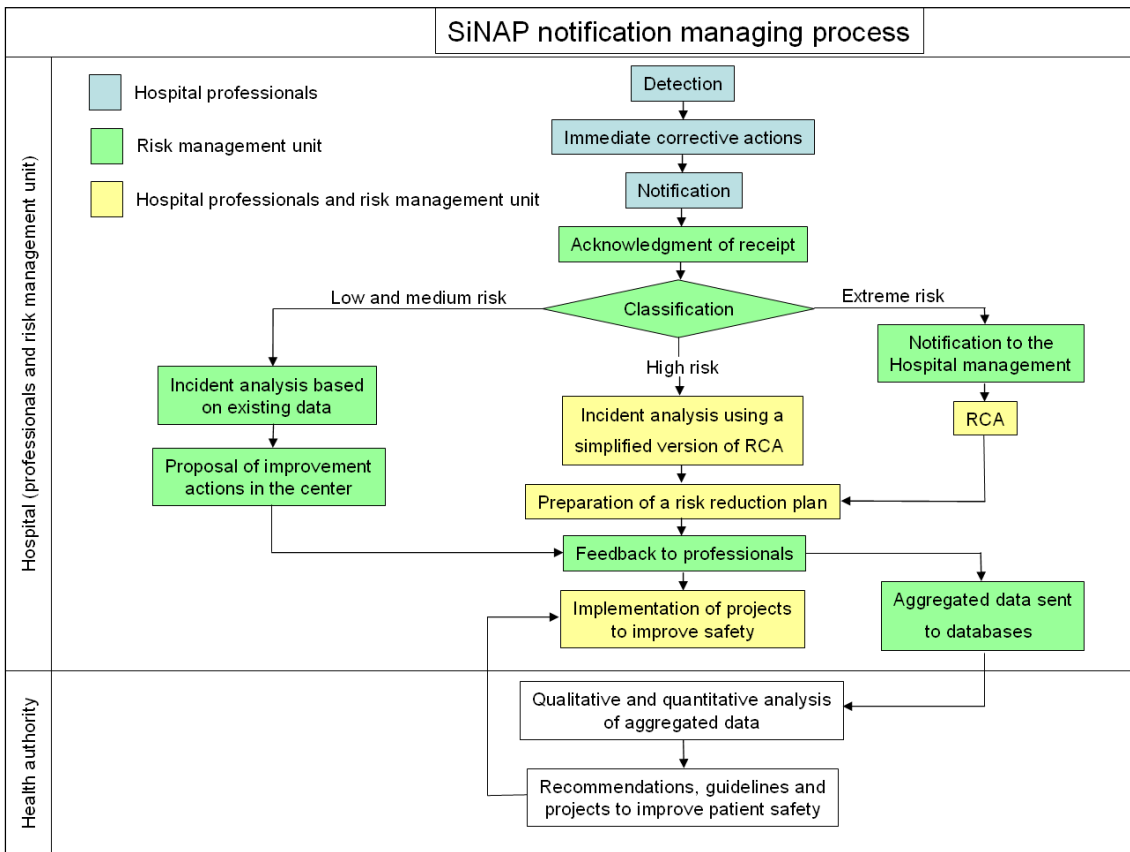


Fig.A3.1. SiNASP notification managing process.

ANNEX 4. Status of risk management in Europe

One of the objectives of the ACCIRAD 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). For this objective, the implementation of risk management in Europe was reviewed by two questionnaires: (1) the overall status and the legal and practical arrangements in EU Member States regarding the implementation of Article 11 of MED, and (2) more detailed information on the systems and guidelines from those countries which had this information available.

The questionnaires were conducted as on-line surveys (LimeSurvey) through project web-site in order to facilitate the data collection and analysis. The first questionnaire was distributed to 38 European countries including all EU Member States. The second questionnaire was distributed to the ten countries having defined “requirements” for proactive risk assessment and/or reactive risk analysis. Further, a particular questionnaire was distributed to a few radiotherapy institutions selected by the national contact points, to get examples on the risk management at an institutional level.

Short summaries of the results of the questionnaires have been presented in the relevant Sections of this Technical Supplement (Sections 4, 5.4, 5.5, 6.5, 6.6 and 7.5). In this Annex, detailed summaries of the questionnaires are presented.

A4.1 Status of MED implementation

A4.1.1 Introduction

In this Section, the status of basic legal provisions (national regulations) to comply with Article 11 of the MED Directive in EU Member States are reviewed, based on the results of the first, general questionnaire of the ACCIRAD project. The general questionnaire also reviewed some background data on national radiotherapy systems. It was also used to assess and confirm proper recipients of the questionnaire, to ensure that both the legal provisions and their implementation in clinical practice would be taken into consideration. The list of recipients for the first questionnaire comprised contact information on the national regulatory authorities (see Annex 5).

The questionnaire was conducted as an on-line survey (LimeSurvey) through project web-site in order to facilitate the data collection and analysis. It was distributed to 38 European countries including all Member States (Belgium, Sweden, Netherlands, Germany, France, Serbia, Spain, Ireland, Switzerland, Republic of Belarus, Republic of Cyprus, Estonia, Lithuania, United Kingdom, Czech Republic, Romania, Turkey, Norway, Portugal, Slovakia, Bosnia and Herzegovina, Ukraine, Hungary, Croatia, Republic of Moldova, Greece, Austria, Finland, Malta, Bulgaria, Iceland, Italy, Macedonia, Latvia, Luxembourg, Slovenia, Poland and Denmark).

A4.1.2 Questionnaire structure

The general questionnaire was composed of three parts:

1. Contact information.
2. Regulatory framework: Existence of
 - legislation or regulations (mandatory requirements issued by authorities)
 - recommendations (not binding; given by authorities)

- guidelines (not mandatory, usually presenting the good practice and given by professional societies)

for

- *Risk management* for patient safety in external beam radiotherapy. Risk management here means all kinds of risk studies, either proactive or reactive, performed to improve safety of the patient. These can be proactive risk analysis to identify potential situations which could lead to adverse events and to prevent errors from occurring (e.g. fault tree analysis or failure modes and effects analysis), and reactive analysis when an adverse event or near miss has occurred, to identify the main causes to avoid it in the future (e.g. root cause analysis).
- *Classification, recording and reporting* of adverse events and near misses in external beam radiotherapy. Adverse event here means an event involving accidental or unintended exposures to patient, and near miss an event potentially involving accidental or unintended exposures to patient.

3. Description of some features of the national system for external beam radiotherapy.

A4.1.3 Statistics of replies

Altogether about 74 % of the countries gave a complete reply to the questionnaire (Fig. A4.1). 6 countries (16 %) gave no reply.

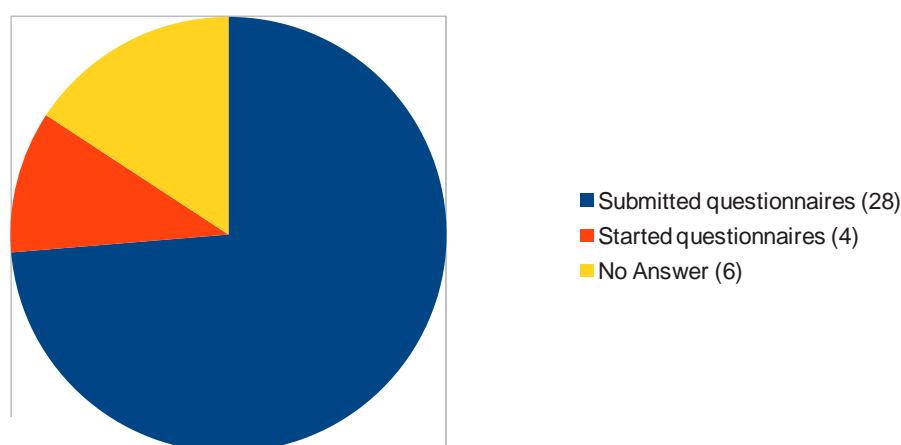


Fig. A4.1. Statistics of replies.

A4.1.4 Regulatory framework and guidelines

A4.1.4.1 Risk management

For risk management, in most of the countries (62 %), legislative requirements were given but these were in most cases (53 %) part of a more general document (a law, decree etc concerning e.g. the health care in general) (Fig. A4.2). In only about 9 % of the countries these requirements were dedicated to radiotherapy.

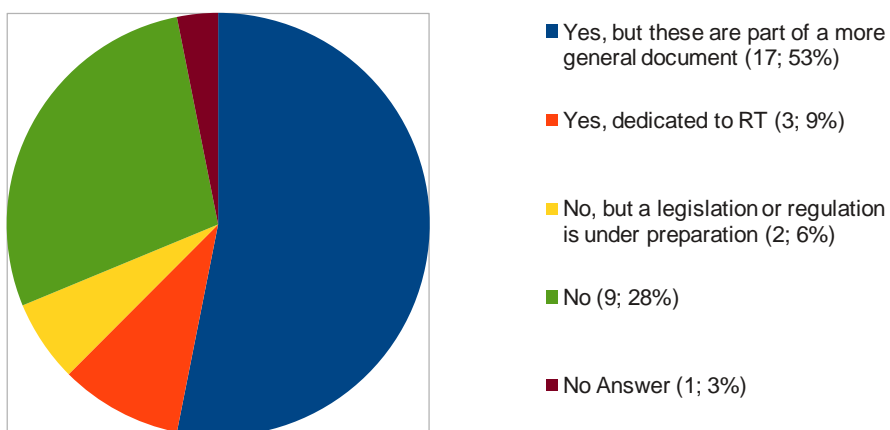


Fig. A4.2. Existence of *legislation or regulations* for risk management

In most countries, no recommendations (59 %) or guidelines (66 %) on risk management existed (Fig. A4.3 and A4.4). In only about 15 % of the countries, recommendations or guidelines dedicated to radiotherapy existed. However, in many countries with no recommendations or guidelines, legislative requirements had existed.

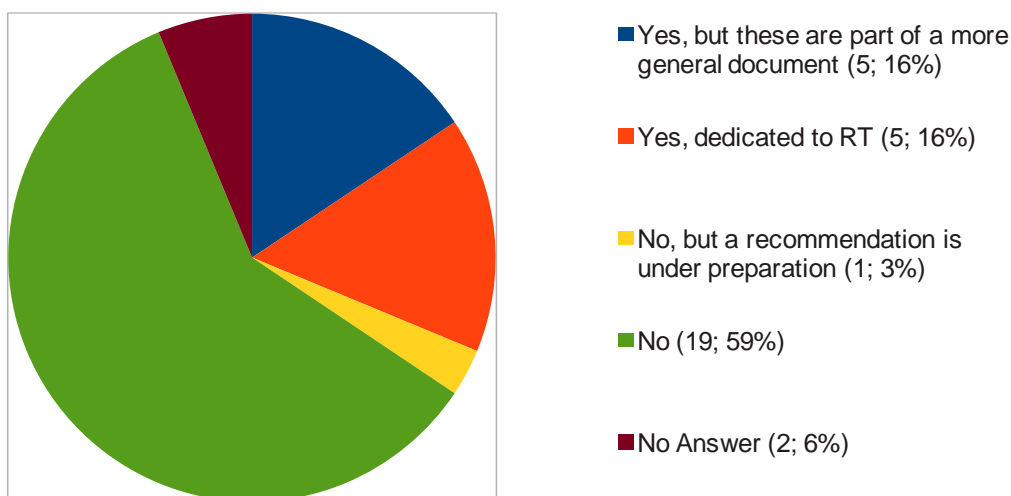


Fig. A4.3. Existence of *recommendations* for risk management.

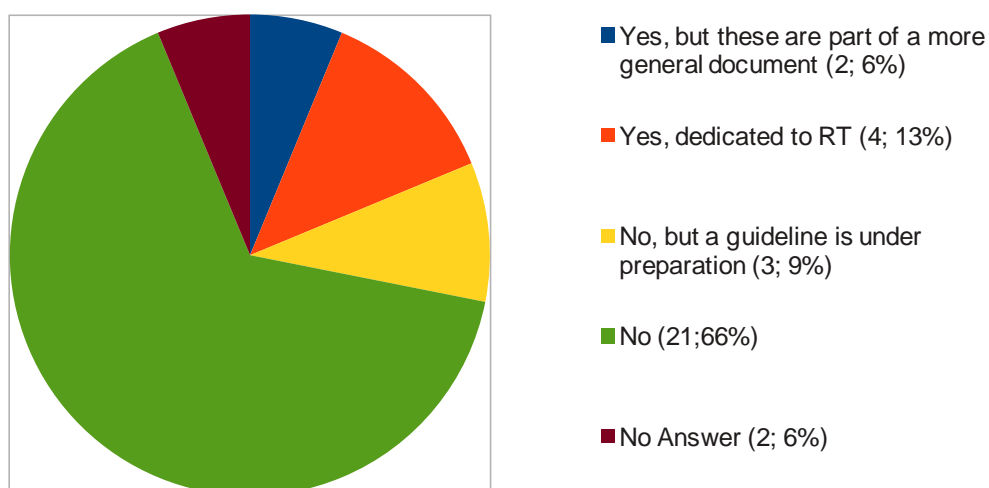


Fig. A4.4. Existence of *guidelines* for risk management.

A4.1.4.2 Classification of adverse error-events and near misses

For classification of adverse error-events and near misses, in most of the countries (56 %), no legislative requirements were given (Fig. A4.5). However, in about one third (35 %) of the countries such requirement existed and in most cases (22%) these were dedicated to radiotherapy.

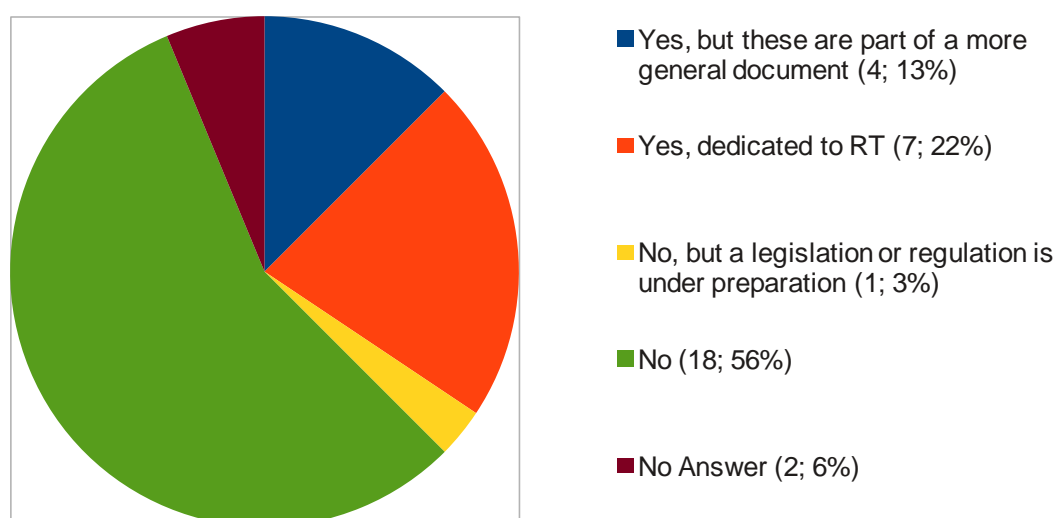


Fig. A4.5. Existence of *legislation or regulations* for classification of adverse error-events and near misses.

In most countries, no recommendations (63 %) or guidelines (66 %) on classification of adverse error-events and near misses existed (Fig. A4.6 and A4.7). However, in some of the countries, recommendations (25 %) or guidelines (16 %) dedicated to radiotherapy existed.



Fig. A4.6. Existence of *recommendations* for classification of adverse error-events and near misses.

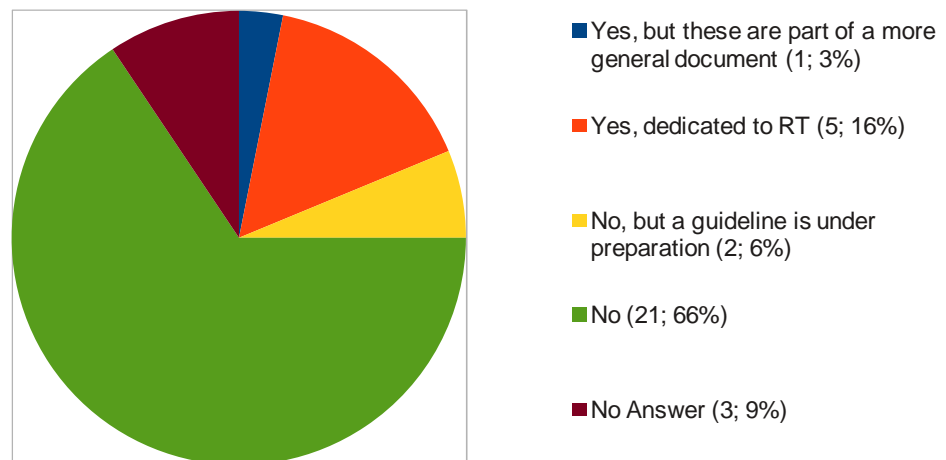


Fig. A4.7. Existence of *guidelines* for classification of adverse error-events and near misses.

A4.1.4.3 Reporting of adverse error-events and near misses

For reporting of adverse error-events, in most of the countries (69 %), legislative requirements were given (Fig. A4.8) but these were in most cases (44 %) part of a more general document. However, in about 25 % of the countries such requirements dedicated to radiotherapy existed. As for reporting of near misses, less than half of the countries (44 %) had legislative requirements, and only 16 % of these were dedicated to radiotherapy.

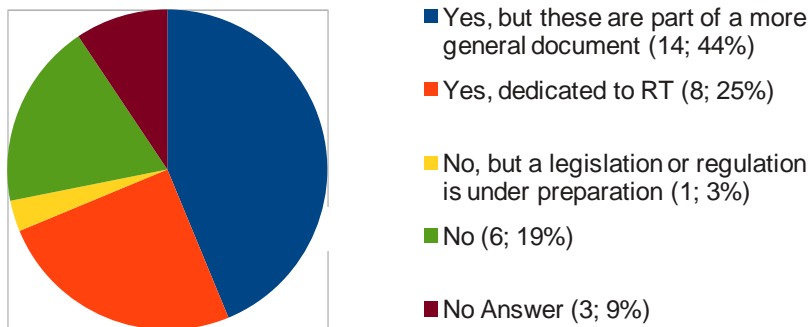


Fig. A4.8. Existence of *legislation or regulations* for reporting of adverse error-events.

In more than half of the countries, no recommendations (56 %) or guidelines (66 %) on reporting of adverse error-events existed (Fig. A4.9 and A4.10). However, in some of the countries, recommendations (25 %) or guidelines (16 %) dedicated to radiotherapy existed.

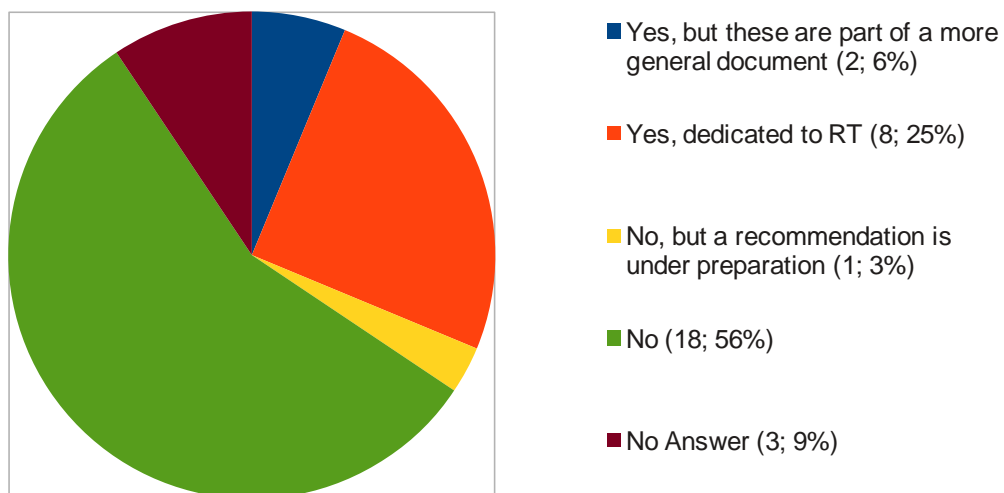


Fig. A4.9. Existence of *recommendations* for reporting of adverse error-events.

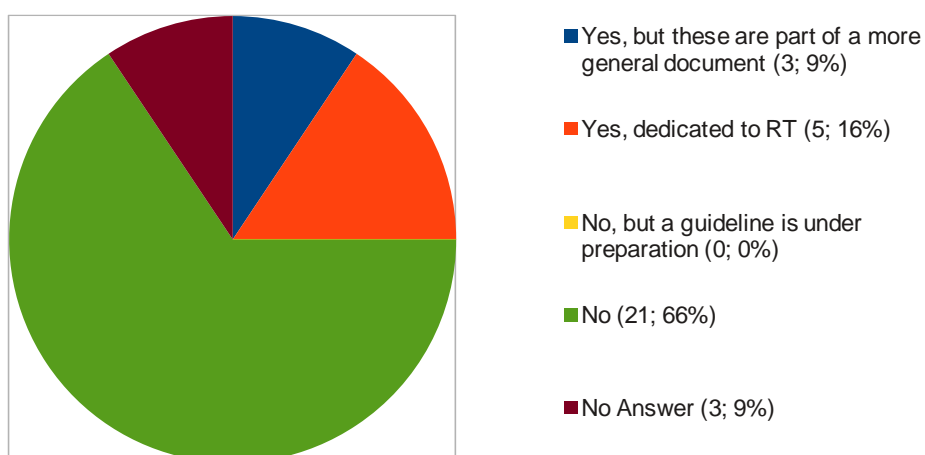


Fig. A4.10. Existence of *guidelines* for reporting of adverse error-events.

A4.1.5 Some national features of external beam radiotherapy

A4.1.5.1 QA and QC programs

In most countries (78 %), there is legislation or regulation on quality assurance (QA) and/or quality control (QC) programs in radiotherapy (Fig. A4.11). In about half of the countries (53 %) national protocols or guidelines on the establishment and content of the QA and/or QC programs had been given (Fig. A4.12).

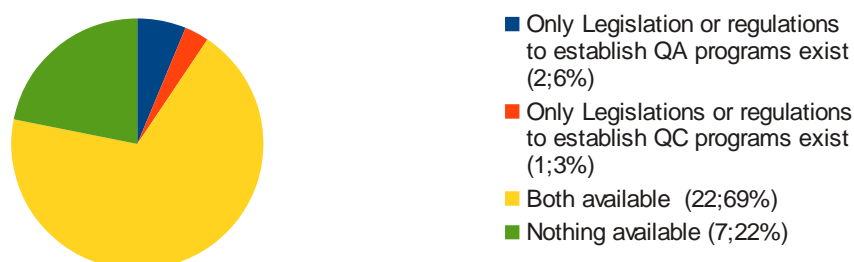


Fig. A4.11. Existence of *legislation or regulations* for QA and QC programs.

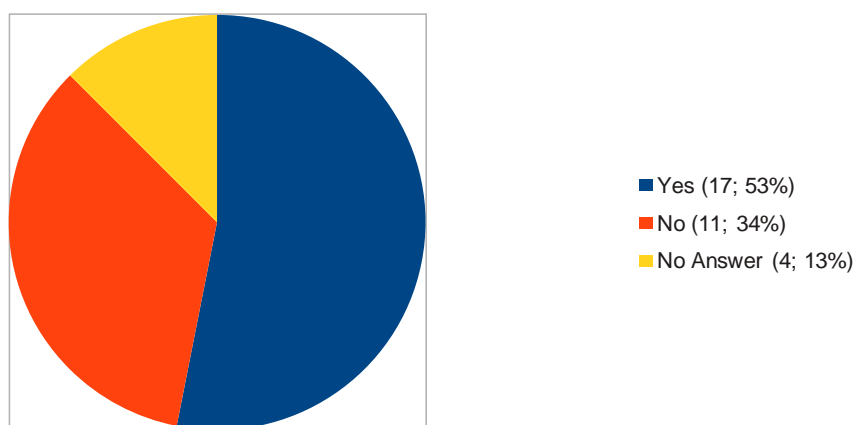


Fig. A4.12. Existence of national protocols or guidelines on the establishment and content of the QA and/or QC programs.

A4.1.5.2 Regulatory control.

In most countries (86 %), regulatory inspection for radiotherapy are carried out, mostly by a regulatory authority (60 %) or by the health authority (26 %) (Fig. A4.13). In less than half (41 %) of the countries, the regulatory authority request dosimetry comparisons or dosimetry audits to be applied by the radiotherapy centres (Fig. A4.14). In about 22 % of the countries, the regulatory authority verifies the local dosimetry system as part of the inspection (Fig.A4.15). In about 31 % of the countries, the regulatory authority carries out inspections and assessments of the efficiency of the QA and QC programs being applied by the radiotherapy centres (Fig. A4.16).

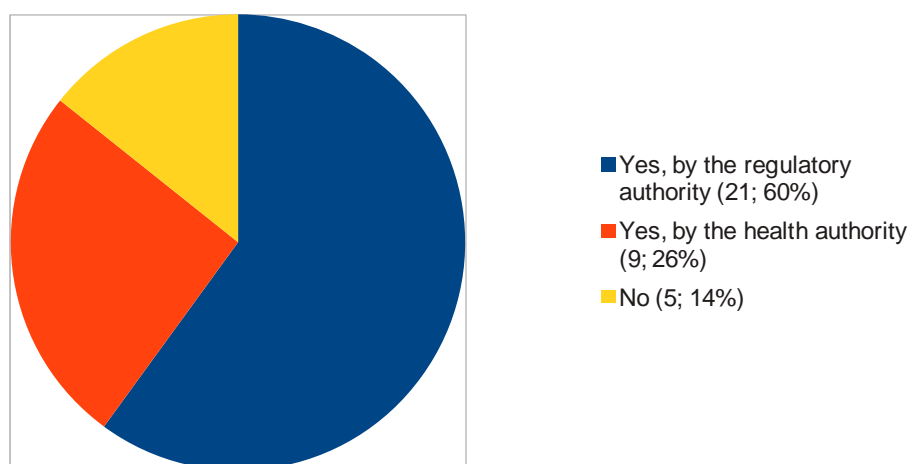


Fig. A4.13 Regulatory inspection for radiotherapy.

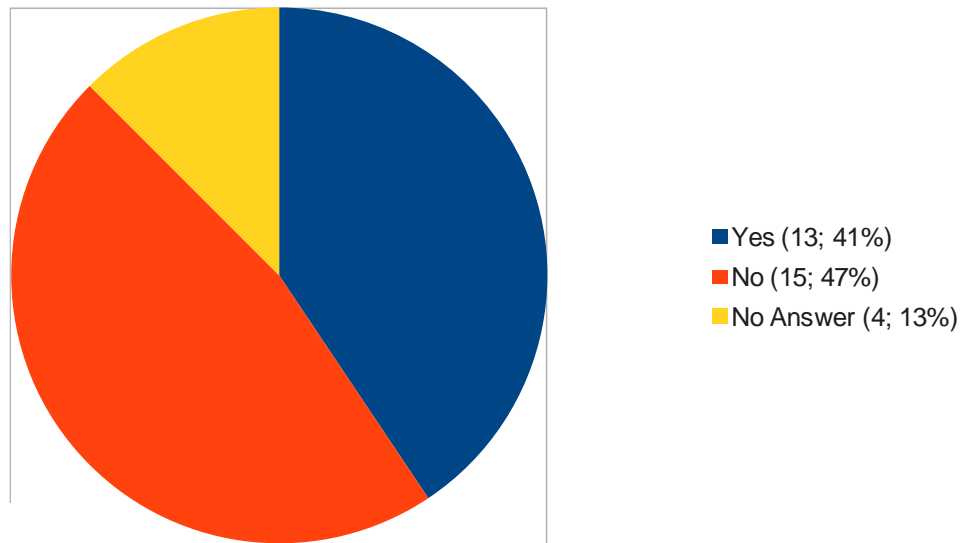


Fig. A4.14. Dosimetry comparisons or dosimetry audits requested by the regulatory authority, to be applied by the radiotherapy centres.

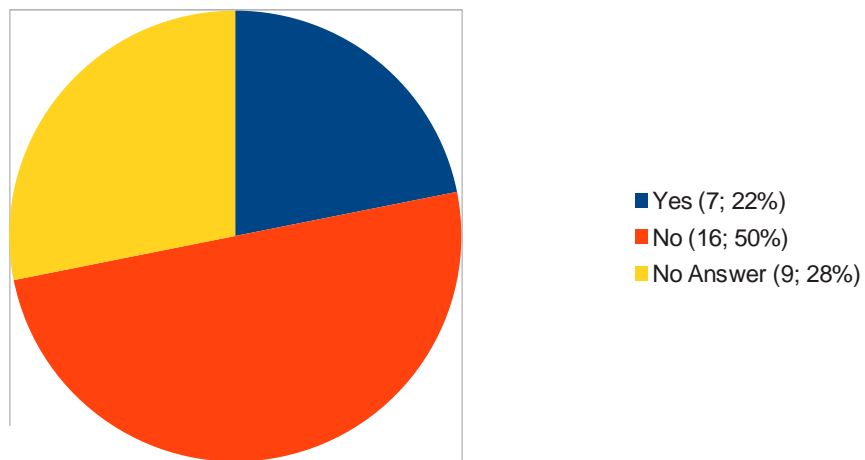


Fig. A4.15. Verification of the local dosimetry system by the regulatory authority as part of the inspection.

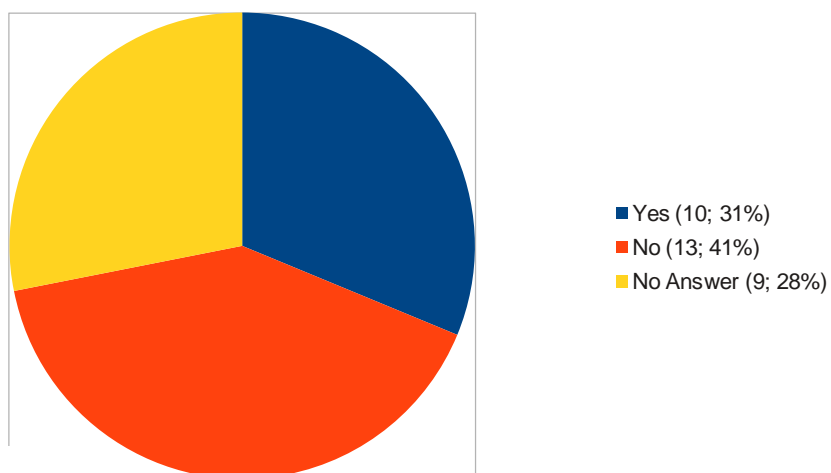


Fig. A4.16. Inspection and assessment by the regulatory authority of the efficiency of the QA and QC programs being applied by the radiotherapy centres.

A4.1.5.3 Clinical audit

In more than one third of the countries (39 %), there are legislations or regulations on clinical audit for radiotherapy, either internal or external audit (Fig. A4.17). In about 22% of the countries, these requirements are for external audit.

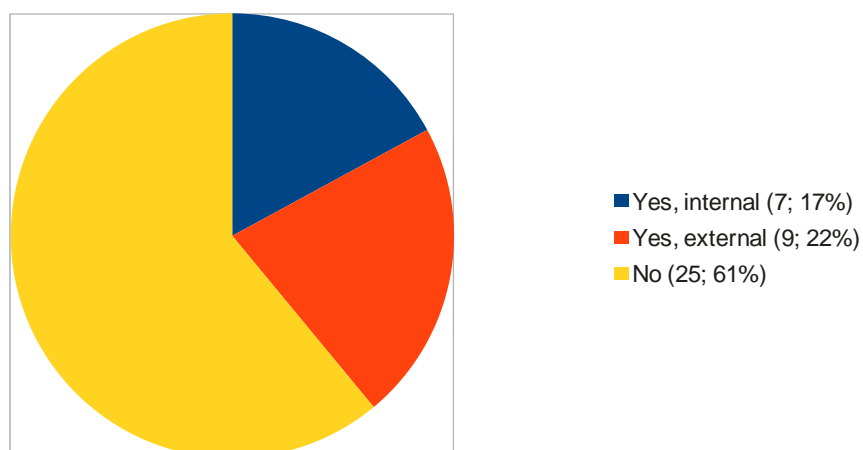


Fig. A4.17 Existence of legislation or regulations on clinical audit.

A4.2 Status of risk management

A4.2.1 Introduction

Following the general questionnaire (section 1) about the basic legal provisions (national regulations) sent to national contact point from 38 countries, the analysis of the 32 answers were used to identify 10 countries having defined “requirements” for proactive risk assessment and/or reactive risk analysis. These “requirements” issued to radiotherapy centres can either be defined by the national authorities by regulations and sometimes by associated guidelines, or be recommended by national professional societies. The aim of the subsequent detailed questionnaire (Questionnaire 2a) was to get information of the main features of the proactive risk assessment and the system for retrospective analysis used in these 10 countries. This section presents the results of the detailed questionnaire of the project (Questionnaire 2a).

The detailed questionnaire was sent to national contact points from Denmark (DK), Ireland (IE), Spain (ES), Finland (FI), France (FR), Italy (IT), Netherlands (NL), Poland (PL), Slovakia (SK) and United Kingdom (UK).

The main points asked were on:

1. general and/or detailed provisions on legislation/regulation;
2. proactive risk assessment method issued at national/regional level mandatory or
3. recommended;
4. reactive risk analysis method issued at national/regional level mandatory or recommended;
5. periodical review of the results of risk assessment conduct by radiotherapy centres;
6. organization for national/regional feedback on risk assessment.

Table A4.1 summarizes the responses by the national contact point to the questionnaire on provision in general regulation related either to healthcare (HC) or to radiation protection (RP), and on recommendations issued to radiotherapy centres by national authorities or professional societies. The detailed contents of the responses are summarized in the rest of this section.

Table A4.1 Regulations and recommendations; results of the detailed questionnaire.

	General regulation	Detailed	Recommendations issued to radiotherapy centres	
DK	No	No	No	
ES	RP/HC	Royal decree	National authorities	
FR	RP/HC	ASN decision	National authorities	
FI	RP/HC	STUK guide	National authorities	
IT	No	No	Professional societies	
IE	RP/HC		National guidelines	
NL	RP/HC	No	Professional societies	
PL	RP	No	National authorities	
SK	RP	HC	No	
UK	RP	RP	National authorities	Professional societies

RP : Radiation protection regulation

HC: healthcare regulation

A4.2.2 Proactive risk assessment

A4.2.2.1 Regulation

In most of the countries having answered to the questionnaire, the regulation in radiation protection implemented in accordance with European directives clearly defines requirements on a priori analysis risks for workers. For patients, however, the implementation of proactive risk assessment is mandatory in few countries (FR, IE,UK) according either to national healthcare regulation (FR, NL), to general radiation protection regulation (IE, UK) or specific to radiotherapy (FR). In others countries, risk assessment is recommended I.

Details are summarized below (no precise data were available from the Netherland).

FI	Binding guide specific to radiotherapy	<p>Guide ST 2.1 Safety in radiation therapy</p> <p>A quality assurance programme is required. It shall define the necessary quality assurance functions, and must also include the principles for preventing in advance errors and mishaps from which radiation doses may arise unintentionally. Quality assurance practices shall be assessed regularly and, when appropriate, changed.</p> <p>Quality assurance shall cover all of the radiation therapy chain</p> <p>Written instructions for the most common procedures in radiotherapy shall cover all stages of the radiotherapy process, as the planning and implementation of treatment requires many kinds of technically demanding apparatus and procedures, and effective collaboration by several professional groups. The written instructions must also include practical directions for responding to and preventing accidents.</p> <p>Abnormal events shall be prevented in advance</p> <p>A quality assurance programme shall include the principles for preventing errors and mishaps which may cause unintended radiation doses. Therapy equipment quality assurance programmes shall therefore include the inspection of the operating conditions of the warning and safety devices that are associated with the therapy equipment and the related premises.</p>
FR	General regulation on healthcare	<p>Certification of healthcare organization.</p> <p>HAS (French Health Authority) has elaborated a general document on certification of healthcare organization (Certification manual V2010). Among the points examined during the certification process, some are about a formalized program to improve the quality and safety of care. This programme should take into account analysis of regulatory compliance; analysis of adverse events, malfunctions, major and recurring care risks identified retrospectively and a priori. The organization for the reporting and analysis of adverse events is assessed. The cause analysis of serious adverse events must be performed involving stakeholders and corrective actions are implemented.</p> <p>Ministerial order n°2010-1408 du 12/11/2010 on fight against adverse events associated with healthcare in health facilities</p> <p>The responsible of an healthcare facility must nominate a coordinator of risk management</p>

	Specific to radiotherapy	<p>ASN decision 103 of 1 July 2008 establishing quality assurance obligations for radiotherapy.</p> <p>Proactive Analysis of the risk to patients of the radiotherapy process</p> <p>The top management of a healthcare establishment carrying out external radiotherapy treatment activities shall ensure that a risk analysis is carried out regarding the risks posed to patients. This analysis should relate as a minimum to risks which could lead to a mistake in the irradiated volume or delivered dose at each stage of the clinical radiotherapy process and must take the use of the various medical devices into consideration. The risk analysis must include a assessment of the risks and the steps taken to mitigate any risks considered to be unacceptable.</p> <p>Risks which do not need to be taken into consideration are those relating to possible side effects, regardless of severity, resulting from a treatment strategy that has been agreed between the practitioner and the patient and accepted in the light of the expected benefits of the treatment, having taken into consideration the principles of justification and optimisation (...).</p> <p>Top management must also ensure that the following are drawn up on the basis of the above-mentioned risk analysis:</p> <ol style="list-style-type: none"> 1. procedures designed to ensure that the delivered dose, the treated volume and the irradiated and protected organs are in compliance with those stated on the medical prescription; 2. methods designed to ensure that the equipment is used correctly.
IE	Radiation protection regulation	<p>Statutory instrument: S.I. No. 478/2002 — European Communities (Medical Ionising Radiation Protection) Regulations 2002 http://www.irishstatutebook.ie/2002/en/si/0478.html</p> <p>21. “Working instructions and written protocols and quality assurance programmes to prevent accidental exposure shall be established and implemented by the practitioner in respect of each installation.”</p> <p>22.1 “Each health board shall establish a committee to be known as the Radiation Safety Committee and that (...) shall advise the chief executive officer on any matter pertaining to the safety of radiological installations in the functional area of the health board and general operational practices in such installations and may issue guidance notes to holders, practitioners, practitioners in charge and prescribers to assist them to comply with the relevant provisions of these regulations”</p>
UK	Radiation protection regulation	<p>The Ionising Radiation Regulations 1999 [IRR99] addresses incidents due to equipment defect or malfunction. http://www.legislation.gov.uk/uksi/1999/3232/contents/made</p> <p>[IRR99] contains a specific regulation pertaining to ‘prior risk assessment’. It requires that before an employer commences a new activity involving work with ionising radiation, he will make a suitable and sufficient assessment of the risk to patients. The assessment must demonstrate that all hazards with the potential to cause a radiation accident have been identified and the nature and magnitude of the risks to patients arising from those hazards have been evaluated. Where the assessment shows that a radiation risk exists the employer must take reasonably practicable steps to prevent any such accident</p>

		<p>and limit the consequences of any such accident which does occur.</p> <p>The Ionising Radiation (Medical Exposure) Regulations 2000 [IR(ME)R] focuses on procedural failures</p> <p>http://www.legislation.gov.uk/uksi/2000/1059/contents/made</p> <p>[IR(EM)R] includes a requirement for employers to have procedures in place to ensure the probability and magnitude of accidental or unintended doses to patients from radiological practices are reduced so far as reasonably practicable.</p> <p> (“employer” means any natural or legal person who, in the course of a trade, business or other undertaking, carries out (other than as an employee), or engages others to carry out, medical exposures or practical aspects, at a given radiological installation;)</p>
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A4.2.2.2 Proactive risk assessment method

In countries where proactive risk assessment is mandatory, no methodology is defined but some general methodologies are recommended by either authorities or by professional societies who have provided guidelines to radiotherapy centers. Spain and France proposed special examples dedicated to radiotherapy while only Slovakia mentioned WHO patient safety radiotherapy risk profile.

Method	ES	FR	NL	SK	UK
FMEA	X	X	X		
Fault tree					X
Event tree					X
Preliminary risk analysis	X		X	X	
Matrix probabilistic risk assessment	X				X
Human factors methods				X	
Others	Money value Barrier analysis			WHO	Dosimetry audit Peer review

Depending on the country, further information was available as summarized in the following.

	Method	
ES	FMEA	This methodology is recommended in the training courses of Risk Management promoted by the Spanish Ministry of Health (Quality National Plan for the National Health System. Spanish Ministry of Health and Consumer Affairs. Madrid, 2006). http://www.seguridaddelpaciente.es/formacion/tutoriales/MS-CD2/entrada.swf
	MPR	Risk Matrix Methodology application to radiotherapy developed by the Ibero-American Forum of Regulators in Nuclear, Radiation and Physical Safety http://www.foroiberam.org/web/index.php
FR	FMEA	ASN Guide n°4: “Guide to risk self-assessment in external beam

	FMEA	radiotherapy" HAS Guideline 2012: "Implement risk management associated with care in health facilities "
NL	FMEA PRA	Recommendation by professional societies
SK		WHO – Radiation risk profile http://www.who.int/patientsafety/activities/technical/radiotherapy_risk_profile.pdf
UK	FT ET MPR	Recommended by national organisations to facilitate proactive risk assessment at a national level across medical exposure disciplines.

FMEA failure mode and effect analysis – FT Fault tree – ET Event tree – PRA Preliminary risk assessment – MPR Matrix probabilistic risk assessment – HF human factor method

A4.2.3 Reactive analysis of events and reporting

A4.2.3.1 Regulation and guidance

For most of the countries, a reactive analysis of event is mandatory and closely related to quality assurance management but also to mandatory recording at hospital level and/or to mandatory reporting at local and national level. The provision for this analysis is related to radiation protection regulation (FL, FR,UK), with specific requirements in radiotherapy (ES, FI, FR) or to healthcare regulation with specific requirements on medical devices regulation (FI, FR, IE). Not-binding guide specific to radiotherapy have been developed in particular in the United Kingdom and Ireland.

ES	Regulation specific to radiotherapy	Royal decree 1566/1998 (Real Decreto 1566/1998, de 17 de julio, por el que se establecen los criterios de calidad en radioterapia) http://www.boe.es/aeboe/consultas/bases_datos/doc.php?id=BOE-A-1998-20644 Includes different statements related to quality assurance and risk management: "The Quality Assurance Committee will send a report to the Head of the Hospital and to the Health Authority, whenever there are radiation absorbed doses to patients other than those prescribed that imply a significant risk to their health, whenever the quality assurance program is not followed, and whenever deemed appropriate." (Art. 4.2) "If during the course of radiation treatment a patient presents a clinical reaction other than expected, the specialist shall investigate the causes and write a report which shall include the investigation and actions taken, as well as possible deviations from the planned treatment." (Art. 6.5)
FI	General regulation on healthcare, radiation	The general requirements for the supervision and quality assurance of medical radiation equipment are laid down in section 40 of the Radiation Act (592/1991), and in sections 18 and 32 of the Decree of the Ministry of Social Affairs and Health on the medical use of radiation (423/2000).

	protection	<p>The Radiation Decree (1512/1991) Section 17 prescribes that STUK must be notified of all abnormal events arising in the use of radiation.</p> <p>The Medical Devices Act (1505/1994) requires professional users of medical devices to notify the National Agency for Medicines of hazardous situations arising in their use.</p> <p>The duty to report to the National Agency for Medicines applies, for example, to hazardous situations involving radiotherapy equipment and materials arising on account of any impairment in their characteristics or functioning, or of any lack of clarity in their instructions for use.</p>
	Binding guide specific to radiotherapy	<p>Guide ST 2.1 Safety in radiation therapy</p> <p>An abnormal event is an adverse incident such as an equipment fault, human error or combination thereof that caused (harmful event) or could have caused (nearmiss incident) hazard to the health of a patient, a member of staff or an outsider.</p> <p>Abnormal events in the use of radiation must be reported to STUK. Professional users of medical devices must report all adverse incidents in the use of these devices to the National Supervisory Authority of Welfare and Health.</p> <p>The responsible party shall report in writing any abnormal event or observation significant for safety, detailing the event or observation, immediate measures, initial evaluations of the reasons for the event the consequences of the event and the measures taken. In addition, the report shall present measures for the prevention of similar events in the future.</p>
FR	General regulation on radiation protection	<p>Public Health code Art R1333-109/III for reactive analysis</p> <p>“I. - In the case of exposure of patients to radiation for medical health professionals involved in the treatment or follow-up of these patients, having knowledge of an incident or accident related to this exposure, make the declaration without delay to the nuclear Safety Authority and the Director of the regional Health agency territorial jurisdiction. (...)</p> <p>II. - Events or incidents mentioned in I are qualified to significant events.</p> <p>III. - The person in charge of a nuclear activity has to analyze the significant events in order to prevent future events, incidents or accidents.”</p>
	Regulation specific to radiotherapy	<p>ASN decision 103 of 1 July 2008 establishing quality assurance obligations for radiotherapy.</p> <p>Internal reporting of failures and adverse events</p> <p>All staff directly involved in the therapeutic management of patients undergoing external radiotherapy must report every organisational, physical or human adverse event or failure to a dedicated structure for analysis of internal reporting and identification of improvement actions. This structure should comprise representative skills from the different professions directly involved in the therapeutic management of patients undergoing radiotherapy.</p> <p>The structure shall:</p> <ol style="list-style-type: none"> 1. analyse internal reports, in particular those that have required a statutory report to be sent to ASN under the radiation vigilance requirements and/or to the national agency for safety of medical

		<p>devices. (ANSM);</p> <ol style="list-style-type: none"> 2. suggest improvement actions for each report analysed; 3. monitor the implementation of these actions and evaluate their effectiveness. <p>Records based on analysis of internal reporting</p> <p>For each internal report analysed a record must be kept, as a minimum of: the names of all the individuals who have taken part in the evaluation, in proposing improvement actions and deciding on the action plans and in identifying the possible causes and justifying the elimination of certain causes, as well as the nature of the proposed improvement actions with their implementation dates, names of persons designated to oversee their implementation and monitoring and completion of the actions.</p>
IE	Guidelines specific to radiotherapy	<p>National guidelines (produced by the National Radiation Safety Committee) for all radiotherapy departments were produced and implemented in 2010 defining radiotherapy incidents, outlining requirements for investigation and external reporting of incidents.</p> <p>The National Baseline Audit on the Implementation of Statutory Instrument (SI) 478 (2002) conducted in 2008 recommended the establishment of a notification system for incidents to patients to be managed by the Medical Exposure Radiation Unit, HSE. The National Radiation Safety Committee is an expert advisory committee established under SI 478 to advise the CEO, HSE on Radiation Safety Issues for Patients.</p> <p>All incidents should be managed through the normal risk management route within the organisation and tabled on the Radiation Safety Committee agenda. All incidents should be recorded, reported, reviewed and investigated, where considered appropriate, locally.</p> <p>The findings of the investigation must be documented in an investigation report. It is recommended that the report should include the following information: recommendations to avoid recurrence, details of follow up actions with staff involved and with patient.</p> <p>All notifiable incidents should be reported upon discovery to the HSE-Medical Exposure Radiation Unit. Notifiable incidents are defined within these guidelines</p> <p>The Medical Exposure Radiation Unit will request each location to submit the total number of incidents that have been recorded in addition to the notifiable incidents. This will be requested every six months.</p> <p>http://www.hse.ie/eng/about/Who/qualityandpatientsafety/Patient_Safety/medexpradionunit/incident%20Definitions.pdf</p> <p>Locations use additional methods to address risks and incidents, e.g., "Towards safer Radiotherapy" and Alberta Canada guidelines ("A reference guide for learning from incidents in radiation treatment" AHFMR –HTA initiative #22 http://www.ihe.ca/documents/HTA-FR22.pdf)</p> <p>An incident which occurs due to a prescriber or practitioner (as defined in S.I. No. 478 of 2002) error is not reportable to the Radiological</p>

		Protection Institute of Ireland. "Guidelines for reporting radiological incidents to the Radiological Protection Institute of Ireland". Only radiotherapy incidents dealing with radiation protection of staff and public are required to be reported to the RPII.
UK	General regulation on radiation protection	Both IR(ME)R & IRR99 require the employer to make an immediate investigation, if he knows or has reason to believe that an incident has or may have occurred. The investigation should include the circumstances of the exposure and an assessment of the dose received. In addition there is a requirement under IR(ME)R that every medical exposure is clinically evaluated irrespective of the outcome including when it is delivered as intended. (5) Where the employer knows or has reason to believe that an incident has or may have occurred in which a person, while undergoing a medical exposure was, otherwise than as a result of a malfunction or defect in equipment, exposed to ionising radiation to an extent much greater than intended, he shall make an immediate preliminary investigation of the incident and, unless that investigation shows beyond a reasonable doubt that no such overexposure has occurred, he shall forthwith notify the appropriate authority and make or arrange for a detailed investigation of the circumstances of the exposure and an assessment of the dose received.
	Guidance specific to radiotherapy	The Ionising Radiation (Medical Exposure) Regulations 2000 – Guidance and notes on good practices http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_064707.pdf This document provides guidance on the Ionising Radiation (Medical Exposure) Regulations 2000 (the Regulations) and notes on good practice. The guidance is not intended to be binding and cannot take the place of legal advice. 6.8.1. This regulation requires the employer to carry out investigations of incidents and appropriate reviews. In most cases, the term 'much greater than intended' as used in this regulation should be interpreted as for IRR 1999. HSE has published specific guidance on doses which are likely to be much greater than intended for particular types of medical exposure. While this guidance was not developed for this purpose, application of this guidance is appropriate. Incidents which occur as a result of equipment malfunction or breakdown must still be reported to the HSE under IRR 1999. 6.8.2. Patients who undergo a procedure that was not intended, as a result of mistaken identification or other procedural failure, and consequently have been exposed to an ionising radiation dose, should be considered as having received an unintended dose of radiation. 6.8.3. The detailed investigation required by the Regulations should be aimed at: - establishing what happened - identifying the failure - deciding on remedial action to minimise the chance of a similar failure - estimating the doses involved. 6.8.4. The notification is required to be made directly to the appropriate

	<p>authority appointed for these Regulations. (...) Further, whilst the Regulations refer to those incidents resulting in exposures much greater than intended, it is recognised that in certain situations e.g. radiotherapy, exposures much lower than intended can also have serious consequences. Whilst not notifiable under these Regulations, as a matter of good practice, the employer may wish to carry out his own investigations in such circumstances.</p>
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A4.2.3.2 Methods for reactive analysis of events

In countries where reactive risk assessment is mandatory, no methodology is defined but some general methodologies are recommended (as shown in the table below) by either authorities or by professional societies who have provided guidelines to radiotherapy centers.

Method	DK	ES	FR	IE	NL	SK	UK
ALARM						x	
Causal tree analysis		x			x	x	
Root cause analysis	x	x		x	x		
ORION [®]			x ¹				
Others		5 why's Ishikawa	HAS ²	TSRT ³ Alberta ⁴		TSRT ³	TSRT ³

1. MeaH 2008: "Improve the safety of care organizations " promoted to French radiotherapy centres
2. HAS Guideline 2012: "Implement risk management associated with care in health facilities "
3. "Towards Safer Radiotherapy"
https://www.rcr.ac.uk/docs/oncology/pdf/Towards_saferRT_final.pdf
4. Alberta Canada guidelines ("A reference guide for learning from incidents in radiation treatment" AHFMR –HTA initiative #22 <http://www.ihe.ca/documents/HTA-FR22.pdf>

Depending on the country, further information was available as summarized in the following table.

	Methods	Why was the methods chosen /documentation related to the methods
es		The methodologies are recommended in the training courses of Risk Management promoted by the Spanish Ministry of Health (Quality National Plan for the National Health System. Spanish Ministry of Health and Consumer Affairs. Madrid, 2006). It allows to systematically analyze the underlying causes and the environment in which the adverse event occurred
IE	RCA	Method promulgated by Health Safety Executive: Toolkit of Documentation to Support the Health Service Executive Incident Management (2009)
FR	ORION [®]	MeaH 2008: "Improve the safety of care organizations " promoted to French radiotherapy centres by ministry of health http://www.anap.fr/uploads/tx_sabasedocu/SECURITE_RADIO.pdf

	Review	HAS – health authority whose role is to enhance the quality and safety in health – has published a guide to healthcare professional in order to promote risk assessment methodologies. HAS Guideline 2012: "Implement risk management associated with care in health facilities " http://www.has-sante.fr/portail/upload/docs/application/pdf/2012-04/okbat_guide_gdr_03_04_12.pdf
UK		Guidance on the Ionising Radiation (Medical Exposure) Regulations 2000 issued by Department of Health (DH) defines the detailed investigation required by the Regulations
	RCA	"Towards Safer Radiotherapy" was published in 2008, in response to several high level incidents. The UK RT professional community recognised the need to provide guidance on improving safety in radiotherapy and to share information related to RTE nationally. A multidisciplinary working party was established including representatives from the professional bodies, patients, the National Patient Safety Agency and the HPA. Inclusion of all stakeholders in the development of this approach in part ensured the early adoption of the recommendations from 'Toward Safer Radiotherapy' (TSRT). The proposed terminology and taxonomies have been adopted for use in radiotherapy departments across the UK. This provides a standard approach by which RT adverse and near misses events can be described, classified and coded locally and nationally. http://www.rcr.ac.uk/publications.aspx?PageID=149&PublicationID=281

A4.2.4 Periodical review of the results of risk assessment conducted by radiotherapy centres

FI	Reviews in radiotherapy centres supervised every two years on inspections by STUK and every five years by clinical auditors
FR	ASN annual inspection
SK	There are conducted in mandatory documentations and agenda according to national laws
UK	Peer Review: Institutions participate in a National Cancer Peer Review Programme. Some of the measures radiotherapy institutions are scored against include risk assessments of specific part of the radiotherapy pathway. The results of the peer review programme are published on a government website at: http://ncat.nhs.uk/sites/default/files/work-docs/resources_reports_NCAT_NCPR_National_Report_2009_10.pdf

A4.2.5 Organization for feedback on risk assessment

DK	Reactive analysis is carried out on a very general level by "Danish Patient Safety Database"
FI	Annual meetings of radiation therapy physicists organized by STUK

FR	<p>National feedback</p> <p>Significant event according to ASN SFRO scale, information on website ASN for level higher than 2, quarterly report for level 1 annual</p> <ul style="list-style-type: none"> • ASN annual Report • Report 2008- 2009 Notifications received by ASN and Afssaps regarding radiation protection and medical device vigilance in radiotherapy • Newsletter ASN-SFRO-AFPPE n°3 2012 "Patient safety" • Letters send to all radiotherapy centres on specific topics <p>Training</p> <ul style="list-style-type: none"> • Meetings, regional seminars organised by ASN, • SFRO congress: special session on safety and quality assurance management in radiation oncology; • SFPM annual scientific days: special session on safety in radiotherapy education • Training sessions (EFEC-School of European Education in Cancer, SFPM Post graduate training on risk assessment...)
IT	<p>Ministerial Commission for monitoring of sentinel events that periodically issues reports and recommendations.</p>
SK	<p>The feed back (from internal and external audits executed by independent organizations with licences for those activities. Results are presented on special conferences and documents are stored in the organization and in regional/national authorities</p>
UK	<p>The Health Protection Agency (HPA is part of Public Health England since April 2013) is an independent organisation whose role is to provide an integrated approach to protecting UK public health. Part of its remit includes the provision of independent advice on radiological practice and radiation safety. The HPA staff liaise with healthcare professionals, professional bodies, government departments and agencies, inspectors for legislation and members of the public.</p> <p>Guidance documents on the application of the coding and classification from TSRT, together with information on how to submit data to the national dataset are available on the HPA radiotherapy webpage. In addition, quarterly newsletters and national 2 yearly reports of the results of data analysis are available at www.hpa.org.uk/radiotherapy</p> <p>“Safer Radiotherapy” published on a quarterly basis. The aim of the newsletter is to provide a regular update on the analysis by the Health Protection Agency (HPA) of radiotherapy error reports. The newsletter is designed to disseminate learning from errors to professionals in the radiotherapy community to influence local practice and improve patient safety.</p> <p>http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1317137761927</p> <p>NHS - National Patient Safety Agency Implementing Towards Safer Radiotherapy: guidance on reporting radiotherapy errors and near misses</p> <p>http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1296688315335</p>

A4.3 Examples of local risk management

A4.3.1 Introduction

In this section, a summary of Project Questionnaire 2b is presented. The aim of this questionnaire was to get information and examples of the main features of proactive risk assessments and systems for retrospective analysis used in /radiotherapy department level.

A4.3.2 Countries and radiotherapy departments

The countries and radiotherapy departments providing replies are shown in Table A4.2.

Table A4.2. Countries and radiotherapy departments providing replies.

United Kingdom	Denmark	Netherland	Spain	Italy	Poland	France
University College Hospital London Hull and East Yorkshire NHS Trust Cottingham	Odense University Hospital Odense	MAASTRO Maastricht Erasmus MC Daniel den Hoed Cancer Centre Rotterdam NKI-AVL Amsterdam	IMO Madrid Hospital clinico San Carlos Madrid	Osp. FBF San Giovanni Rome Istituto Clinico Humanitas Rozzano	Greater Poland Cancer Center Poznan	Sainte-Catherine Institute Avignon

A4.3.3 Summary for proactive risk assessment

The replies on proactive risk assessment are summarized in the following according to the main points asked from each radiotherapy department.

Criteria for setting up proactive risk assessment

The main criteria for performing proactive risk assessment is typically due to changes in practice or procedures, to assess their impact on the broader processes crossing all disciplines. Changes might be minor (e.g., changes to the quality control schedule) or major (e.g., implementation of new treatment equipment or a new treatment technique), impacting either small work groups or being systemic or departmental wide (e.g., 'going paper-free/paper-lite' or introduction of a new clinical service).

Updating of software and hardware PC and IT related issues could also led to implement or to review a risk assessment.

For some centres, a revision of risk assessment is also made after action review held when near misses are identified

Method for proactive risk assessment

According to the countries or in the same country for different centres the method chosen are quite variable but some of them can be mentioned:

In UK, one hospital has developed a PRA by using a peer review approach in order to identify hazards and then a risk matrix is used to grade the risk and to decide if actions are needed. The risk matrix is not specific for radiotherapy but used for all activities in the hospital. A specific sheet is offered as a practical support to performed the study and different scales for likelihood and severity (impact) scores – 5 levels for each- are developed.

For another one, not any formal risk analysis methodology that would be used for all occasions is defined. At their simplest, risk assessments are exploratory analysis of a process or proposed process, identifying the risk points for failure (Event tree-like) which is performed by individuals or by focus group discussion. Internal guidance document on identification and management of higher risk radiotherapy treatments has been developed.

In SP, some hospitals have implemented the Matrix Probabilistic Risk Assessment method developed by the FORO^{9,10} for radiotherapy. The identification of dangers associated with a practice is done by the failure mode and effects analysis (FMEA).

In NL, a systemic approach called SAFER (Scenario Analysis of Failure Modes, Effects and Risks) adapted to health care processes in Dutch hospitals, has been developed following a systemic evaluation of prospective risk analysis using Healthcare Failure Mode and Effect Analysis (HFMEA™). HFMEA™ is a systematic method for prospective risk analysis developed by the American Veterans Affairs' National Center for Patient Safety.

In IT, the hospital involved in this survey are using FMEA¹¹. Some radiotherapy departments have developed specific analysis on intraoperative radiotherapy¹² and proton therapy.

Details of its implementation in RT practice

For the hospitals, the risk assessment is realised by a multidisciplinary team made up specially in most cases and involving risk manager, radiation oncologists, medical physicist, radiation therapist. Management of radiotherapy department or of the establishment is not always involved in the process.

An example of the way to implement risk assessment is given hereafter:

“After a detailed process analysis, failures are identified through interviews performed by the facilitator (the Risk Manager) with the process experts in order to focus the attention on the process steps more prone to errors and to draft a list of hazards. Beside this, the facilitator performs some site visits in order to observe those criticalities under estimated by the experts during interviews. “

⁹ Prevention of accidental exposure in radiotherapy: the risk matrix approach

J.J. Vilaragut, C. Duménigo, J.M. Delgado, J. Morales, J.D. McDonnell, R. Ferro, P. Ortiz López, M.L. Ramírez, A. Pérez Mulas, S. Papadopulos, M. Gonçalves, R. López Morones, C. Sánchez Cayuela, A. Cascajo Castresana, F. Somoano, C. Álvarez, A. Guillén, M. Rodríguez, P.P. Pereira, and A. Nader - Health Physics February 2013, Volume 104, Number 2

¹⁰ IAEA-TECDOC-1685/S : Aplicacion del Metodo de Analisis de Matriz de Riesgo a la Radioterapia -2012

¹¹ Applying failure mode effects and criticality analysis in radiotherapy: Lessons learned and perspectives of enhancement

Marta Scorsetti, Chiara Signori, Paola Lattuada, Gaetano Urso, Mario Bignardi, Pierina Navarra, Simona Castiglioni, Pietro Mancosu, Paolo Trucco - Radiotherapy and Oncology 94 (2010) 367–374

¹² Application of failure mode and effects analysis to ontraoperative radiation therapy using mobile electron linear accelerator.

Ciocca M, Cantone MC, Veronese I, Cattani F, Pedroli G, Molinelli S, Vitolo V, Orecchia R. Int J Radiat Oncol Biol Phys. 2012 Feb 1;82(2):

Benefits and problems encountered

As benefits performing risk analysis improve the knowledge of the team and aware all on the risk to manage.

The main problems had been

- Availability of the staff and time consuming to implement the risk analyses.
- Difficulties to evaluate hazards or previous failures.
- Need of an « external » point of view to make an agreement for rate evaluation.
- Management implication in risk reduction

A4.3.4 Summary for analysis of events

The replies on the analysis of events are summarized in the following according to the main points asked from each radiotherapy department.

Selection criteria for events to be analyzed

Depending of the practice of department, criteria for analysis of event is related in most cases to all of criteria proposed within the questionnaire:

- selected event (including near misses) reported at local level and considered as relevant for improvement of safety of treatments
- considering severity of actual or potential consequences
- radiotherapy department defined criteria
- request of 'authorities' following an event notification
- obligation for every event reported

In some case, the criteria is closely linked to the reporting system used e.g DSPD- Danish safety Patient Database in DK, PRISMA-RT in NL where the system give possibility to benchmark the data on cause analysis for the 18 radiotherapy departments involved, methodology developed in “Toward safer radiotherapy” and DATIX in UK and IE.

The near misses events are always analysed in NL leading a radiotherapy department to analyse more 1400 events per year.

Details of its implementation, Time of analysis

The implementation of reactive analysis is always done by a multidisciplinary team and the method use is generally root cause analysis. But one hospital has indicated that the chosen method is related to the type of event: probabilistic analysis, fishbone analysis or root cause analysis. In F, the ORION method is widely used because it had been promoted by the national cancer institute and the ministry of health with financial support of hospitals.

Time of analysis is very different from department to another ranging from “as soon as possible” to 2 days or on a monthly basis analysis of events registered. In one hospital, the time of analysis is related to the type of event ranging from 24 h for miss event with dose deviation greater than 5%, to 5 days for others miss events and to one month for near misses

Benefits and problems encountered

As for benefits, performing risk analysis improves the knowledge of the team on the residual risk to manage. Lessons from incidents can be shared to monitor progress. Whole staff group can benefit from the learning outcomes. Staff feels that they can report adverse events/ errors without fear of repercussion.

The main problems had been

- Poor availability of the staff and time consuming to implement the risk analyses.
- Lack of active participation of staff as early as possible while the situation (event) is still in mind.
- Overkill actions, amount of reports. When the culture is changing and people is increasing their reporting the amount of report can be a problem.
- Management implication in risk reduction. Impossibility to improve
- Admit mistakes, free speaking.

A4.3.5 Detailed summary of each local practice

University College Hospital London (UK)

A. Description of local pro-active risk analysis practice

A Risk assessment is carried out if developing a new technique or a significant change in technique, new equipment, new process or significant process change, updating of software and hardware PC and IT related issues. A Pro-active analysis is also made after action review held if near misses are identified.

Preliminary Risk Analysis and Matrix Probabilistic Risk Assessment methodologies recommended by trust policy are used to perform Pro-active Analysis. The assessment is implemented by a multidisciplinary team made up specifically. The “Preliminary Risk Analysis” performed is hazards identification by using a peer review approach, then the team evaluate the risk using a Risk Matrix to grade the risk and decide whether further precautions need to be taken. The pro-active risk analysis allows the determination of risk reducing actions. The Risk Matrix is not specific for RTH but us for all activities in the hospital. A specific sheet is offered as a practical support to perform the study.

B. Description of local retrospective risk analysis practice

A reportable incident is defined as any unintended or unexpected even that could have or did lead to harm. So near misses are also reported. All of them or recorded with details within 24 hours using Datix Web system.

The retrospective risk analysis is performed within 48h by a multidisciplinary team made up specifically using Causal Tree and Root Cause methods. Fishbone and error chains methods, recommended by the Trust and by Towards Safer Radiotherapy are also used.

C. Description of local risk management

All of above actions are investigated, documented and reported to the committee responsible for overseeing the changes. A Risk Management Policy and Procedure not specific

for RTH is available, it details Incident Reporting, Risk Assessment, Risk Registers, Learning from Incidents, Complaints and Claims.

All risk reducing actions to be taken are mentioned in a check list which is signed off by the appropriate member of the MDT(multi disciplinary team). A business continuity plan (BCP) is in place, it identifies all the organisational interfaces with radiotherapy together with single or combined failures of equipment etc. The BCP also contains corrective recovery action over a series of time scales and are held centrally by the Trust.

The Trust uses Datix Web for logging all risks and managing the outcomes of these. The department holds a list of all assessments undertaken with the outcomes this is reviewed by the governance group. Initially the local governance group will monitor any actions but will escalate if there are any concerns.

So, in terms of organisation there is:

- a Local Governance group who will escalate if required.
- an Overarching team called the Radiotherapy Services Team (Multiprofessional) Radiotherapy Governance feeds into this group.

And if required they will escalate to Cancer Divisional Governance - who may then escalate to Quality and safety Committee for the Trust . The Trust has a risk lead who can advise.

D. Benefits and problems encountered

Two types of benefits are mentioned. First is the team awareness of all the risks involved and if any measures need to be taken to reduce the risk but it required good record keeping. Second, is that retrospective risk analysis makes everyone understands what caused the event and what support is needed to prevent recurrence and that change can be implemented.

The main problems encountered concerned resources: financial, specific time frame that cannot be delivered to, staffing Priority rating from Trust or directorate risk register and, they may be individuals who are resistant to change.

Hull and East Yorkshire NHS Trust- Cottingham (UK)

A. Description of local pro-active risk analysis practice

The department takes a multi-disciplinary approach involving the Physics/Radiography (RTT), Oncology and managerial staff. Therefore criteria for performing risk analysis is typically for changes in practice or procedures in order to assess the impact on the broader processes crossing all disciplines. The belief is that errors occur when information doesn't correctly flow. Changes might be minor (eg. changes to QC schedule) or major (eg replacement of a Linac) impacting small work groups or systemic or departmental wide (eg. 'going paper-free/paper-lite' or introduction of a new clinical service).

These changes of practice might arise from departmental strategy, analysis of Audit, response to an adverse event or suggestions from staff. The Quality system was (re-)built around performing risk assessments at the 'hand-over points' or interfaces between the responsible 'sub-groups' in the department.

There is not any formal Risk Analysis methodology that would be used for all occasions. At their simplest, risk assessments are exploratory analysis of a process or proposed process, identifying the risk points for failure (Event tree-like) which is performed by individuals or by Focus group discussion. Following this, obvious actions are immediately progressed through Quality System and possibly resulting in an action plan which is reported through an appropriate managerial channel. This method evolved over a few years and has remained the method of choice. There is a standard Trust format that is used when appropriate, like when reporting outside of the Radiotherapy department. A standardised approach for IRMER/IRR method has also been developed to ensure Radiotherapy and Radiology follows the same process.

The primary aim is to understand the scope, the resources and the required enablers in order to implement a new process, which has an overarching requirement that it promotes safe practice. The above suggestions are examples of considerations that would be expected to be brought out of a 'prior' risk assessment. Once a potential failure point has been identified consideration of controls would be expected to reduce that risk. Within a large project or complex process a contingency or an alternative planning is considered in order to prevent major delays or degenerative effect.

B. Description of local retrospective analysis practice

Incident and near misses are reporting, and a short analysis is required for all for registration in 'DATIX' system. Fuller and longer report may be commissioned. Radiotherapy committee also define criteria for event to be analyzed. Furthermore, Care Quality Commission can request report following an event notification.

Those analyses are performed by a multidisciplinary team using the Root Cause analysis method. They are done monthly, but in event of a reportable incident, dedicated meetings are scheduled.

The objectives of this method are to identify the cause of failure and to understand the circumstances and why it happened. Then learn from the event to propose changes to practice that would minimise the likelihood of re-occurrence actions. For example: counselling or supporting staff, education or retraining of staff, reassessment of competencies, changes to practice within the department, new or revision of documentation, feed-back to all staff for generally awareness and learning. All outcomes are aimed at proactively supporting the staff groups, a no-blame culture is promoted.

C. Description of local risk management

The centre of all the risk management is a dedicated Quality manager with experience from outside the medical field.

There is also a Radiotherapy Committee that is responsible for the service and reports 'upwards'. It is informed by a number of groups, such as Radiation Safety group, Quality Management Group, IMRT, IGRT, Service Development group, Brachytherapy and IVD. Additional groups are formed for the lifetime of major projects (such as upgrade of 'Aria system' or implementation of a new Linac). Furthermore temporary sub-groups or focus groups are commissioned by the groups for specific work streams. All these groups and sub-groups would create project plans or action plans for their projects or work streams and are responsible for identification of risks (safety, procedural breakdown, workforce, financial,), minimising their existence and reporting and managing failures.

RT committee is chaired by the Lead Radiotherapy Oncologist and has the Head of Radiation Physics, Radiotherapy Manager, and Divisional Business manager as its membership. The other groups are Chaired by some of the above and senior members from the Multidisciplinary team. The groups consist of staff (predominantly senior people) involved in the relevant work streams - either implementation wise or operationally. Further involvement may be sought from invited members as when they are required. The Chairs of the individual groups are responsible for monitoring the actions. The RT committee ratifies and monitors the major work streams (and consequences) are effectively managed.

In the department organisation there is a managerial structure that consists of the following. The RT committee reports to a Divisional Management Group (Divisional Nurse manager, Division Business manager and Clinical Director (an Oncologist)). This Divisional management team reports to a Healthcare group management team (General Manager, head of Nursing and Medical Director) who in turn report to the hospital CEO and Board of Director. Projects with large financial implications are monitored and has input from the 'wide hospital management team' such as CFO or COO or their deputies.

All resultant documentation would be issued or updated through the Quality management system, which is available on line in the department. All staff is expected and mandated to use it. This compliance is monitored by the requirement for staff to acknowledge the issue of all new documentation relevant to their work area and practice. Furthermore, the adherence to the ISO9001:2008 Quality system standard required to perform effectiveness review on changes to practice within the department. This is a valuable tool to managing the residual risk following an interventional change.

D. Benefits and problems encountered

The safety governance processes employed, such as the pro-active management of risk and feedback following adverse events and errors, give the department confidence that unsafe and inefficient practice will be trapped and that they will be improved once identified. Furthermore, Quality system, hospital error reporting process and legislative requirements have been integrated into 'one managerial process' whereas before a number of different systems had to be maintained.

Thanks to this work, whole staff group can learn and benefit from the learning outcomes and the staffs feel they can report adverse events or errors without fear of repercussion. Different staff groups are even working together to try to further minimise risk of errors.

However, it took a long time to achieve that. For example, it took approximately 18 months to rebuild the entire Quality management system from scratch and it have been done by people doing it alongside their day-jobs with the help of a professional Quality Manager form outside of healthcare hired to promote better practice.

Odense University Hospital -Odense (DK)

A. Description of local pro-active analysis practice

There is no formal Pro-active Risk Assessment. A risk impact evaluation is performed whenever new techniques, new treatment modalities, new equipment etc. are introduce and when these changes might influence the patients treatment.

Analyses are performed by a multidisciplinary team made up specifically within using a formalized method. Hazards and failure are identified by discussion. The severity of potential consequences of each failure identified is evaluated according to its nature and complexity. Depending on the grade of changes it sometimes ends up with very little Quality Assurance and sometimes it is more comprehensive.

B. Description of local retrospective analysis practice

Retrospective risk analyses are performed for selected events, considering defined criteria and if request of authorities.

The method used is Root Cause; those assessments are led as short as possible after the event by a multidisciplinary team made up specially.

C. Description of local risk management

Actions decision is taken by the head of physics based on advice from a multidisciplinary team.

D. Benefits and problems encountered

The way studies are performed seems to work well and avoid unnecessary work to be done. In fact, it not allows an exhaustive identification of hazards.

MAASTRO– Maastricht (NL)

A. Description of local pro-active analysis practice

New processes, new machinery, changes within processes, process redesigns and unsafe processes which are detected through reporting/retrospective analyses will trigger a pro-active analysis.

The FMEA method was chosen after a comparison of all available methods (Master thesis in 2002). It's called a HFMEA because failure mode causes considered can be technical, organisational and human (professional related and patient related) It is performed by a multidisciplinary team of professionals who are well known with comparable processes.

The objective of this method is, first, to detect all possible risks involved, then prioritise risk using a risk matrix and select actions to reduce them.

B. Description of local retrospective analysis practice

Every miss or near miss events are analysed using Root cause method and PRISMA-medical methods description and classification for registration. The time response for those retroactive analyses depends of the event kind. Miss events with >5% of dose-deviation has to be launched within 24 hours and within 5 days for others miss events. Near miss analyses have 1 month delay.

After the analysis is done, reports are presented and actions are defined using an action-classification matrix.

As for pro-active analysis, those methods were chosen following the research done for the same. Similarly, the analysis is implemented by the management or a special committee designated by management.

C. Description of local risk management

The FMEA is documented and recorded by mostly the patient safety manager and a process owner who has been selected. The process owner is responsible for coordinate the actions taken. The patient safety manager sends every few weeks a notification by mail to the people who have to perform the actions for an update.

The management or a special committee designated by management is then in charge of implementing the risk assessment method: HFMEA, Event Tree or Matrix probabilistic risk assessment. Those methods were chosen through research for Master thesis in 2002 that compared all the available pro-active risk method. The department was the first in Netherlands to get a certification for patient safety system in the health care in 2008.

They also advise the action that should be taken to reduce the risks. Actions they can perform themselves are direct implemented. Actions that cost time and money are discussed with management. The responsibility of the FMEA lies with the management.

One month after the end of the last FMEA session, the process owner has to present the FMEA to management for review.

For the retrospective analysis, feedbacks are done monthly.

D. Benefits and problems encountered

The HFMEA method is very safety, quality driven and gives a lot of insight expertise to the people who conduct it. However it is also very time consuming. Sometimes there is an overkill of actions to be taken. That is why occasionally a lighter version of FMEA called SAFER has been developed, works better and the flexibility of this method allows doing so.

Following the same idea, when the culture is changing and people are increasing their reporting the amount of report can be a problem. Currently all reports are still analyzed (1400 reports yearly).

Cooperation between 17 radiotherapy department via Prisma

A. Description of local pro-active analysis practice

Pro-active analyses are performed when there is a change of practice or a new process with high risk potential. For those events, the hospital Board prescribes the use of the HFMEA method which is adjusted to the Dutch healthcare (called SAFER).

Those assessments are realized by a multidisciplinary team made up specially and their objectives are to obtain a combination of severity and probability in order to design provisions or tools to prevent and detect failures.

B. Description of local retrospective analysis practice

Every time an event is reported, a retrospective analysis is setup within a month by the risk manager or other person specialized within this area.

This analysis will be led using the root cause analysis and PRISMA characterisation for registration. PRISMA-RT is a cooperation between 17 Dutch radiotherapy departments, so it offers the possibility to benchmark with those 17 others RT departments in the Netherlands.

The objectives of the method are to identify root causes of the event, gaps in compliance with procedures defined according to quality assurance management, drifts of practice, detection provisions that have not functioned, recovery provision that have not functioned. And thus lead to the identification of improvement actions to be implemented in order to prevent the event to happen again.

C. Description of local risk management

Recommendations of the multidisciplinary team are discussed with the management of the radiotherapy department by the risk manager. Management decides on major actions (the most expensive) and the multidisciplinary team implements simple cheap actions. Those actions are then monitored by the risk manager.

D. Benefits and problems encountered

The main issue is that those processes are time consuming and the time for implementation is limited.

But benefits are also to be recognized. Now there are smoother and safer processes and better guaranteed for patient safety. Furthermore, HFMEA team members were highly enthusiastic and liked to perform analyses and finally, a more general awareness of safety was achieved by HFMEA team members.

A. Description of local pro-active analysis practice

Pro-active analyses are made when there is a change in processes, a change of practice planned or implemented and following on feedbacks of retrospective analysis from an event or near misses.

Because there was no proper system available, the department use a home-made method for those assessments. A multidisciplinary team analyze the process and attribute the Severity and Likelihood of the events. The objective is also to setup a safety conscience environment.

B. Description of local retrospective analysis practice

Every two weeks, depending on Severity and Frequency criteria, a multidisciplinary team, is performing retrospective analysis using the Root cause method and PRISMA registration which is widely used in the Netherlands.

Thanks to this method, there is a good working feedback system and the risk awareness in the department is upgrading.

C. Description of local risk management

Everything seems to be managed by the multidisciplinary team.

D. Benefits and problems encountered

It is difficult to make people report near miss incidents. More generally, it is difficult to find time for analyses and to oversee all the potential problems.

But those methods are a smooth introduction of new RT technique and, thanks to them, there is a better documentation within the department.

A. Description of local pro-active analysis practice

A pro-active analysis is performed for any changes in the process or in the practice. A multidisciplinary team made up specially will then apply the Matrix Probabilistic Risk Assessment method. This method has been chosen because the department got knowledge of the work developed by the FORO¹³.

Hazards and failures are listed by analysing the process and internal or external feedback.

B. Description of local retrospective analysis practice

¹³ <http://www.foroiberam.org/web/index.php>

No information concerning when and how this analyse is performed. The retrospective risk analyse is implemented by management or a special committee, by a multidisciplinary team made up specially and by the risk manager or other person specialised within this area.

C. Description of local risk management

To decide actions, the multidisciplinary team first makes proposals, then the Management Board of the IMO group decide to implement or not the actions resulting from the analysis.

The monitoring of those actions is made by internal audits and update of processes and clinical protocols and thanks to the Quality Assurance Program.

D. Benefits and problems encountered

Thanks to this method, awareness of the risks involved in the radiotherapy process increased. It also helps getting an in-depth knowledge of the process, of its weakness and of the strength of the existing barriers. Besides, it gives the possibility to count with a tool to systematically review processes and associated risks. With it, new barriers to reduce risks have been identified and the risk profile associated to each step in the radiotherapy process has been obtained.

But there are also some issues. Analysis of risks is time consuming. Furthermore, staffs tend to hide or to make up their real way of working because they may feel ashamed or afraid of possible implications. There are also difficulties to involve the Management to implement actions that imply new resources.

Hospital Clinico San Carlos- Madrid (ES)

A. Description of local pro-active analysis practice

A pro-active analysis is performed for any changes in the process or in the practice. A multidisciplinary team made up specially will then apply the Matrix Probabilistic Risk Assessment method. This method has been chosen because the department got knowledge of the work developed by the FORO¹⁴.

This method permits to identify hazards and failures by analysing the process and internal or external feedback, and thanks to previously elaborated list of hazards.

Then, the method helps to determine and organise risk reduction actions.

B. Description of local retrospective analysis practice

No information concerning when and how this analyse is performed. The retrospective risk analyse is implemented by management or a special committee, by a multidisciplinary team made up specially and by the risk manager or other person specialised within this area.

C. Description of local risk management

¹⁴ <http://www.foroiberam.org/web/index.php>

To decide actions, the multidisciplinary team first makes proposals, and then the Head of the Radiotherapy and Medical Physics Departments decide to implement or not the actions resulting from the analysis.

The multidisciplinary team in charge of the risk analysis review the actions to reduce risks and implement them in the Quality Assurance Program.

D. Benefits and problems encountered

Thanks to this method, awareness of the risks involved in the radiotherapy process increased. It also helps getting an in-depth knowledge of the process, of its weakness and of the strength of the existing barriers. Besides, it gives the possibility to count with a tool to systematically review processes and associated risks. With it, new barriers to reduce risks have been identified and the risk profile associated to each step in the radiotherapy process has been obtained.

But there are also some issues. Analysis of risks is time consuming. Furthermore, staffs tend to hide or to make up their real way of working because they may feel ashamed or afraid of possible implications. There are also difficulties to involve the Management to implement actions that imply new resources.

Osp FBF S Giovanni CALIBITA – Rome (IT)

A. Description of local pro-active analysis practice

There is no structured pro-active analysis method. Instead, the department use “Human Factor method” that means a discussion involving most experienced professional within the multidisciplinary team. This way is the simplest and fastest way to analyze problems when there is not a rigorous scientific method of analysis.

The risk manager performs the assessment. The analysis should result in the identification of recovery action to implement as for the provisions and tools to setup in order to detect failure and limit the consequences.

A risk analysis is ongoing based on the FMEA method relevant to dose calculation in radiotherapy.

B. Description of local retrospective analysis practice

As for the pro-active analysis, there is no structural method for retrospective analysis. When events are reported as relevant or considering severity of actual or potential consequences, a multidisciplinary team is immediately made up to discuss among professionals.

The purpose of those discussions is to identify the underlying causes (root causes) of the event, to identify the detection and recovery provisions that have not functioned and to identify the improvement actions to be implemented in order to prevent the event to happen again.

C. Description of local risk management

The organization is defined as follow: the chief of medical physics and Radiation oncology department involving the whole department working team and their knowledge decide which actions are the best and easiest to be applied from people involved in radiation treatment. There is no specific method to determine and organize risk reducing actions.

The monitoring is not fully organized but there is periodical check. Residual risks are not managed.

D. Benefits and problems encountered

Currently, the centre is involved in the development of a quality system for RT. So procedure and risk analyses assessed in the past have been useful to build the basis of a more structured risk analysis. It also helps to diffuse a risk analysis culture.

But still, sometimes professionals of RT department see risk analysis as a sort of control and judgment particularly in case of retrospective risk analysis for the people directly involved in the event.

Istituto Clinico Humanitas- Rozzano (IT)

A. Description of local pro-active analysis practice

The first criteria according to which a proactive risk assessment is started is the trend of near misses or adverse events in a particular area, showing that the process needs to be analyzed and re-organized in order to decrease the risk associated. The analysis is started when global changes in the process are introduced or when the introduction of new equipment introduces organizational changes, as well.

The risk manager or other person specialised within this area is then in charge of implementing the assessment. The FMEA/FMECA methodology is chosen as it allows carrying out a multi-disciplinary and detailed process analysis and an in-depth evaluation of the potential risks associated to the process. For this reason it is the most complete technique that best suits to complex processes as Radiotherapy. It is also chosen for its feasibility, sustainability and effectiveness.

After a detailed process analysis, failures are identified through interviews performed by the facilitator (the Risk Manager) with the process experts in order to focus the attention on the process steps more prone to errors and to draft a list of hazards. Beside this, the facilitator performs some site visits in order to observe those criticalities under estimated by the experts during interviews. The principal aim of this analysis is a complete risk assessment of the process in order to identify barriers to prevent failure and to plan corrective actions to reduce risk. This allows a precise re-organization of the process, in order to make it safer. Moreover, this method allows planning risk reducing actions on the basis of the risk analysis performed. Among the most frequent actions they can find training, organisational procedures and introduction of new equipment.

B. Description of local retrospective analysis practice

In the case of retrospective analyses, they are triggered considering severity of actual or potential consequences and for selected event, including near misses, reported at local level and considered as relevant for improvement of treatments safety.

The chosen method is the Root Cause Analysis method as it is the most traditional and complete for retrospective analysis of adverse events. It allows to analyze minutely an event and to detect the deep and organizational causes that led to it. It is setup by the risk manager and the objectives are to identify deep and organizational causes of the event and to define the planning of improvement actions to be implemented in order to prevent the event to happen again. Those assessments have to be started in the immediate days after the event.

C. Description of local risk management

Corrective actions are planned by the risk manager together with the department management and then they are submitted to the general management decision. Afterward, the actions are monitored by the risk manager and the radiotherapy department manager.

Among corrective actions, some safety indicators are always defined. That allows monitoring the residual risks connected to the process analyzed. By monitoring them, it is possible to plan audit or analysis whenever the trend gets worse, in order to intervene promptly.

D. Benefits and problems encountered

It is likely that the analysis contribute to an observed reduction in the number of errors reported, mainly by means of the improvement of technical procedures, quality checks and communication flows. Beside this, the FMECA study has been very well accepted by the operators, which further increased their commitment to patient safety. Same for the staff involvement in the discussion about organizational problems that led to events and about the planning and implementation of corrective actions, they feel more concerned about risk management.

However, the risk evaluation process (calculation of the risk index) is often substantially subjective and qualitative and the professionals are often influenced by concrete experiences, when defining or evaluating failures. Furthermore, at the beginning of a Root Cause Analysis, people - especially those who have never been involved in this kind of analysis - are sometimes afraid of speaking frankly about the event or the problems connected.

Greater Poland Cancer Center- Poznan (PL)

A. Description of local pro-active analysis practice

In case of change in the process or new equipment (new facet of communication among various professional groups) must be taken into account and new procedures have to be realized.

The following criteria are analyzed: probability, frequency and potential effect of risk occurrence. The events classification is function of the impact on patient: minor event (low threat on patients), medium event (average threat on patients) and major event (major threat on patients).

In case of change in practice, the same criteria are analyzed. As only certain parts are changed, there is the possibility to compare with the previous one and so to maintain criteria at average level.

Those analyses are done by a multidisciplinary team using FMEA and Matrix Probabilistic Assessment methods. Those methods were chosen because they provide an overall outlook of the whole process and are easy to implement, and to develop. Furthermore, due to the fact that the methods encompass all processes at various levels it is easy to identify all hazards or failures in radiotherapy department.

The analyses objectives are to identify the hazards occurrence probability and the provisions and the tools to detect the failure and limit the consequences.

B. Description of local retrospective analysis practice

Retrospective analysis is trigger according to severity and frequency criteria. Because the implementation is only at the beginning, it is too soon to identify relevant event that could be selected in addition of the criteria.

A multidisciplinary team made up specially is in charge of the analysis following the Root Cause Analysis method (4 times why). Ideally, the analysis should be done immediately after the event.

C. Description of local risk management

The implementation of those methods is at the beginning so the residual risk management is not mature enough for the moment, but the global organisation of the Risk Management is already setup.

The actions are decided upon in the following order: first, the person designated to risk assessment together with multidisciplinary team involved in it; then, the Head of Radiotherapy Department and the Head of Medical Physics Department; and finally, Director of the Hospital.

The same hierarchy, except for the Director of the Hospital, is used to monitor the actions.

D. Benefits and problems encountered

Thanks to the implementation, the general awareness of potential risk increased in the department. Furthermore, with those methods the process is mapped at all possible level in radiotherapy. Therefore, it is possible to react immediately to potential and non-potential risks and then to come up with fully elaborated procedures.

The problem is that the preparation and implementation are time-consuming and there are questions about the cost-effectiveness. Moreover, human nature is not willing to admit mistake and to think about possible threats. So, due to above, it is hard to motivate the team.

Sainte-Catherine Institute- Avignon (FR)

A. Description of local pro-active analysis practice

Pro-active analyses are set-up following a posteriori analysis and feedback from an event or analysis of near misses etc.

For those assessments, performed by the risk manager or any other personnel specialized within this area, FMEA including Human Factor (to deal with human mistakes) is used because it is exhaustive, accurate, and relevant.

The primary goals of those analyses are to define the severity of potential consequence and to identify the barriers to prevent failure if the severity level reaches the “unacceptable” rate. Hazards and failures are identified by small groups of experts on process analyse.

The analyse is performed by the risk manager or any other personnel specialized in this area.

B. Description of local retrospective analysis practice

In the case of retrospective analysis, an analysis leader is designated by the Experience Feed-Back Committee. He gets an educational support from AFM42 consultants. One relevant event is analysed at a time and a limited number of improvements stem from the assessment.

Those analyses are performed once per month and the whole Radiotherapy team is implicated in the Experience Feed-Back Committee.

The objectives of those assessments are to identify the event’s root causes, gaps in compliance with procedures defined according to quality assurance management, drifts in practice, detection or recovery provisions that have not functioned well and improvement actions to be implemented in order to prevent the event to happen again. These monthly analyses are also an opportunity to monitor the improvement actions and define quality indicators.

C. Description of local risk management

The management (head of RT dept, Physicist-in-chief) with the technical assistance of risk manager decides the actions after the analyses. Those actions are then monitored by the risk manager.

Check-lists are currently developed in order to manage residual risk. Procedural work is also very helpful to address this issue. Assessment of professional practice is scheduled for 2013.

D. Benefits and problems encountered

Thanks to those applications, communication within the department and the staff culture of quality and security has been significantly upgraded, as for identity vigilance. Medical mistakes have also been reduced.

However, there are still some issues. For example, the same near-misses happen all the time and are under-declared and coordination with other department is still complex. Moreover all those applications – FMEA, monitoring and implementing the improvement actions – are time and resource consuming. In addition, functional problems within the department cannot be addressed to the CREX and should be dealt with otherwise by the radiation oncology dept. committee of care.

A4.4 Status of classification and reporting of adverse error-events and near misses

A4.4.1 Introduction

In this section, a summary of ACCIRAD detailed questionnaire on event reporting and learning systems is presented. The aim of this part of the questionnaire was to get information of the main features of the event reporting and learning system(s) used in Europe.

The questionnaire was composed of nine parts:

1. Identification and Legal Basis of the System
2. General Description of the System
3. Accessibility to the System
4. Reporting Form
5. Reportable Events
6. Classification
7. Notification Managing Process
8. Feedback
9. Additional Information

20 questionnaires were completed, coming from 9 countries and representing 18 different reporting and learning systems (the State Claim Agency from Ireland sent two different replies and the DATIX web from the UK sent two different replies from two hospitals in the UK). In these 18 different Reporting and Learning Systems, 8 languages are used.

The countries, the system and the organization providing replies are shown in Table A4.3.

Other reporting and learning systems dedicated to Radiotherapy but not associated with a specific country (ROSI, SAFRON) were not included in this questionnaire. A review of these and some other systems is included in Annex 3.

Table A4.3. Replies to the detailed questionnaire on event reporting and learning systems.

Country	Provided replies of Event Reporting and Learning Systems
Denmark	DPSD (National Agency for Patients' Rights and Complaints)
Finland	STUK (Radiation and Nuclear Safety Authority, Finland)
France	Vigie-Radiotherapie (ASN-ANSM, Autorité de sûreté Nucléaire-Agence Nationale de Sécurité du Médicament et des produits de santé)
Ireland	IIMS (Incident Information Management System). HSE (Health Service Executive) Starsweb (State Claims Agency)
Italy	Incident Reporting System of Radiotherapy Activity in medical Physics Dpt (Atienza Ospedaliero Universitaria Udine S. Maria della Misericordia) Hospital Incident Reporting System (AOUUD S. Maria della Misericordia)
Luxembourg	CFB (Centre François Baclesse)
Netherlands	PRISMA (Prevention Recovery Information System for Monitoring and Analyses for radiotherapy). Maastrro Clinic
Spain	Radiotherapy reporting system at Hospital Clínico San Carlos Local system for event notification and registration in radiotherapy (Hospital U. Puerta del Mar de Cádiz) ISO 9001:2008 (Institut Català d'Oncologia-Girona) Notification of Deficiencias, CSN (Consejo de Seguridad Nuclear) Registre d'incidències ANTARES (Hospital Sant Pau, Barcelona) ROSIH_HVH (Physics Department - Hospital de la Vall d'Hebron, Barcelona) SINASP (Sistema de Notificación y Aprendizaje para la Seguridad del Paciente), Spanish Ministry of Health
United Kingdom	NRLS (National Reporting and Learning System) Radiotherapy Reporting System. Health Protection Agency (HPA) Datix Web (University College London Hospital) Datix Web (Hull & East Yorkshire NHS Hospitals Trust)

A4.4.2 Results

Half of the 18 reporting and learning systems are specific for radiotherapy, 7 are general patient safety reporting and learning systems where events of radiotherapy can be reported and 2 out of 18 are radiation protection reporting systems where data from radiotherapy can be reported (Fig. A4.18).

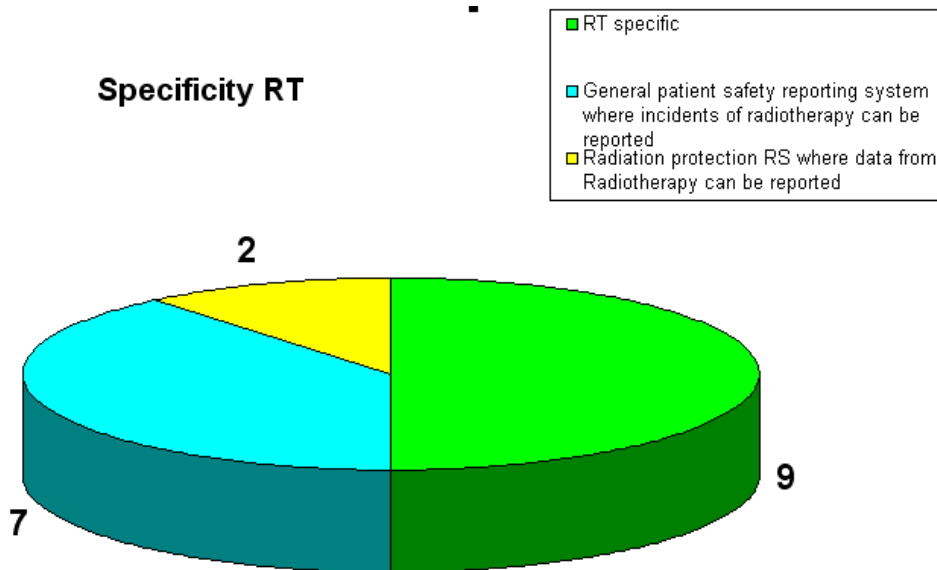


Fig. A4.18. Specificity for radiotherapy of the reporting and learning systems

Reports can be voluntary or mandatory (Fig. A4.19). In some cases they are both voluntary and mandatory, for example, some systems are voluntary for events of none or low severity and mandatory for adverse events. Most of the systems are reported to be voluntary, 4 are mandatory and 3 are both voluntary and mandatory.

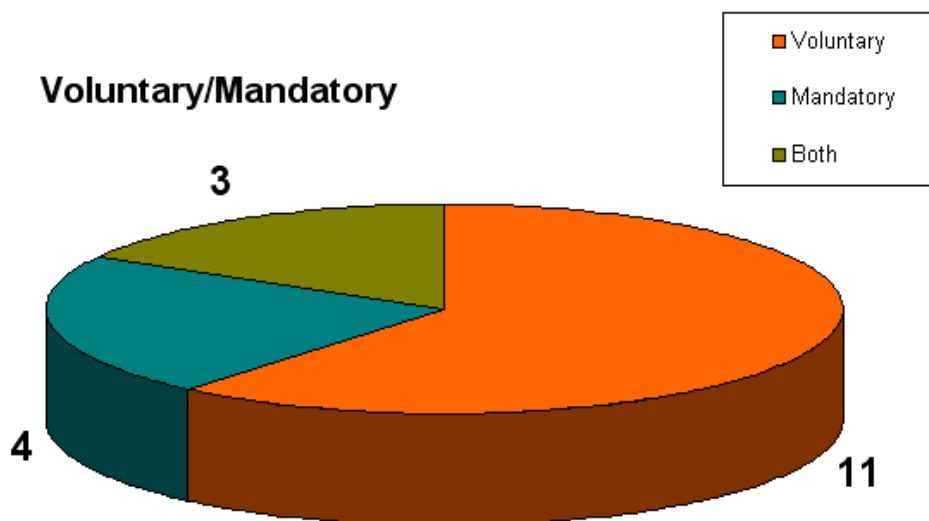


Fig. A4.19. Voluntary or Mandatory reporting and learning systems

Fig. A4.20 is a combination of the information of Fig. A4.18 and Fig. A4.19, and shows that event reporting and learning systems specific for radiotherapy tend to be voluntary, while systems that are mandatory are general reporting and learning systems (for patient safety or for radiation protection).



Fig. 4.20. Voluntary or mandatory reporting and learning systems as a function of specificity of the system for radiotherapy.

There are 6 systems that are local (radiotherapy department or hospital reporting and learning system), 6 systems that are external (reports are made to a regional, national or international event database) and 6 that are both local and external (local with the possibility of sending information to external systems or external with the possibility of filtering data from an Institution so that the system can also be used locally).

It is important that the system works locally because the analysis of events has to be made locally, as well as the design of specific prevention actions or barriers and the follow-up of the implementation of these actions. On the other hand, external reporting and learning systems identify and analyze events on a larger scale, facilitate learning from rarely occurring events and with them we can benefit from the experience of others and raise awareness. Therefore, probably the best option is a combination between local and external reporting and learning systems.

In 8 of the systems, registration to get access to the system is required, specially in those that are both local and external (Fig. A4.21).

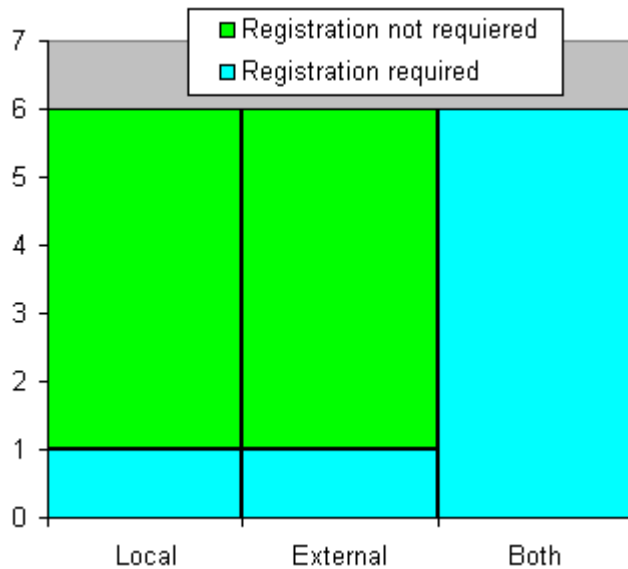


Fig. A4.21. Registration requirement to use the reporting and learning systems.

The type of registration in these 8 systems is personal in 2 system, Institutional in 3 and personal in institutions previously registered in other 3 systems (Fig. A4.22).



Fig. A4.22. Type of registration in those reporting and learning systems where it is required.

There are different confidentiality policies in the different systems:

- In confidential systems identifying data (reporter, patient, department, hospital) are kept secret or private (only known by the managers of the reporting and learning system). These data are known but they are not revealed.
- In anonymous systems the reporter does not reveal his/her identity and it is unknown for everybody, the managers of the system included.

A system might be confidential for incidents of none or low severity and non-confidential for adverse error-events. A systems may be confidential for the workers involved but not for the Centre or the Department.

9 systems are confidential, 3 are anonymous, 2 are confidential while the analysis is being made and all the data are anonymised afterwards (Fig. A4.23). 2 of the systems are non confidential but in both the access to the system is restricted (so data are non confidential but only registered users can access to the data). Finally, in the case of the ASN-ANSM system, depending on the severity of the event the name of the department and hospital might be revealed (events rated 2 and above in the ASN-SFRO scale).

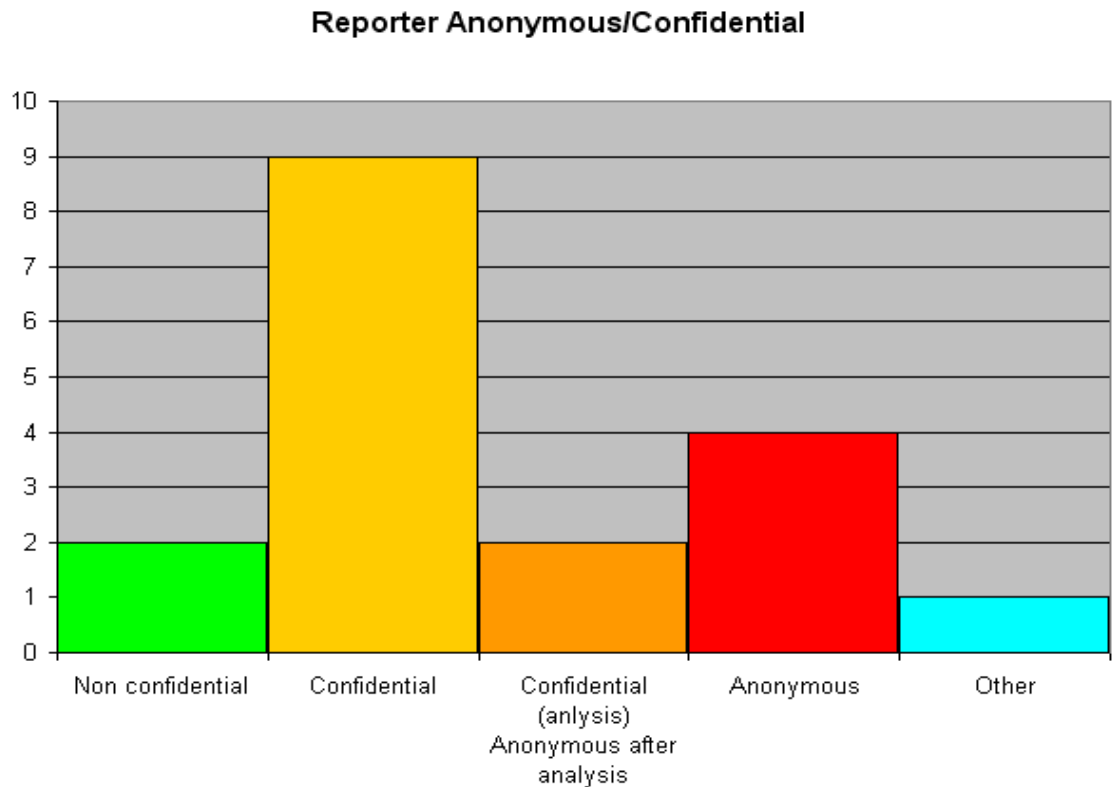


Fig. A4.23. Confidentiality policy for the reporters.

A combination of confidential and anonymous systems could be the best option. If the system is confidential, the dialog with the reporter is possible, making it possible to get additional information, to suggest corrective actions and to motivate the reporter through the perception that the system works actively in the reports. The report can become fully anonymous once the investigation has finished, to publicly spreading the information from the event and the lessons learned. Universal access to anonymised data with the possibility of filtering the information and searching by key words helps in the dissemination of lessons learnt among professionals and could be an answer to the public’s right to know about events in radiotherapy.

Data entry is made via Web or e-mail in most of the systems (10 out of 18), in some it is made in paper (4) or in an intranet or local database (2) and there are some that use a mix of paper+web (1) or electronic+web (1) (Fig. A4.24). The local systems tend to use paper or electronic data entry, while external systems tend to use the internet. There is a local system that uses a web solution using Google docs.

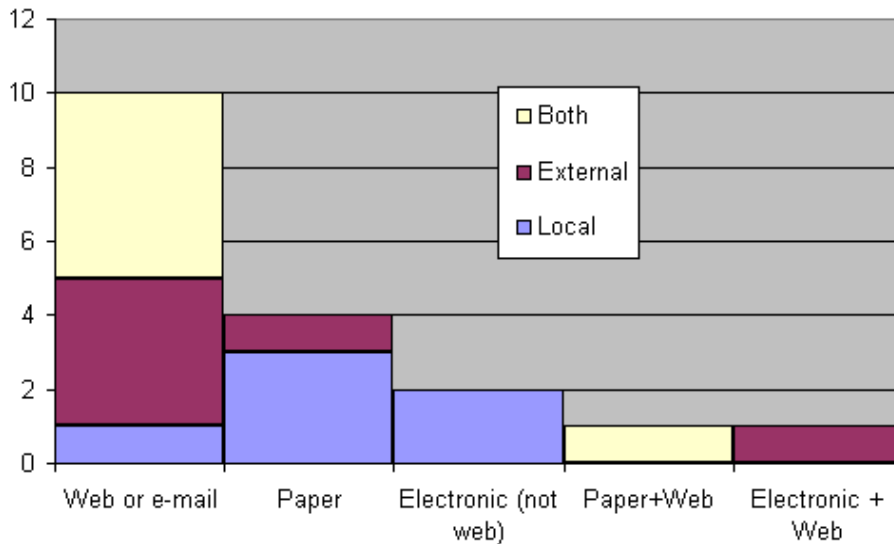


Fig. A4.24. Data entry to the reporting and learning systems.

Public information access means that the information is accessible by the public and by professionals from other Institutions.

In 13 systems there is restricted access to the reports and in 5 the reports cannot be consulted (they are only accessible for the managers of the event reporting and learning system) (Fig. A4.25). Summaries of reports have restricted access to users of the system in 15 of the systems (most of them used locally as can be seen in Fig. A4.26) and can be publicly consulted in 3 of the systems.

Public information feedback

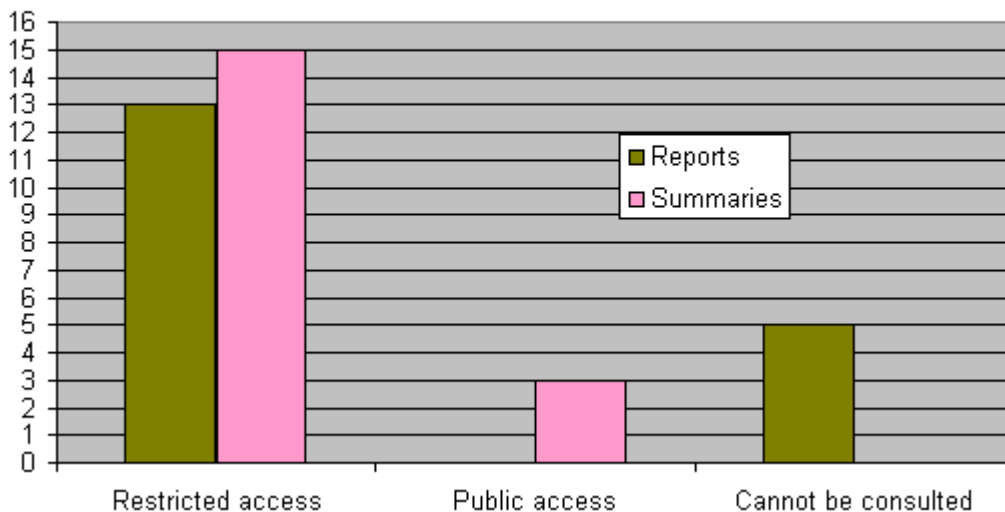


Fig. A4.25. Access to reports and to summaries of reports.

Access to summaries

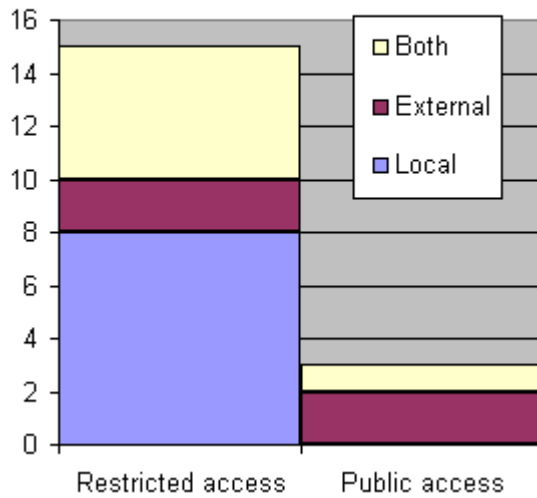


Fig. A4.26. Access to summaries of reports in local systems, external systems and both local and external.

To search information about previous reported events, a word search tool is available in 9 systems and there are utilities to filter the information of reports by some fields in 13 systems.

Almost all the systems have a classification of severity. In 2 of the systems no data about the classification of severity have been provided, but probably they use some kind of classification on severity. Nevertheless, there are almost as many classifications of severity as reporting and learning systems, using different grades and different wording. So there is little homogeneity.

A classification of the stage in the process where the error occurs is used in 7 of the systems. Among the replies to the questionnaire, the more developed system of classification of the stage in the process where the error occurs is the one used in the National Reporting and Learning System that uses the classification proposed in "Towards safer Radiotherapy" that breaks down the radiotherapy pathway into constituent processes that are described in terms of 21 codes and 196 sub-codes.

A classification of detection (how the error was discovered) is only used in 2 of the systems.

A classification of causes and contributing factors is used in 4 systems. The PRISMA system from the Netherlands is specifically designed to find out the root causes of near-misses and misses (events with none or very mild consequences), and uses the very well developed Eindhoven-Classification Model.

A classification of remedial actions is used in 2 systems, being the classification used in the PRISMA the more developed one. It makes use of the Classification/Action Matrix.

Other criteria of classification are used in 2 systems. Among these additional criteria of classification we can find: who detected or reported the event, type of event, type of occurrence and whether the event is linked with a failure of a medical device or not.

There is a great variation in the frequency of feedback. There are systems with no established feedback and in some systems the feedback occurs after the investigation and only

to the staff directly involved in the event. There are many different frequencies of feedback, ranging from weekly or monthly to quarterly or yearly feedback.

Figure A4.27 shows that feedback is normally made through specific or general recommendations as well as through a follow-up of actions taken. Some systems organize also courses or seminars or publish summaries, newsletters or alerts. Other technologies to spread the lessons learned such as mailing lists or podcasts are less used.

	Specific recommendations of actions to take	General recommendations	Follow-up of actions taken	Seminars	Courses	Summaries	Newsletters	Alerts	Mailing lists	Podcasts	Others
	✓	✓	✓			✓	✓				
	✓	✓									
	✓	✓	✓	✓		✓					
	✓										
	✓	✓	✓	✓		✓		✓			
	✓	✓		✓	✓	✓	✓				
	✓	✓	✓	✓	✓						
	✓	✓	✓			✓		✓			
	✓	✓	✓	✓							
	✓		✓			✓		✓			
	✓		✓	✓	✓			✓			
						✓		✓			
	✓	✓	✓	✓	✓	✓	✓	✓			

Fig. A4.27. Options used to make information feedback on the lessons learned from the reported events. The shade patterns correspond to systems with no answer to this question. Each row represents a reporting system and each mark in the cells means that the item shown by the column heading has been included in this reporting system.

From the question about the economic resources necessary for the sustainability of the reporting and learning system, the typical situation is that there are no economic resources in local systems (they are mainly departmental or personal initiatives) and external systems have the support of the external Organization that promotes the system. Those systems that are both local and external have the support of the Institution for the analysis and Investigation and

the support of the external Organization for managing the external databases and the systems of feedback.

To the question: “do you know if someone has been punished as a consequence of a report to the system?”. The answer is unanimous: “No, never”. So, it seems that the fair to possible sanctions is not based on the reality. Nevertheless, to the question, “can the system be used in case of litigation?”, the answer is not so clear. Of course for anonymous systems the answer is No. The system from Denmark declares that their legislation stipulates that the reporter cannot be punished as a consequence of the report made. Some systems declare that they don’t know whether the system can be used in case of litigation or not, and finally some other declare that the system could theoretically be used in case of litigation, but it would be against the scope of the system, as it is implemented to improve care safety and quality only.

The main problem for reporting and learning systems is Underreporting and almost all the answers (93%) (Fig. A4.28). Insufficient support of leaders (Government or the Head of hospitals or Departments), lack of motivation and embarrassment or fear to possible sanctions are also identified as important problems. Finally the lack of resources, the lack of specificity of the system for Radiotherapy and the lack of staff training in the utility and the way to use the system are also identified as problems.

Underreporting	Embarrassment or fear to possible sanctions	Lack of resources	System too unspecific	Insufficient support	Lack of motivation	Staff not trained in the utility of the system
✓		✓		✓		✓
✓	✓	✓		✓		
✓				✓	✓	
✓			✓			
✓		✓		✓	✓	✓
✓	✓		✓	✓	✓	
✓	✓				✓	✓
✓	✓		✓			
✓	✓			✓	✓	
		✓		✓		✓
✓					✓	
✓						
✓	✓		✓		✓	
✓		✓			✓	✓
93%	40%	33%	27%	47%	53%	33%

Fig. A4.28. Main problems stated in the reporting and learning systems. The shade patterns correspond to systems with no answer to this question. Each row represents a reporting system and each mark in the cells means that the problem shown by the column heading has been stated in this reporting system.

The number of reports for radiotherapy is an important indicator of the utility of the system. This does not mean that more reports means better, because as it has been shown in the revision of existing reporting and learning systems, there are very good systems that do not look for a large number of reports and in fact they discard many of the reports, making a special effort of analysis and feedback from those reports that are specially representative or have lessons for others. But of course, the number of reports is an important indicator of the performance of the system.

In Fig. A4.29 (first column) the number of reports and the period of time is shown. A different color has been given for systems that are specific for radiotherapy (green), general reporting systems for patient safety (blue) or general reporting systems for radiation protection (yellow) where events from radiotherapy can be theoretically be reported.

5000 in 3 years	5000 in 3 years	5000 in 3 years
We don't know		
7 in 2 years		
230 in 2 years	230 in 2 years	230 in 2 years
183 events in 3 years	183 events in 3 years	183 events in 3 years
None		
1 to 3 annually		
904 in 4 years	904 in 4 years	904 in 4 years
We don't know		
524 in 2,5 years	524 in 2,5 years	524 in 2,5 years
69	69	69
1 since June 2012		
58 in 2,5 years	58 in 2,5 years	58 in 2,5 years
350 in 1 year	350 in 1 year	350 in 1 year
310 in 2,5 years	310 in 2,5 years	310 in 2,5 years
No answer		
59 in 3,5 years	59 in 3,5 years	59 in 3,5 years
1400 every year	1400 every year	1400 every year

■ RT specific

■ General patient safety reporting system where incidents of radiotherapy can be reported

■ Radiation protection RS where data from Radiotherapy can be reported

Fig. A4.29. The number of reports. Each row represents information from one reporting system.

In the second column, the systems with no reports, systems that answer “we don’t know” (because they do not have fields to filter the events from radiotherapy) or very few reports has been erased. We see that most of the systems are specific for radiotherapy. Two of the general patient safety reporting and learning systems use the codes of Towards Safer Radiotherapy, so they gain the necessary specificity for radiotherapy (column 3). So it seems still more clear that, to get a significant number of reports, it is very important that the system is somehow specific for radiotherapy.

A4.4.3 Conclusions

There is a great variety of event reporting and learning systems in Europe. From local to international, from radiotherapy-specific to general health-care or general radiation protection systems, from those where only near misses are reported to those where only adverse events are reported, from voluntary to mandatory, with different levels of accessibility, feedback, classification of information and terminology.

None of the reporting systems is perfect, although they can be very useful in their intended application.

One of the main problem in systems with unknown, few or no reports is that they are not specific for radiotherapy. Specificity for radiotherapy is working in local systems, but also in general patient safety reporting systems with the use of specific codes for radiotherapy. The main stated problem for reporting and learning systems is Underreporting. Insufficient support of leaders (Government or the Head of hospitals or Departments), lack of motivation and embarrassment or fear to possible sanctions are also identified as important problems. In none of the systems a professional has ever been punished as a consequence of a report to the system. Nevertheless, it is not always known or clear whether the system can be used in case of litigation or not.

There is little uniformity in the criteria for severity, but also for other less used classification criteria, such as the stage in the process, detection, causes, actions taken, etc. Consensus about the classification would greatly facilitate analysis and integration of systems.

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EDITORIAL NOTE

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