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Radiation Oncology Safety Information System (ROSIS)

A Reporting and Learning System for Radiation Oncology

Joanne Cunningham

(Siobhán Ní Chuinneagáin)

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University of Dublin, Trinity College

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Abstract

Background and Purpose: Incident reporting is a recognised tool for learning from incidents. The Radiation Oncology Safety Information System (ROSIS) was established in 2001, to collate and share information on incidents and near-incidents in radiotherapy, and to learn from these incidents in the context of departmental infrastructure and procedures. This work describes the development of ROSIS, analyses the data collected in the first five years of the reporting system, defines a classification system for reporting and learning from incidents in radiation oncology, and designs department and incident report forms to incorporate this classification.

Materials and Methods: The data was collected from online Department Description and Incident Report Forms. 101 Departments and 1074 Incident reports are evaluated using simple descriptive statistics. Most incident data is reported directly, but the stage of incident occurrence, and the contribution of data transfer or record and verify systems were determined retrospectively. A hazard identification was prepared, and a frequency analysis conducted on 600 ROSIS incidents. A classification system was designed to organize reports and facilitate learning. A sub-class, the process classification, was tested for inter-rater reliability and a frequency analysis was undertaken on 500 ROSIS incident reports. Datasets were defined for the classification.

Results: The ROSIS Departments represent about 150,000 patients, 343 megavoltage (MV) units, and 114 Brachytherapy units. On average, there are 437 Patients per MV unit, 281 per Radiation Oncologist, 387 per Physicist and 353 per Radiation Therapy Technologist (RT/RTT). Only 14 departments have a completely networked system of electronic data transfer, while ten departments have no electronic data transfer. On average seven quality assurance (QA) or quality control (QC) methods are used at each department. A total of 1074 ROSIS reports were analysed; 97.7% relate to external beam radiation treatment and 50% resulted in incorrect irradiation. Many incidents arise pre-treatment, but are not detected until later in the treatment process. Where an incident is not detected prior to treatment, an average of 22% of prescribed treatment fractions were delivered incorrectly. The most commonly reported detection methods were "found at time of patient treatment" and during "chart-check".
From the hazard identification frequency analysis, the most common hazards were related to dose (32%), target volume (31%), and accessories (20%).

A classification system was developed with four main classes – Event/Occurrence, Outcome, Causes/Classification, and Detection. With the exception of the category "Treatment Preparation", the process classification showed good inter-rater reliability (Pearson Chi-Square 8.134, p=0.616). Most incidents originated in the pre-treatment stages of the RO process (359 of 500). The most commonly reported incorrect parameters were the position of the isocentre within the patient, and the field geometrical parameters.

Datasets were defined for the classification, and dynamic web-forms were developed encompassing these datasets to enable classification of information at source by the reporter. Recommendations for analyses are made based on the additional information and/or detail to be obtained from these forms.

Conclusion: The feasibility of the ROSIS system is demonstrated. While the majority of the incidents reported are of minor dosimetric consequence, they affect on average more than 20% of the patient's treatment fractions, despite defence-in-depth being apparent – indicating a need for further evaluation of the effectiveness of quality controls. This may be facilitated through the standardised collection of detailed information on the origin and detection of incidents, as proposed by the ROSIS classification. The incorporation of the classification into dynamic forms should facilitate the prospective collection of the classification dataset, but should be evaluated for validity and reliability. ROSIS can improve its analysis and feedback, ensuring lessons learned are disseminated to the RO Community.

Summary

This thesis aims to:

1. Describe the development of ROSIS – a voluntary external online reporting and learning system in radiation oncology
2. Analyse the data collected by ROSIS from 2003-2008
3. Define a classification system for the collection and analysis of information on incidents in RO
4. Develop a revised reporting and learning system and make recommendations for further development of this

A review of the literature on safety in health care and in Radiation Oncology (RO) was conducted (Chapter 1), focussing specifically on incident reporting and learning systems and classification systems in health care. This review revealed that incidents occur in health care, and in RO. Evidence from acute health care settings suggests an incident rate of approximately 10%; it is not possible to derive an overall incident rate for RO from the existing scientific literature. It is well-recognised that there is significant potential for mistakes to occur in RO, and significant potential for harm as a result of a mistake. The ability to detect mistakes before or during treatment is a longstanding safety feature of RO. However, the confidence of patients has been seriously undermined by reports in the popular press and academic literature which describe system failures leading to injury and death. These incidents have highlighted the importance of having effective quality and safety mechanisms in place in RO and have resulted in an increased awareness of the importance of learning and improvement from past mistakes.

Learning lessons from past mistakes is a recurrent theme in all safety-related literature, and whilst significant advancement has been made in identifying and addressing iatrogenic injuries there is still substantial room for improvement in most medical disciplines, among them RO. Emphasis is placed on systems design for patient safety. One method of improving safety is incident reporting, – through identifying and learning from mistakes. Incident reporting should encompass both incidents and near misses, though analyses of incident databases should be carefully conducted since reporting is inherently biased. Nonetheless, it is useful in establishing the types, causes, and detection of mistakes. This is important since analysis and feedback should be core activities of a reporting and learning system; activities which can be enhanced by classifying incidents. Classification is a useful

tool in collating, analysing and learning from incidents, and efforts are being made to coordinate the collection of incident data on a global scale. There is a role for disciplinary-specific classifications and reporting systems, though these should be compatible with and comparable to global classification schemes as far as possible.

This work describes the development, implementation, and initial results of a safety information system established to enable international, cross-organisational, voluntary and confidential sharing of and learning from safety experiences in RO. This is ROSIS: the Radiation Oncology Safety Information System. This work analyses the data collected in the first five years of the reporting system, defines a classification system for reporting and learning from incidents in radiation oncology, and revises the ROSIS department and incident report forms to incorporate this classification.

The development of ROSIS is described in Chapter 0. The feasibility of the ROSIS system is clearly demonstrated in: the recruitment of ROSIS departments, the volume of reports submitted, and the system's growing international recognition and impact. The methodology is explained in Chapter 3. Information reported to ROSIS can be used to investigate incident occurrence and detection. Simple descriptive statistics are used to evaluate the ROSIS department and incident data. Data analysis is undertaken in MS Access and MS Excel. Each incident report is retrospectively examined to identify the most likely stage of incident occurrence, and whether data transfer and data input into R&V were contributing factors. The average number of patients per staff category was obtained by first calculating the ratio per department, and then calculating the overall average ratio across all departments. All other data is reported directly. A hazard identification was prepared, and a frequency analysis conducted on 600 ROSIS incidents.

A classification system was designed to organize reports and facilitate learning, and to encompass all incidents and near-incidents relevant to a Radiation Oncology department. A sub-class of this classification, the process classification, was tested for inter-rater reliability (using SPSS and a Pearson Chi-Squared analysis) and a frequency analysis was undertaken on 500 ROSIS incident reports. Datasets were defined for the classification, and were incorporated into ROSIS forms to enable classification of information at source by the reporter.

Chapter 1 describes the results. In 2008, the ROSIS Database contained 101 departments and 1074 incident reports for analysis. The ROSIS Departments

represent about 150,000 patients, 343 megavoltage (MV) units, and 114 Brachytherapy units. On average, there are 437 Patients per MV unit, 281 per Radiation Oncologist, 387 per Physicist and 353 per Radiation Therapy Technologist (RT/RTT). Only 14 departments have a completely networked system of electronic data transfer, while ten departments have no electronic data transfer. On average seven quality assurance (QA) or quality control (QC) methods are used at each department. A total of 1074 ROSIS reports are analysed; 97.7% relate to external beam radiation treatment and 50% resulted in incorrect irradiation. Many incidents arise pre-treatment, but are not detected until later in the treatment process. Where an incident is not detected prior to treatment, an average of 22% of prescribed treatment fractions were delivered incorrectly. Data transfer was found to be a cause/contributing factor in almost half of 600 incidents evaluated, and proportionally more data transfer errors occur pre-treatment than non-data transfer errors.

The most common hazards were related to target volume, dose and accessories. A classification system was developed with four main classes – Event/Occurrence, Outcome, Causes/Classification, and Detection. The process class is a sub-class of Event/Occurrence. With the exception of the category "Treatment Preparation", the process classification showed good inter-rater reliability. Most incidents originated in the pre-treatment stages of the RO process (359 of 500). The most common incorrect parameters were the position of the isocentre within the patient, and the field geometrical parameters.

These results are discussed in Chapter 1, where it is seen that ROSIS covers a broad patient population and varying infrastructures, but with reasonable averages of Patients per MV unit, per Oncologist, and per Physicist. It is difficult to draw conclusions from the number of Patients per RT/RTT. Some level of defence-in-depth is apparent in most departments.

The majority of ROSIS reports relate to external beam radiation treatment; half of the events reported resulted in some treatment delivered incorrectly. The results from reporting systems need to be carefully interpreted and not over-analysed; however, areas for improvement can be identified since many incidents appear to arise pre-treatment, but are not detected until later in the treatment process. The most commonly reported detection methods were "found at time of patient treatment" and "chart-check", with a higher proportion of near-incidents detected by chart-check. The importance of chart checking is well-documented in the

literature, and although recommendations exist regarding working with awareness, there is not much evidence for the value of this defence in the scientific literature. While the majority of the incidents reported are of minor dosimetric consequence, they affect a substantial proportion of the patient's treatment fractions. The contribution of data transfer to incident occurrence is consistent with that reported in the literature. Recommendations for safety improvement are made.

Most elements of the classification are suitable for local, national and international data collection; however, in the case of local application, modifications are needed to ensure that additional local learning can take place. The classes of Outcome and Causes/Contributing factors were modified for ROSIS data collection. The classification is based on a stable framework, but elements of the classes must be adaptable to respond to future changes in RO.

Mechanisms of analysis and feedback for ROSIS are discussed. Currently, this is a limitation of ROSIS. Other limitations include the language barrier, duplicate or triplicate reporting, and funding.

Notwithstanding these limitations, ROSIS is steadily recruiting participants, and must meet their needs. In order to achieve this, ROSIS should aim to become self-sustainable under a social entrepreneurship business model. Areas for development and expansion are proposed.

In conclusion, an international cross-organisational reporting system has been developed and implemented, yielding opportunities for learning from mistakes in Radiation Oncology. While the majority of the incidents reported to this international cross-organisational reporting system are of minor dosimetric consequence, they affect
on average more than 20% of the patient's treatment fractions. Nonetheless, defence-in-depth is apparent in departments registered with ROSIS. This indicates a need for further evaluation of the effectiveness of quality controls. Responding to the need for more standardised data collection, a classification system has been devised and implemented prospectively via department and incident forms – together with a revised website, these should enhance data analysis and feedback.

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1 Chapter 1: Literature Review

This chapter reviews the literature on safety in health care and more specifically in radiation oncology (RO). The occurrence of incidents, and the detection of incidents in RO is investigated, and lessons are taken from incident reporting and learning systems. Finally, classification systems recommended for and in use in health care are examined.

1.1 SAFER HEALTH CARE

1.1.1 Safer Health Care – the evolution of health care risk management

The state of the art in quality and safety has been defined by industry during the last century. With the exception of anaesthesia, health care is a relative newcomer to this discipline. A number of landmark studies conducted in the 1980s, 90s and 2000s in acute hospital settings have established that iatrogenic injury is a common occurrence for patients. Rates of adverse events from 3-16% of acute hospital admissions are reported in the literature, using varying definitions of the severity of an adverse event [1-5]. This included a rate of 2-4% who suffered serious disability or death. It should be noted that these studies were all retrospective case-record analyses, whereas reports from observational studies suggest much higher rates of error [6]. As well as an alarming human cost, these errors incurred substantial economic loss – estimated to be £1bn a year in the UK in terms of additional bed days alone [5], $8.8bn in the US, and 8% of all hospital bed days in Australia. These studies form part of a growing body of literature on quality and safety initiatives within health care systems. Clearly there is a societal obligation to learn from these studies which provide ample evidence that the quality of hospital care and patient safety can and should be improved. Leape et al [2] identified 58% of adverse events as being due to errors in management, nearly half of which were classed as being negligent. There is consensus that at least 50% of these adverse events are preventable [1-3, 5, 7-8], and the focus has now turned to identification and prevention of these failures.

State of the art safety reporting systems are found in high-reliability organizations (HRO), such as aviation, air traffic control, the process industry, and nuclear power sector. Health care has fallen well behind in the adoption of error identification and reduction strategies with regard to basic safety [9-10], but has recently began to seriously examine the widespread existence and effect of errors within itself [3]. This work has rapidly expanded in the past years. Safer practice will only result from the realisation that error is a threat to patients, and the inclusion of error reduction strategies at every stage of clinical practice [11].

The models of causation of accidents that were developed for these industries can also be applied with equal effect to most aspects of health care, as can the diagnostic and remedial measures they employ [12]. Historically, the perceived infallibility of health care professionals (both in society and amongst themselves), inadequate investment in quality measurement strategies, the lack of media attention due to the individual nature of errors, and the reluctance of patients to litigate have all contributed to the current culture and lack of safety awareness in health care. Some of these have changed – society and health care professionals alike are beginning to realise and acknowledge that health care professionals are human too; media attention is focussing on errors, now that their impact is appreciated; and society is becoming increasingly litigious. Programmes of error reduction strategies are receiving funding in some countries, as recent publications on the extent and cost of medical errors have highlighted the long term benefit of any such investment.

Safety is promoted as being an integral component of any activity. Organisations are encouraged to develop a culture of safety. The term "safety culture" originates from an IAEA report subsequent to the Chernobyl accident [13], and was later defined by the International Nuclear Safety Advisory Group (INSAG) as
"...that assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, nuclear plant safety issues receive the attention warranted by their significance."[14]
(The IAEA also published other reports giving further clarification on the term "safety culture", and guidance as to how to develop and assess a safety culture.[15-18])

The INSAG highlight that their definition (above [14]) *"was carefully composed to emphasize that Safety Culture is attitudinal as well as structural, relates both to*

organizations and individuals, and concerns the requirement to match all safety issues with appropriate perceptions and action.

The definition relates Safety Culture to personal attitudes and habits of thought and to the style of organizations. A second proposition then follows, namely that such matters are generally intangible; that nevertheless such qualities lead to tangible manifestations; and that a principal requirement is the development of means to use the tangible manifestations to test what is underlying.

INSAG takes the view that sound procedures and good practices are not fully adequate if merely practised mechanically. This leads to a third proposition: that Safety Culture requires all duties important to safety to be carried out correctly, with alertness, due thought and full knowledge, sound judgement and a proper sense of accountability.

In its manifestation, Safety Culture has two major components: the framework determined by organizational policy and by managerial action, and the response of individuals in working within and benefiting by the framework. Success depends, however, on commitment and competence, provided both in the policy and managerial context and by individuals themselves." These elements of safety culture are nicely illustrated by the INSAG, and reproduced here in Figure 1-1.

Zhang et al [19] reviewed 30 articles on safety culture, (and/or safety climate), and found several commonalities among the definition of the term:

- *"Safety culture is a concept defined at group level or higher, which refers to the shared values among all the group or organization members.*
- *Safety culture is concerned with formal safety issues in an organization, and closely related to, but not restricted to, the management and supervisory systems.*
- *Safety culture emphasizes the contribution from everyone at every level of an organization.*
- *The safety culture of an organization has an impact on its members' behaviour at work.*
- *Safety culture is usually reflected in the contingency between reward system and safety performance.*
- *Safety culture is reflected in an organization's willingness to develop and learn from errors, incidents, and accidents.*
- *Safety culture is relatively enduring, stable and resistant to change."*

These are broadly consistent with the view of the INSAG, however, tend to focus more on the formal procedures and less on the intangible – e.g. they lack an

emphasis on the attitude of the individual in working with awareness as described in the INSAG's third proposition above.

It is also said that a safety culture can be established in an organisation through an informed culture. An informed culture has four main components: [3]

1. A Reporting Culture – staff must be prepared to report their own errors. Vital to the success of this is that staff must see the value of these reports, they must be properly analysed and fed back to the staff involved, or even all staff, to show action taken to prevent incident in future.
2. A Just Culture – where there is an atmosphere of trust, so that people are encouraged to share their experiences and provide safety-related information. A just culture acknowledges the pervasiveness of hindsight bias, and doesn't judge staff on this basis.
3. A Flexible Culture – this respects the skills and knowledge of front line staff and allows control to pass to task experts on the spot.
4. A Learning Culture – this requires a desire and ability to draw the correct conclusions from the incident reporting systems and the power/will to implement major reforms where needed.

West suggests that the risk of incidents may be decreased if more attention is given by an organisation to honouring the role of the individual in promoting patient safety and high-quality care, and if the responsibility for decreasing the number and seriousness of incidents is seen as an organisational as well as an individual responsibility [20]

There is consensus that there must be a visible management commitment to safety and safety must be proclaimed to be the responsibility of all staff [3, 7, 14-15, 19-20].

In light of these developments, health care has begun exploring proactive methods of managing this newly-acknowledged liability. These strategies are incorporated in the philosophy of risk management.

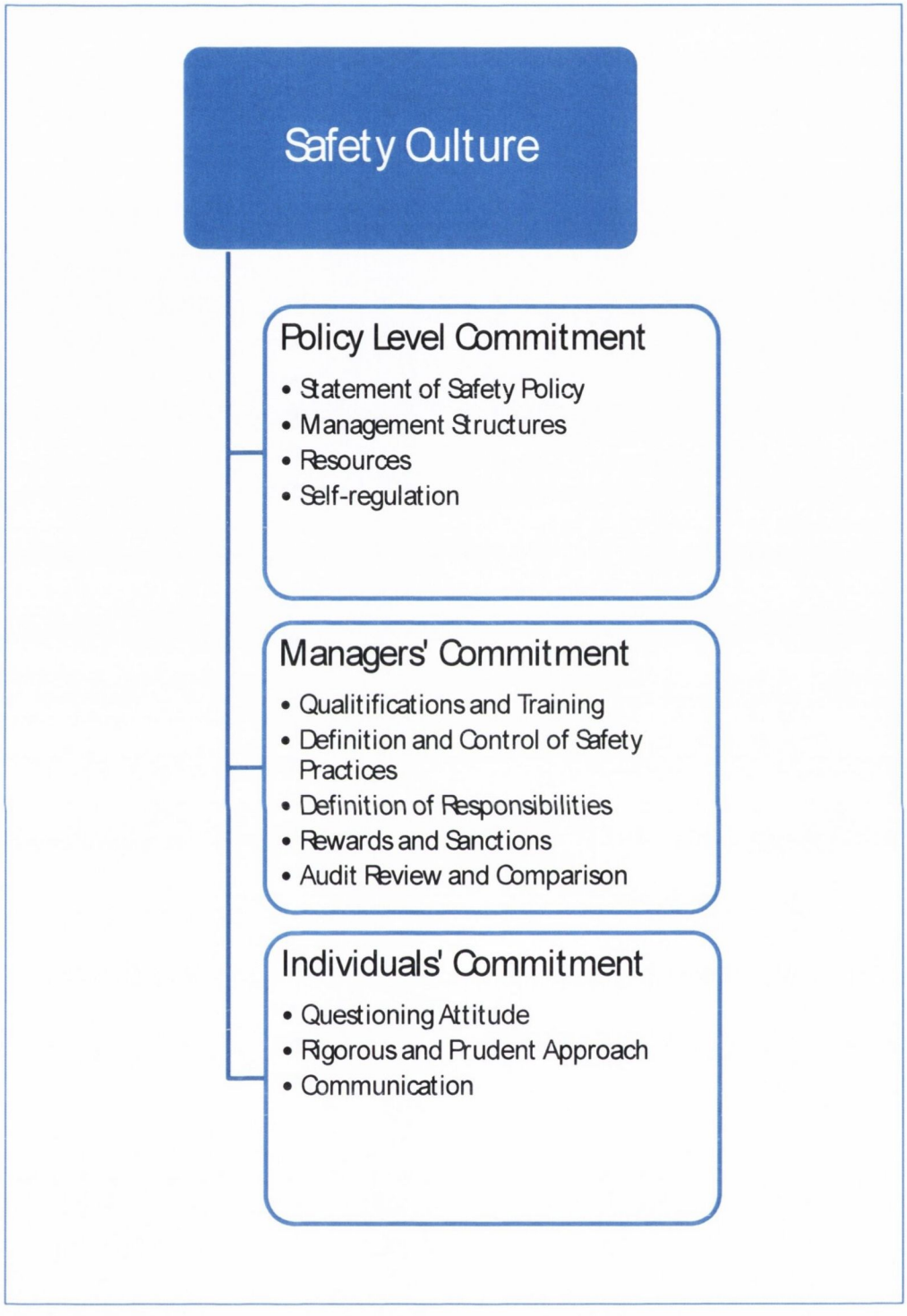

Figure 1-1: Illustration of the presentation of safety culture [14]

1.1.2 Risk Management in Health Care

Risk is "the likelihood, high or low, that somebody or something will be harmed by a hazard, multiplied by the severity of the potential harm" [3].

It is essential that risk management encompasses all aspects of an organisation – not just clinical care. Clinical risk management should also be integrated with clinical audit and other quality assurance activities, rather than being just a means of avoiding litigation [21].

The drive for developing risk management in health care in the United States (US) was the severe medico-legal pressure that health care was under, and is a positive off-shoot of litigation. Initially, the purpose of risk management was to reduce the number and severity of litigious claims, however, paradoxically, it is now acknowledged that costs of litigation are only the tip of the iceberg as far as the economic consequences of errors are concerned [21]. For example, additional treatment, prolonged hospitalisation, and further medical procedures constitute substantially greater drains on health care resources than litigation, and these can also impact on the economy in terms of lost working days, disability payments and other benefits [21]. Patient satisfaction and trust can be severely diminished by errors, especially if they feel that they have not been dealt with in a considerate and timely manner.

Ultimately, risk management is concerned with reducing the possibility of errors, and where errors occur, to mitigate their effect so that the loss incurred is small. Instead of being merely a strategy for the reduction in the incidence and cost of medical litigation, its primary function is to improve the quality of care delivered to the patient. Its main concern is to reduce those errors which are costly in terms of damage, discomfort, disability, or distress to an individual, and to limit financial loss to an organisation [22]. It does this through identifying, reporting and assessing risks, and then correcting actual or potential deficiencies in the process of care that could lead to errors which are significant either in the eyes of the individual patient, or to the economic business of health care [22-23]. Of course, no treatment is risk free, but safety should be recognised as an important part of the quality of the treatment [6, 21].

RO itself has not had a perfect record. In the past, there have been many incidents – several involving a substantial number of patients – some of whom have died as a result of erroneous treatment [24]. Encouragingly, the existence of incidents in

RO is often acknowledged and referred to in quality-related literature, and there is a growing literature dedicated solely to the subject of incidents in RO [24-46]. This is explored in more detail in Section 1.2.

A reporting system is one element of a risk management programme; incident reporting systems will be examined in Section 1.3. However, one of the pre-requirements of a reporting system is what to report – what constitutes an adverse event or an incident?

1.1.3 Definitions of Adverse Events and Incidents

Adverse events are especially relevant in medical settings as they are in direct contradiction of the time-honoured injunction that medicine should "first do no harm" [20].

Not all clinical adverse events are due to medical error [7], but research suggests that about half of adverse events are preventable [2-3, 5, 7-8].

There are a number of definitions of an adverse event, varying in the degree of severity and preventability of the event, e.g. *"an event or omission arising during clinical care and causing physical or psychological injury to a patient"* [3]. An apparent inconsistency in some definitions is whether the adverse event is preventable or is an unavoidable consequence of the medical care.

A universal definition has been proposed by the WHO World Alliance for Patient Safety in the International Classification for Patient Safety [47]:

> *"An adverse event is an incident which results in harm to a patient."* [47]

A definition of an incident is also proposed:

> *"A patient safety incident is an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient. "*[47]

This WHO Classification is straightforward - an incident that causes harm is termed an adverse event; an incident that did not cause harm is defined as a "near miss" [47].

The RO literature lacks a discipline specific definition of an adverse event, but focuses on the occurrence of accidents, incidents and near-misses. The IAEA have defined

- a radiation accident as *"an unintended event (operating error, equipment failure or other mishaps) that has or may have consequences."* [24, 48]
- an incident as *"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."* [48]
- a near miss as: *"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."* [48]

In the radiation safety literature, the terms accident and incident may be interchanged – or the term accident is used for events with severe consequences, whereas incident is used to describe minor or potential accidents [48-49]. However, the term "incident" is more commonly used in the RO literature, and the definitions above are relatively consistent with the general WHO use of the terms "incident" and "near miss". In the WHO Radiotherapy Risk Profile [44], the terms "incident" and "near miss" as defined by the IAEA Safety Standards [48] were retained.

With regard to adverse events in RO, it may be more difficult to determine whether a particular clinical outcome is due to an incident, or whether it is predominantly the result of inherent characteristics of the individual person and/or tumour biology. In RO, the objective is to deliver a prescribed dose of radiation to the prescribed target volume, avoiding unnecessary irradiation of normal tissue. The dose distribution across the target should be homogenous – the ICRU recommends that "an accuracy of +/- 5% in the delivered absorbed dose to a target volume should be obtained if the eradication of the primary tumour is sought" [50]. Incidents in RO where the dose delivered to a patient differs substantially from the prescribed dose could result in an obvious adverse event; the situation is less clear-cut for minor dose deviation incidents.

In some cases the severity of the incident gives rise to sub-classifications – e.g. Cooke et al [51] refer to an incident in which *"a deviation from a prescription exceeds a predetermined value"* as a misadministration.

The Royal College of Radiographers (RCR) publication, Towards Safer Radiotherapy [40], defines multiple types of "Radiation Incidents" (RI). The text of these definitions is given in Figure 1-2, and this author's interpretation of the relationships between these definitions is illustrated in Figure 1-3. This interpretation based on the text definitions seems to be inconsistent with the graphical decision-tree / classification of error used by the RCR (Figure 1-4).

Based on the text definitions, it would appear that a Correctable RI may also be a Reportable RI. However, although correctable, it still remains reportable according to the text; i.e. whether or not it is correctable does not alter its reportable status (which is based on a level of dose discrepancy). Again based on the text definitions, Correctable RI and Minor RI should probably be mutually exclusive – although an area of overlap in the two definitions is "no actual clinical significance", the fact that Minor RIs include RIs that have "no potential or actual clinical significance" would suggest that it cannot include RIs, which if not corrected, would potentially have been clinically significant. However, this is not the interpretation in the diagram, where a Non-reportable Correctable RI is automatically a Minor RI, whether or not it was potentially significant. To be in keeping with the diagram, perhaps the Minor RI should be defined as *"an RI in the technical sense, but one with no potential* ***and/ or*** *actual clinical significance."* There is also the fact that the Minor RI here falls under the definition of a Near Miss according to both the WHO International Classification for Patient Safety [47] and IAEA [48].

Although this classification is useful for determining what should be reported, it may be otherwise unwieldy and impractical due to overlapping definitions. When sub-classifying incidents, it may be more useful to incorporate actual and potential estimates of severity. A glaring omission of the classification is that underdoses are not reportable.

It is important to have consistent, valid and reliable definitions of incidents and near misses, to allow comparisons across organisations, and to monitor their occurrence over time. It is likely that the spirit and scope of the IAEA and WHO classifications will be retained in future RO publications.

It is also important to monitor the environment in which incidents and near misses occur, to enable observation of factors influencing their occurrence, and draw conclusions on how errors leading to incidents may be mitigated. The next section

considers the significance of system design in patient safety; as Berwick states: "every system is perfectly designed to achieve the results it achieves" [52].

Radiotherapy error	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 and can lead to radiation incidents (defined below) st t Not all radiotherapy errors lead to radiation incidents – for example, because the error is detected before the patient is treated or because the error happens not to affect the treatment delivery.
Radiation incident (RI)	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.
Correctable RI	An RI that can be compensated for, such that radiobiologically the final outcome is not different in terms of clinical significance from that which was intended. The term 'non-correctable' is not used in this terminology.
Reportable RI	An RI that falls into the category of reportable under any of the statutory instruments – IR(ME)R,[32] IRR99[29] and so on. A reportable RI will generally be clinically significant, but may not be if it is a correctable RI (such as a 20% overdose on the first fraction where the doses in the remaining fractions have been reduced to compensate).
Non-reportable RI	An RI not reportable as above, but of potential or actual clinical significance. An example would be a 10% underdose over the whole course of treatment due to a calculation error. Underdoses are not reportable under IR(ME)R. However, reporting clinically significant RIs to the statutory authority is good clinical governance even if there is no legal requirement to do so.
Minor RI	A RI in the technical sense but one of no potential or actual clinical significance. The term 'major' RI is not used in this terminology.
Near miss	A potential radiation incident that was detected and prevented before treatment delivery. 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. Notice that the term 'miss' is used in the context of falling short of being an actual RI, rather than in the narrower sense of a geometric miss.
Other non-conformance	None of the above; that is, non-compliance with some other aspect of a documented procedure but not directly affecting radiotherapy delivery.

Figure 1-2: RCR Definitions of radiotherapy events [40]

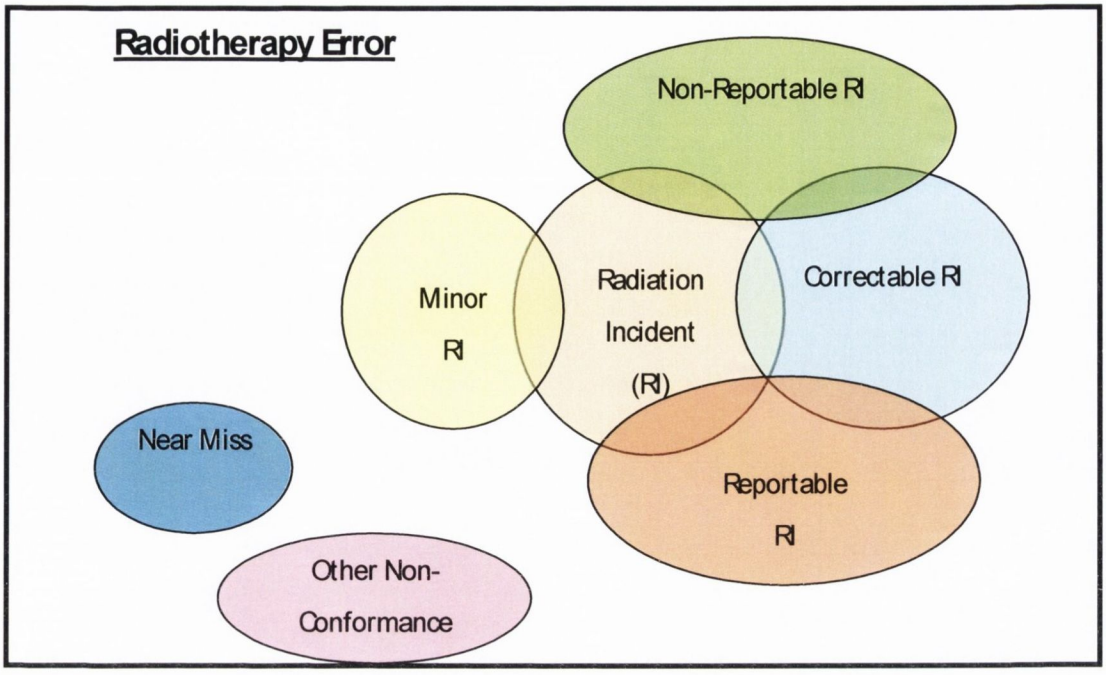

Figure 1-3: Conceptual map of relationship between RCR definitions

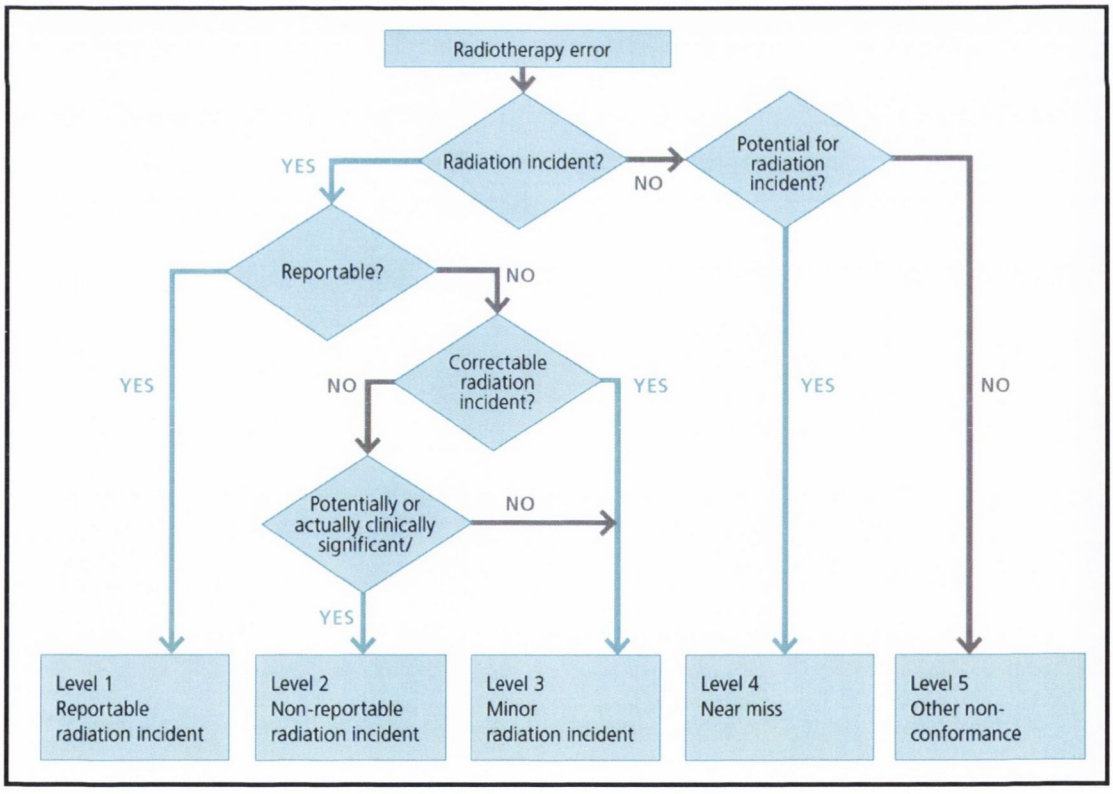

Figure 1-4: RCR Classification of Radiotherapy Errors [40]

1.1.4 The Systems Approach

Error can be defined as "the failure to complete a planned action as intended, or the use of an incorrect plan of action to achieve a given aim" [3]. It therefore has its roots in psychological processes. Reason [53] defines error as: "a generic term to encompass all those occasions in which a planned sequence of mental or physical activities fails to achieve its intended outcome, and when these failures cannot be attributed to the intervention of some chance agency."

Similarly, the WHO International Classification for Patient Safety states that: "An error is a failure to carry out a planned action as intended or application of an incorrect plan, and may manifest by doing the wrong thing (an error of commission) or by failing to do the right thing (an error of omission), at either the planning or execution phase" [47].

A commonality between the spirit of these definitions is that there is an intention to achieve a particular (beneficial) outcome, however, due to a failure in either the execution of the intended action, or the application of an incorrect plan of action, the intended outcome was not achieved. This suggests that the individual involved did not intend a poor outcome; rather that for some reason, "rooted in psychological processes", the optimal action or inaction was not achieved. "To err is human"; "human" – since error results from the physiological and psychological limitations of humans [54], and can include problems in practice, products, procedures and systems [7].

These definitions all support a systems approach to incident analysis and prevention, where humans are seen as fallible and errors are to be expected, even in the best organisations [3]. Here, errors are seen as the outcome rather than being the cause – the cause is within the system [20]. Defences are built into the system to safeguard against the faults inherent in the system. If an incident occurs, the important question is not who made the error, but how and why the incident arose and system defences failed.

This approach is appropriate, as psychological research has demonstrated that adverse work conditions such as high workload, inadequate supervision, poor communication and rapid change within an organisation are factors that increase susceptibility to error [55]. In fact, the need for a systems approach is summed up

by Reason: "we cannot change the human condition, but we can change the conditions under which humans work" [56].

The alternative to the systems approach, and historically, the approach which was more prevalent within health care, was the person approach. This focuses on those at the "sharp-end" and on the deviant psychological processes from which the error arose, e.g. inattention, poor motivation, carelessness, forgetfulness, negligence and recklessness [3]. Blaming and punishing the individual is in the short term the easiest way for management to deal with the immediate problem of an error. This led to the name, blame and shame culture in evidence in health care. Fear of disciplinary measures and the threat of litigation led to errors being viewed as moral violations, and not acknowledged or discussed. The person approach does not consider the contribution of the system to the individual's "unsafe act". This means that a person whose work is normally excellent can be punished for just one lapse. Conversely, even the legal systems (at least in Ireland and the UK) acknowledge the existence of pure mishap – *"Even the most excessively careful person will sometimes have an accident". [57]*

Crucially, dealing with each error in the context of the individual does not allow for the similarity of errors or factors contributing to the errors to be considered. Punishing the individual and then considering the error eliminated means that there is no continuity in recognising errors. As errors tend to fall into recurrent patterns once the same set of circumstances exist [3, 56] (irrespective of the people involved), this means that the potential for improving safety is not met, as the investigator fails to find and remove the error-causing properties within the system. This can be illustrated by rail disasters – telling qualified train drivers that they are not to pass signals at danger does not prevent this from happening, even though the drivers may be jeopardising their own lives by doing so. "Signal Passed at Danger" (SPAD) is a common problem in the rail industry. It is unlikely that drivers intentionally do this and therefore disciplining the driver is probably not the solution. But a safety tool that over-rides the driver and forces the train to stop if the driver makes such a mistake would prevent this type of accident recurring.

As aforementioned, industries have already successfully adopted the systems approach. Their solution was to design the system (in which people worked) so that [58]:

(a) errors were less likely to occur;

(b) where errors occurred, they would be discovered and rectified before they resulted in an adverse event; and

(c) where errors were not discovered and intercepted, procedures would be in place to mitigate the resulting adverse event.

The theory is that humans will make mistakes and in the inevitable event of a mistake it is the system that must be responsible for identifying and eliminating it. In other words, although it may not be possible to reduce mistakes to zero, a system must aim to reduce the number of mistakes that result in an adverse event to zero. Should the error culminate in an adverse event, the person will not be punished, rather there is an investigation into why the system failed – how the mistake slipped through the defences – and the system should then be modified to prevent its reoccurrence. This change in the approach to mistakes was extremely successful for those industries where it was introduced, resulting in substantial increases both in safety and productivity, and decreases in incidents, saving both life and money.[3] Typically, these approaches have incorporated an element of process redesign, so as to streamline the operation and remove unnecessary redundancy. Of course, the health system is patient-driven rather than process-driven, contains considerable reliance on people, and patient care is often unpredictable and may necessitate deviation from normal practice. Nonetheless, the introduction of prospective, process-oriented approaches such as those of the International Organisation for Standardisation (ISO), and Lean Production (LEAN) seem to hold promise.

The role of the wider organisational context in incident occurrence is illustrated by Reason's Model of Organisational Accidents [59] (Figure 1-5). This was first developed for use in complex industrial systems but is also applicable to health care.

From an investigative and preventative viewpoint, the active failures described in the figure above are "the last and probably the least manageable part of the causal sequence leading up to some adverse event."[3] It is therefore crucial to identify earlier causative and contributing factors in incident occurrence.

It has been put forward that under the systems approach people's attitude towards their work may become irresponsible; this should not be an issue in an organisation with a strong safety culture and whose staff strive for excellence. Naturally, care must be taken to ensure that the systems approach is not applied to unethical

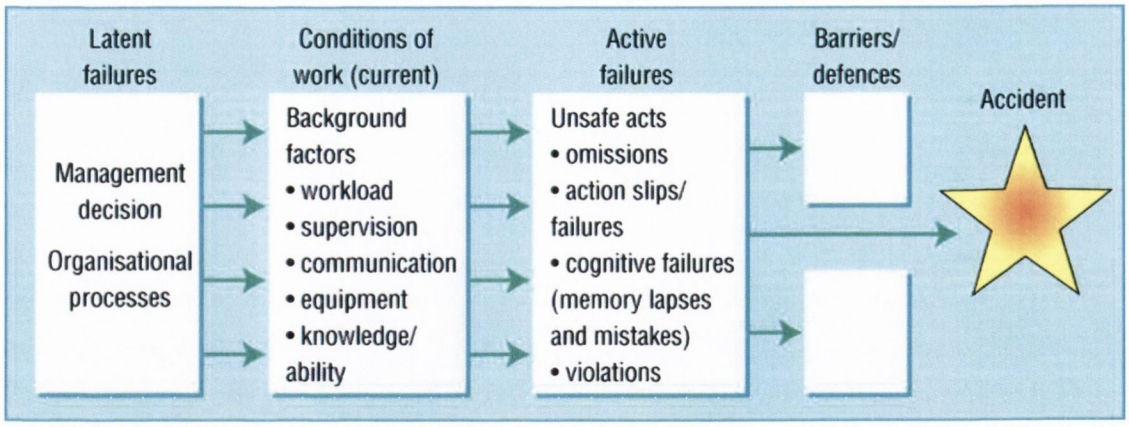

Figure 1-5: Reason's Model of Organisational Accidents [59]

health care professionals. Harold Shipman and others have illustrated that some health care professionals can take advantage of their patients, and/or deliberately harm them.[3] Fortunately these "bad apples" are a small minority, but where they exist they cannot be excused under the systems approach, as the poor outcome was intended. Mechanisms must exist within safety systems to prevent/identify situations where patients are deliberately and maliciously harmed. Health care is acknowledging that "although a particular action/omission may be the immediate cause of an incident, closer analysis usually reveals a series of events and departures from safe practice, each influenced by the working environment and the wider organisational context."[59] Leape has described that 78% of adverse drug reactions are due to system failures.[7]

Information on how, where, why and what incidents arise is vital for future incident prevention[54]. Information on incident occurrence can be obtained from e.g. retrospective studies of patient charts, from prospective "fault-tree analysis", or from incident reporting systems. Incident reporting systems are the focus here, and radiation oncology is the health care area of interest.

1.2 RADIATION ONCOLOGY

1.2.1 The Process of Radiation Oncology

Approximately 1 in 3 people will develop cancer during their lifetime, and it is estimated that 52% of cancer patients should receive RO in the course of their overall treatment [60]. According to the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), approximately 0.9 per 1,000 inhabitants worldwide receive RT annually; with a world population of seven billion, this equates to an annual RT patient population of 6.3 million people.[61] The proportion of cancer patients receiving RO is likely to change with the increased detection of cases through screening and the expansion of indications for the use of RO.

RO alone can be used in the treatment of some cancers; more commonly it is combined with other treatment modalities, e.g. surgery and chemotherapy. Multi-modality treatments yield additional complexity in terms of temporal arrangement, time-span of overall hospital contact, and multidisciplinary interaction. However, this work will focus on risks within RO.

Not only is RO a part of a multidisciplinary process, RO itself consists of multidisciplinary teams, comprising the radiation oncologist, medical physicist, radiation therapist, dosimetrists, nurses, engineers and technicians. This team is responsible for the prescription, preparation and delivery of accurate RO. Delivery of RO has become highly individualised, and specific and evolving skill sets are required of staff to plan, prepare and deliver optimum treatment. There are now many steps involved in preparing and delivering a course of RO treatment (Figure 1-6), using various equipment and technologies, requiring specialist knowledge, and involving a number of different people and disciplines in the overall process. A survey of European recommendations (QUANtification of Radiation Therapy Infrastructure and Staffing Needs – QUARTs) showed the existence of guidelines for infrastructure and staffing in some countries, but with differences within these. The QUARTs project made recommendations of one MV unit per 450 patient treatments per year ("MV unit" includes Co-60), a workload of 200-250 patients per Radiation Oncologist per year, and 450-500 patients annually per physicist.[62] These figures can change substantially with a different case mix, or introducing new techniques and procedures.

As RO becomes more diverse and complex, and as the number of steps and people involved in preparing and delivering treatment increases, so too does the potential for adverse events to occur.[20, 24, 63]

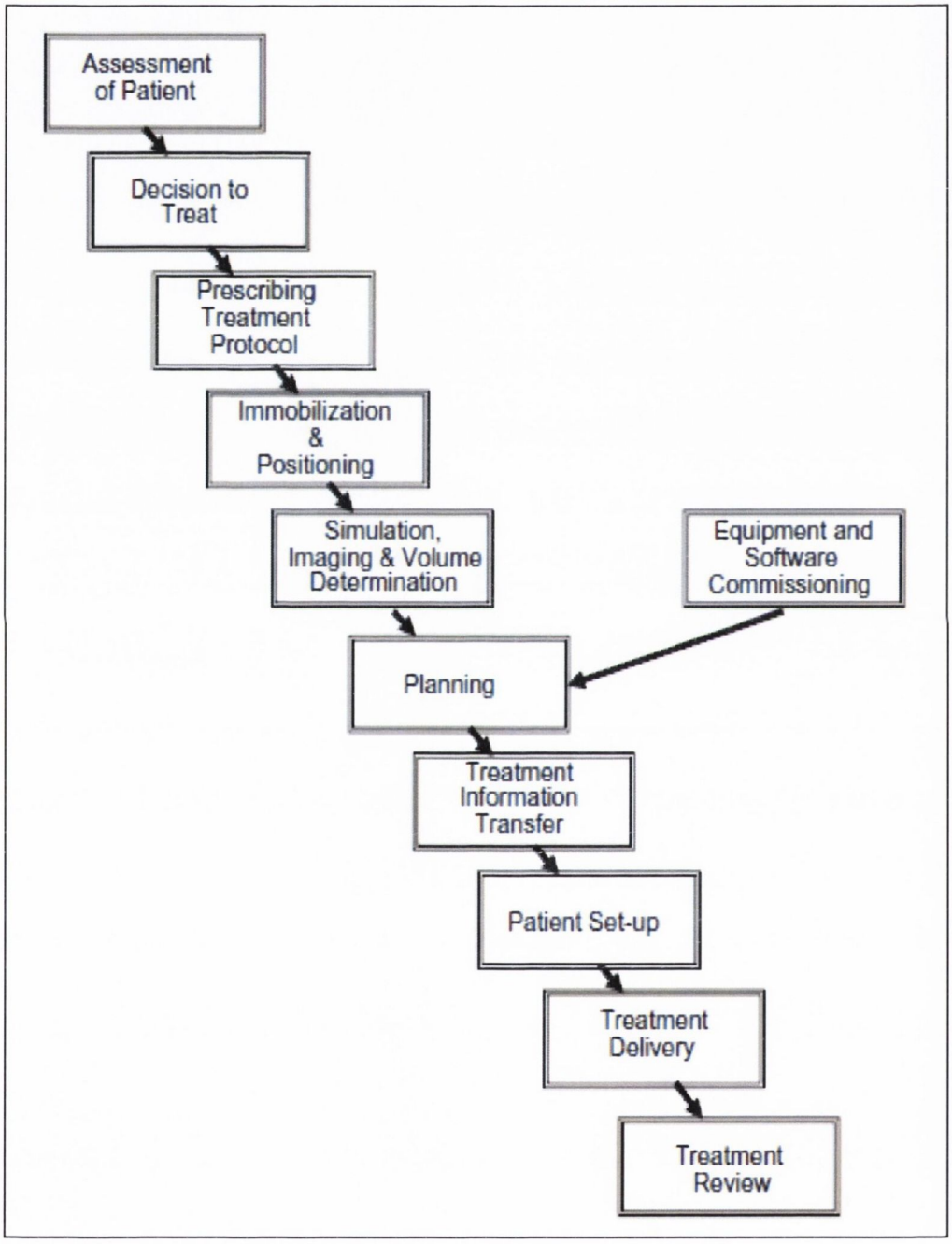

Figure 1-6: Radiotherapy Process of Care [46]

The RO process is protracted; preparation and planning may take some days/weeks, and the duration of treatment can be eight weeks or longer. This treatment may consist of different phases – requiring new preparation and/or planning stages, and may also consist of different modalities of treatment (e.g. brachytherapy and external beam therapy). Modern RO relies heavily on computer control and assistance to plan and deliver the treatment, thus incorporating a large element of human-computer interface/interaction [64].

There are a number of technical or mechanical uncertainties involved in delivering any RO treatment: one of the priorities of a Quality Assurance program of any RO department is to ensure these uncertainties lie within acceptable limits. In addition to these, there are also discrepancies in the set-up and position of a target volume due to patient or organ motion. Combined, they should give a maximum uncertainty in dose delivered in the order of 5-6% [24, 65]. It is suggested that for some tumours, a maximum dose uncertainty of 3.5% is appropriate [44].

These uncertainties have always been recognised in RO, and have been substantially reduced over the years with improved technology, positioning/immobilisation, and imaging and verification strategies. In addition, their existence is incorporated into the treatment plan as part of the clinical target volume (CTV) to planning target volume (PTV) expansion [50, 66]. Although they obviously impact on treatment in that they necessitate geometric margins, and so require that a larger volume of normal tissue is irradiated (at worst restricting dose delivered in order to minimise complications); since their existence is known and they are taken into account they should have no adverse effect on the expected treatment outcome.

It is not these uncertainties or "intrinsic errors" which are of consequence here, since they are accounted for in the treatment plan; rather it is the unplanned and unexpected mistakes that threaten the safety of patients which will be explored.

The delivery of RO is the end-stage of a process consisting of a number of different stages and disciplines – and therefore multiple manipulations and translations of patient and treatment information, each with opportunity for human or systems error. For example, information transfer errors are well documented, and are a threat to the integrity of the patient's planned treatment.

Safety in RO is becoming a focus of national and international organisations, and there is a robust scientific literature on quality and safety in RO [24-46, 67].

1.2.2 Safety in Radiation Oncology

Quality assurance (QA) is a long-standing feature of RO safety, with scientific literature and professional guidelines both emphasising its necessity [34, 68-71]. A common criticism of QA in RO is that it has traditionally been focussed on the technical aspects of the treatment, without considering the processes and clinical decision aspects of treatment.[46]

There is usually a complicated combination of factors leading to an incident, which can include the task, the team and the working conditions.[21, 55, 59, 72] Research in acute hospital care has demonstrated that there is a greater risk of injury to patients who are medically more ill, who are subjected to multiple interventions, and who have a longer stay in hospital.[6] One RO study would seem to indicate that a similar scenario exists in RO – patients who have a higher Complexity Index (COMIX)* have a statistically significantly increased risk of error.[67] Information on contributing factors to incidents in RO has generally been derived from investigations of single large accidents; these focus on provision of adequate resources – equipment and personnel, staff education and training, procedures and policies, and communication and documentation.[34] There is scope for further research and learning in the areas of individual, human and machine error in RO.[44]

As previously discussed, RO typically requires multiple steps and involves various disciplines, and there is significant potential for error.[73] Treatment delivery alone, with a treatment session of four fields and thirty fractions, can involve about one thousand parameters for the entire procedure; if conformal therapy is used, the number of parameters is much larger.[24] Where well-trained personnel use similar amounts of data in a repetitive manner in the manufacturing industry, the expected error rate is 3%.[24] Given the amount of data and repetition, it is not surprising that automaticity is inherent in RO – where certain tasks are so common as to eventually be performed "automatically". This is often advantageous, as it

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* COMIX (= number of PTVs x number of courses of RO

means that these tasks do not demand significant attention, which can be diverted elsewhere. However, as Toft points out, automaticity can also be dangerous, where checks are not given due attention.[64] Human reliability has not been specifically evaluated in RO.

It is not possible to completely eliminate errors from the RO process, but it is feasible to hope to discover them before treatment commences. Therefore, error reduction in RO requires "special and specific safety measures"[24]. The International Basic Safety Standards (BSS) [74] recommend incorporating multiple and independent layers of defences. Some redundancy in checking systems is clearly optimal, but is also resource intensive. Checking systems should be carefully selected, used and monitored to ensure appropriate allocation of resources, and an adequate level of redundancy. Macklis et al [39] suggest that through the analysis of errors, prevention strategies may be designed which are in line with the frequency, severity and predisposing causes of many potential RO errors. Klein [37] considered the dosimetric impact of error in RO in terms of detectability, and considered that

"The error pathway can be categorized into three types:

1. **An error that is easily detected after the first fraction by a port film.** Although these are high in frequency, they are almost always detected before the second fraction and therefore have neither longevity nor subsequent dosimetric impact
2. **An error that is not detectable by port film but has a high likelihood of being detected by in vivo (diode) dosimeters and/ or initial physicist chart review. These checks should take place before the second fraction but have gone as long as five fractions.** In any case, there is minimal longevity, and, therefore, only minimal dosimetric impact
3. **An error that is not detectable by port film or central axis diode or initial physicist review.** These errors, although infrequent, have the chance to go undetected for many fractions and in many cases (e.g. an incorrectly oriented accessory) have very high dosimetric impact."

Table 1-1 illustrates the origin of accidents in external beam RO as described by the ICRP [24]. This is derived from reports of major incidents in RO, and as such mainly reflects risk areas for major incidents involving several patients, rather than the typical clinical risk to individual patients.

Table 1-1: Origin of accidents in External Beam Radiotherapy[24]

Accidents in external beam therapy	Percentage of cases
Equipment design	6.5%
Calibration of the beams	30%
Maintenance	6.5%
Treatment planning and dose calculation	28%
Simulation	9%
Treatment set-up and delivery	20%
Total	100%

An expert group under the WHO produced a Radiotherapy Risk Profile [44] outlining risks in the RO process of either a medium or high impact. An oversight of this report is that there is no definition given of medium or high impact outcomes, and the basis for deciding the impact – whether it is potential dose discrepancy per fraction, per treatment, etc, is not specified. Nonetheless, this report is probably more indicative than the previous ICRP report of the risks for any individual patient in the RO department. Ten stages in the RO process are considered (Figure 1-6):

1. Assessment of the patient
2. Decision to treat
3. Prescribing treatment protocol
4. Positioning and immobilization
5. Simulation, imaging and volume determination
6. Planning
7. Treatment information transfer
8. Patient setup
9. Treatment delivery
10. Treatment verification and monitoring

The report identified nine safety processes relevant throughout the RO process; these are [44]:

1. Patient identification
2. Audit of equipment commissioning and processes
3. Staff competency assessment
4. Process and equipment quality assurance
5. Information transfer with redundancy

6. Process governance
7. Error reporting and quality improvement
8. External checking
9. Adequate staffing

Planning protocol checklists, independent checking and specific competency certification are also highlighted as interventions with a high efficacy across multiple stages [44].

RO incidents are often irreversible, and can compromise the efficacy of the treatment in terms of tumour and/or symptom control, while also modifying the risk of complications to surrounding normal tissue and organs at risk. In a few cases, and where the mistake has been detected sufficiently early, it might be possible to fully achieve the desired treatment outcome by appropriate compensation in the remaining treatments. In other cases, this may not be possible, e.g. without exceeding the tolerance dose of organs at risk from the originally carefully planned treatment.

Although some incidents are severe enough to directly cause death, most incidents compromise the patient's chances of cure/control, and affect their projected quality of life following treatment [44, 46].

A more recent and timely addition to the literature on safety in RO is the use of prospective risk identification methods [30, 41, 75-76]. Nonetheless, similar to most areas in health care, information on incidents in RO is predominantly from retrospective studies.

1.2.3 Reported incident rates in RO

Reported incident rates in individual RO departments using record and verify systems range from 0.5% to 3% [77]. There is a suggested average incident rate of 1% over all courses of RO in the UK, whilst Sweden have incident rates (defined as greater than 5% of dose, and detected with in-vivo dosimetry) ranging from 1 to 13% in various departments [78]. The criteria for identifying and reporting incidents have varied greatly in these studies, and these incident rates are not comparable. It must also be remembered that these studies are concerned with reporting specific preventable incidents, not adverse events; that they often use

one exclusive method of identifying incidents, and consequently do not provide a comprehensive picture of the rate of incidents in RO.

It could be said that RO has a good history of recognising error, and installing defences to reduce/mitigate the occurrence of errors, possibly comparable to anaesthesiology[79]. Some of these defences are extremely complex, and technological; others are simple and easy. Record and verify systems could be described as an example of technological advancement, and are indispensable. The older and simpler practice of photography is also valuable in terms of providing information on identification, set-up and positioning which may prevent errors arising from patient selection, or treatment position due to an inadequate or unclear description of same.

It is difficult to derive an absolute figure for the occurrence of incidents in RO. The literature tends to focus on a specific detection method, and/or on a specific type of mistake, and although many authors report an "incident" or "error" rate, it is unlikely that any of these reported rates alone actually reflect the full spectrum of incidents in RO.

Specific detection methods commonly identified in the literature are:

- In-vivo dosimetry [27, 80-84]
- Portal imaging [81, 84]
- Independent check of calculation [80, 85]
- Chart checking [31, 42, 67, 77, 80-81, 84-86]
- Record and Verify [87-88]
- Incident reporting / logging [31, 39, 45, 77, 89]

Some studies have focussed on a specific type of error, e.g. during

- Data transfer [81]
- Planning/calculation [31, 80, 85]
- Use of record and verify [87-88, 90-91]

Others look for the detection of any error in the treatment process [39, 77].

The literature on specific types of error, and/or detection methods, will be considered below:

1.2.3.1 Data transfer

1.2.3.2 Planning/calculation

1.2.3.1 Errors due to Data transfer

Data transfer is a common problem across many activities, and is well recognised as a challenge in radiotherapy. "Data transfer errors are mostly due to human mistakes or inattention. The reasons for these errors are transcription errors, rounding off errors, forgotten data or interchange of data . . ."[81]

As the complexity of radiotherapy increases, so too does the amount of data that must be transferred between the various stages of treatment preparation and delivery.[24] The transfer of data is often made more complicated by the fact that some data must also be transformed from one type to another (e.g. from text to an image), and from one format to another (e.g. from paper to computer monitor). Failure to correctly transfer all data for a patient treatment has the potential to result in major under-/over-doses and/or geographic misses.

The literature testifies to the existence of mistakes in radiotherapy due to incorrect data transfer. Most recently, the WHO have reported that 38% of incidents (without any known adverse events) were related to errors in the transfer of information [44].

Leunens et al [81] investigated the frequency and sources of data transfer errors. In a prospective study, they performed an independent check of numerical data after the 1st treatment (464 pts). Over nine months on one unit, with a record and verify system, they checked for both minor and major errors in the treatment prescription sheet, the treatment simulation sheet, the computed dose distributions, the parameters used for the calculation of the MUs, the treatment chart, and the print-out of the check-and-confirm system. They found that 139/24128 parameters were transferred incorrectly (< 1%), which affected 26% of the checked treatments (119 of 464 patients). Major deviations (large geographical misses or over-/under-dosage greater than 5%) were found in 0.1% of transferred parameters; these affected 5% of the new treatments (25 patients). The authors state that the use of in-vivo dosimetry and portal imaging would have

detected 24 of these major deviations. They emphasis that: "It is of prime importance to verify the whole treatment set-up with a parallel procedure [volume with portal imaging, dose with in-vivo] during the first irradiation session or as early as posible during therapy"[81].

Valli et al [42] report on a study where over a 2 month period they recorded the errors in 227 treatment plans. They found 155 cases of wrong data, consisting of 24/227 in compilation(10.5%), 22/3744 in execution(0.58%), and 109/3744 in registration phases (2.9%). Missing data accounted for 4.4% of errors detected.

Yeung et al [45] reported on an evaluation of 624 incident reports made over 10 years in their department. 42.1% of reported incidents related to errors in documentation - most of which were either data transfer errors or errors in communication.

Macklis et al [39] specifically investigated transfer errors in the treatment preparation chain which actually resulted in incorrect treatment. Their study ran for one year, and included 1925 patients. They found 59 mistakes in treatment due to data transfer.

Mistakes made in the transfer of the data are often missed where adequate checking procedures are not in place, or where they are in place but have not been used properly. In these instances, it is common for some of the patient's treatment to be delivered incorrectly before the mistake is found. Fiorino et al [27] used data transfer checks pre-treatment, and in this way were able to discover two-thirds of all errors before treatment delivery.

Data transfer occurs throughout the RO process, and is vulnerable to active failures, due to the large number of steps and people involved [81]. Nevertheless, it is imperative that this data is transferred accurately as it relates to treatment parameters, and errors in data transfer will be reflected throughout the remaining steps, and, unless recognised, will result in a systematic error in daily treatment [81]. Elimination of much of the human component of this error can be achieved by integrated computer systems, where data transfer between areas in the department is electronic. This may however, result in a different risk profile of automated data transfer errors.

1.2.3.2 Errors in Planning/ Calculation

At the time of this study, the literature in this area is mainly limited to 2D and 3D techniques, with one identified clinical report on the occurrence of errors while using more sophisticated techniques [67].

A major study in this area is that of Holmberg and McClean [31], where all mistakes in the planning process in one department were documented over a three year period, yielding extensive information on the type of mistakes occurring. In this study, computer-based plans (2.5 or 3D) resulted in a 42% higher occurrence of mistakes than manual plans, and had 30 types of mistakes as compared to 23. There was a similar rate of calculation mistakes in each category (29.1 per 1000 for manual; 28.4 per 1000 for computer based); however, TPS usage mainly accounted for the excess mistakes in the computer plan category. The additional data associated with computer plans also gave rise to more errors and types of errors in recording in the computer plans (5.1 per 1000 vs 1 per 1000). The most common type of near miss was a mistake in the arithmetic of the calculation. Dual independent plan checking mechanisms were shown to be effective here, with an incident:near miss ratio of 13.8:1.

Two Italian studies from the same department (one in 1993, one in 1997) have also focussed on mistakes in the planning process [80, 85], with an error rate of between 1 and 2%. Mistakes in data transfer (misreading and transcription errors) were the most common cause in both studies, leading to an incorrect MU or dose distribution calculation error. There was a mix of manual and TPS plans, however, the ratio of these is not specified, and so it is difficult to compare this data with the study by Holmberg and McClean [31]. An almost identical near miss rate of 34.6 per 1000 charts was identified by Calandrino et al [85] as in the Irish study above (34.4 per 1000 charts) [31]. Mistakes in data transfer during the treatment planning process were also the most common type of mistakes discovered by Noel et al [82].

1.2.3.3 Disadvantages and Advantages of Record and Verify Systems

Record and verify systems (R&V systems), or check and confirm systems, have been a crucial part of the technological advancement in Radiation Oncology –

enabling the delivery of more sophisticated and complex treatments. However, although the implementation of R&V systems has reduced some types of "random" mistakes, new risks were also introduced [77, 81, 87, 90].

These systems can convey a false sense of security [39, 53] and are not to be trusted implicitly: having been designed by humans (giving rise to latent condition type errors) and operated by humans (active failures) [53]. Macklis et al [39] report that 15% of their adverse events were directly due to the use of a R&V system.

Many R&V-related mistakes arise during manual input of data. Reliance on computers often leads to operators trusting the information they contain – forgetting that the information could either be electronically corrupted, or that often the information may have been entered into the computer by a fallible human. A false sense of security can exist in instances where much of the data is electronically transferred but some is manually transferred.

As this data forms the basis of the patient's treatment, it is imperative that it is always correct. Comprehensive checking procedures prior to the use of any data in the R&V system, and appropriate independent checks during the first treatments (or when using any new data) should ensure that most mistakes are detected at an early stage.[39] As with any other area, it is important that the checking procedures are appropriate. For example – checking data on an R&V system computer screen against original data on paper can itself be very error prone. The data is presented in different formats (on-screen versus on paper), and the sequencing of data elements is possibly also different. The checker must be careful to avoid an "expectation bias" – i.e. where he/she sees a gantry angle of "0" on the paper, and looks to find a "0" on the screen, without also consciously checking that that "0" falls under the heading of gantry angle on screen.

Leunens et al[81] reported that almost half of their major deviations due to data transfer were as a result of data transfer from the treatment sheet to the R&V system. In 1995, De Graaff and van Kleffens[88] described a system they developed to minimize manual data entry errors. This system was based on a programme, which automatically checked two independent manual data inputs, and highlighted any inconsistencies to the second inputter. They found that the "introduction of this system has shown a remarkable decrease in data entry errors on our machines."

Data entry, checks etc should all be conducted in a quiet area with no distractions or stressors, as it has been demonstrated that these increase the rate of active failures. It is also recommended that the initial set-up is conducted with only the treatment sheet, and then the R&V system will block treatment if it is not in accordance with the set-up parameters, thereby illustrating an error [81, 84, 87]. Field name, dimensions, beam energy and modality, monitor units, wedge fraction, shielding, should be checked against the treatment sheet at every fraction in case of electronic data corruption. Ideally, additional information on a record and verify system should be entered in standard notation (e.g. BB= Bellyboard, BrB= Breastboard) to avoid confusion among staff as to the meaning of a phrase or acronym.

1.2.3.4 Errors detected by In-Vivo Dosimetry

In-vivo dosimetry measures the dose delivered to the patient and can identify a large range of errors – e.g. beam output (once the diode has not been calibrated against the beam), monitor unit calculations, the set-up of treatment parameters, and patient positioning [92].

Similar rates of detection of serious mistakes (1-2% of checks; >5% dose error) using in-vivo dosimetry are reported in the literature [27, 80, 82-83]. Approximately half of these mistakes would have caused greater than 10% dose discrepancy.

There are difficulties in using in-vivo dosimetry, including difficulty positioning the device. Fiorino et al [27] found that there was a higher recheck and lower accuracy rate for breast and neck anatomical regions, as compared to brain and vertebrae. In addition, the cut-off for in-vivo dosimetry is typically a +/-5% dose discrepancy, whereas for some cancers (particularly in the difficult head and neck region), a dose accuracy of +/- 3.5% might be necessary for tumour control.

The value of in-vivo dosimetry in detecting errors, particularly serious errors which have by-passed previous checks, is consistently stated in these studies [27, 81-82]. However, there is debate on the cost-benefit of in-vivo dosimetry. It is suggested that the value of in-vivo dosimetry may be indirectly related to the comprehensiveness of checks prior to treatment [67]. In terms of practicalities,

its value is however moderated by its cost, and there is a lack of consensus as regards its value in the context of its cost-benefit [27, 86, 93-95].

1.2.3.5 Errors detected by Portal Imaging

Portal imaging (PI) provides a means of verifying the position of the treatment field relative to the patient's anatomy/target volume. It can be useful in detecting errors in field size, gantry rotation, couch rotation, incorrect shielding etc. Imaging can be on film, or electronic, and there is now the capability for 3-D volumetric imaging and 4-D imaging. This has been an area of major advancement for RO in the past years, where imaging capabilities have dramatically increased with the possibility of using kV tubes to acquire treatment verification images on-set. Automated comparisons between treatment images and planning images facilitate interpretation of translations and rotations, and repositioning can be realised quickly by remotely controlled treatment beds.

Film-based imaging can be time consuming, and may not achieve a high degree of accuracy [96]. On-line portal imaging or electronic portal imaging (EPI) accommodates the immediate checking of electronic portal images against the planning image. Both these techniques are based on bony landmarks, or fiducial markers. Volumetric imaging with a cone beam CT enables visualisation of the soft tissue, and more accurate alignment with the target volume. While it is an excellent method of verifying patient position (and target position), it does not check the treatment field parameters, and this must be done separately.

Leunens et al [81] reported that the use of PI in their department would have detected over 30% of major deviations that occurred during the study. They recommended that PI also should be conducted for each initial treatment session. This practice is also proposed by Valli et al [42] as "[a] way of checking for possible errors made during the preparation of the treatment plan", and has been recommended by the AAPM Radiation Therapy Committee Task Group 40 [84], who also recommend that portal or verification films be obtained for all fields once a week. This is probably outdated, as the reality with the advent of image guided radiotherapy (IGRT), is that many patients will be imaged on a daily basis.

1.2.3.6 Errors detected by Chart Checking

Chart checks constitute another major method of detection. In general, chart checks provide an excellent opportunity to detect incidents pre-treatment. In "Lessons learned from accidental exposures in radiotherapy", the IAEA note that "in some of the accidents, even the review of charts and calculations failed to detect a mistake"[34]. The importance of, and sometimes failure of, chart checking is a common feature in the literature [27, 31, 42, 45, 67, 80-81].

Failure of chart checking can occur for a number of reasons. Primarily, people can be too trusting, and may expect to validate the work rather than find a mistake. Secondly, the power of the suggestion can be very strong – we see what we want to see, hear what we want to hear, and read what we want to read. Quickly read the following aloud:

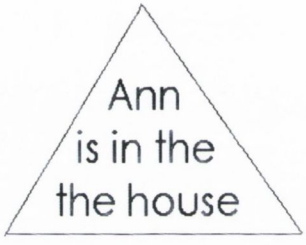

Figure 1-7: A Common "Mind-trip"

Most people who have not seen Figure 1-7 before will read it out loud as "Ann is in the house". There are two "the"s in the sentence. It doesn't make sense and it isn't convenient for us to say, so we subconsciously "delete" the other "the". It could be said that the active failure here was the slip, but the latent conditions are the shape of the sentence, and the pressure to read it quickly.

The danger of checking something that is already done is that the checker may expect to find that it is correct, and so may not consciously identify an error, especially if under pressure. "Under stressful and hurried conditions it is so easy for the second person to make the same calculation mistake as the first" [97]. Mistakes in the methodology of a calculation, or in reading tables are especially vulnerable to the second checker missing an error [98], unless an independent check is performed. It is stated that an independent check of monitor unit calculations is an important tool in discovering errors, and should always be carried out before treatment begins [85-86].

At least two studies highlight the value of multi-layered detection systems, incorporating a double chart-check [31, 67].

1.2.3.7 Summary

It is clear from these studies from individual departments that mistakes and incidents do occur in RO. However, it is not possible to derive an overall incident-rate from these studies, since they are department-specific and typically focus on an aspect of the RO process or on incidents detected using a specific detection method.

Nonetheless, there are a number of messages which can be taken from the above studies:

1. If you look closely at the radiotherapy treatment process for a number of patients or over a period of time, you will find mistakes
2. It is clear that a combination of independent detection methods is necessary in order to cover the spread of incidents which might occur
3. Detection methods can also fail, resulting in incidents if there is not sufficient redundancy built into in the system

Once the potential for mistakes has been recognised, strategies to eliminate or mitigate these mistakes can be developed and implemented.

1.3 INCIDENT REPORTING AND LEARNING

"The primary purpose of reporting is to learn from experience." Leape [99]

Incident reporting is recognised as an important safety tool for any activity, and has long been established in manufacturing, aviation and nuclear power generation, among others. More recently, it has become prevalent in health care, and RO [31, 40, 43, 45-46, 89, 100-106].

Although reporting of incidents and near-incidents is subject to biases, it reveals valuable information on the types, causes and detection of mistakes which occur [107]. It is also important for monitoring progress in the prevention of errors [99]. One limitation of incident reporting is that it is a retrospective technique, although reporting of near-incidents allows early evaluation of risks inherent in the system [40, 43, 46, 101, 108].

Article 11 of EURATOM 97/43 [109] states that:

> *"Member States shall ensure that all reasonable steps to reduce the probability and the magnitude of accidental or unintended doses of patients from radiological practices are taken, economic and social factors being taken into account.*
>
> *The main emphasis in accident prevention should be on the equipment and procedures in radiotherapy, but some attention should be paid to accidents with diagnostic equipment."*

Incident reporting can be used as one method of improving and monitoring safety. Regulations governing the reporting of incidents in RO can derive from legislation on radiation protection and/or health. Mandatory incident reporting at a national level is prevalent in Europe; in some countries this falls under radiation protection legislation; in other countries, reporting of RO incidents falls under health legislation. Some countries stipulate that local recording of incidents is mandatory; in some cases mandatory national and local reporting also includes potential incidents.

Incident reporting systems can give users a sense of ownership, and be seen as a collaborative effort for safety improvement. Conversely, they can also be viewed

as a threat by staff. The introduction of a reporting and learning system is a delicate process, requiring careful and sensitive management. Reporting can be on either a confidential or anonymous basis. In general, the recommended local system is a voluntary confidential one, where an effective safety culture will nourish voluntary reporting [9]. Anonymous reporting, while possibly advantageous in the very early stages of a reporting system, is not recommended in the longer term as the reporter cannot be contacted for more information, and these reports also risk being unreliable [9]. In some situations, it can be difficult to guarantee anonymity. Voluntary confidential reporting is supported by research which has suggested that under the right conditions, health care professionals are willing to accept and acknowledge their own mistakes [110-111]. In reality this is to be expected, as ethically and morally health care professionals are expected to safeguard the best interests and the safety of their patients. Mandatory reporting imposed by regulators allows monitoring and enforcement of safety practices, and requires accountability of health care providers [99].

Incidents are notoriously under-reported, with rates of under-reporting estimated at 50-96% [9]. Under-reporting occurs in all systems (whether mandatory, voluntary, confidential, anonymous), and may occur for many reasons. Factors thought to influence reporting levels are: fear of staff being blamed (especially junior staff), high workload, lack of understanding of what constituted a reportable adverse event, unfamiliarity with the reporting system, and the belief that no benefit will be gained by reporting [9, 112-113].

In addition to under-reporting, opportunities for learning from mistakes are often lost, as experiences in individual departments are not shared with the wider community. This loss of shared learning is especially significant in the context of the rapidly changing technologies and techniques of RO. This can be addressed on a national or international basis by coordinating external collection of reports. Combining reports from different systems to learn lessons is often tedious, or may even be impossible. The work of the WHO, in proposing an International Classification for Patient Safety [47], is an important step in harmonising the collection of incident data between organisations and disciplines.

Incidents are not the only source of information on safety. Reporting near misses is enormously beneficial. Since the 1920s, it has been observed in industry that for each accident causing serious injury, there are a far greater number of accidents resulting in minor injuries or no injury at all (Figure 1-8) [3]. If these valuable "free lessons" were ignored, organisations may risk missing information on incident

occurrence that might otherwise have prevented future incidents [3]. This is especially true where organisations are small and a very limited number of incidents occur.

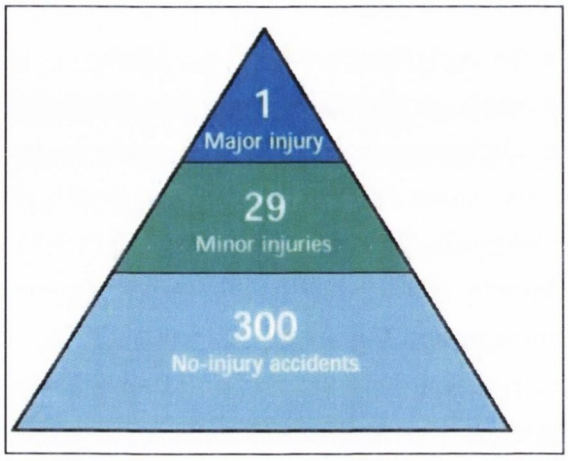

Figure 1-8: The Heinrich ratio

Toft, in an article entitled "The Failure of Hindsight" [114], presents the view that:

> "The evidence also suggests that accidents are not the product of divine caprice, nor a set of random chance events which are not likely to recur, but that they are incidents, created by people which can be analysed, and that the lessons learned from that analysis, if implemented, will help to prevent similar events from taking place again. For where lessons are not learned in hindsight the evidence suggests that similar events can and do recur. Thus, "near misses" should not be shrugged off but instead should be treated as fortunately benign learning experiences, since if the same events were to repeat themselves in less forgiving circumstances then disaster might ensue. There is little doubt that such active learning can assist organisations."

There are other benefits of reporting near misses [115];

- Since near misses are more prevalent more staff are involved in identifying and reporting them – this promotes safety as everybody's responsibility.
- Individuals may be safer, since they will be more aware of and feel more responsible for the occurrence of near misses.

It is possible that a person or body ignorant of the intricacies of reporting could interpret a high number of reported near misses as being indicative of dangerous practice. It is important that, as is stated in the above report, "...the collection of near misses must always be viewed favourably...any attempt to associate a positive correlation between an accident rate, and the number of reported near-misses is unwarranted and moreover, is bad practice. To suggest that a high number of identified near-misses translate to a high accident rate, will only suppress the disclosure of incidents, which in turn will increase risk exposure. If there are instances of both high disclosure rates and a high number of accidents, what must be scrutinised is whether near-miss disclosures are suitably managed." [115]

In communications regarding safety, it should be emphasised that an effective reporting and learning system should identify relatively more near misses and less major injuries [3, 115]. A high rate of both near misses and incidents would suggest that, at a managerial level, lessons are not being learned or safety improvements implemented.

This may also be true of a safe organisation – an organisation which embraces a safety culture should expect to have more near misses than actual major injuries. An informed culture is one aspect of a safety culture. Analysis and feedback systems can be very beneficial in encouraging and establishing an informed culture. In order for staff to report incidents, they must regard it as a worthwhile exercise. They should see that the reports are being ably and properly analysed, and that changes are being recommended to those who are in a position to implement them. These changes should be made, or clear reasons provided why it is not feasible to do so, otherwise staff may become disillusioned with the entire system. The other key element to encourage participation is feedback. Timely and usable feedback is crucial in making the system useful to those who report [7, 9]. It is beneficial to promote open discussion and feedback to the entire department on safety issues – this can be achieved in different ways, e.g. regular meetings, presentations, newsletters.

Incident reporting systems themselves should be in a constant state of analysis (Figure 1-9); to be effective there should be a loop connecting: reporting incidents, analysing these incidents, changes to the system made to prevent these incidents, and reporting within these changes to assess their effectiveness and to identify any incidents arising as a result of these changes. In order for the change to be successful, the correct active and latent errors must be identified from the

investigation. Ideally, details of the incident and the investigation would be furnished to an external body who would conduct analyses on aggregate incident information and ensure its dissemination to the wider community [99]. Characteristics of three major healthcare reporting systems are given in Table 1-2.

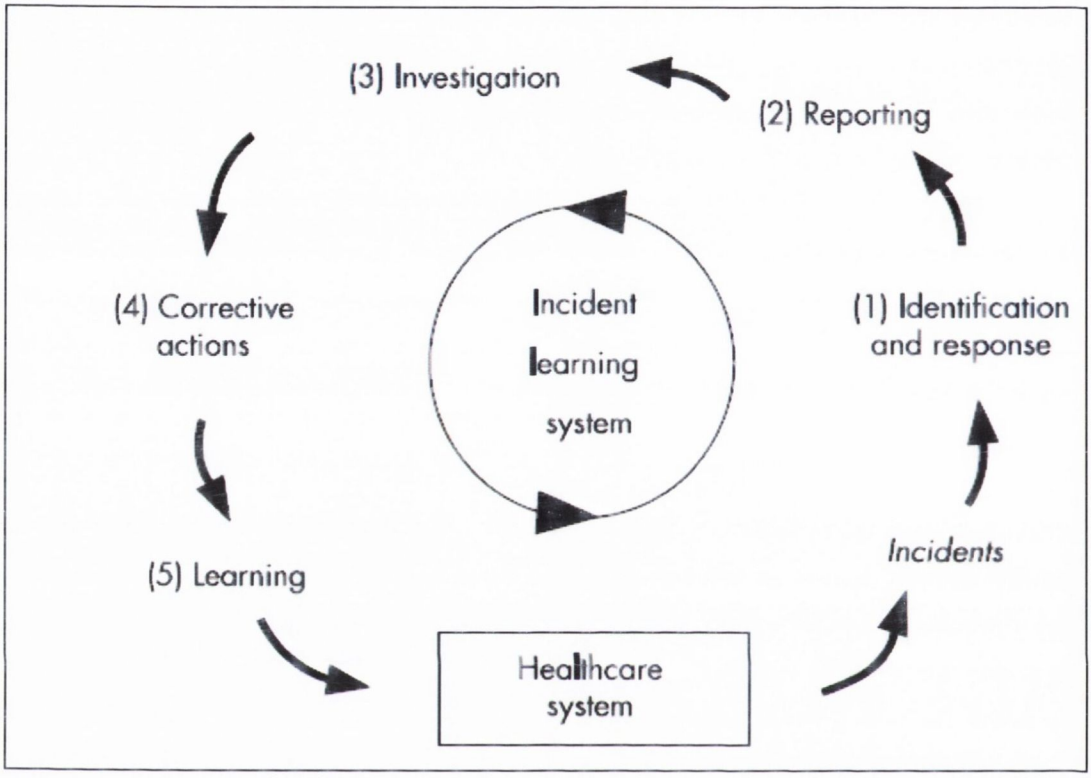

Figure 1-9: The reporting and learning system [89]

Learning from incident reporting systems is not straightforward. It is said that voluntary incident reporting may not reveal the true cross-section of incidents - although it is likely that neither does most mandatory reporting [107]. In addition, all reporting is subject to biases: in that not all types of incidents, nor the true frequency of each incident type, nor the absolute relative frequency of the incidents, might be reported [107]. Incident reporting is only one method of identifying risk, and to obtain a comprehensive overview of risk must be combined with other prospective and retrospective techniques. Nonetheless, incident reporting is traditionally one of the mainstays of risk management in health care, and its role is further consolidated by the work of the WHO in co-ordinating the type and format of data collected.

Table 1-2: Comparison of three major reporting systems in healthcare [116]

	AIMS (Australia) (Generic AIMS Speciality AIMS) *	**JCAHO #** (USA)	**NRLS** (England and Wales)
Type of reporting system	National, Private, Voluntary, Confidential *Promotes learning of new hazards, risk factors, trends and contributing factors*	National, Private, Voluntary, Confidential *Sentinel event reporting system*	National, Public, Voluntary, Confidential *Promotes an open reporting and learning culture*
Who reports	Hospitals, emergency departments, community care, nursing homes, professionals, patients and families, anonymous sources	Healthcare organisations, Other sources (media, complaints, the state health department)	Healthcare staff, NHS Trusts **, patients and carers
Input	Pre-defined Sentinel events, adverse events, near misses, equipment failures, new hazards	Sentinel events +	Patient safety incidents and near misses
Methods of reporting	Paper, electronically, phone	Any accredited healthcare organisation can submit reports	Electronically using electronic risk management system or an e-form /phone
Outcomes/ Outputs	Newsletters, publications, advice and recommendations	Sentinel Event Alerts are published detailing the event, causes, and strategies for prevention. An organisations action plan/corrective actions are monitored.	Publications, feedback to reporting organisations on incident trends and solutions. NPSA provides root cause analysis training.

* Australian Incident Monitoring System (AIMS)- Generic AIMS is used in the public health system in most of Australia, and there are also Speciality AIMS designed for specialist groups, such as anaesthesia.

Joint Commission on Accreditation of Healthcare Organisations (JCAHO)

+ A sentinel event is a serious incident not related to the natural course of a patient's underlying condition or illness, such as unexpected death, or surgery to the wrong body part.

** NHS Trusts: Primary Care, Acute, Mental Health or Ambulance Service

Leape [99] identifies four main methods by which external reporting (either voluntary or mandatory) can lead to improved safety:

1. Issuing Alerts about new hazards
2. Dissemination of individual experiences in safety improvement methods
3. Identification of trends and hazards through central analysis of reports
4. Recommendations on best practice, arising from analyses

A core element of any reporting and learning system is the incident report form. There is no universally accepted format for incident reporting forms – although the WHO ICPS will promote the collection of incident data in common themes and formats. Incident report forms are normally designed to meet the individual needs of each organisation/department, and altered as the need arises. The forms should be compatible with a suitable computer software system. They need to be self-explanatory and easy for staff to use, whilst obtaining information pertinent to risk identification and management purposes. Generally, they require information on the time, date, and place of incident, the name of the patient involved, and a brief description of the incident – enough information to give the investigator a starting point to investigate an individual incident.

Many report forms are now computer-based; one study [117] looked at the use of a structured computerised interviewing technique to conduct a critical incident technique (CIT, origin in aviation). Their findings were that there was a clear learning effect, with the first of five scenarios taking the longest, then the second, but there was no difference between the third, fourth and fifth scenarios. Participants also expressed a preference for this technique over manual or interview methods of reporting.

A review of the Australian Incident Monitoring System (AIMS) found that the report form was too generic, and there could be no root cause analysis as not all incident data was captured. [118]

Apart from the above and the ROSIS evaluations referred to earlier, there is limited work on the format or content of report forms. However there is a general consensus that the forms should be accessible for reporters, and reporting should not be too time-consuming. Either the forms themselves, or a follow-up investigation, should yield sufficient information to learn from the incident.

Aggregate data from the incident reporting system should identify areas where adverse events recur, and results from incident reporting systems should be furnished to the relevant management body [119]. Analysis of incident databases can be facilitated by classification of incidents.

1.4 CLASSIFICATION

1.4.1 Recommendations on Classification

"Taxonomy is simply a classification or ordering into groups or categories. The key in the definition is ordering or having an organisation behind the categories, rather than simply a listing." [120]

"A classification comprises a set of concepts linked by semantic relationships. It provides a structure for organizing information to be used for a variety of other purposes, including national statistics, descriptive studies and evaluative research. It is important to distinguish a classification from a reporting system, which provides an interface to enable users to collect, store and retrieve data in a reliable and organized fashion." [47]

A classification or taxonomy is a tool for learning from incidents, particularly to identify similarities between incidents not otherwise considered comparable. Classifying incidents is not an end in itself, but is a means to better understand incident occurrence, prevention, and recovery. As such, it is imperative that a classification system of incidents is reliable and valid, and that the classification is diligently applied. [121] The basis of any classification system should be the provision of aggregated data in a form amenable to analysis and learning. [121-124]

Key elements to be considered in the design are the purpose of the system, the types of data that are available, and the resources that are available to maintain the system. [124] These are practical considerations for any system, though can be difficult to apply to a cross-organisational or international system. Fundamentally, an international classification system should

- "address a broad and diverse range of patient safety issues and concerns across multiple health-care settings.
- identify high-priority patient safety data elements that are important to health-care systems.
- classify information related to what, where and how medical management goes wrong, the reasons why medical incidents occur, and what preventive and corrective strategies can be developed to keep them from occurring or to ameliorate their effects in health care.

- provide a meaningful and comprehensive linkage between the contributory factors and the errors and systems failures that lead to adverse events.
- facilitate the monitoring, reporting, and investigation of adverse events and near misses at the public health level – allowing aggregated data to be combined and tracked." [125]

In a later report, the WHO [124] list the important aspects of a classification system, under three headings: Principles, Structural Criteria, and Functional Criteria (Figure 1-10). These principles and criteria should be adhered to in designing any classification.

Finally, to achieve the learning aspects of a reporting and learning system, the classified data must be analysed in a meaningful manner. The classification should be devised in such a way as to facilitate the required analysis. Analysis can be straightforward (e.g. hazard identification, and summaries and descriptions), or more analytic (e.g. trends and cluster analysis, correlations, risk analysis, causal analysis, and systems analysis). [121]

The literature was consulted for examples of how other reporting systems have organised and categorised their data. Defining

1. outcome and
2. causes and contributing factors

were felt to be common across many systems and therefore ROSIS should specifically investigate the literature in these areas. This literature is reported below.

I. ***Principles***

A classification should:

- be based upon sound taxonomic and error reduction/prevention theory;
- have a clear organizing principle to ensure elements are logically related;
- be able to classify information in a comprehensive manner that enables knowledge discovery in addition to data warehousing (i.e., allow for the development of hypotheses by explicitly elucidating relationships amongst the data elements);
- provide a method to represent the features of adverse events and/or near misses "along as many dimensions as possible;"
- be useful to a variety of users (such as policy makers, health care providers, administrators, researchers);
- have a stable core framework; and
- be generally accepted within the health care community.

II. ***Structural Criteria***

A classification should:

- use a standardized coding system with an associated terminology that is descriptive within the patient safety domain;
- use primary classification modules that can be applied in any health care delivery setting, in any health care specialty and toward any adverse event or near miss;
- be scaleable (i.e., able to incorporate new or different knowledge without threatening the integrity of its organizational structure); and
- be multidimensional.

III. ***Functional Criteria***

A classification should:

- use an unambiguous, common terminology for patient safety events (i.e., avoid any term that has the potential to cause confusion or misunderstanding);
- ideally be compatible with existing reporting systems so as to facilitate adoption;
- facilitate data aggregation at multiple levels;
- be minimally disruptive (i.e., lessen the reporting burden on health care organizations without extensive reengineering of existing systems); and
- generate reproducible results (i.e., different users should be able to "classify the same problem in the same way").

Figure 1-10: Principles and criteria a classification system must meet[124]

1.4.2 Capturing Outcome of Incidents / Near Incidents

1.4.2.1 Clinical Significance of Incidents in RO

An incident in RO could have clinical significance in terms of an increase in the incidence and severity of early or late complications, a decrease in the probability of tumour control and cure, or a decrease in the probability of symptom control.

Based on an understanding of the radiobiology of tumours and normal tissues, a small change in dose can have a large influence on tumour control probability (TCP) and normal tissue complication probability (NTCP)[126], as is evident from the steep slopes in the simplistic dose-effect curves in tissue (Figure 1-11). Since a dose is decided on the basis of the delicate balance between its TCP and NTCP, any deviation from the planned treatment can have potential consequences for either of these outcomes.

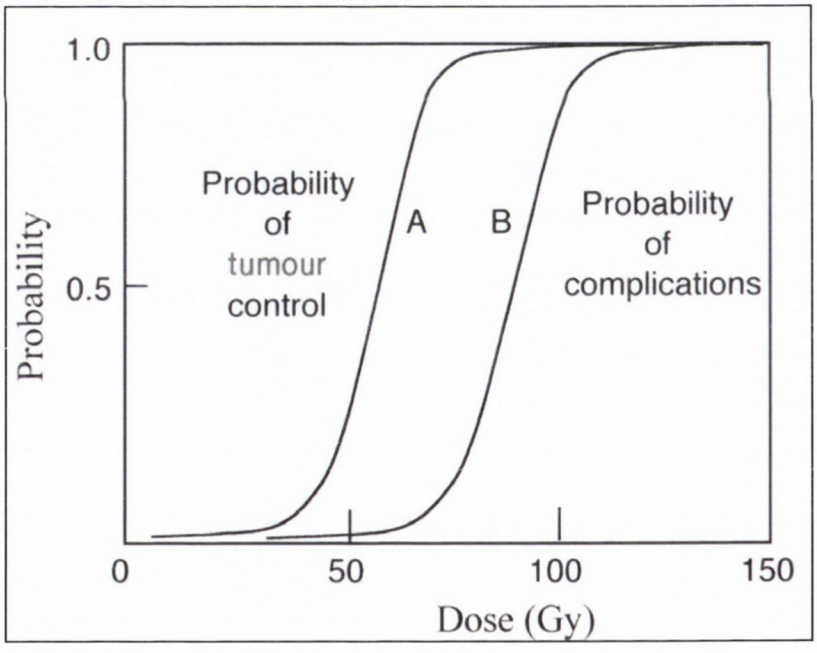

Figure 1-11: Schematic diagram of dose-effect curves for tumour cure and normal tissue damage [127]

Underdoses have not traditionally been recognised as serious adverse events, perhaps because they are more difficult to detect clinically, and discovery is typically after the treatment has been completed, has failed, and there is tumour

recurrence. However, they can have a clear adverse effect on the patient, and conceptually should be included as an incident as defined above. In some cases [40, 49] the implementation of incident reporting under Euratom 97/43 has been done without mandating reporting of underdoses, although it is recommended that these are voluntarily reported as good clinical practice. [40]

1.4.2.2 Published scales on severity of clinical incidents

A number of scales have been devised to classify the severity of clinical incidents: [24, 27, 37, 39-40, 47, 49, 51, 67, 80-81, 85, 87, 128-133]

- General Health Care
  - Advanced Incident Monitoring System (AIMS) [133]
  - International Classification for Patient Safety (ICPS) [47]
  - Joint Commission for Accreditation of Healthcare Organisations (JCAHO) [129]
  - National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) [130]
  - UK National Reporting and Learning Service (UK NRLS) [131]
  - New South Wales Severity Assessment Code (NSW SAC)[132]
- RO-specific
  - American Association of Physicists in Medicine (AAPM) [128] with modifications by International Commission on Radiological Protection (ICRP) [24]
  - Autorité de Sûreté Nucléaire – Societé Français Radio Oncologie (ASN-SFRO) [49]
  - Health Technology Assessment, Canada (HTA Canada) [51]
  - United Kingdom Royal College of Radiologists - Towards Safer RT (UK RCR) [40]
  - RO literature [27, 37, 39, 67, 80-81, 85, 87]

Table 1-3 broadly compares these scales in terms of their range. These scales range from a minimum of no effect to a maximum of death, with the number of levels within the scale ranging from 5 to 9. Some of the scales allow notations to indicate that there were multiple patients involved.

Whilst near misses are captured in most of these scales, the method by which they are incorporated may limit the usefulness of the data collected.

The AIMS Outcome classification (Table B-i; p248), an otherwise comprehensive scale, is one such example. Levels 1 and 2 are near misses; however, because the near miss is immediately assigned at the lower end of the scale, it does not seem to capture information on the potential effect of near misses. Capturing this information would allow the value of safety interventions and staff awareness to be identified, and rewarded. It would also allow prioritisation of risk management strategies.

A similar scenario is found with the NCC MERP scale. This is a complex nine-category scale (Figure B-i; p251), which can be mapped to four basic levels ([no error] / [error, no harm] / [error, harm] / [error, death]). Having more information and the ability to map to different levels makes this scale quite flexible, enabling broad comparison with other scales. Nonetheless, it does not capture the potential severity of near misses.

A characteristic of the scales in use in General Health care is that they also consider psychological or emotional harm to the patient (Table 1-3). The NSW SAC uses the same five levels (minimum/major/moderate/minor/serious) to cover clinical consequences for the patient (physical and psychological), and corporate consequences (environmental, financial, services, visitors, or staff). The JCAHO classification (Figure B-ii; p252) uses a similar nine-point scale for both physical and psychological outcomes, and unusually also considers non-medical impact in the categories of legal, social and economic.

Two other aspects of these general medical scales are of importance:

1. The NCC MERP provides a decision-tree, which assists the reporter and probably enhances the reliability of responses.
2. In the NSW SAC, there are also five levels of likelihood (rare/unlikely/possible/likely/frequent), and a matrix is used to define required action (four levels – low/medium/high/extreme risk) based on the product of the consequence and likelihood.

The classification of patient outcomes by the ICPS is illustrated in Figure B-iii; (p253). Table B-ii (p250) lists the corresponding descriptors for degree of harm, and a comparison between these and possible equivalent levels on the French and the ROSIS outcome scales, which are broadly comparable.

Table 1-3: Comparison of Clinical Incident Outcome Scales

	Scope	No of Levels	Severity		
			Physical	Psychological	Economical
AIMS	General	8	√	√ (incorporated)	-
ICPS	General	8	√	√ (incorporated, but separate category within scale)	√ (7 categories)
JCAHO	General	9	√	√ (separate, 9 categories)	√ (3x1)
MERS	Medication	9 categories /4 levels	√	Not Specified	-
UK NRLS	General	4	√	√	-
NSW SAC	General	5	√	√	√ (5 categories)
AAPM	RO	3	√	-	-
ASN-SFRO	RO	8	√	-	-
HTA Canada	RO	6	√	-	√(separate)
UK Towards Safer RT	RO	5	√	-	-
RO Literature	RO	2-3	√	-	-

National bodies in the UK have published a general health care scale (UK NRLS) [131], and a scale specific to RO (RCR) [40]. Unfortunately, these scales are not comparable. In the first instance, the NRLS consists of four levels; the UK RCR of five levels.

The National Reporting and Learning System (UK NRLS) uses the categories: low, moderate, severe, death. Although the examples under these descriptors all relate to physical harm, there is a question to determine if the harm was physical, psychological, social or other. There is also a separate reporting area for no-harm incidents or near-misses.

The RO Scale proposed by the UK RCR [40] uses the same categories as per the classification of events (described in Section 1.1.3):

1. Reportable RI
    a. This could map to any of the four NRLS categories
2. Non-reportable RI
    a. This would most likely map to "no-harm incident"
3. Minor RI
    a. This would most likely map to "low"
4. Near Miss
5. Other Non-conformance

The UK RCR recommendations do not include mandatory reporting of underdosage, although they do suggest underdosage events be reported voluntarily. Mandatory reporting of medical radiation incidents is also required under the IR(ME)R regulations; this is also mandatory only in respect of exposures "much greater than intended"[134]. Although this report form does not specifically request details on the severity or outcome, it does capture whether the incident resulted in an overdose or an underdose.

It can be seen from the discussion that these different national scales within the one country are very diverse, and inconsistent. Without further detail, it is difficult to compare the UK RCR Scale with other scales.

Although the UK RCR scale is based on the concept of a reportable incident, in general scales in RO are based on dose discrepancy. This can be considered either in terms of actual dose delivered, or in terms of likely consequences.

The AAPM consider two classes of hazards: [24, 128]

- Class I hazards – which have the potential to cause death/serious injury; and
- Class II hazards – where the risk of serious injury is small

Class I Hazards are subdivided into Type A and Type B hazards, shown in Table B-iii (p.254) [24]. Type A hazards are those resulting in an overdose of 25% or more of the total prescribed dose; Type B hazards are those of 5-25% ovedose, and most underdoses. The AAPM includes underdose situations as Type B adverse events as it is assumed that the error would be discovered quickly (within one week), and therefore that remedial action could be taken swiftly. In reality, some underdosages may not be detected during treatment, and in this case, it may be too late to take remedial action, with the patient seriously adversely affected. The ICRP suggests that cases with >25% underdosage be classed as Type A events.[24]

The ASN-SFRO Scale (Table B-iv; p255) is linked to the classification of events:

- Level 0 and 1 = events with no clinical consequence
- Level 2 and 3 = events categorised as "incidents"
- Levels 4 to 7 = events categorised as "accidents"

This scale is related to the CTCAE grades [135] already in use by oncology professionals. They show a clear relationship between the ASN-SFRO scale, and the CTCAE grades, and with this comparison the ASN-SFRO scale may be more straightforward to implement, and may be used in a more valid and reliable manner. A limitation of this scale is that it does not consider adverse clinical outcomes as a result of underdosage.

The Canadian model has some levels reflecting potential severity, which is lacking in many scales; however, it is only specified for the two middle severity levels and is not available at either end of the scale, which may lead to inconsistent use or interpretation of potential events (Table B-v; page 256)

The dosimetric definition of an error in the RO literature has typically been described in a less structured manner. In most cases, a serious deviation is >5% dose error [27, 80-81, 85, 87], and this may be either an over- or an underdose. Since these studies were in single institutions, this low cut-off in comparison to the National RO scales described above probably reflects the low occurrence of major dose discrepancies in any one centre. However, some authors have attempted a greater discrimination of dose errors; mainly based on dose discrepancy rather than clinical severity or outcome.

In a recent article investigating the effectiveness of checking systems on the detection of mistakes, Morganti et al [67] defined four levels of error magnitude:

- < 1% error
- 1-5% error
- 5-10% error
- > 10% error

Macklis et al [39] defined three levels, with the main focus on clinical effects rather than dose discrepancy per se:

- Level I = minor dose discrepancies that generally resulted in < 5% dose difference to target volume
- Level II = minor dose discrepancies that were judged to have a low but not negligible chance of adverse event
- Level III = any dose delivery discrepancy of any kind that resulted in a significant and documented adverse clinical outcome, or an increase in NTCP or a decrease in TCP

Klein et al [37] considered the dosimetric impact of error in RO, and describes three levels of dosimetric impact, according to the error of dose and/or treated volume. Interestingly, these are specified as error per fraction:

- High – error of potentially > 20% per fraction in terms of dose and/or treated volume
- Medium – error between 10 and 20% per fraction in terms of dose and/or treated volume
- Low – error < 10% per fraction in terms of dose and/or treated volume

While these systems have the benefit of more levels, they also have their drawbacks. Macklis et al [39] is heavily reliant on expert opinion and there may be substantial overlap between interpretations of Level II and Level III. In their study, all errors detected were at Level I, so their definitions of Levels II and III were not tested. Although the scale of Klein et al [37] also specifies dose to the treated volume, a major limitation of this scale is that it does not include the ICRU recommendation of dose homogeneity of 5% across the target volume [50, 66]. Morganti et al [67] include two levels above and below this 5% cut-off level. Similar to Klein et al, it is only specified in terms of percentage error, rather than possible outcome.

Despite a low occurrence of major dose deviations in an individual centre, it can still be worthwhile to capture a greater range of actual and potential dose discrepancy other than greater or less than 5%. In fact, having more levels is probably more important in assessing the potential severity of near-incidents, or incidents detected at an early stage. These would be expected to occur more frequently, and exhibit severities at the mid/higher end of the scales. If this information is collected, it can be assessed to determine whether the detection and prevention of incidents results in less clinical adverse effects. Where a shift is found from higher potential to lower actual dose discrepancies, this information can be used to illustrate the value and effectiveness of safety measures in place, and justify safety-related resource investment in safety.

A criticism of most of the scales – general medical or RO specific – is that they are vague and highly subjective. The validity and reliability of these scales has not typically been investigated, but is of concern since one of the purposes of scoring severity is to assess, prioritise and manage the risk based on its risk rating – normally a combination of likelihood to occur and severity. Failure to appropriately capture information on either of these variables could result in inappropriate prioritisation and management of risks, and allocation of resources.

A UK study[136] has investigated the inter-rater reliability in determining severity of clinical incidents where the outcome is not known - a scenario typical of many incidents in RO. Thirty participants scored 50 medication incidents on a visual analogue scale of 0 to 10. For a reliable, valid method of scoring the severity of these errors, the mean score from four judges was required (independent of profession).

This study was later replicated in Germany[137], where ten professionals were recruited from each of three disciplines, and asked to score the severity of 49 medication incidents. This study found that an acceptable reliability was achieved when three professionals scored the incidents, and was slightly increased when this represented a professional from each of the disciplines.

A point of interest for any international system is that there was a statistically significant lower mean score (0.9 lower) attributed to the same scenarios in the German study than in the UK study. This suggests that although the same scale was used in each study, and proven to be reliable under certain conditions, it may

not be reliable for use internationally. Cultural variations should be taken into account when testing for reliability and validity.

An outcome classification in RO should as a minimum encompass physical harm, and could focus on either actual dose discrepancy, or anticipated outcome. It must include underdose events as well as overdoses. Since there is normally opportunity for detection and recovery within the RO process, any outcome classification in RO should capture the actual harm (or dose/volume discrepancy) as well as the potential harm (or dose/volume discrepancy).

1.4.3 Capturing Causes and Contributing Factors

"A contributing factor is a circumstance, action or influence (such as poor rostering or task allocation) that is thought to have played a part in the origin or development, or to increase the risk, of an incident. Contributing factors may be external (not under the control of a facility or organisation), organizational (e.g. unavailability of accepted protocols), related to a staff factor (e.g. an individual cognitive or behavioural defect, poor team work or inadequate communication) or patient-related (e.g. non-adherence). A contributing factor may be a necessary precursor of an incident and may or may not be sufficient to cause the incident." [138]

Identifying causes and contributing factors is an essential step in managing risk, and in preventing incident occurrence. Nonetheless, this is probably one of the weakest areas of current health care risk management programmes. A limitation to the application of these classifications in the clinical context is that the extent of investigation and level of expertise that may be necessary to accurately and comprehensively identify the multiple causes and contributing factors which are typical of health care incidents is not commonly available to health care organisations. Similarly, there is a lack of evidence to prove that recommended interventions are effective in preventing incidents in the complex socio-technical clinical setting.

Similar to the situation with outcomes scales, there are various classifications of causes and/or contributing factors, for general health care – either modified from industry or designed specifically for general health care, with some devised for RO.

The classifications of causes and contributing factors will be considered together, and without exploration of the underlying psychological theory. All of these classifications are based on the systems theory of accidents, identifying active failures and latent conditions (discussed in Section 0).

The following examples will be considered:

4.1. General Health Care

- Framework of factors influencing clinical practice [59]
- Advanced Incident Monitoring System (AIMS) [133]
- International Classification for Patient Safety (ICPS) [47]
- Joint Commission for Accreditation of Healthcare Organisations (JCAHO) [129]
- Eindhoven Classification Model (ECM) [139]

4.2. RO-specific

- International Commission on Radiological Protection (ICRP) [24]
- International Atomic Energy Agency (IAEA) [34]
- Health Technology Assessment, Canada (HTA Canada) [51]
- RO literature

1.4.3.1 General Health Care

The Framework of factors influencing clinical practice [59] is based on Reason's Model of Organisational Accidents, and is modified for use in the healthcare setting. Since it is based on Reason's Model, it also incorporates active and latent failures. It is intended that for each active failure, multiple (latent) contributing factors may be identified.

Both the AIMS and the ICPS identify both active and latent failures, and in general, there are many similarities between both the AIMS and the ICPS classifications. The AIMS looks for causal factors under the broad headings of Human (subject / staff / other), Organisational / service, Environmental/ work area and Other factors; the ICPS consider these and additionally External factors.

However, rather than causative factors, the ICPS only considers a category of contributing factors, without discriminating between causes and contributing factors – this seems a practical and reasonable approach. Despite this, the expanded list of factors is not very user-friendly (Figure ; p258, and Table C-i; p259), and there may be overlap within the list. It is likely that the ICPS will move to the Eindhoven

Classification Matrix in the future *(van der Schaaf, personal communication, November 2008)*.

The AIMS system also captures specific information about contributing factors; if either a device or document was felt to contribute to the incident, then its name was sought.

The Joint Commission for the Accreditation of Healthcare Organisations (JCAHO) also makes a distinction between human errors and those of systems origin. There are three main categories (Figure C-ii; p261), within each category there are subcategories which are manageable within the organisation, and there is also a category ("External") to reflect those items with are beyond the control of the organisation. Unlike AIMS and ICPS, this system specifies technical factors as an independent, high level factor. Rasmussen's model of human error is the basis of the active failures, and the latent failures are organisational and technical. This conceptual layout is very similar to the earlier Eindhoven Classification Model.

Unlike the systems outlined above, the Eindhoven system was initially devised for use in the chemical industry in 1992. [139] It was the first system to identify causes and recommend remedial actions validated to improve safety. It has been modified for use in the medical domain, and has been used in anaesthesiology, blood-bank operations, and RO [140].

The medical Eindhoven system consists of four main categories:

1. Technological Factors
2. Organisational Factors
3. Human Factors
4. Patient-related

Human factors represent the active failures, and are based on Rasmussen's model of human error (
Table 1-4). Classifying causes of error under this system is facilitated by a decision tree (Figure 1-12). These causes can then be mapped to a matrix to discover the most appropriate managerial response(s) to reduce the probability of the incident.

A key element of the design of the Eindhoven system is that the decision tree begins with technical factors, and doesn't consider human factors until near the end. This is to encourage discovery of factors other than human, which is also

significant for risk management since particularly technical factors provide more reliable means of incident prevention. The use and structure of the decision-tree also promotes objectivity in this system, an attribute which is lacking in many others.

Table 1-4: Eindhoven Classification Model (Medical Version) [141]

		Code	Category	Definition
Technical		T-EX	External	Technical failures beyond the control and responsibility of the investigating organisation.
		TD	Design	Failures due to poor design of equipment, software, labels or forms.
		TC	Construction	Correct design, which was not constructed properly or was set up in inaccessible areas.
		TM	Materials	Material defects not classified under TD or TC.
Organisational		O-EX	External	Failures at an organisational level beyond the control and responsibility of the investigating organisation, such as in another department or area (address by collaborative systems).
		OK	Transfer of knowledge	Failures resulting from inadequate measures taken to ensure that situational or domain-specific knowledge or information is transferred to all new or inexperienced staff.
		OP	Protocols	Failures relating to the quality and availability of the protocols within the department (too complicated, inaccurate, unrealistic, absent, or poorly presented).
		OM	Management priorities	Internal management decisions in which safety is relegated to an inferior position when faced with conflicting demands or objectives. This is a conflict between production needs and safety. An example of this category is decisions that are made about staffing levels.
		OC	Culture	Failures resulting from collective approach and its attendant modes of behaviour to risks in the investigating organisation.
Human		H-EX	External	Human failures originating beyond the control and responsibility of the investigating organisation. This could apply to individuals in another department.
	Knowledge-based behaviour	HKK	Knowledge-based behaviour	The inability of an individual to apply their existing knowledge to a novel situation. Example: a trained blood bank technologist who is unable to solve a complex antibody identification problem.
	Rule-based behaviour	HRQ	Qualifications	The incorrect fit between an individuals training or education and a particular task. Example: expecting a technician to solve the same type of difficult problems as a technologist.
		HRC	Coordination	A lack of task coordination within a health cares team in an organisation. Example: an essential task not being performed because everyone thought that someone else had completed the task.
		HRV	Verification	The correct and complete assessment of a situation including related conditions of the patient and materials to be used *before* starting the intervention. Example: failure to correctly identify a patient by checking the wristband.
		HRI	Intervention	Failures that result from faulty task planning and execution. Example: washing red cells by the same protocol as platelets.
		HRM	Monitoring	Monitoring a process or patient status. Example: a trained technologist operating an automated instrument and not realizing that a pipette that dispenses reagents is clogged.
	Skill-based behaviour	HSS	Slips	Failures in performance of highly developed skills. Example: a technologist adding drops of reagents to a row of test tubes and than missing the tube or a computer entry error.
		HST	Tripping	Failures in whole body movements. These errors are often referred to as "slipping, tripping, or falling". Examples: a blood bag slipping out of one's hands and breaking or tripping over a loose tile on the floor.
Other factors		PRF	Patient related factor	Failures related to patient characteristics or conditions, which are beyond the control of staff and influence treatment.
		X	Unclassifiable	Failures that cannot be classified in any other category.

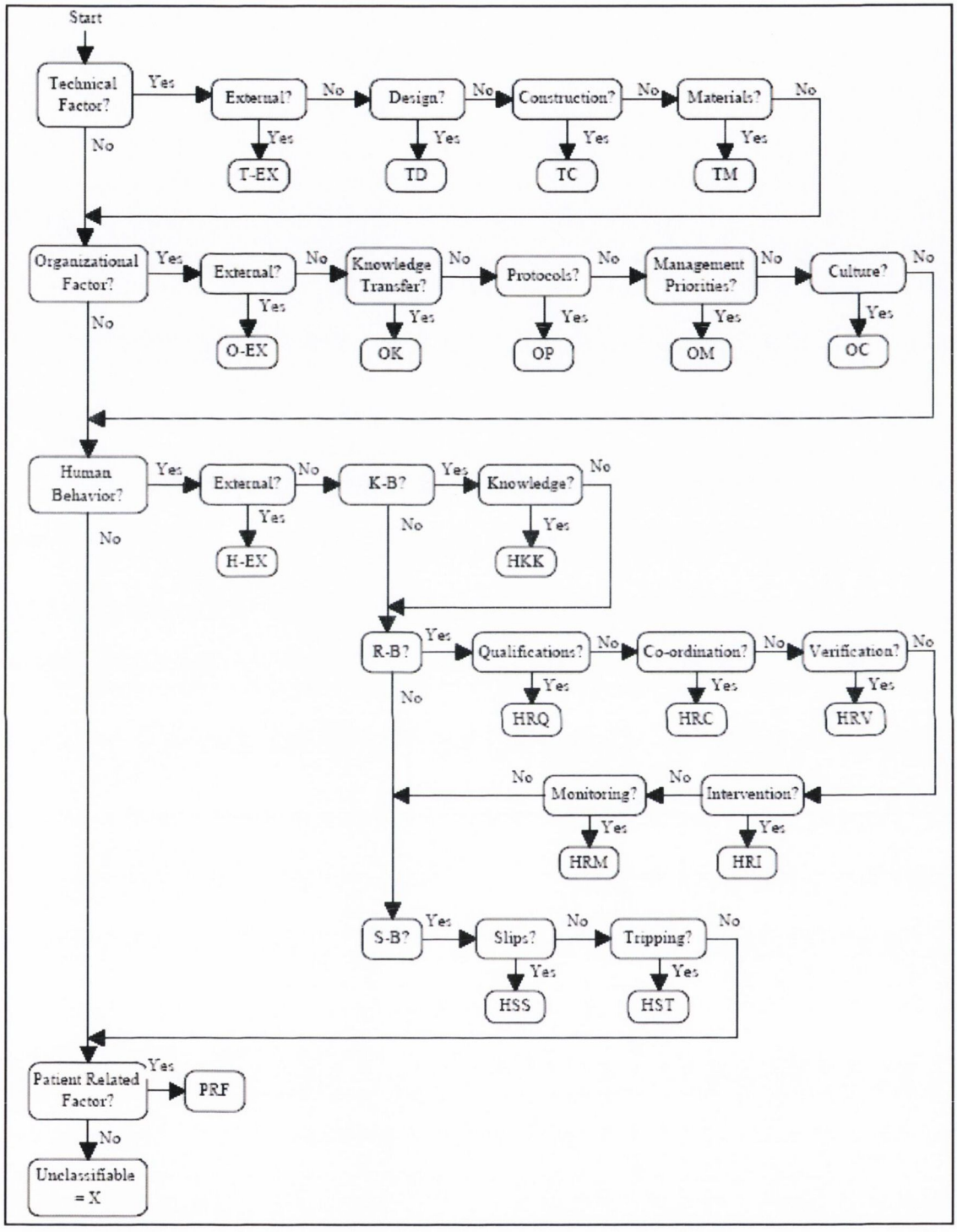

Figure 1-12: Eindhoven Classification Model: Medical Version[141]

If a near-incident is being reported, the classification can also be used to identify recovery factors, using the prefix P for Planned recovery, or NP for not planned (e.g. P-H for Planned Human performance factors in recovery, NP-H for Human-led recovery which was Not Planned). [140]

The Eindhoven Classification Matrix is combined with the causal tree incident description method and the classification/action matrix to create the PRISMA system. PRISMA stands for Prevention and Recovery Information System for Monitoring and Analysis. The combination of these three tools – a root cause analysis, a cause classification, and a managerial action matrix – provides a system of tracking and managing particularly latent failures within an organisation. The system is designed to identify failures which cross many incidents, based on the input of many incidents rather than relying on the investigation of individual cases. A PRISMA-RT system has been developed and has been adopted for use throughout the Netherlands. [142]

1.4.3.2 Radiation Oncology Specific

In general, and with the exception of in-depth analysis of individual serious accidents, the causal analysis of incidents in RO does not seem to be based on a particular systematic application of organisational or psychological theory, but is more an ad-hoc list when compared to systems originating from industry. For example, causal analysis reported in the recent WHO Risk Profile appears to be of limited scope and is focussed on what happened in terms of active failures. [44] Interestingly, it is also reported that although a large proportion of incidents were reported to be due to system failures, inexperience and inadequate knowledge of staff was under-reported. [46]

Based on analyses of accidents over a 25 year period, the ICRP [24] identified that the following headings of causes/contributing factors were common to many RO accident scenarios. There appears to be overlap between some of these categories (e.g. lack of independent checks, and deficiencies in procedures and protocols), although the categories do seem to cover technical, organisational, and human factors:

1. Deficiencies in education and training
2. Deficiencies in procedures and protocols
3. Equipment faults
4. Deficient communication and transfer of essential information

5. Lack of independent checks (defence in depth)
6. Inattention and unawareness
7. Unsecured long-term storage or abandonment of RT sources [24]

Similar scope and difficulties arise with the IAEA Safety Series 17. The purpose of this report [34] was to collect and collate a large selection of events and contributing factors. Contributing factors identified were in eleven major categories, with subcategories (see Table C-iii; p263). As a whole, this list is similar to that of the ICRP [24].

A Canadian Health Technology Assessment initiative on Learning from Incidents in RO [51] directly utilised a Basic Causes table from the Chemical Industry (from NOVA Chemical Corporation [143]) for reporting RO incidents (Table C-iv; p265). This has a very broad scope, but like many industrial systems, may not sufficiently consider the variability inherent in clinical situations. In general terms, the Eindhoven categories of Technical, Organisational and Human factors are covered here, although divided into different areas. Interestingly, the failure to recognize or appropriately respond to a hazard is included in this table. This could be seen as a significant element of a safe clinical process, and worth documenting as a cause / contributing factor to the occurrence of an incident.

One published study [41] has applied the models of causes and contributing factors from industry to RO, analysing 134 reported cases in brachytherapy. Three models were used:

1. Rasmussen (What, How and Why)
2. Eindhoven (SMART)
3. Kapp and Caldwell (SCOPE)

Although the models yielded sensible results, a limitation was that they were overly focussed on machine/technical failure (appropriate to industrial applications) and mainly considered the human element as a response to an initiating event, as opposed to being the initiating event as is common in healthcare. The authors felt that they did not receive adequately detailed information on the nature of the human failures using these models, and that a model specifically designed for the medical field would be more appropriate.

Two of these authors later devised such a model – the Madison Medical Taxonomy – using aspects of reported models including the three models evaluated in their above paper. [120] This taxonomy has four levels:

1. What happened?
2. Which major component of the action failed?
3. What contributed to the failure?
4. Why did it fail?

The outputs of this taxonomy are used to identify appropriate remedial actions, according to a matrix similar to that of the PRISMA system.

In this model, there is a greater emphasis on the human element and less on the technical aspect of initiating factors. This approach looks promising, although lengthy, and should be tested and validated in the health care setting.

Overall, the only consensus on causes and contributing factors is that both active and latent failures must be captured. The Eindhoven Model is probably the most established model shown to lead to safety improvement; however, this is mainly outside of health care. Within health care, it may not capture sufficient information on the human component, although it is also true that identifying and addressing failings from the technical aspect is more effective. In theory, the Madison Medical Taxonomy claims to account for the additional diversity and uncertainty created by the variability of humans in the medical domain, and shows promise. Classification systems of causation and contributing factors must be tested more thoroughly in the medical setting before they can be relied on for safety improvement.

1.5 SUMMARY OF LITERATURE REVIEW

Incidents occur in health care, and in RO. Evidence from acute health care settings suggests an incident rate of approximately 10%; it is not possible to derive an overall incident rate for RO from the existing scientific literature.

RO requires the careful delivery of radiation according to a prescription and plan. It is multidisciplinary and the preparation and delivery of treatment has a number of stages, typically requiring sophisticated equipment and a well-trained workforce. There is significant potential for mistakes to occur, and significant potential for harm as a result of a mistake. The ability to detect mistakes before or during treatment is a longstanding safety aspect of RO.

Whilst significant advancement has been made in identifying and addressing iatrogenic injuries there is still substantial room for improvement in most medical disciplines, among them RO. Emphasis is placed on systems design for patient safety. One method of improving safety – through identifying and learning from incidents and near-incidents – is incident reporting. Incident reporting should encompass both incidents and near misses, and while it is useful in establishing the types, causes, and detection of mistakes, it is inherently biased. Analysis and feedback should be core activities of a reporting and learning system, once based on careful interpretation of the reporting data.

Classification is a useful tool in collating, analysing and learning from incidents, and efforts are being made to coordinate the collection of incident data on a global scale. There is a role for disciplinary-specific classifications and reporting systems, though these should be compatible with and comparable to global classification schemes as far as possible.

1.6 AIMS

This thesis aims to:

1. Describe the development of ROSIS – a voluntary external online reporting and learning system in radiation oncology
2. Analyse the data collected by ROSIS from 2003-2008
3. Define a classification system for the collection and analysis of information on incidents in RO
4. Develop a revised reporting and learning system and make recommendations for further development of this

2 Chapter 2: Development and Implementation of ROSIS

2.1 INTRODUCTION

Mandatory reporting of incidents in RO at a national level is common practice in Europe, and has existed in several countries for decades under regulations that derive from radiation protection and/or health legislation. At a local level, departments in several countries have well developed local reporting systems for incidents and near-incidents. However information from these systems has not been extensively shared. This loss of shared learning is especially significant in the context of the rapidly changing technologies and techniques of RO. With a vision to encourage the sharing of information on local incidents and near-incidents with the wider community – to reduce the potential for repetition in other settings, and to raise the level of awareness of the potential for incidents, the Radiation Oncology Safety Information System – ROSIS – was created as a learning tool.

The main aims of the ROSIS System are to:

- Establish an international reporting system in RO, and
- Use this system to reduce the occurrence of incidents in RO by
    - Enabling RO departments to share reports on incidents with other departments as well as with other stakeholders such as scientific and professional bodies
    - Collecting and analysing information on the occurrence, detection, severity and correction of RO incidents
    - Disseminating these results and generally promoting awareness of incidents and a safety culture in RO.

The development and implementation of ROSIS will be described under three main headings:

1. Concept and background research
2. Development of ROSIS
3. ROSIS Feedback Mechanisms

2.2 ROSIS: CONCEPT AND BACKGROUND RESEARCH

A review of incident reporting in industry and health care was undertaken.
A baseline in relation to incident reporting in RO in Europe was established through three measures:

1. Questionnaire on national regulations on incident reporting in radiation oncology and the implementation of 97/43/Euratom
2. Evaluation of report forms in use by RO departments
3. Analysis of RO incident reports received by RO departments

2.2.1 National Regulations on Incident Reporting in Radiation Oncology

A baseline of reporting structures in European countries was obtained through a self-administered questionnaire survey of National Radiation Protection bodies, European Federation of Medical Physicists (EFOMP) affiliated National Physics bodies and clinical departments. This survey, in 2001, also specifically addressed the understanding of the implementation and application of regulations relating to incident reporting in accordance with the transposition of 97/43/EURATOM. This was sent to 16 countries; 10 countries (63%) responded. The survey and results can be seen in Appendix D.

The survey of reporting structures throughout Europe revealed substantial variation in the interpretation and implementation of the regulations for radiotherapy incident reporting within these countries, with variations of interpretation and implementation evident also within single countries. The responsibility for transposing the European Directive into national legislation was generally reported as being the responsibility of one government department (either Radiation Protection (Environment), or Health), although it was divided among three governmental departments within one country. Variation was also observed in who to report to (Health or Radiation Protection Authority), whether or not reporting of incidents was mandatory at a local or national level, and whether or not near-incidents were included.

The reported variation in the implementation of European Commission Directive 97/43 EURATOM in different countries, and the different interpretations of national

legislation within individual countries, highlights some of the difficulties facing a unified approach to mandatory incident reporting. In some countries, the lines of authority are not clear, possibly resulting in confusion amongst the RO community regarding where to report and what to report. Similar to other mandatory systems [99], these systems are unlikely to be compatible with each other for the purposes of an international reporting and learning system.

These are national requirements with a regulatory focus. Whilst regulation can be one important aspect of reporting, there are other purposes of reporting: including improving and monitoring patient safety. There was a vision for an international, voluntary, reporting and learning system in RO. The next phase was to establish the scope and type of information being reported in individual departments.

2.2.1.1 Evaluation of incident report forms

The first ROSIS Clinical Partners (45 departments from 14 countries) were recruited through mailshot by the European Society for Therapeutic Radiology and Oncology (ESTRO). They were asked to provide data on local incident reporting systems and/or retrospective incident reports. A total of 27 sample report forms were received from 22 departments; spanning nine countries [UK, Ireland, Italy, Denmark, Norway, Sweden, Finland, The Netherlands, and Switzerland].

These incident report forms were analysed to benchmark the type of data on incidents that was being collected by RT departments, and to develop a common report form.

The evaluation of the local report forms revealed that in general, four categories of information were sought:

1. Administrative information
2. Patient information
3. Incident information
4. Action information

The frequency of data items under these categories can be seen in Table 2-1.

Table 2-1: Information sought on local report forms

[n= 27 forms from 22 departments]

ADMINISTRATIVE INFORMATION	No of forms where item requested
Incident / Near miss	12
Raised by	7
Who filled form	17
Date form filled	19
Report# (incident #)	11
Patient related incident	4
Internal / external report	4
High priority?	1
Department	7
Management signature	12
Senior RT signature	3
Physicist signature	3
Blame	1
Report closed and date	4
PATIENT AND TREATMENT INFORMATION	**No of forms where item requested**
Patient Name	18
Patient ID	18
Patient date of birth	5
Diagnosis	4
Consultant	12
In-Patient / Out-Patient	1
Treatment Body site	5
Treatment intent (rad/pall)	3
Treatment technique	7
Treatment Plan number	1
No of fields	1
Total number of fractions	8
Daily dose	6
Total dose	6
Responsible Senior RT	1

INCIDENT INFORMATION	No of forms where item requested
Description of event	26
Possible cause of error	9
Number of fractions affected	10
Occurrence	
Date	18
Time	12
Day	1
Machine(area)/treatment modality	16
Energy	4
Number of fields affected	4
Origin of error treatment process	4
Detection	
How	4
Who	2
Work area	1
Date	3
Estimation of deviation	
Clinical significance	8
Effect on critical organs/healthy tissue	3
Risk to pt	6
Dose error	2
Dose error after correction	2
Geographical error	1
Correctable or not	3
Contributing factors	
General comment	4
Complex/simple plan	1
QA present/not/incomplete	1
Number of staff on machine on day	2
Number of staff at time of incident	2
"Rostered" vs "covering" staff at time	2
Experienced staff at time	2
Staff in dept (staffing levels)	2
Staff on leave	1

Distractions	1
Other information	
Error type	4
Name of RTs involved	4
Comments	3

ACTION INFORMATION	No of forms where item requested
Corrective action	
corrective action required	12
(to be) taken by	3
date for completion	5
Record that corrective action taken	17
Preventative action	
recommended action to prevent recurrence	10
amendment to procedures/document	2
Preventative action confirmed	3
Communication	
Responsible physician informed	13
Patient informed	4
authority informed	9
general *(blank)*	6
feedback given to staff/reporter	1

There was a wide variation in the purpose and scope of departmental incident report forms. Some departments had more than one form, possibly reflecting different reporting levels (near-incident versus incident) or different aspects of risk management (clinical versus administrative/insurance).

There were very few specific data items common to all or nearly all report forms, whereas most forms did request information under the general headings of administrative, patient, and incident information. This is a problem encountered in many intra-disciplinary but disparate reporting systems.[20, 21] Differences in information collected also indicates differences in organisational learning from the

reporting system, in that organisational learning is directly influenced by the information collected and analysed, and the methods used.[144]

The information collected was used as a baseline of existing reporting structures within Europe, and formed the basis for the ROSIS incident report form.

A limitation of these forms (and therefore the original ROSIS forms which were based on these) is that they do not capture specific information e.g. on the RO Technology, the specific technique that was in use, and/or the treatment site.

2.2.1.2 Retrospective analysis of RO incident reports

ROSIS Clinical Partners also provided data for a preliminary analysis of retrospective incident reports. A total of 910 incident and near-incident reports were collected for the year 2001 from ten departments, representing four countries. These incidents were analysed to assess the nature and scope of reported incidents, and to conduct a hazard identification based on the types of incidents that occur in different RO departments.

The vast majority of the reports were near-incidents or minor incidents, with most reported incidents being detected at treatment, although the majority of these seem to have originated pre-treatment. Detailed comparison of incidents between departments was confounded by the level and type of information available on report forms.

A hazard identification was undertaken on these reports in 2003, to identify the most common types of errors occurring, and to identify the most likely stage of occurrence and detection of incidents. Hazards were identified, and organised into six main categories, which were expanded (Appendix 7G). Each report was evaluated to determine the type and subtype(s) of event that occurred (Figure 2-1 and Table 2-2). This classification of hazards proved useful in organising reports and comparing incident occurrence, although depending on the amount and type of information given in the report forms it was occasionally difficult to retrospectively organise reports into these categories. [25, 145] More than three-quarters of the reports fell into the categories of accessories, treatment volume, and dose (Figure 2-1). The hazard identification was continued and expanded based on prospectively submitted ROSIS incident reports (Section 4.4; and Figure 4-17 to Figure 4-25).

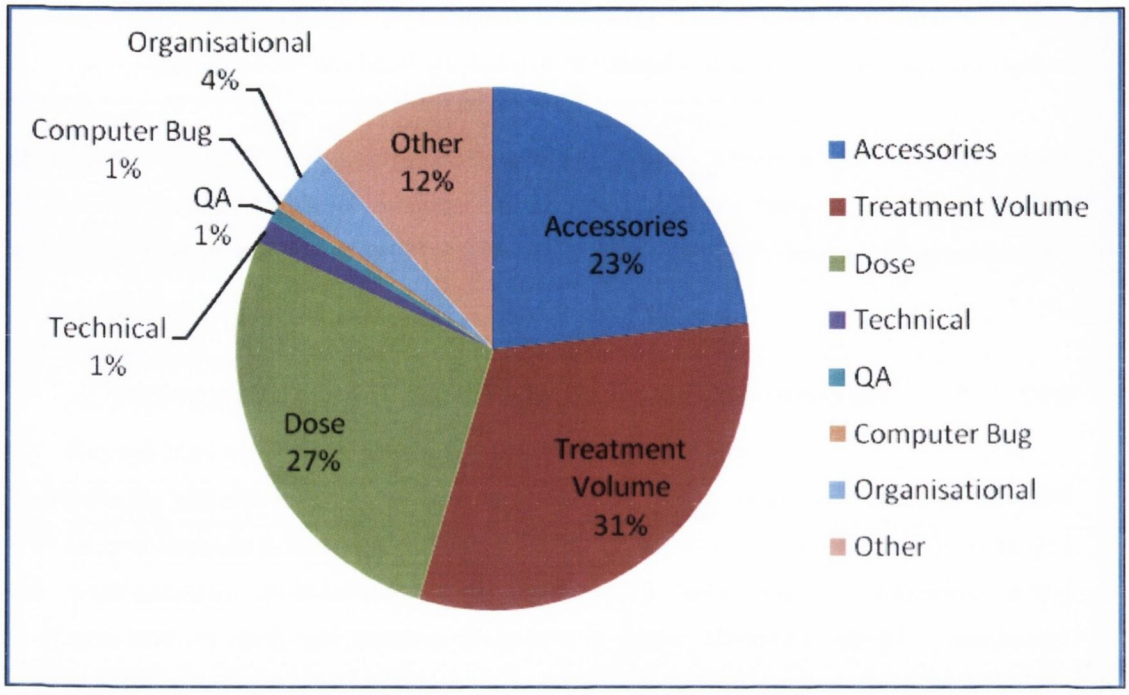

Figure 2-1: Distribution of hazards among 910 retrospective incident reports

Table 2-2: Distribution of hazards including sub-categories among 910 retrospective incident reports

Hazards	Number of reports	Percentage of reports
Accessories	213	23.4%
Bolus	39	4.3%
Compensator	9	1.0%
Customised Lead shielding	93	10.2%
Electron Cutouts	7	0.8%
MLC	32	3.5%
Wedge/filter	19	2.1%
Immobilisation devices	10	1.1%
Mouth bite	4	0.4%
Treatment Volume	285	31.3%
Image Acquisition	11	1.2%
Volume definition	23	2.5%
Asymmetrics	12	1.3%
Field	76	8.4%
Markings	17	1.9%
Reference moves	58	6.4%
Field Placement	57	6.3%
Patient Selection	14	1.5%
Patient Position	11	1.2%
Brachytherapy	6	0.7%
Dose	245	26.9%
Mus	171	18.8%
FSD	22	2.4%
Prescription	52	5.7%
Technical	14	1.5%
Not in Clinical mode	5	0.5%
Technical fault on LA/Sim	9	1.0%
QA	8	0.9%
Computer Bug	5	0.5%
Organisational	33	3.6%
Other	107	11.8%
Total	910	100.0%

2.3 DEVELOPMENT OF ROSIS

Based on the original research and review of the literature, ROSIS was developed as an international, voluntary, web-based, reporting and learning system for RO.

The key elements of the ROSIS system are that it is:

- Non-punitive. ROSIS has no regulatory activity or authority, and is independent of any such authority.
- Web-based, allowing ease of participation.
- Confidential. It is a voluntary system, where reports are made on a de-identified basis. The number of departments registered with ROSIS and their geographic spread allows more assurances of anonymity.
- A Learning System. The system includes both incidents and near-incidents, and focuses on system safety rather than on individuals. Feedback is provided via
    - an online, searchable database, containing original anonymised text of reports, pre-set and customisable searches
    - spotlight themes and analyses prepared by experts
    - email communication with ROSIS contacts

In general, these are consistent with the key elements of a successful reporting system compiled by Leape [99] (Table 2-3). These elements are also seen in the Aviation Safety Reporting System (ASRS), whose success is attributed to three key criteria from the reporter's perspective– it is safe (non-punitive, confidential, independent), simple (one-page report form) and worthwhile (timely expert analysis, feedback, responsive, and systems-oriented). However, it requires significant investment – costing $70 per report.[99]

Investment in reporting systems is often a limiting factor, evidenced by the lack of a federal reporting system in many US states where resources are not made available.[99] Efficiency of reporting and analysis is an important consideration for any reporting system.

The ROSIS system consists of a Department form (Figure 2-2 and Appendix E), an Incident form (Figure 2-3 and Appendix F), and database; all online.

Table 2-3: Characteristics of Successful Reporting Systems [99]

Characteristic	Explanation
Nonpunitive	Reporters are free of fear of retaliation or punishment from others as a result
Confidential	The identities of the patient, reporter, and institution are never revealed to a third party
Independent	The program is independent of any authority with power to punish the reporter or organization
Expert analysis	Reports are evaluated by experts who understand the clinical circumstances and who are trained to recognize underlying systems causes
Timely	Reports are analyzed promptly, and recommendations are rapidly disseminated to those who need to know, especially when serious hazards are identified
Systems-oriented	Recommendations focus on changes in systems, processes, or products, rather than on individual performance
Responsive	The agency that receives reports is capable of disseminating recommendations, and participating organizations agree to implementing recommendations when possible

One aim of ROSIS is to take a systems-approach to safety and to consider the occurrence of incidents in the context of the infrastructure and procedures of departments. A department form was created to capture this information (Figure 2-2). Briefly, the department form collects information on the

- Identity of the department,
- ROSIS contact person and contact details
- Radiotherapy treatment equipment
- Patient numbers
- Complexity (% CT Plans)
- Availability of Record and Verify on Treatment units
- Availability and integration of electronic network
- Number of FTE staff, under six categories
- Whether technical maintenance is in-house or by contract
- Quality Assurance methods used in the departments.

The Department form is completed once only per department. Maintaining the confidentiality of the reporting clinic was a key element of the form design. Once departments register with ROSIS via the Department Form, they are issued with an

identification code (Clinic ID) which they use to submit reports, and therefore do not directly identify themselves on reports.

The Incident form (Figure 2-3) collects details on the incident: treatment modality, date of occurrence, discipline(s) and QA method(s) that detected the incident, and where in the process it was detected. In relation to the outcome, questions are included on who was affected (patient/staff/visitor), the likely outcome, the potential outcome if the incident had not been detected, and the number of fractions delivered incorrectly. Further information is then sought on the incident, its cause and suggestions for future prevention. If the incident is related to hardware/software, specific information is sought on the make and model/version.

For the purposes of reporting, an incident is defined as the incorrect delivery of radiation. A near-incident / near miss is considered to be any event, which may have resulted in an incident, but for some reason there was no incorrect irradiation.

This definition of an incident may be considered to cover more events than either the WHO ICPS definition [47], or the IAEA Safety Standards definitions [48] which were also adopted in the WHO Radiotherapy Risk Profile. The key difference between the ROSIS definition and the others named is the concept of harm. Except for serious errors, the concept of harm is difficult to quantify in the RO setting. In the case of most individual departments, the incidence of events causing serious harm is low, mainly due to effective defences and detection methods. Nonetheless, gravity is attached to any incorrect delivery of radiation, perhaps because if the defences fail, there is a real potential to continue incorrect treatment delivery and result in significant harm. Another explanation may be the potential carcinogenic effect of low doses of radiation in normal tissue, and abiding by the concept of ALARA (as low as reasonably achievable) for normal tissues.

The definition of a near-incident or near-miss is consistent with that of others (described in Section 1.1.3).

The Department form consists of the following:

- Contact details *(free-text boxes)*
  - Name and address of hospital / clinic
  - Name of local contact person
  - Email address of the local contact person
- Equipment *(all free-text boxes for numbers)*
  - Number of treatment units
    - Linacs
    - Cobalt units
    - Brachytherapy units
  - Approximate number of new patients per year
  - Estimate the proportion of CT-based treatment plans (%)
- R&V on ... *(radio-buttons, one selection possible)*
  - No units
  - Some units
  - All units
- Network - presence and level of Integration of network/areas *(tickboxes, multiple selections possible)*
  - None (no network between units or TPS or R&V)
  - Treatment planning systems sends RT parameters to treatment units
  - Simulator sends RT parameters to treatment unit
  - Full networking of RT parameters (i.e. field size settings, MU etc)
  - Full networking of RT images (i.e. electronic portal images, DRR etc)
- Staffing - FTE (defined as your normal working day) per Category of Staff
  - Six preselected staff categories *(all free-text boxes for numbers)*
    - Radiation oncologists (physicians)
    - Medical physicists
    - Radiation therapists / Staff at treatment units treating patients
    - Radiation therapists / Staff at simulator and/or in-house CT
    - Staff doing dosimetry i.e. treatment planning etc
    - Staff doing technical maintenance on the radiotherapy equipment
  - For other staff not included above, a free-text box is provided to specify category and FTE
- Equipment maintenance *(radio-buttons, one selection possible)*
  - In house service, or
  - Service contract
- QA Methods *(tickboxes, multiple selections possible)*
  - Treatment charts are independently checked
  - In-vivo dosimetry is used for most new patients
  - Peer-review (planning conference) is done for most new patient prescriptions (dose and location)
  - Portal films (or electronic images) are taken for most new patients
  - Regular clinical review (of side effects etc.) of most patients
  - Written quality control procedures and records for most treatment checks
  - Written procedures for most of the clinical processes
  - Formal quality management system (ISO etc)
  - Regular quality assurance of treatment units
  - External dosimetry audit by EQUAL or other, please specify
  - Other QA, please specify
- Comments / Additional information *(free-text box)*

Figure 2-2: Information sought on Department Form

The Incident form consists of the following:

- Clinic ID *(free-text box)*
- Modality *(radio-buttons, one selection possible)*
  - External beam
  - Brachytherapy
  - Other
- Date of discovery *(free-text box)*
- Who Detected *(tickboxes, multiple selections possible)*
  - 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
  - Other (please specify)
- How was the incident discovered *(tickboxes, multiple selections possible)*
  - Chart check
  - In vivo dosimetry
  - Portal imaging (radiographic film or EPID)
  - Clinical review of patient
  - Quality control of equipment
  - Found at time of 1st patient treatment during regular checks
  - Found at later stage during patient treatment
  - External audit
  - Other (please specify)
- Where in the process was the incident found *(radio-buttons, one selection possible)*
  - Pretreatment (e.g. CT, simulator, planning)
  - Treatment
  - Follow-up
  - Non patient specific process
- Was anyone affected by the incident? *(tickboxes, multiple selections possible)*
  - Yes, several patients, number of patients affected: __
  - Yes, one patient
  - Yes, staff or other non-patient
  - None (but they could have been - potential incident)
- Was any treatment delivered incorrectly? *(radio-buttons, one selection possible)*
  - Yes
  - No
- If Yes how many fractions were delivered incorrectly, and what was the total number of fractions prescribed? *(two free-text boxes)*
- Outcome for the patient(s)/person(s) affected *(radio-buttons, one selection possible)*
  - None
  - Light (e.g. corrective action possible)
  - Moderate (some clinical adverse affect cannot be ruled out)
  - High (clinical adverse effect is likely)
  - Severe (high probability for severe adverse effects or demonstrated effect)
  - Comments regarding severity: *(free-text box)*
- Potential outcome for the patient(s)/person(s) if the incident was not detected/corrected *(radio-buttons, one selection possible)*
  - None

- Light (e.g. corrective action possible)
- Moderate (some clinical adverse effect cannot be ruled out)
- High (clinical adverse effect is likely)
- Severe (high probability for severe adverse effects or demonstrated effect)
- Comments regarding potential outcome *(free-text box)*

- Summarise the incident in one single sentence headline *(free-text box)*
- If the incident-cause is related to equipment (hardware or software), please specify the make model including version number. *(free-text box)*
- Description of the incident *(free-text box)*
- Cause of the incident *(free-text box)*
- Suggestions for preventive action(s) *(free-text box)*
- Suggestions or comments regarding ROSIS and or this form *(free-text box)*

Figure 2-3: Information sought on Incident Form

2.3.1 Web-design

The two forms were written in SQL, and were placed online in January 2003, initially hosted by the ESTRO web-server (www.estro.be/rosis/; later hosted by ROSIS and available at www.rosis.info). The department representative could go to this website, and fill out the form. When they pressed "submit", it was then emailed to the ROSIS group.

An access database was created, and the information from department and report forms was manually entered into the database for feedback and analysis.

Minor changes were made to both forms following initial data collection and analysis. Additional fields were included as follows: inclusion of "% CT plans" on department form, and "found at time of 1st patient treatment", "found at time of later patient treatment" "stage in process incident discovered", "date discovered", "No. of fractions given incorrectly" and "total number of fractions" on the incident form.

A dedicated ROSIS website (Figure 2-4) was developed under the domain name: www.rosis.info, and launched at ESTRO 23 in Amsterdam (October 2004). All incident reports are de-identified, stored in an online searchable database and made available on this website in their original text.

The initial homepage and logo is shown in Figure 2-4, and the website structure is shown in Figure 2-6.

In 2005 the services of a web-design company were engaged to give the ROSIS website a more professional look and feel (Figure 2-5). This resulted in a new website structure (Figure 2-7). For financial reasons, the original methodology of form information being emailed and manually entered into the database was retained.

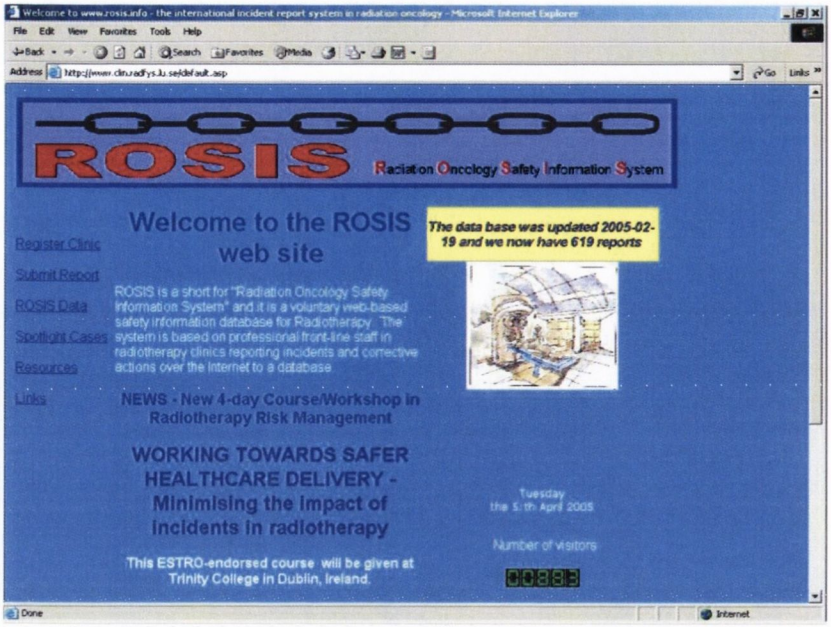

Figure 2-4: Initial ROSIS Homepage, 2004 – 2006

Figure 2-5: ROSIS Homepage, 2006 – present

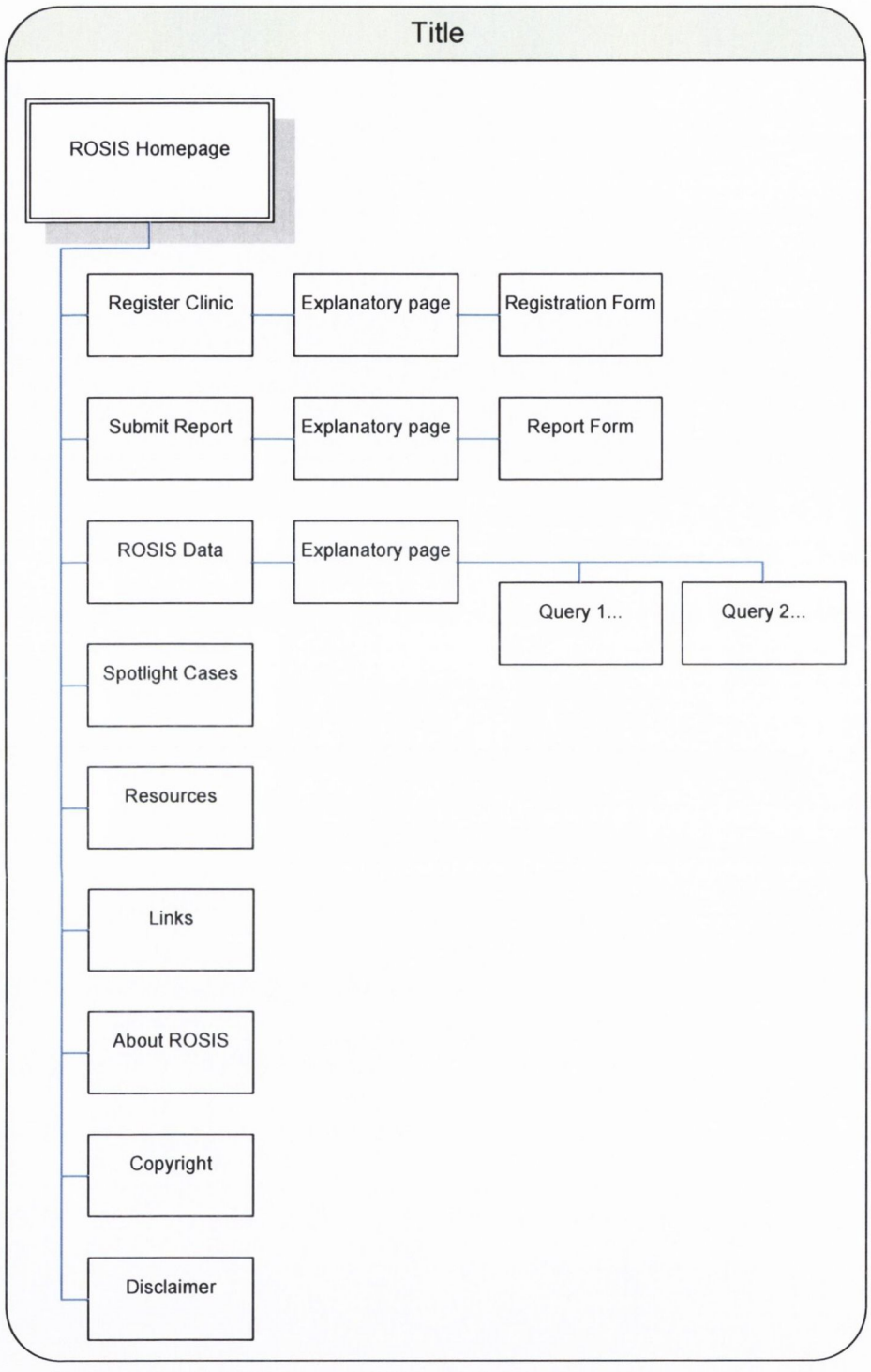

Figure 2-6: Structure of First ROSIS Website 2004-2006

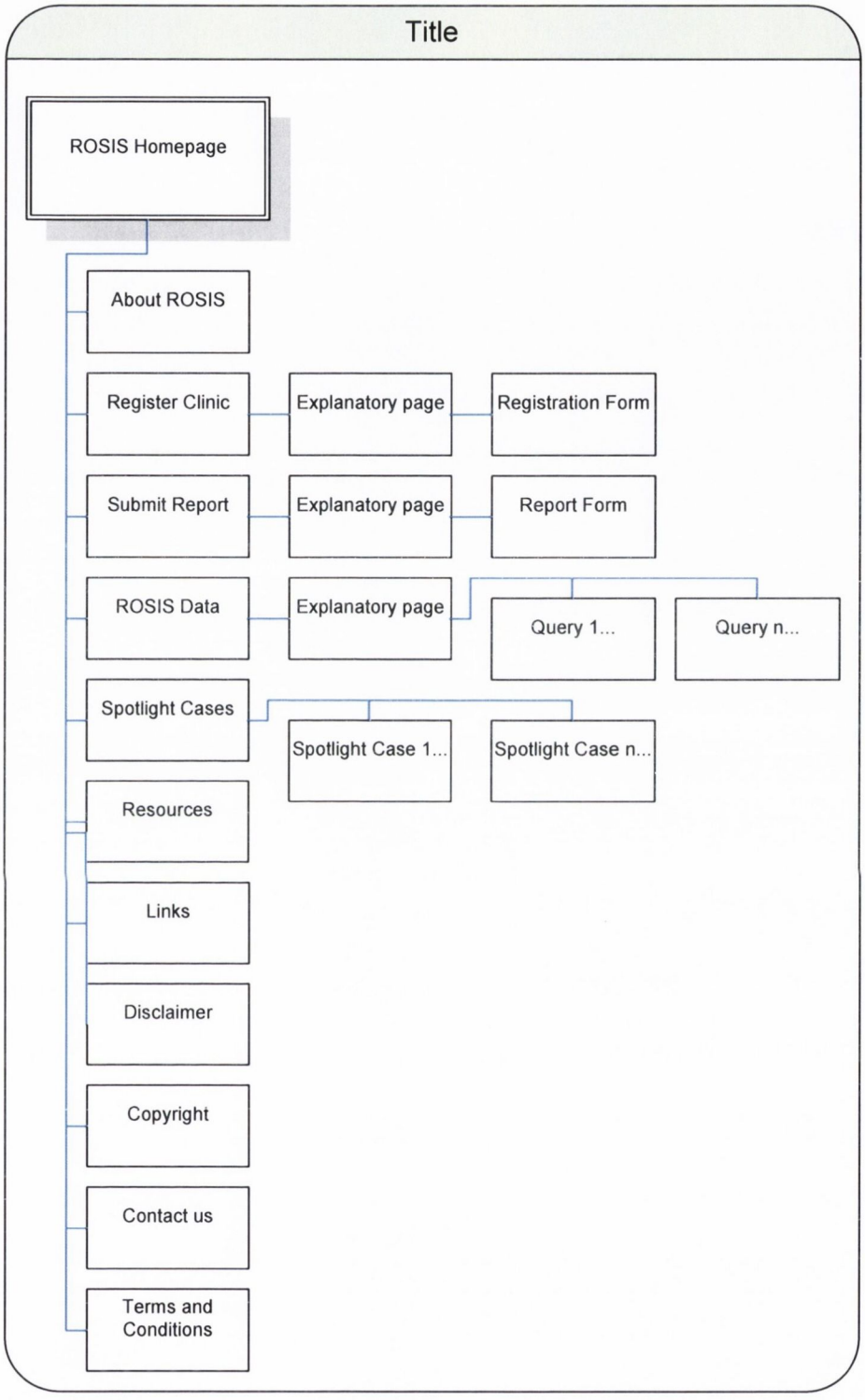

Figure 2-7: Structure of ROSIS Website, 2006 - present

In 2006, substantial changes were proposed to both the forms and automatic entry into the database became more of a necessity. Because of financial constraints, this work was undertaken by IT professionals on a voluntary basis, and in their spare-time. The dynamic forms which automatically insert into the database were completed in 2009.

The first annual short course "Working towards safer health care delivery: minimising the impact of incidents in radiotherapy" was delivered in 2005.

Figure 2-8 illustrates the developmental timeline of ROSIS.

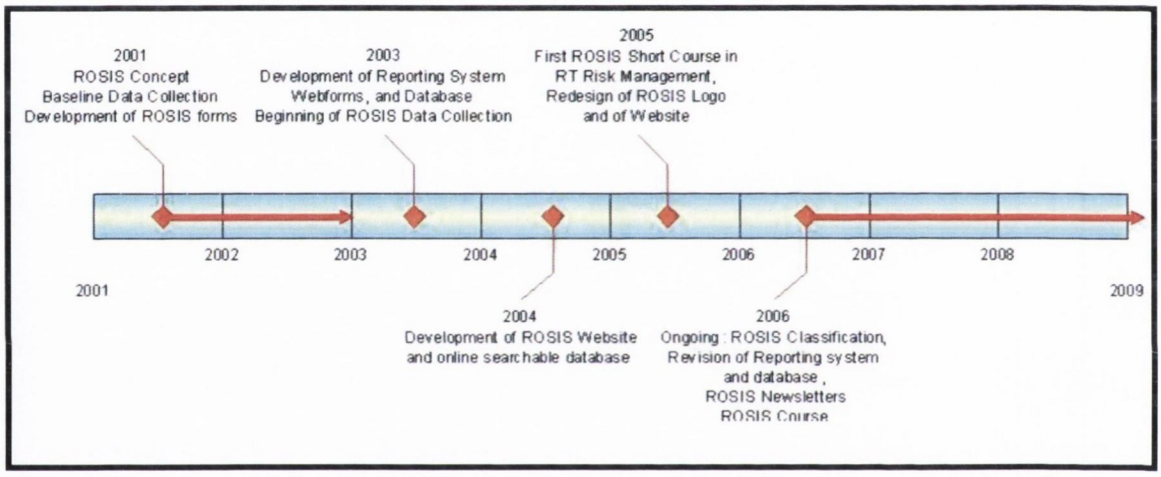

Figure 2-8: The timeline for the development of the ROSIS system.

2.4 ROSIS FEEDBACK MECHANISMS

Multi-directional feedback has been initiated:

- Feedback from ROSIS to Departments and the RO Community – Learning from Incidents in Radiation Oncology
- Feedback to ROSIS from Departments - Evaluation of the System

2.4.1 Feedback from ROSIS to Departments and the RO Community – Learning from Incidents in Radiation Oncology

Central to the success of any voluntary reporting system is the dissemination of the reports and lessons learned. For ROSIS, a number of methods of sharing the reports and their lessons are used, including:

- making the database, analyses, and custom searches available at www.rosis.info
- presentation of the system and analyses at conferences
- circulation of ROSIS Newsletters
- delivering a short course in Risk Management in Radiation Oncology
- publication of reports and analysis of the database.

ROSIS has been the subject of many presentations on its development and data analysis, including ESTRO Conferences, and National Conferences. In addition, in 2005 ROSIS established an annual short course in Radiation Oncology Risk Management – "Working towards safer healthcare delivery: minimising the impact of incidents in radiotherapy".

ROSIS has produced four Newsletters on "Spotlight Cases" (Appendix H; also available at www.rosis.info)

- In-vivo dosimetry [146]
- Patient identification [147]
- Data transfer [148]
- Record and verify systems [149]

ROSIS is also widely reported in the scientific literature e.g. [25, 40, 43-44, 103, 105-106, 150].

A regular email circulation of all ROSIS departments was the first ROSIS feedback. This consisted of approximately 20 de-identified reports, but was terminated once the database was made available on the www.rosis.info website. This change caused a drop in reporting, and the ROSIS group realised that regular feedback was probably acting as a prompt to ROSIS departments to report. Another explanation was that, in the past, only those listed as partners to ROSIS received feedback; whereas now it is available to all via the web. It is proposed that in the future certain elements of data analysis will need to be reserved for those departments actively participating in ROSIS, whilst ensuring that general lessons can still reach the RO community.

2.4.2 Feedback to ROSIS from Departments - Evaluation of the System

An evaluation of the initial system was devised and undertaken in 2007 on behalf of the ROSIS group.[151-152] All ROSIS participants (53 at that time) were invited to participate in an anonymous study covering their experience of their local reporting system and their views on the ROSIS database. In total, 23 participants returned the comprehensive (40 minute) online questionnaire.

The participants expressed enthusiasm for ROSIS, and had contributed to the project for a number of reasons, mainly:

- QA: monitoring errors/trends
- Sharing of information
- Personal/professional interest in system
- As an aid in developing own local system

While the users applauded the system, a number of areas were identified for improvement. The main deterrents to reporting were identified as: time constraints, language barriers, duplicate data entry, and not delegating a staff member to report to ROSIS. Departments reported that each report took 5-10min (45%) or 3-5mins (36%) to complete.

ROSIS Departments suggested that improvements might be made under the headings of publications, the website, and data analysis methods.

Under the heading of publications, the spotlight cases were applauded and found to be useful clinically, but the lack of peer-reviewed scientific papers in international journals was highlighted.

Similarly, participants felt that the website could be better designed, with more options for data presentation and viewing the database. A major barrier highlighted was the need to report to multiple systems, and a method of linking ROSIS with these was requested. Ability of individual departments to access their own information on incidents and to be able to update their department demographics was sought. Finally, a recurring problem was that of language – that it is difficult for non-english speakers to report to and learn from the system.

In terms of data analysis, the use of error pathways or chains was suggested to learn from incidents, and also to display results of analysis in graphical format. More user-friendly queries were sought to enable learning from the incidents, and a suggestion to update and to include new treatments e.g. IMRT.

Limitations to the above study included a lengthy and difficult questionnaire, in the English language, and with many open questions, factors which deterred a number of potential participants.

Another user survey was undertaken on behalf of ROSIS in 2009-2010 [116]. This mainly consisted of closed questions and focussed on using the website to disseminate lessons learned. Both ROSIS departments and ESTRO members were consulted, although with a low response. Most participants use or would use a web-based safety information system to learn about safety in RO; most ESTRO members reported that they received more information on safety in RO from sources other than through their department.

When given a list of items relating to incident reporting, participants in both groups rated the cause of the incident as the most important factor to know and for learning from incidents. This and the other factors rated can be seen in Figure 2-9.

Participants expressed an appreciation for the Spotlight Cases produced by ROSIS, but would like to see more communication from ROSIS, in terms of analyses of the database, alerts on new hazards or equipment-related reports.

ROSIS has clearly established itself as an online voluntary confidential reporting system, but has room to improve in learning from incidents and disseminating this information.

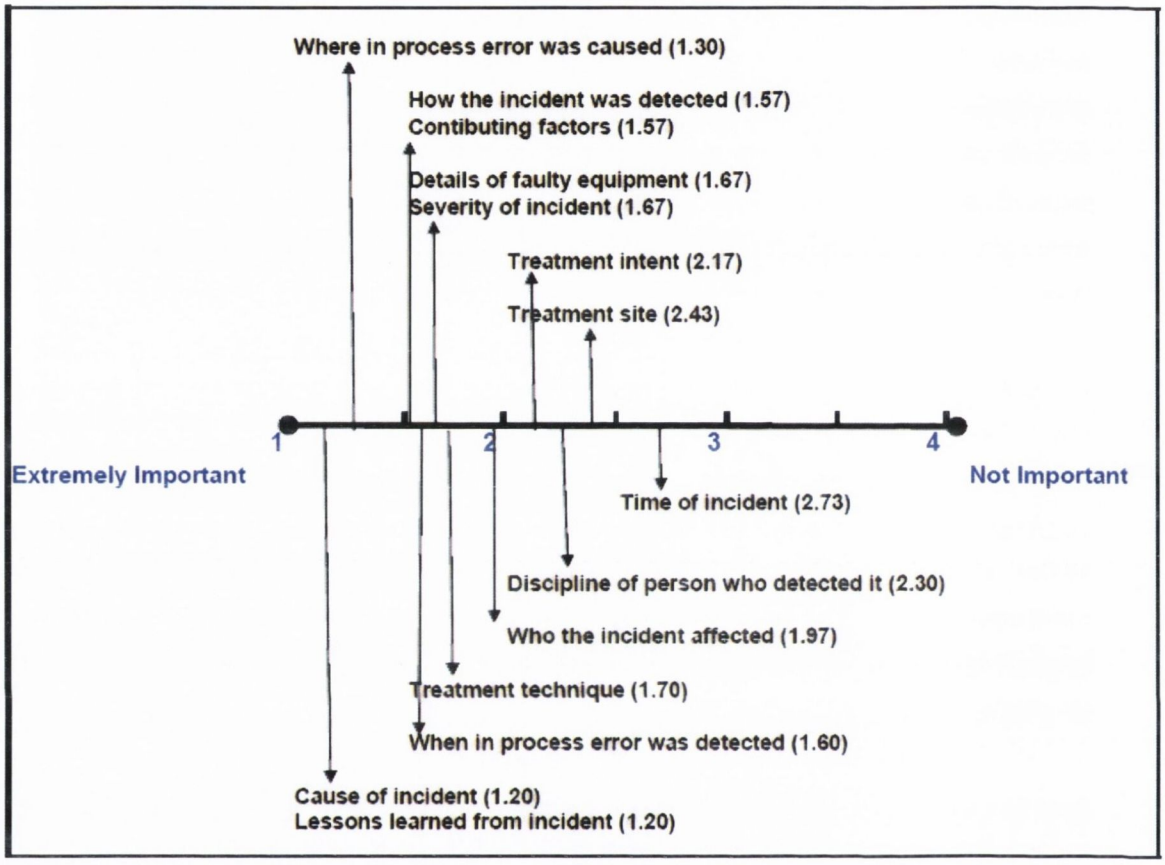

Figure 2-9: The importance of factors in learning from incidents according to ROSIS departments. ROSIS Survey by Margaret Looby, 2010 [116]

3 Chapter 3: Methodology of Data Analysis and Classification

The development of ROSIS has been described in Chapter 0.

The methodology for the remaining aims are outlined in this chapter:

1. To analyse the data collected by ROSIS from 2003-2008
2. To define a classification system for the collection and analysis of information on incidents in RO
3. Develop a revised reporting and learning system and make recommendations for further development.

3.1 ROSIS DATA ANALYSIS

The aim of the ROSIS System is to collect information on incidents and near-incidents, and to put these in the context of the infrastructure and procedures of the department.

Two distinct forms are used for data collection:

- A Department Form – to collect information on the department infrastructure and procedures
- An Incident Report Form – to collect information on the incident / near-incident

An outline of the basic topics in these forms can be seen in Table 3.1 and has been presented in detail in Chapter 2.

Information from Department Forms and Incident Reports are emailed via a web server, and are then manually entered into an MS Access Database. Data analysis is undertaken in MS Access and MS Excel. Each incident report is retrospectively examined to identify the most likely stage of incident occurrence, and whether data

Table 3-1: Topics in the two forms for reporting into the ROSIS system.

Department Form	Incident Form
Dept name and location; contact person	Modality
Type and number of machines	Who Detected
No of patients treated/year	Error/Near Miss
Record and verify	Who and how many involved
Integration of network/areas	How Detected
FTE per Category of Staff	Outcome / potential outcome
Service Contract	Description, Cause, Suggestion for prevention
QA Methods	Comments

transfer and data input into R&V were contributing factors. The average number of patients per staff category was obtained by first calculating the ratio per department, and then calculating the overall average ratio across all departments. All other data is reported directly.

In keeping with best practice on reporting systems, simple descriptive statistics are used to evaluate the ROSIS department and incident data. The term incident is used to collectively refer to incidents and near misses, unless otherwise stated. It is important that data from incident reporting systems is interpreted carefully and not over-analysed. In this work, the term "reported" will be used to highlight this, and the focus will be on the existence, types, causes and detection of mistakes which occur in the radiotherapy process [107].

For reasons of confidentiality, certain data items are not reported (e.g. minimum and maximum number of units per department) as this information could identify individual departments as participants in ROSIS.

3.1.1 Hazard Identification and Classification

To further refine and develop the ROSIS system in order to facilitate ease of reporting, data analysis and feedback, a hazard classification was conducted. This built on the earlier hazard identification from the 910 retrospective reports.

Each retrospective report (n=910) and the first 600 ROSIS reports were evaluated to ascertain where possible, what had occurred in the incident / near-incident - i.e. what was the end-result in terms of the treatment process. Examples of how the hazard classification is applied are given in Table 3-2.

Table 3-2: Examples of applying hazard classification to ROSIS reports

ROSIS Incident Report #	Excerpt/Synopsis of Report Text	Hazard Classification
20	"both fields treated with VW wedge in opposite orientation to that intended"	Accessories – wedge – Trt SU+Del – wrong orientation
38	"_____ 'prepped' the prescription without MLCs when in fact it required MLCs"	Accessories – trt set-up and delivery - MLC - omitted
4	"Prescription was 20Gy in 5 fractions and written 20Gy with 2Gy fractions"	Dose – prescription – request – fractionation schedule incorrectly written
28	"incorrectly prescribed for field"	Dose – prescription – request - field not required but prescribed
17	"prescribed for isocentric treatment but calc done + checked for MPD"	Dose – mu – calc method – iso vs MPD
9	"omission of carbon fibre couch top factor on plan for posterior field"	Dose – mu – calc – omission of factor
26	"CT scan done as Prone mislabelled Supine"	TV – image acquisition – incorrectly labelled
69	"Determination of the target in the ct was wrong"	TV – target vol definition – target volume delineation
37	"2.0 cm too inferior field"	TV – field – wrong size
27	"offsets not noticed when preparing treatment"	Target Volume (TV) – field – offsets
6	"incorrectly transcribed the position of the tumour centre in relation to the tattoo, on the pt chart/plan"	TV – Geographical Miss – reference moves – defined incorrectly
22	"3 fields treated on incorrect isocentre"	TV – Geographical Miss – Field Placement – wrong iso

3.1.2 ROSIS Classification: Materials and Methods

The aim was to revise the existing Radiation Oncology Safety Information System in order to

- Collect more detailed information
- Classify data
- Enable data classification at source by reporter
- Facilitate provision of the system in other languages
- Generate clinically relevant lessons for the RO community

The revision of the forms and the creation of the classification in early 2006 was built on

- a review of existing classification systems in health care
- analyses of the necessary data for maximum learning and in order to prioritise safety measures
- three years experience of administering the online ROSIS system (January 2003 – January 2006)
- analysis of 500+ RO-incident types from the ROSIS database.

The WHO criteria [124] were taken into account in defining the ROSIS classification system. In the development, there were three main requirements of this classification

- It needed to be an effective tool for analysis and learning
- It needed to be flexible
    - So that it could be applied to different departments and processes
    - So that it can be translated into different languages
- It needed to be incorporated into the reporting system

The purpose of the classification was to organize reports, in order to facilitate analyses of the data and ultimately to improve safety and raise awareness. The intent of the system is to maximize learning; therefore detailed information about the incident must be collected.

The scope of the classification was envisaged to encompass all incidents and near-incidents relevant to a Radiation Oncology department. An incident is defined as the incorrect delivery of radiation. A near-incident / near miss is considered to be any event, which may have resulted in an incident, but for some reason there was

no incorrect irradiation. The classification should also include the collection of information on preventative and corrective factors.

Learning lessons could be enhanced by investigating the steps in the RO process which are error-prone, or which fail to detect mistakes. A process classification was designed as a sub-category of the overall ROSIS Classification, and was devised using incidents in the ROSIS database.

560 consecutive reports were reviewed for the process classification; 60 of these were excluded on the basis that the incident was

- Not related to RO
- Not related to external beam treatment
- Related to a non process event, e.g.
    - Equipment malfunction
    - Patient injury (slips/trips/falls)
- Related to managerial issues or QA violations rather than an incident per se

500 ROSIS "process-related reports" were analysed and a process classification devised for external beam RT. The process classification was designed with two aims in mind:

1. To determine **where** in the external beam radiotherapy process the incident originated, and where it was discovered
2. To determine **what** element was affected.

The element of the RO procedure which was affected links back into the Hazard identification which had been previously defined (Sections 3.1.1 and 4.4).

The process classification, being the most complex subset of the entire classification, was further tested for reliability.

3.1.2.1 Reliability testing of process classification

The process classification, being the most complex subset of the entire classification, was tested for inter-rater reliability.

3.1.2.1.1 Method

Three people (two RTTs and one Physicist) were given the images above of the process classification, a custom-made MS Access Database containing the incident reports and a classification area, and the instruction to classify according to where the incident originated.

Each classifier retrospectively classified the first 200 ROSIS reports, entering their data directly into the MS Access Database.

Twenty-one reports were excluded from the analysis, leaving 179 reports for comparison. Reports were excluded on the basis that they were

- Non-process reports (n= 16)
- Non-RT specific reports (n= 2), or
- Not completed at Level 1 (n= 3).

These 179 reports were compared on two criteria:

1. Frequency of use of categories
2. Agreement between classifiers

Frequency of use of categories was evaluated in SPSS using Pearson's Chi-Squared test.

Agreement between classifiers was evaluated by comparing each individual's selection per report using an MS Excel spreadsheet.

3.1.2.1.2 Results

When Level 1 was compared (Figure 3-1 and Figure 3-2), significant differences were discovered in the classification (Pearson Chi-Square 21.494; $p < 0.05$). However, it was clear that the treatment preparation stage of the classification was responsible for the most variation, so this was excluded and the test repeated, this time showing good agreement between classifiers on the remaining categories (Pearson Chi-Square 8.134; $p = 0.616$). This can also be seen in the decreased variation in Figure 3-2, where the top graph consists of all stages, whereas the treatment preparation stage was excluded from the bottom graph.

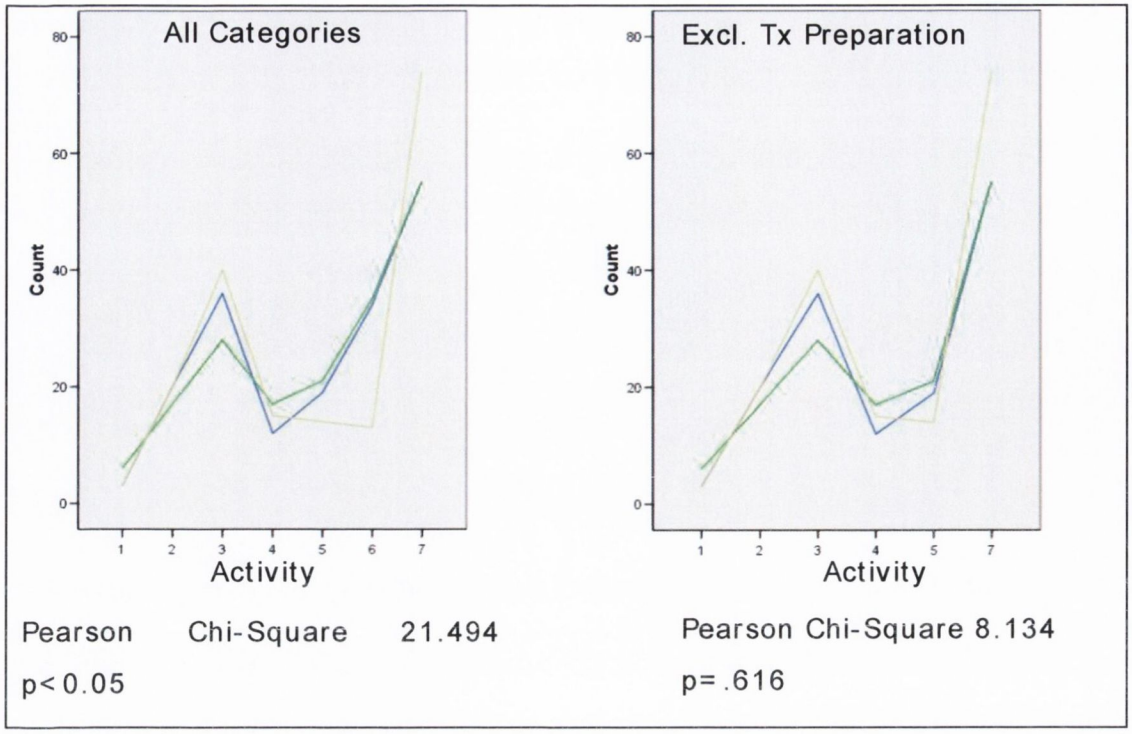

Figure 3-1: Comparison of classification (Level 1) among three classifiers

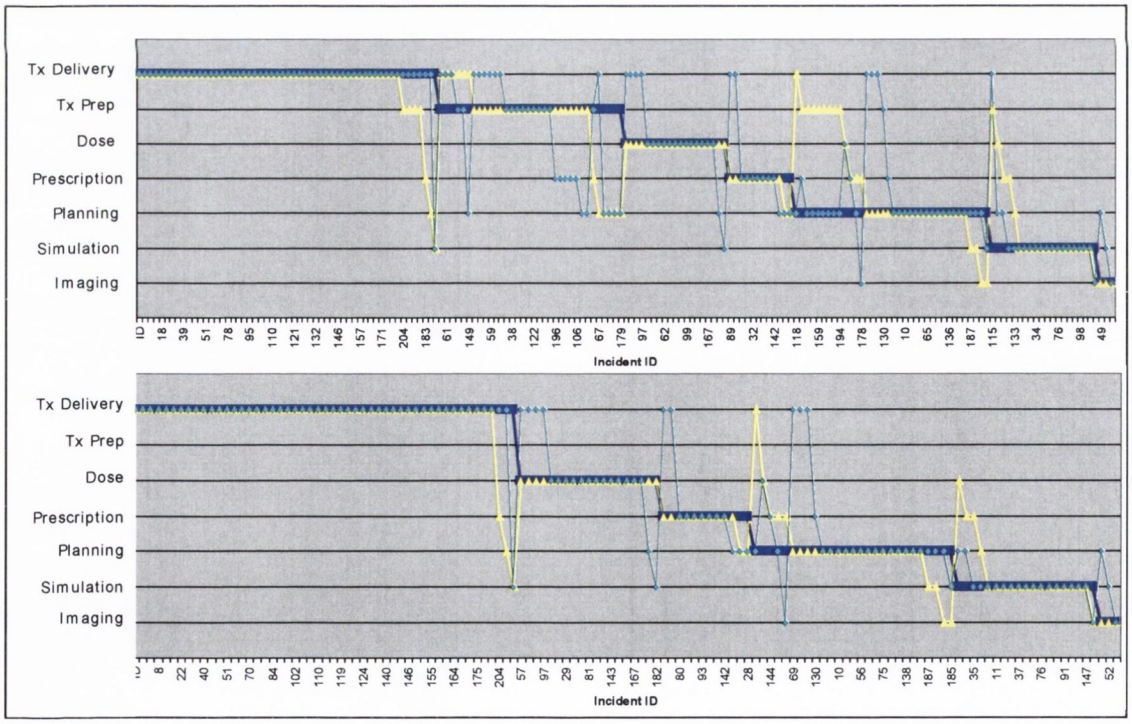

Figure 3-2: Agreement between three classifiers (lines) on each individual incident (points), including and excluding the treatment preparation phase.

Figure 3-1 and Figure 3-2 illustrate only Level 1, but the agreement between classifiers on Levels 1, 2 and 3 is shown in Table 3-3.

Table 3-3: Agreement between classifiers on Levels 1 – 3.

	Level 1 (%)	Level 2 (%)	Level 3 (%)
All same	106 (59)	80 (49)	79 (54)
2 same	65 (34)	69 (43)	49 (34)
All different	8 (5)	13 (8)	18 (12)
Totals	179 (100)	162 (100)	146 (100)

Classifiers identified "what" was wrong in each incident; with the same element being identified by all three classifiers in 138 of 179 (77%) reports evaluated.

4 Chapter 4: Results

4.1 RESULTS

Results are divided into four sections:

1. Department information
    a. Profiles of departments participating in ROSIS
    b. Profiles of departments with a minimum of 20 reports
2. Incident information
    a. Analysis of ROSIS incident information
    b. Case studies on ROSIS incidents
        i. Data transfer
        ii. Use of record and verify systems
        iii. Errors detected by chart checking
        iv. Errors detected by in-vivo dosimetry
        v. Errors detected by portal imaging
        vi. Errors in Planning/Calculation
3. Hazard identification and ROSIS Classification
    a. Hazard identification
        i. Frequency analysis
    b. ROSIS classification
        i. Details of ROSIS Classification
        ii. Inter-rater reliability of process classification
        iii. Process classification frequency analysis
4. Integration of Classification System into Department and Incident Forms
    a. Dataset for Department form
    b. Dataset for Incident form
        i. Dataset for Incident form
        ii. Dataset for Process Classification
        iii. Initial dataset for Severity Classification
        iv. Initial dataset for Cause/Contributing factors Classification

4.2 DEPARTMENT INFORMATION

4.2.1 Profiles of departments participating in ROSIS

Registration of departments has grown steadily since the ROSIS reporting system was introduced (Figure 4-1).

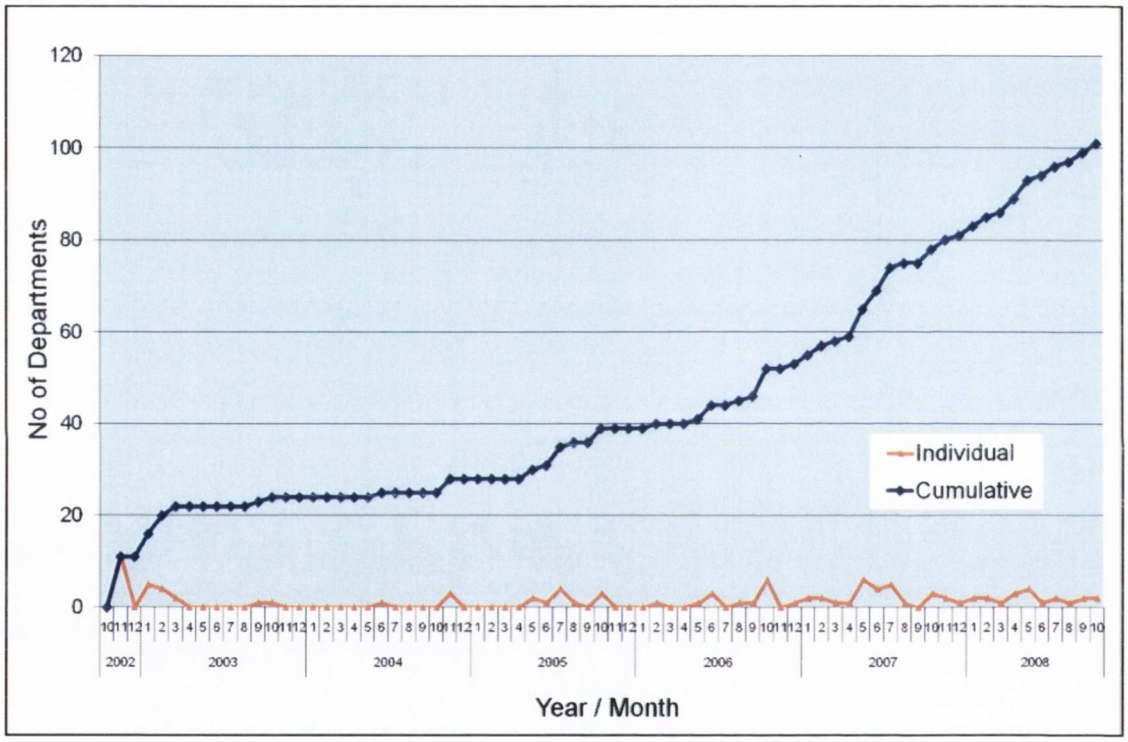

Figure 4-1: Registration of ROSIS departments since the start of the project.

In early 2009, there are 101 departments registered; 70 from Europe and between 2 and 12 from each of the following regions:

- Africa
- Asia
- Australia and the Pacific
- North America
- South and Central America.

With respect to infrastructure, the departments represent a total of

- 309 Linear Accelerators (avg 3 per dept)
- 34 Cobalt Machines (avg 0.3 per dept)
- 114 Brachytherapy machines (avg 1.1 per dept)
- and a Patient population of over 150,000 new patients per year (average 1497 per dept; range 50 - 6,500)

Twenty-three departments are equipped only with Linacs, 23 have a minimum of one Co-60 unit, and 76 have a minimum of one brachytherapy machine. The complexity of treatments within departments varies greatly, with an average of 74% CT planned treatments (range 0 to 100%).

While most departments have at minimum a method of networked data transfer from simulator or treatment planning system to treatment unit, 10 do not have any electronic data transfer (>10%) (Table 2). There is considerable variation in the level of networking within the group as a whole, with only 24 departments having a single form of network throughout their department. It is also noteworthy that there are often several networking arrangements within one department – on average, there were 2.4 options selected out of a possible 4. Two combinations were used by 27 departments, three by 17 departments, and the maximum of all four combinations were in use in 23 departments. The most advanced solution of full data transfer including images was exclusively in use in only 14 departments.

Table 4-1: Networking capabilities available in departments

Network options	Number of Departments*
None (no network between units or TPS or R&V)	10
Treatment planning system sends RT parameters to treatment unit	55
Simulator sends RT parameters to treatment unit	28
Full networking of RT parameters (i.e. field size settings, MU etc.)	69
Full networking of RT images (i.e. electronic portal images, DRR etc.)	69

** Departments may select more than one option*

Two thirds (68%) of departments have record and verify on all units, one-quarter (26%) on some units, and 6% have no R&V system in the department.

The average number of patients per member of staff is displayed in Table 4-2.

Table 4-2: Number of patients per FTE member of staff

Staff Discipline	Avg	Median
Oncologists	281	250
Physicists	387	111
Radiation Therapists at treatment units	159	125
Radiation Therapists at simulator / CT	546	450
Dosimetrists	549	467
Technical Maintenance	833	667

Of the participating departments, 54 have contracts for equipment service/maintenance, whereas for 40 this is performed in-house. One department has a 50:50 mix between contract and in-house, and there is no data for two departments.

Participants were asked to report quality assurance procedures in place in their department. Most departments have a system of QA or QC that monitors the radiotherapy process at several steps. Thus, a defence-in-depth system is implemented to various degrees at different hospitals. If the category "Other QA" is excluded, the minimum number of remaining QA methods used in any one department is three; the maximum is ten. Both the average and median of number of methods used is seven (Table 4-3). This list encompasses the quality assurance (QA) planning and managerial activities, (e.g. formal quality management systems) as well as routine quality control (QC) monitoring activities (e.g. chart checking, portal imaging, in-vivo dosimetry). The most common procedures are regular quality control of treatment units (97% of departments), portal imaging (93%), chart checking (90%), and quality control procedures (90%). In-vivo dosimetry and formal quality management systems are the least common (33 and 34% respectively).

The majority of departments (68%) participate in an audit programme, as follows:

- IAEA – 10 departments
- EQUAL (ESTRO) - 18 departments
- RPC (Radiological Physics Center at MD Anderson) – 7 departments
- Other Regional/National - 23 departments
- Specific audit programme not specified - 24 departments

Table 4-3: Departmental Quality Assurance (QA) / Quality Control (QC) procedures

QA/QC Activity	Total (%)
Chart Check	90 (89)
In-vivo dosimetry	34 (34)
Peer review	56 (55)
Portal images	94 (93)
Regular clinical review	73 (72)
Quality control procedures	91 (90)
Procedures for clinical processes	69 (68)
Formal Quality Management System	35 (35)
Regular QC of treatment units	98 (97)
Audit programme	69 (68)
Other QA	28 (28)

4.2.2 Profile of Departments with a minimum of 20 reports

Since most of the reports (1031) have been submitted by just ten departments, the profiles of these departments are also considered here.

These ten departments are all within Europe, and have submitted a minimum of 23 reports, a maximum of 203 reports, an average of 103 reports per department and a median of 115 reports.

Their infrastructure is as follows:

- 45 Linear Accelerators (avg 4.5 per dept)
- 6 Cobalt Machines (avg 0.6 per dept)

- 14 Brachytherapy machines (avg 1.4 per dept)
- and a Patient population of 28,800 new patients per year (average 2880 per dept; range 650 - 6,500)

Two departments had no network in place in the department, where a network does exist the average number of network options selected was 2, and the most common selection (six departments) was "Full networking of RT parameters (i.e. field size settings, MU etc)".

All ten departments had record and verify, but only three departments reported record and verify on all units. There is no information on treatment complexity for any of these departments.

The average number of patients per staff is displayed in Table 4-4.

Table 4-4: Number of patients per FTE member of staff (ten departments)

Staff Discipline	Avg	Median
Oncologists	344	330
Physicists	402	307
Radiation Therapists at treatment units	111	119
Radiation Therapists at simulator / CT	500	450
Dosimetrists	688	500
Technical Maintenance	583	464

Technical service is provided inhouse in six departments, by contract in three departments, and a mixture of the two in one department.

Excluding the category of Other QA, a minimum of six, a maximum of nine, and an average and median of eight methods are used in these departments. Chart checking, Quality control procedures, Procedures for clinical process, Regular QC of treatment units, and an Audit programme are used in all departments. Audit programmes include EQUAL (5 departments), IAEA (1), and regional or national programmes (5). In vivo dosimetry was used routinely in only one department. Table 4-5 lists the QA and QC activities used in departments.

Table 4-5: Departmental Quality Assurance (QA) / Quality Control (QC) procedures (ten departments)

QA/QC Activity	Total (%)
Chart Check	10 (100)
In-vivo dosimetry	1 (10)
Peer review	4 (40)
Portal images	9 (90)
Regular clinical review	9 (90)
Quality control procedures	10 (100)
Procedures for clinical processes	10 (100)
Formal Quality Management System	5 (50)
Regular QC of treatment units	10 (100)
Audit programme	10 (100)
Other QA	5 (50)

4.3 INCIDENT INFORMATION

4.3.1 Analysis of ROSIS incident data

Of the 1074 reports submitted to ROSIS between January 2003 and August 2008, 97.7% (1049) relate to the use of external beam radiation, 1.9% (20) to brachytherapy, and 0.5% (5) to other occurrences (mainly non-process). Incidents are classified as either process-related, where the occurrence of the incident is related to a failure in the process, or non-process related, where the process had no real bearing on the occurrence of the incident (e.g. hardware or software failures, slips/trips/falls). Process-related incidents are divided into subprocesses (pre-treatment/treatment/follow-up), or into activity related processes (e.g. imaging/simulation/planning etc.).

Most reported incidents (73%) were detected at the treatment stage of the radiotherapy process, with 25% detected pre-treatment, and 2% at follow-up.

The majority of the reported incidents were detected by Therapists at the treatment unit (Figure 4-2), and were found during a patient treatment appointment i.e. *"found at the time of patient treatment"*(43%) (Figure 4-3). Detection by the QC process chart check was the next most common method of detection (33%) (Figure 4-3). Approximately 50% (168) of the chart check reports were detected pre-treatment, and 50% (167) were found during treatment or at follow-up.

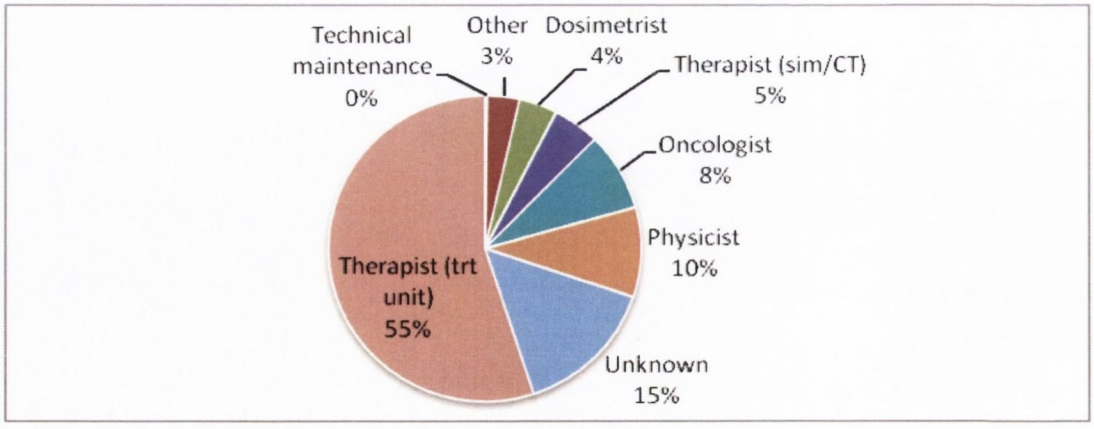

Figure 4-2: Discipline who detected the incident

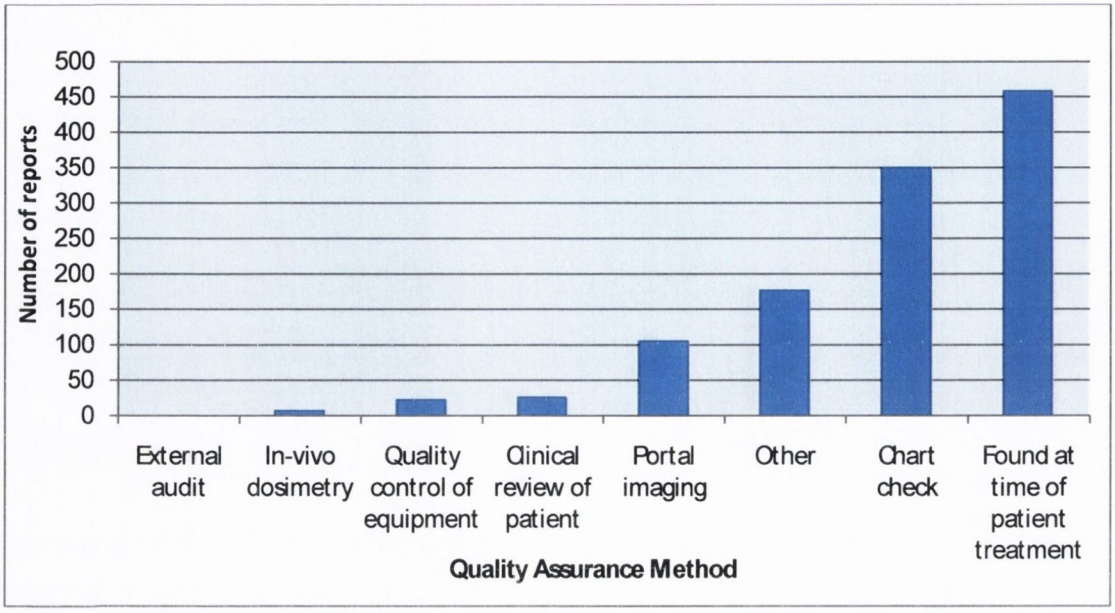

Figure 4-3: Quality assurance method by which the incident was detected (n=1074 reports)

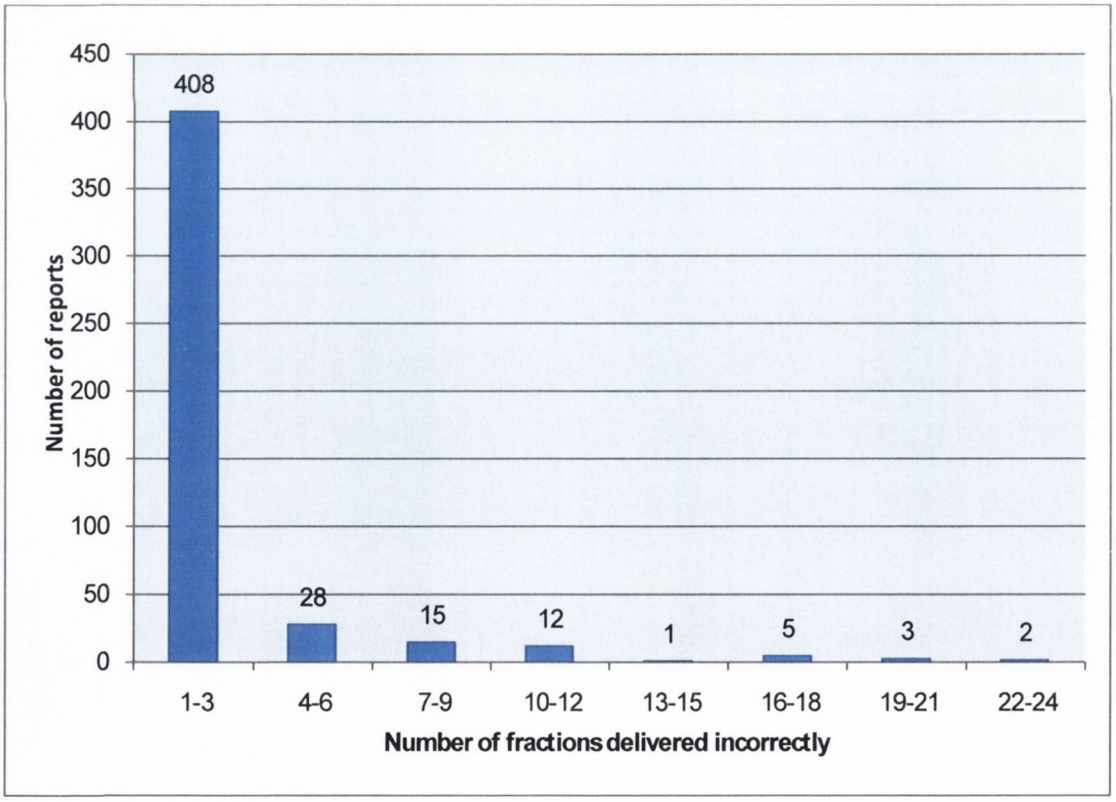

Figure 4-4: Number of treatment fractions delivered incorrectly (N=473 reports)

Two reports relate to an incident involving staff or non-patient. 21 reports relate to incidents involving several patients (range: 2 to 7 patients).

Treatment was delivered incorrectly in 546 reports (51%). This refers to any incorrect delivery of radiation, and is an incident as defined by ROSIS. For 473 of these 546 reports (87%), the number of fractions treated incorrectly is known (Figure 4-4):

1-3 fractions incorrect = 408 reports (75% of 546 / 86% of 473)

4-10 fractions incorrect = 53 reports (10% of 546 / 11% of 473)

11-24 fractions incorrect = 12 reports (2% of 546 / 3% of 473)

For 199 of these reports (42% of 473), the total number of fractions prescribed is also known. Using this information, the reported incidents range from between 3 to 100% of the treatment delivered incorrectly, with an average of 22% of prescribed treatment fractions incorrect (Figure 4-5).

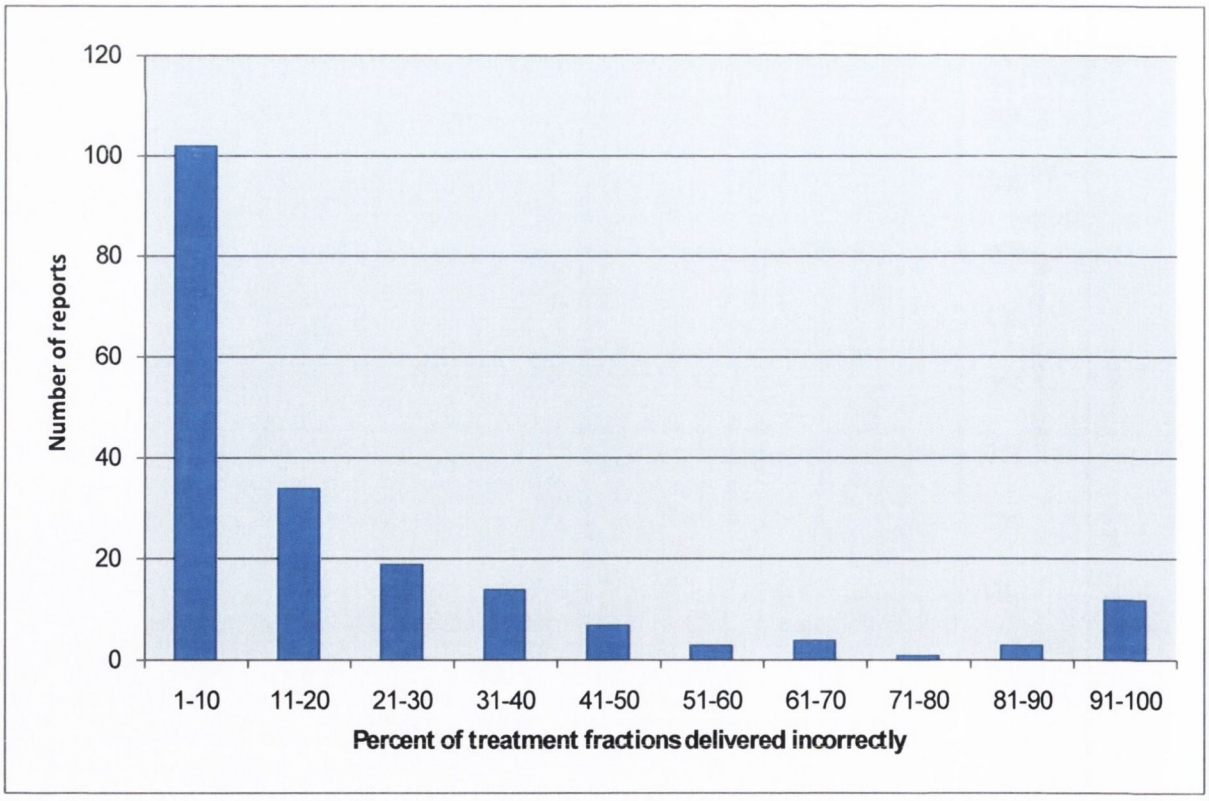

Figure 4-5: Percent of treatment fractions delivered incorrectly (N=199 reports)

Table 4-6 gives the relationship between the incident and the QA method by which it was detected. Where data is available, this table also illustrates the number of fractions where treatment was given incorrectly.

Table 4-7 highlights the QA methods which were the most common detection method per activity, with chart-checks having the most application across different activities.

Initially a category of "Found at time of patient treatment" was used, but it soon became apparent that this category was one of the most common; therefore this category was subdivided into "found at time of first patient treatment" and "found at time of later patient treatment" to capture those mistakes found during the first patient set-up.

This includes two reports where the incident was detected at the first patient treatment, but was not corrected until the third fraction, and two fractions were (knowingly) given incorrectly.

Figure 4-6 and Figure 4-7 also relate to the detection of the incident. Figure 4-6 illustrates the detection methods by which 500 mistakes were identified at each stage of the process. Figure 4-7 illustrates the relative distribution of incident occurrence and detection among ten departments, with an average of 48 reports per department (range 17-94).

Table 4-6: Cross-tabulation of incorrect treatment delivered with detection method.

		Chart check	Found at time of patient treatment			In-vivo dosim-etry	Portal Imaging	Clinical review of patient	Quality control of equipment	Other	External audit
			All data*	1st patient treatment only*	Later patient treatment only*						
All reports – total per detection method		335	451	73	127	7	103	22	20	164	0
Reports where treatment was delivered incorrectly	Treatment delivered incorrectly (% of all reports for this detection method)	124 (37.0)	302 (67.0)	37 (50.7)	99 (78.0)	5 (71.4)	68 (66.0)	11 (50.0)	13 (65.0)	62 (37.8)	0
	Range of number of fractions treated incorrectly	1-24# (n=107)	1-24# (n=262)	1-2# † (n=35)	1-21# (n=97)	1-8# (n=4)	1-10# (n=56)	2-18# (n=11)	1-6# (n=12)	1-13# (n=56)	0
	Average number of fractions treated incorrectly	3 (n=107)	2 (n=262)	1 (n=35)	2.6 (n=97)	3 (n=4)	2.2 (n=56)	3.7 (n=11)	2.4 (n=12)	2.4 (n=56)	0

Initially a category of "Found at time of patient treatment" was used, but it soon became apparent that this category was one of the most common; therefore this category was later subdivided into "found at time of first patient treatment" and "found at time of later patient treatment" to capture those mistakes found during the first patient set-up.

† This includes two reports where the incident was detected at the first patient treatment, but was not corrected until the third fraction, and two fractions were given incorrectly.

Table 4-7: The most common method of discovery of incidents at different stages of the process.

Discovery method / Stage of Process	Chart check	Found at time of patient treatment	In-vivo dosimetry	Portal Imaging	Clinical review of patient	Quality control of equipment	Other	External audit
Imaging							√	
Simulation	√						√	
Planning							√	
Prescription	√							
Dose Calculation	√							
Treatment Preparation	√							
Treatment Delivery		√						
Follow-Up	√							

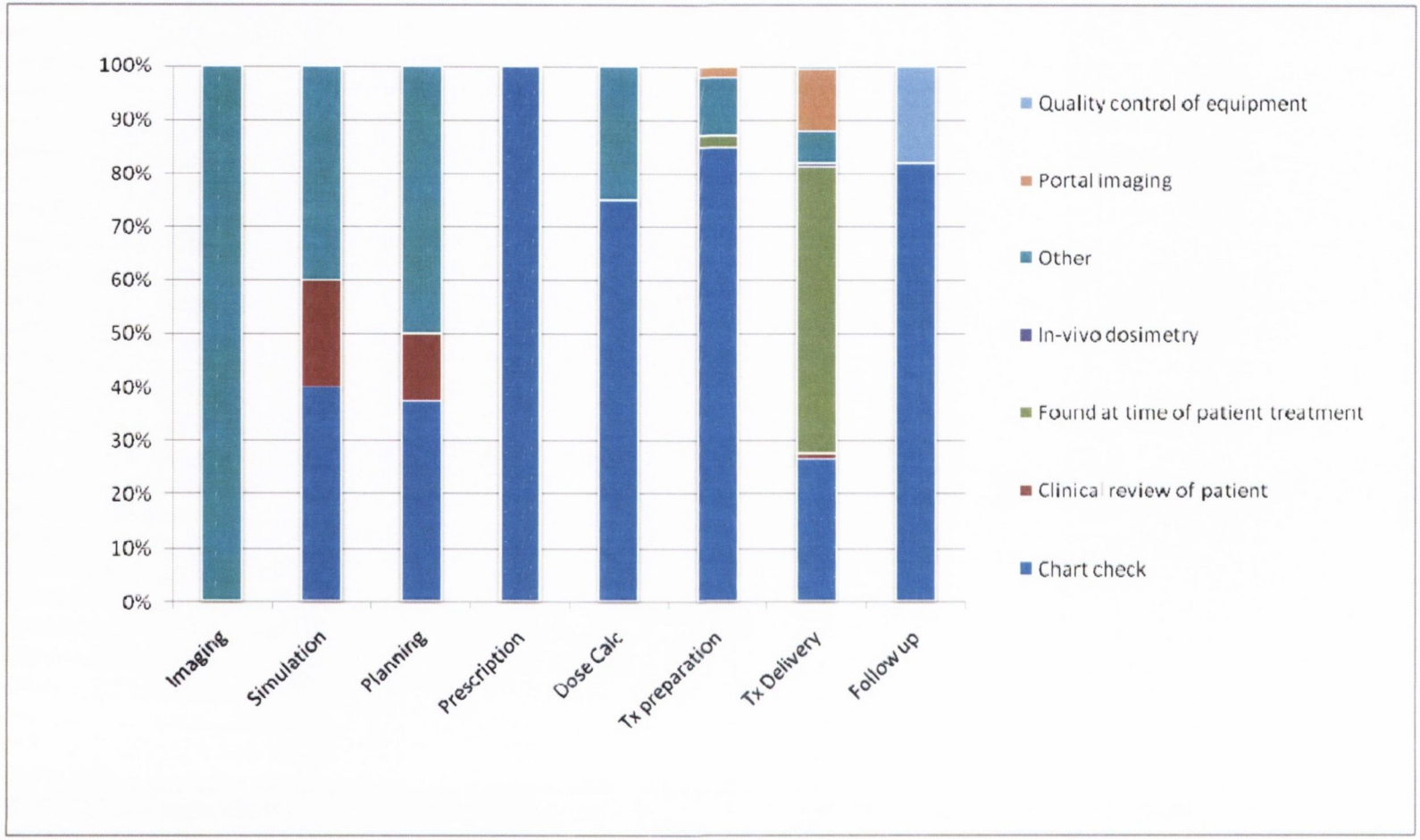

Figure 4-6: Relative detection of mistakes (n=500) throughout the process by quality control measures

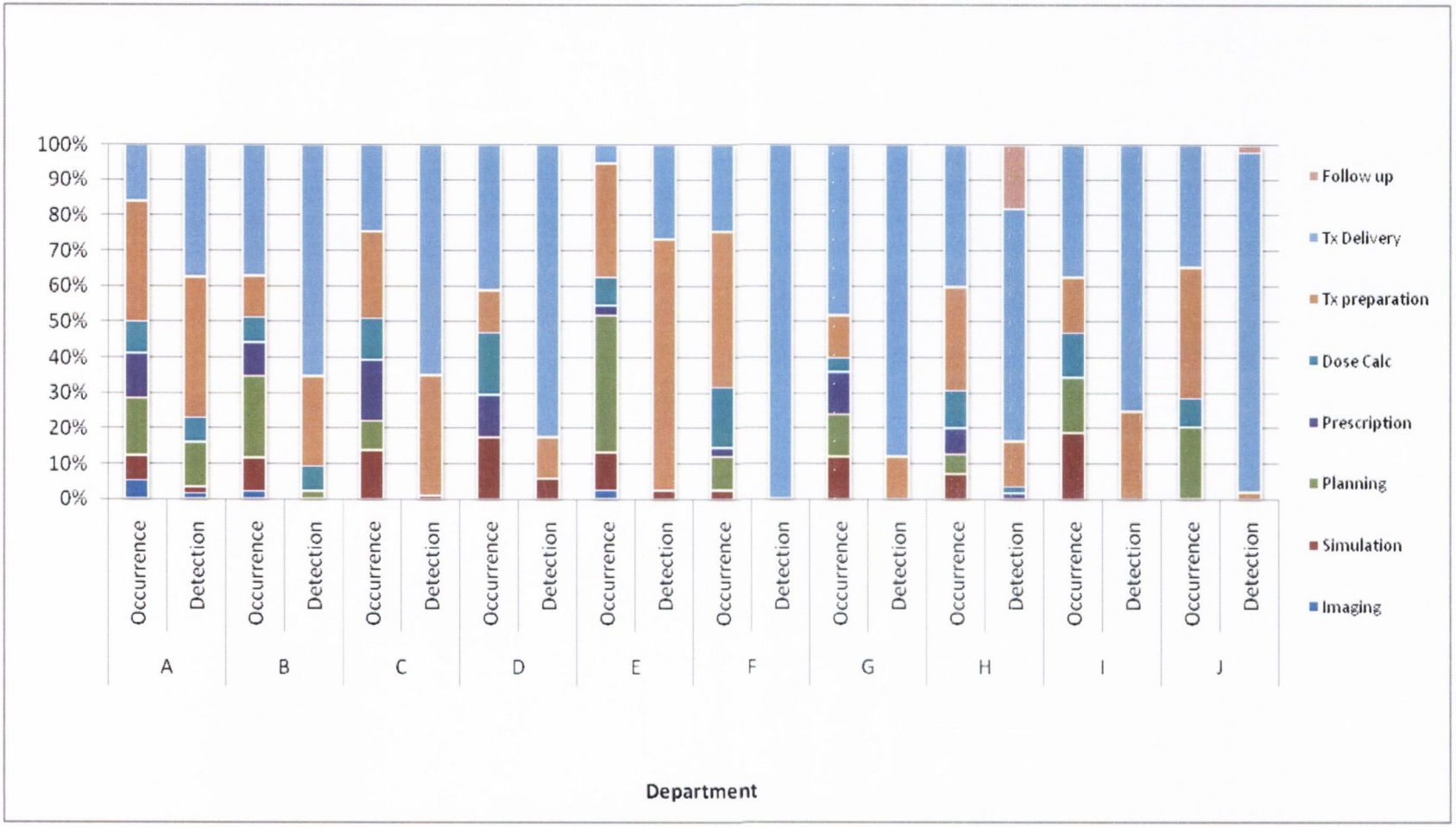

Figure 4-7: Relative distribution of incident occurrence and detection among ten departments

4.3.2 Case studies

The literature contains information on RO incidents under defined headings, and their occurrence in the ROSIS database was specifically investigated for correlation.

4.3.2.1 Data Transfer

Of the first 600 ROSIS reports, nearly half (49%; 294/600) were considered to have an element of data transfer which either directly caused or contributed to the occurrence of the incident. 130 of these 294 (44%) resulted in incorrect treatment being delivered (for at least one fraction). The reports were from a total of thirteen departments – six of whom had record and verify on all treatment units, and seven who had it on some units. The level and degree of integration of networking varied inter- and intra-departments.

A substantial number of these data transfer errors had originated pre-treatment, but were not detected until treatment. The origin of incidents is shown in Figure 4-8, and subdivided into incidents with an element of data transfer, and those without. Based on a Pearson Chi-Squared analysis of the data transfer incidents, significantly more data transfer errors were reported in the pre-treatment phase than in the treatment phase ($p < 0.001$).

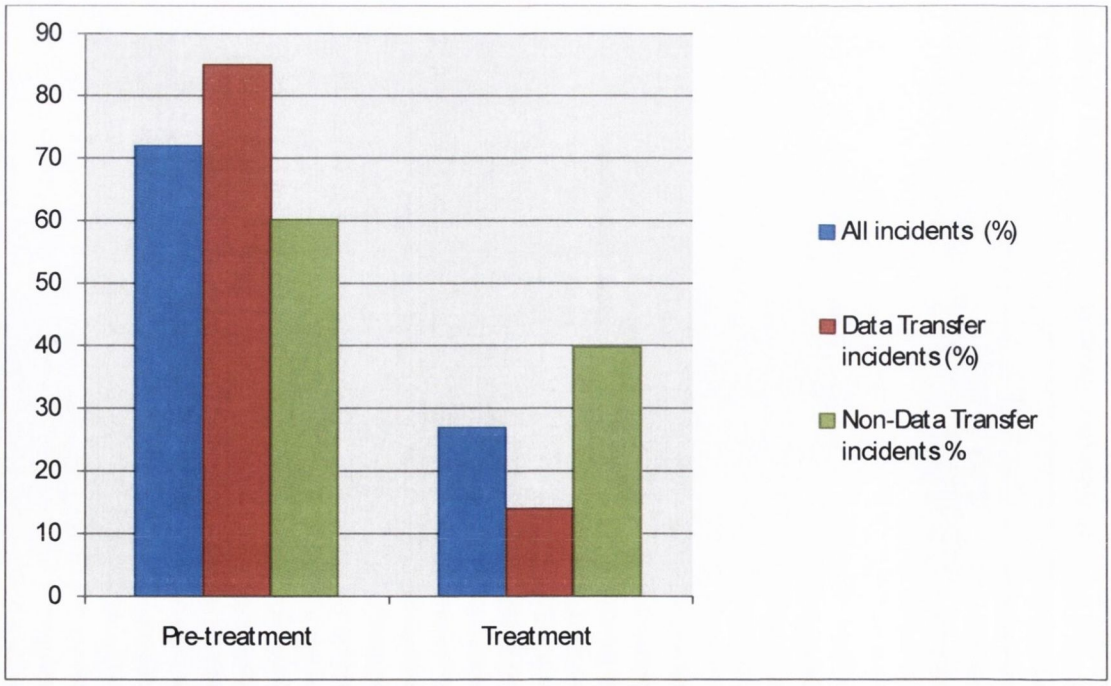

Figure 4-8: Origin of Incidents

62% of the data transfer incidents were discovered at treatment, and of the non-data transfer incidents, 63% are discovered at treatment with a further 5% discovered subsequently at follow-up.

Of the 294 data transfer incidents (Figure 4-9),

- 156 (53%) were detected by chart check
- 100 (34%) were detected at the time of patient treatment
- 21 (7%) were detected by portal imaging
- 22 (7%) were detected by other means
- 8 (3%) were detected by quality assurance of equipment
- 7 (2%) were detected by clinical review
- 1 (0%) was detected by in-vivo dosimetry
- (More than 1 detection method may be listed per report)

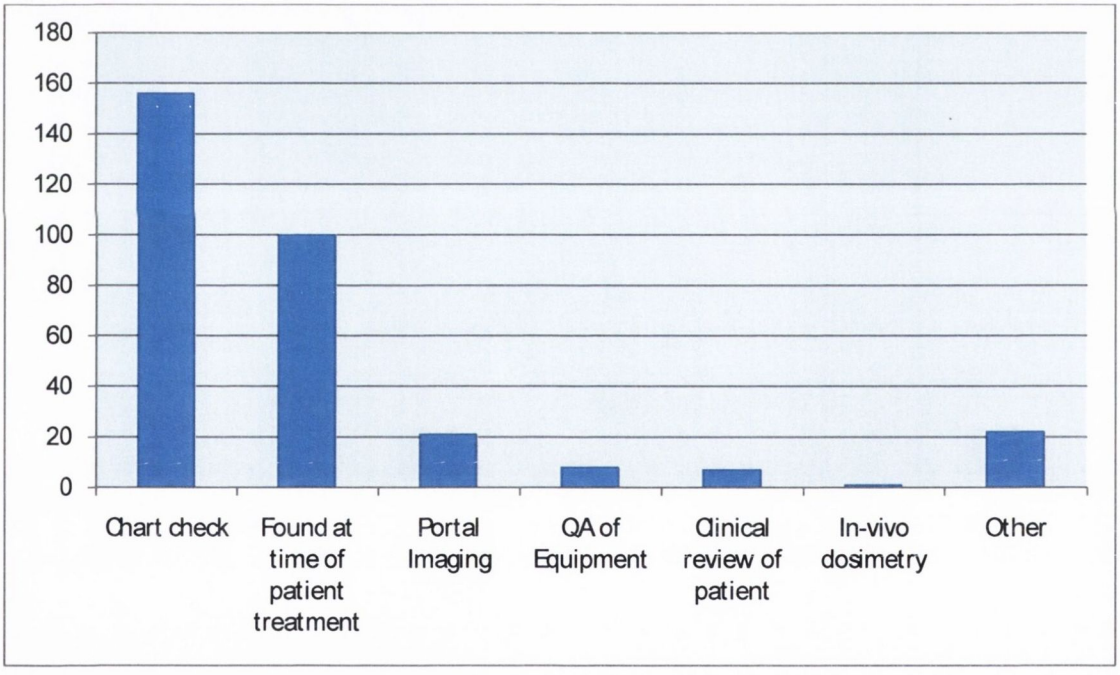

Figure 4-9: Detection of data transfer incidents

45% of data transfer incidents resulted in the incorrect treatment being delivered.

Examples of specific reports categorised as containing a data transfer error can be seen in Appendix H, in the Spotlight on Data Transfer.

4.3.2.2 Use of Record and Verify Systems

Approximately one-fifth of the first 600 reports in the ROSIS database related to incorrect data input into R&V systems, of which nearly half resulted in incorrect treatment delivery for at least one fraction. Other mistakes related to R&V systems were due to software / network problems, violations of approved procedure, or failure to update the R&V data with treatment changes. These additional mistakes brought the contribution of record and verify to 25% of 600 reported incidents.

Figure 4-10 demonstrates that target volume hazards were particularly susceptible to incorrect data entry into record and verify systems. Figure 4-11 contains a breakdown of the elements affected by the incorrect data input, while Figure 4-12 illustrates the stage at which incorrect data input into record and verify is detected.

Examples of specific reports categorised as related to the use of a record and verify system can be seen in Appendix H, in the Spotlight on Record and Verify.

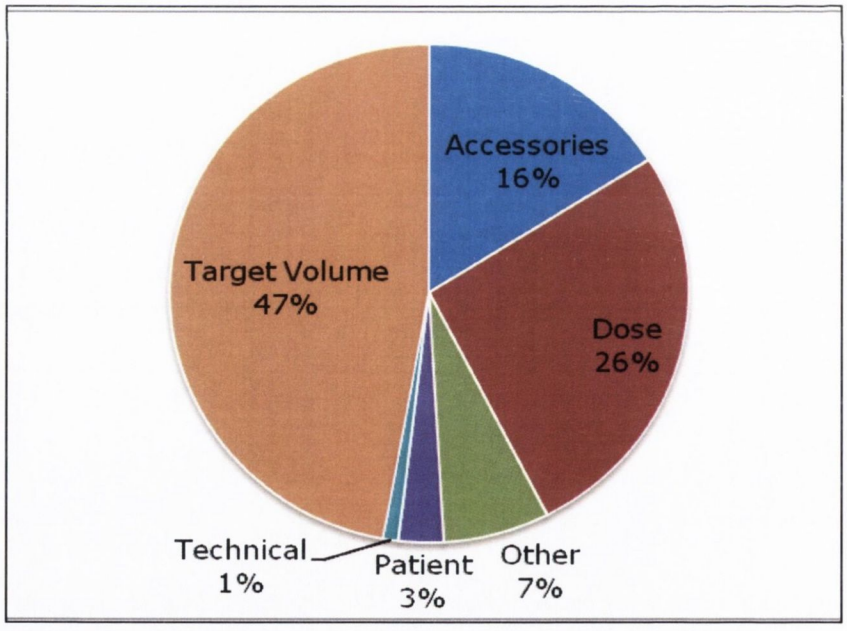

Figure 4-10: Distribution of Hazards caused by Data Input into R&V (n=120)

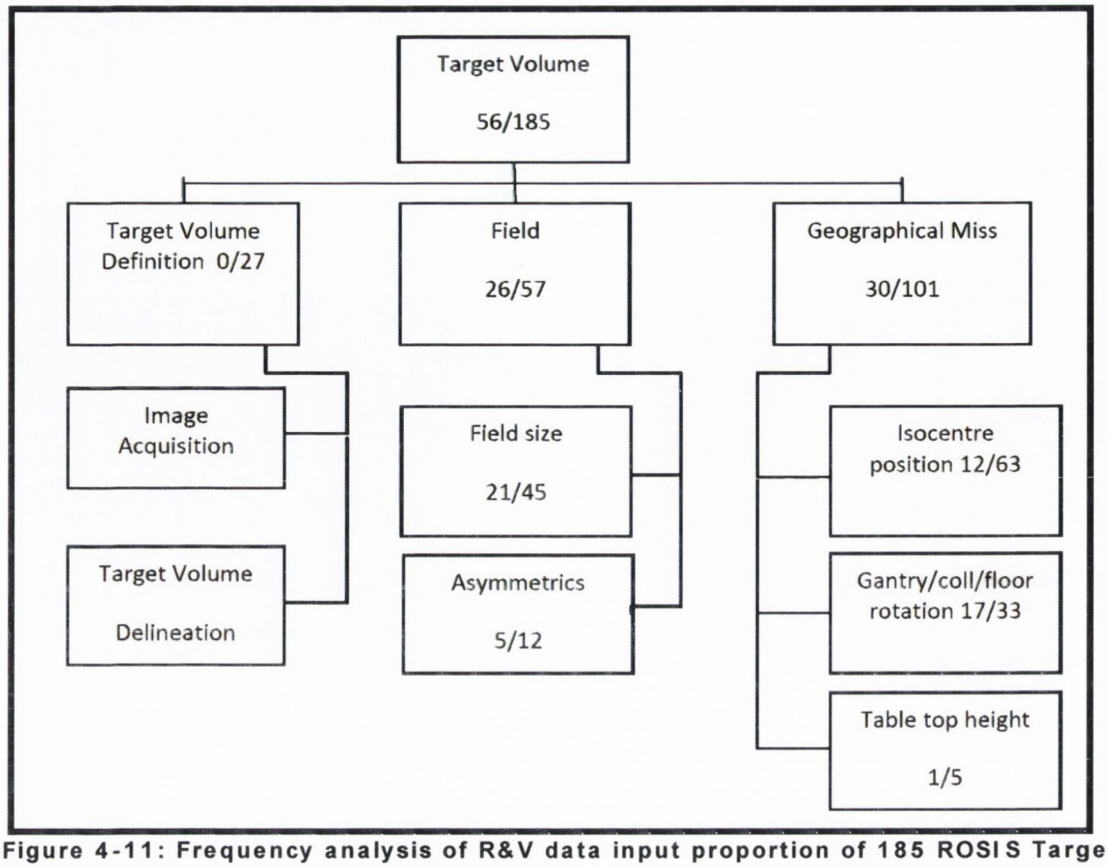

Figure 4-11: Frequency analysis of R&V data input proportion of 185 ROSIS Target Volume errors

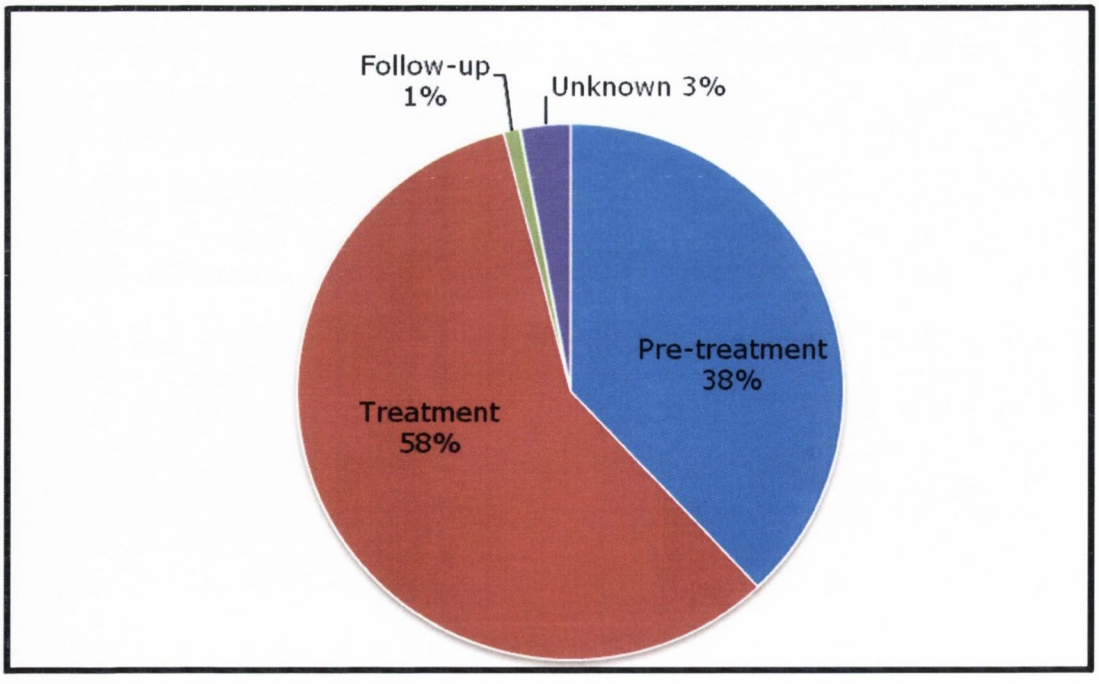

Figure 4-12: Stage of detection of incorrect R&V data input

4.3.2.3 Errors detected by Chart Checking

A total of 351 of the 1074 incidents were detected by chart checking; 350 of these related to EBRT, and one to another modality.

For 281 of these, both the origin and detection are known

- 247 occurred pre-treatment
  - No incorrect treatment in 174
    - 152 discovered pre- treatment
    - 22 discovered at treatment, but no incorrect treatment delivery
  - Treatment delivered incorrectly in 60
    - 55 were discovered at treatment
    - five discovered at follow up
  - Unknown = 13
- 34 occurred at treatment
  - 9 discovered at follow up
  - 25 discovered at treatment

The number of fractions given incorrectly is known for 47 of the 60 incidents where the origin was pre-treatment but treatment was delivered incorrectly. Of these 47 incidents, a total of 112 treatment fractions were affected, with a range of 1-20, mode of 1, and average of 2.4.
For 20 incidents which originated at treatment, there were a total of 25 fractions affected, with a range of 1-3, average of 1 and mode of 1.

Almost half of the incidents detected through chart checking were discovered by Therapists at the treatment unit (Figure 4-13). Figure 4-14 shows that proportionally more of the incidents detected by disciplines other than Therapist or Dosimetrist resulted in incorrect treatment delivery.

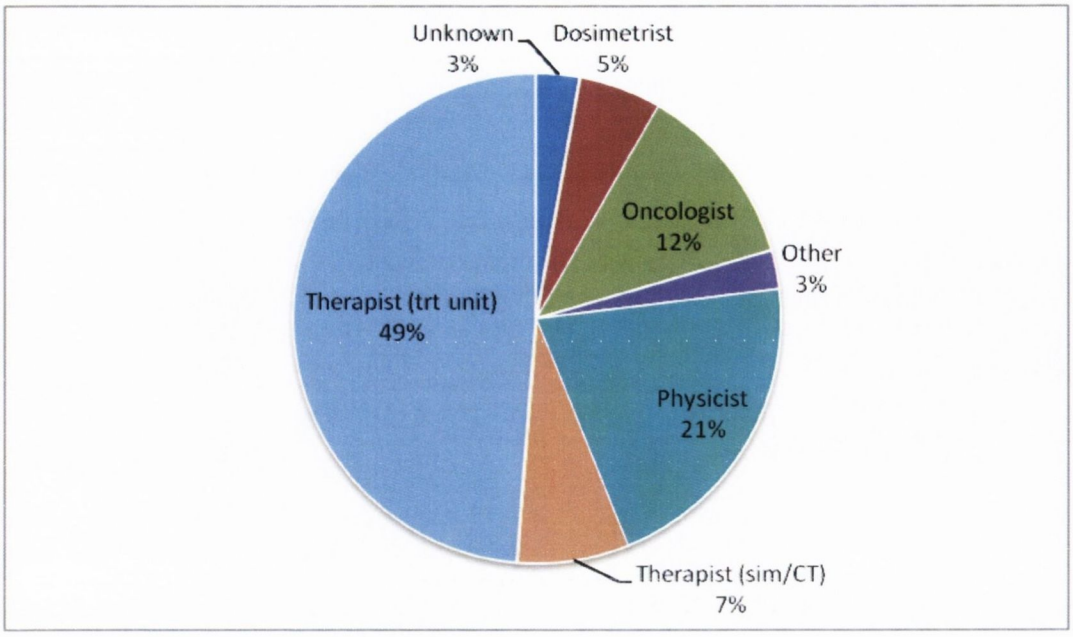

Figure 4-13: Discipline who detected the incident through chart checking (n= 351)

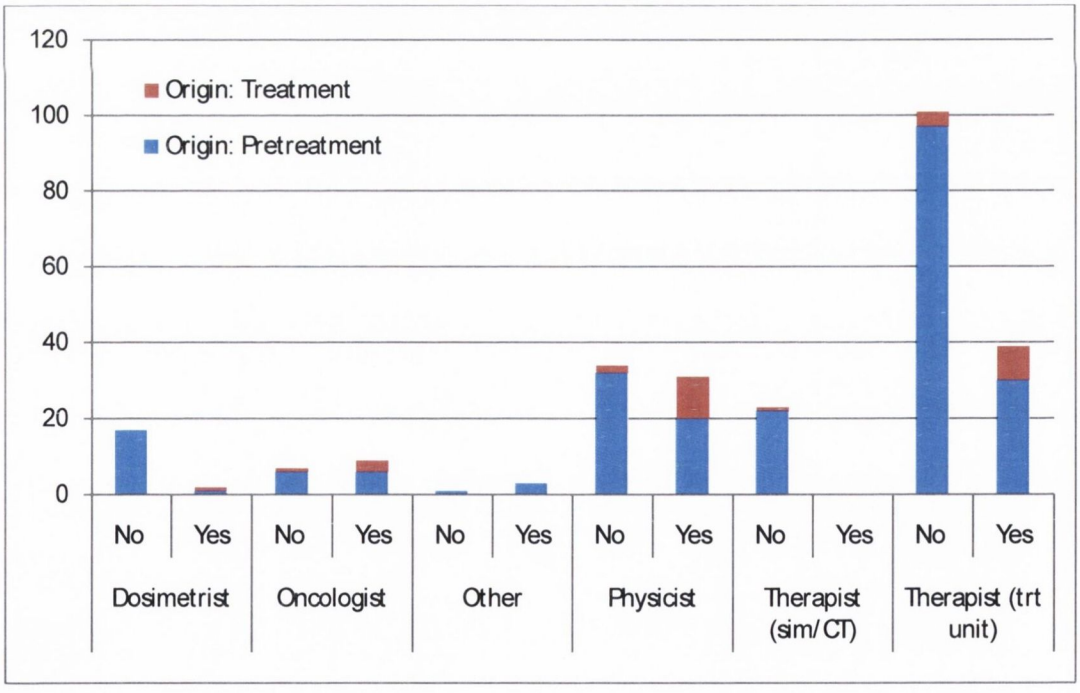

Figure 4-14: Discipline who detected the incident and whether treatment was delivered incorrectly

4.3.2.4 Errors detected by In-Vivo Dosimetry

In-vivo dosimetry detected seven of 1074 incidents, five of these originated pre-treatment, and two at treatment. All were discovered at treatment, five by a therapist at the treatment unit; two by a physicist. Three of the incidents were discovered with one fraction incorrect; in one incident it was discovered after eight incorrect fractions.

4.3.2.5 Errors detected by Portal Imaging

A total of 105 of 1074 incidents were detected by portal imaging (PI), one of these was due to a problem with the portal imaging equipment itself, while 104 were reports on process-related incidents.

Most incidents detected with PI were detected at the treatment stage (88); with 15 discovered pre-treatment, and one unknown.

Where the origin is known (48)

- 38 originated pre-treatment
    - ten discovered pre-treatment
    - 28 discovered at treatment
- Ten originated at treatment
    - all discovered at treatment

The discipline who discovered the incident through PI is illustrated in Figure 4-15.

4.3.2.6 Errors in Planning/ calculation

Based on the process classification frequency analysis (Section 4.4.4), 26.8% of incidents (134 of 500) were deemed to originate in either Planning or Calculation stages. See Figure 4-32 and Figure 4-34. Half of the Planning errors were in documentation of the parameters Figure 4-32; the most common calculation error was the incorrect application or calculation of factors, followed by calculation of dose per fraction Figure 4-34.

Data transfer is a factor in 71 of the 134 incidents (over 50%), 52 did not appear to be due to data transfer; this could not be established for eleven incidents.

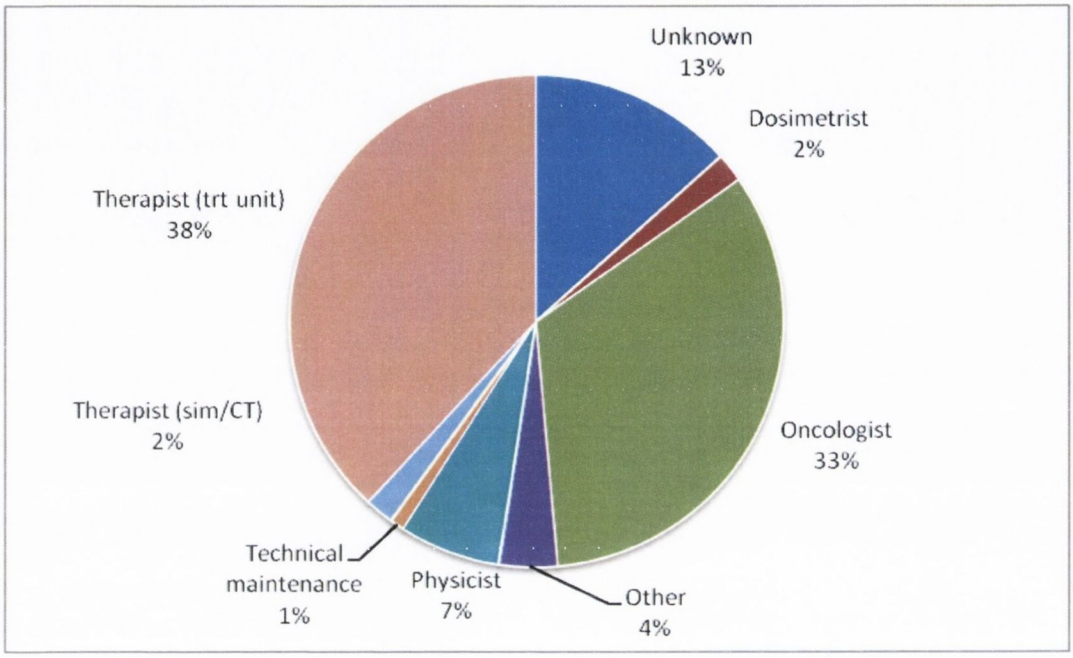

Figure 4-15: Discipline who discovered incident through Portal Imaging (n=105)

4.4 HAZARD IDENTIFICATION AND ROSIS CLASSIFICATION

4.4.1 Hazard Identification

Hazards were identified, and organised into six main categories (Figure 4-17 to Figure 4-25 – *two categories under accessories (electron cutouts and compensators) are not illustrated below*). Up to five layers of hazards could exist, i.e. up to four layers under each of the main categories. Table 4-8 shows the number of items per level of hazard classification, the corresponding levels are shown in Figure 4-16.

Table 4-8: Number of items per level of hazard classification

Level of Classification	Number of items
Level 1	6
Level 2	22
Level 3	30
Level 4	71
Level 5	30

This hazard identification has been further modified and incorporated into a new process classification of incidents (Section 4.4.3.1) [25].

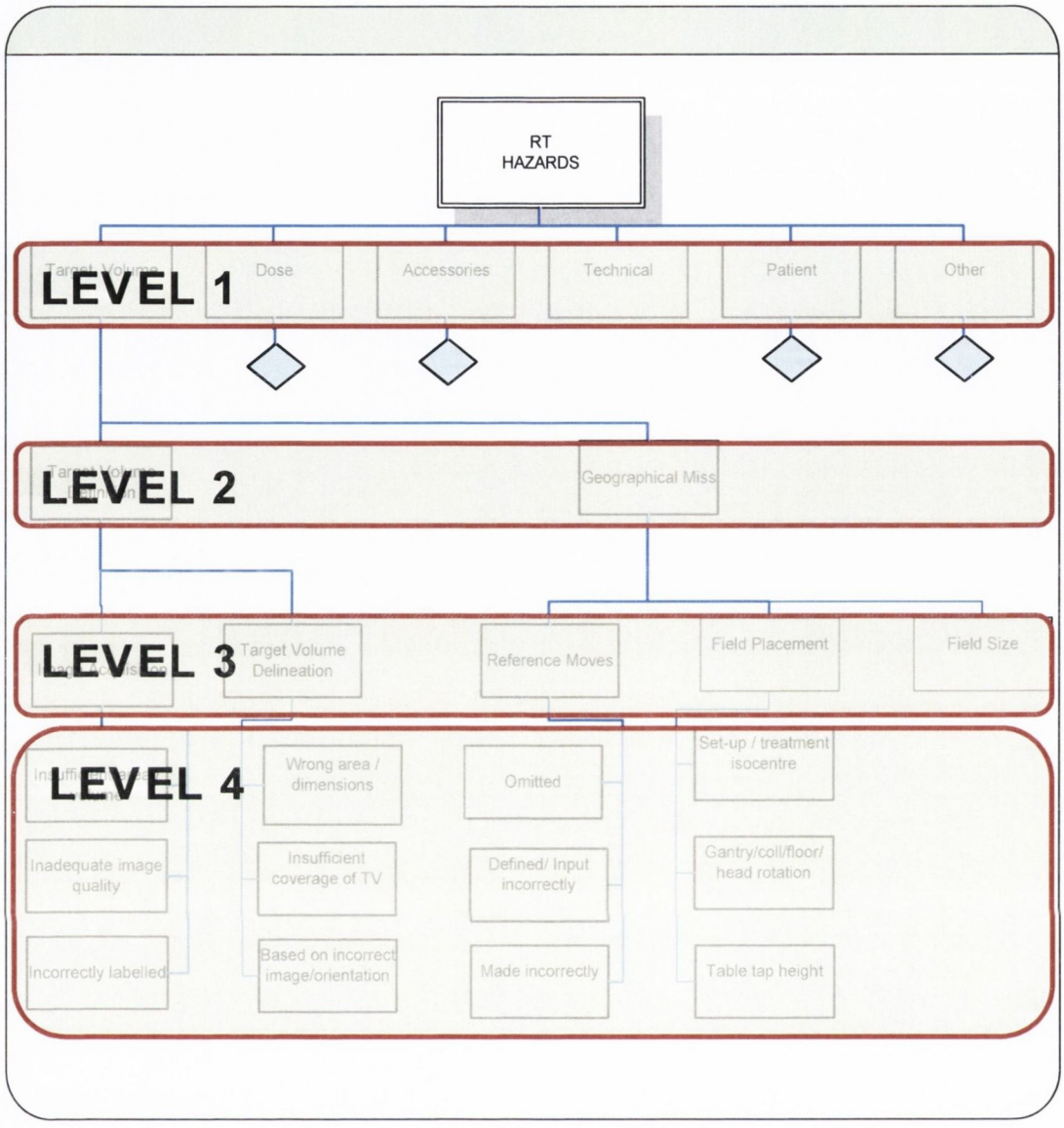

Figure 4-16: Illustration of levels of hazard classification

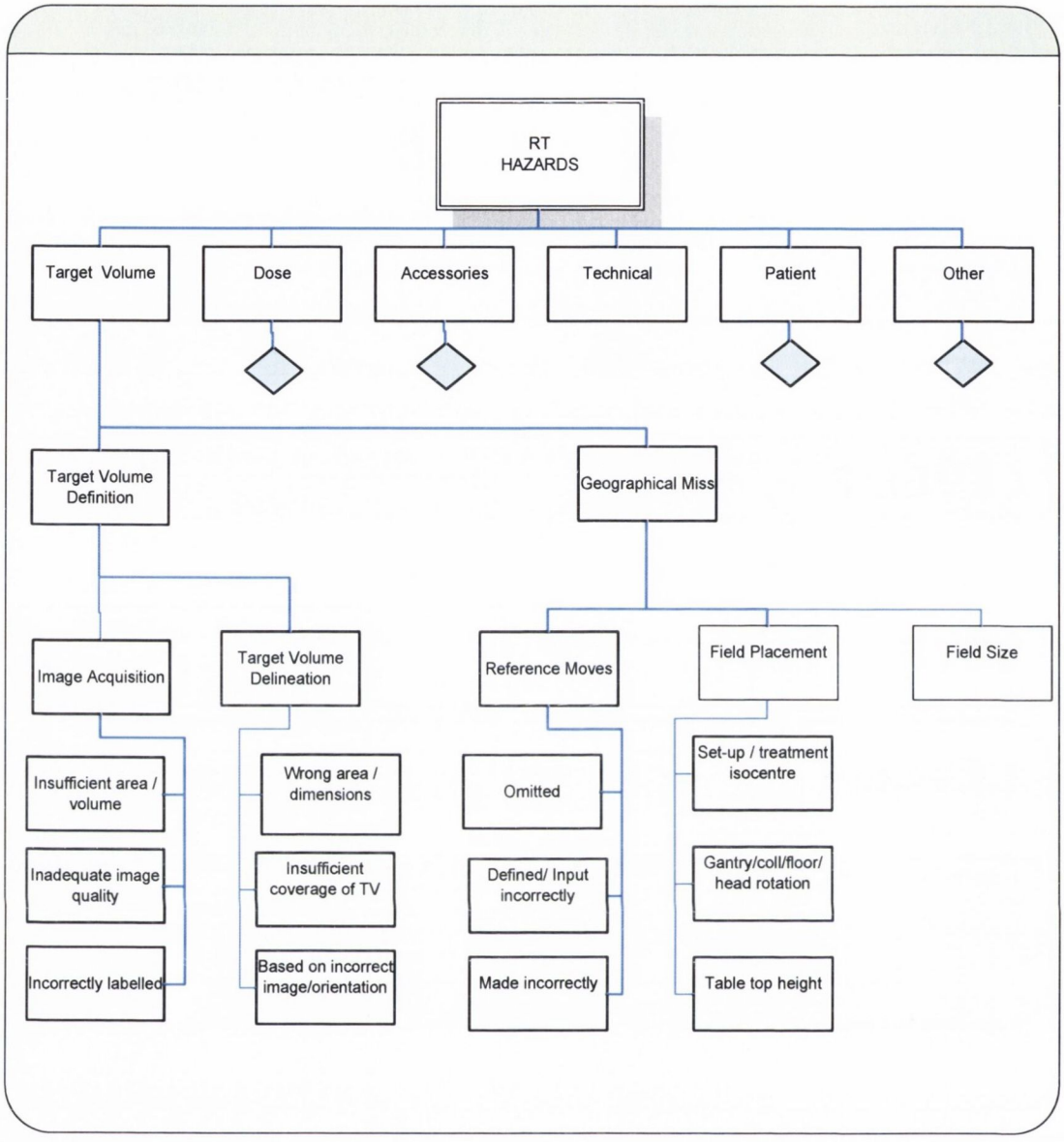

Figure 4-17: Target Volume Errors

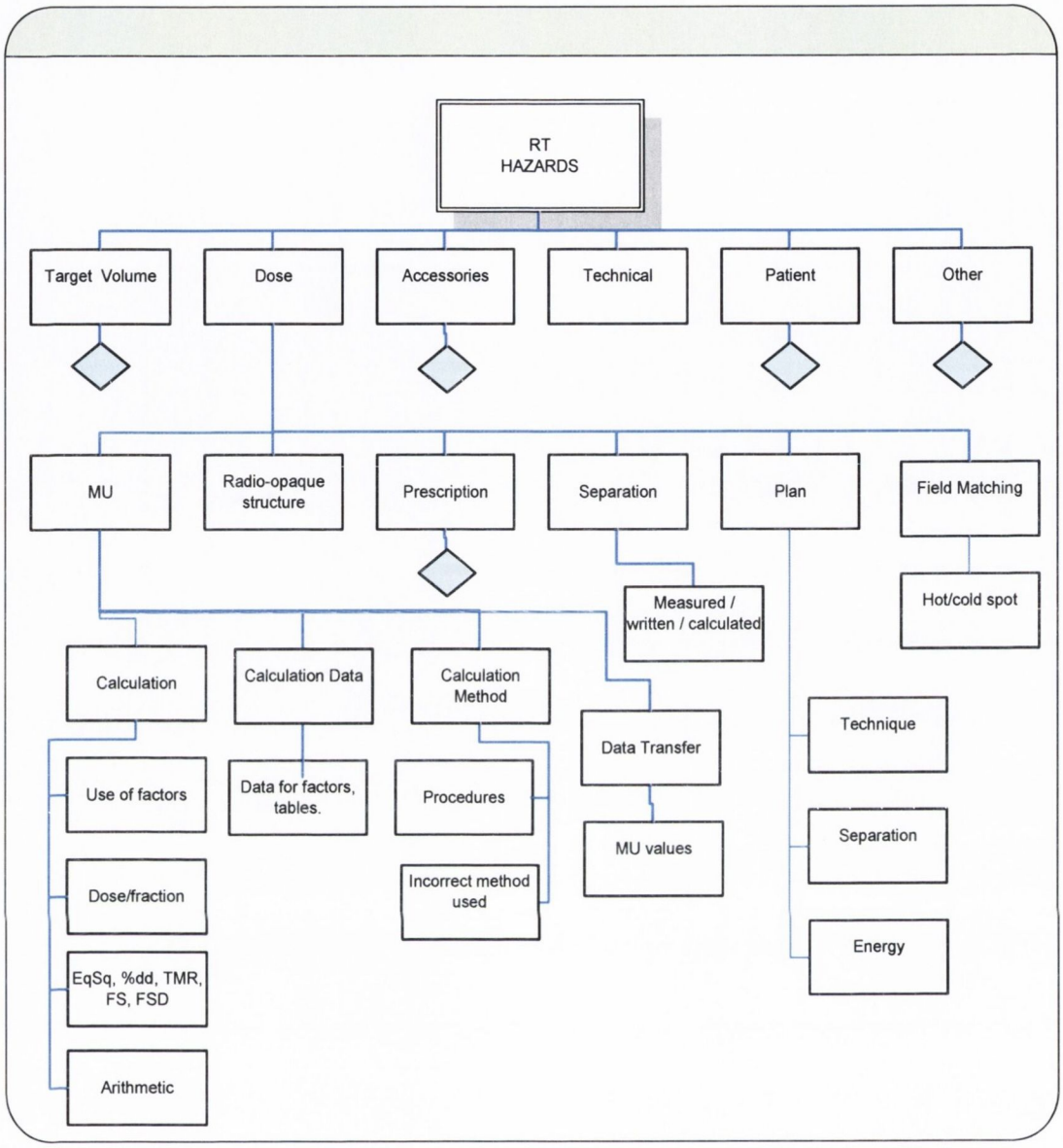

Figure 4-18: Dose errors, but prescription undeveloped

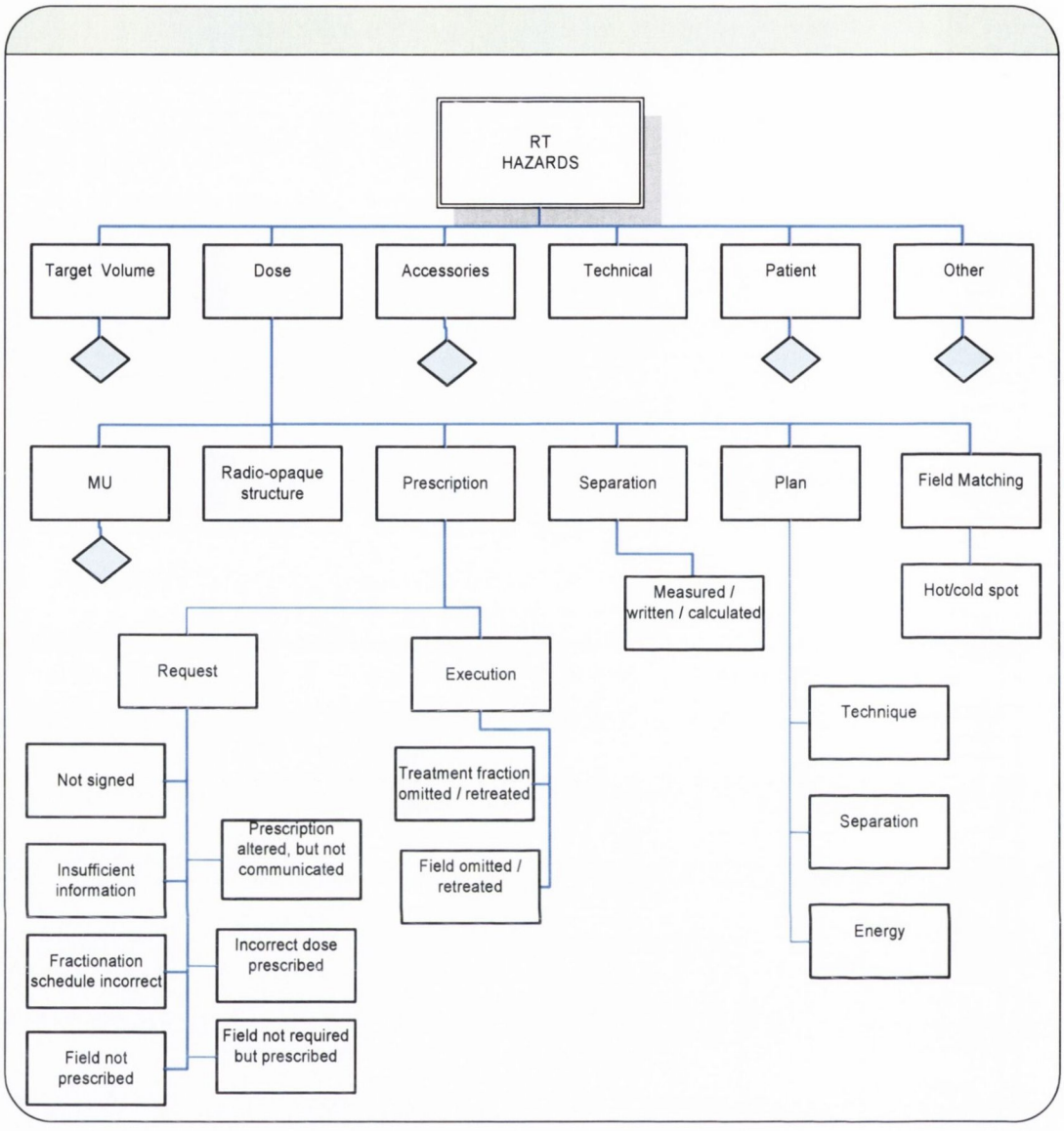

Figure 4-19: Dose errors, prescription errors developed

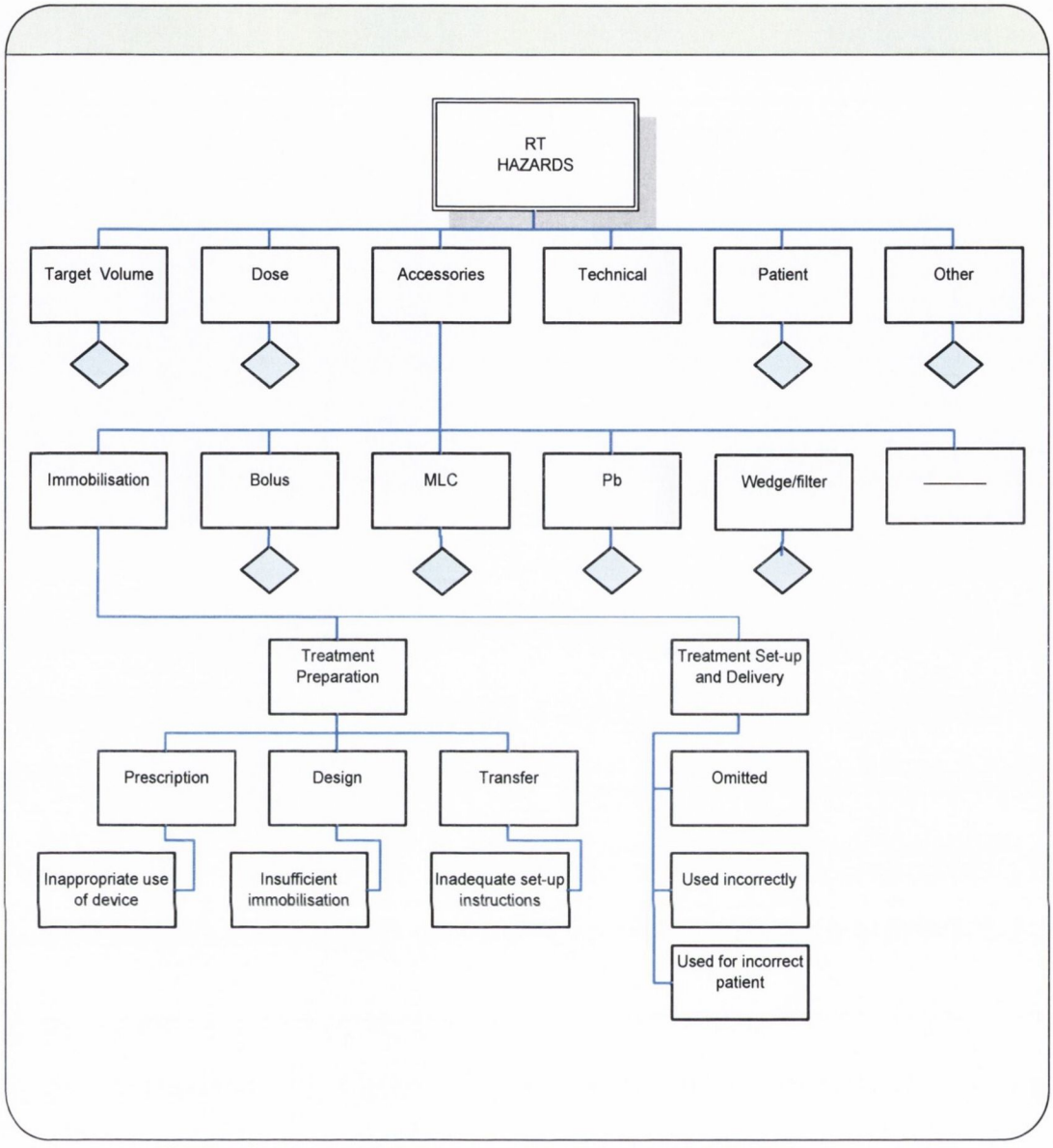

Figure 4-20: Accessory errors - Immobilisation

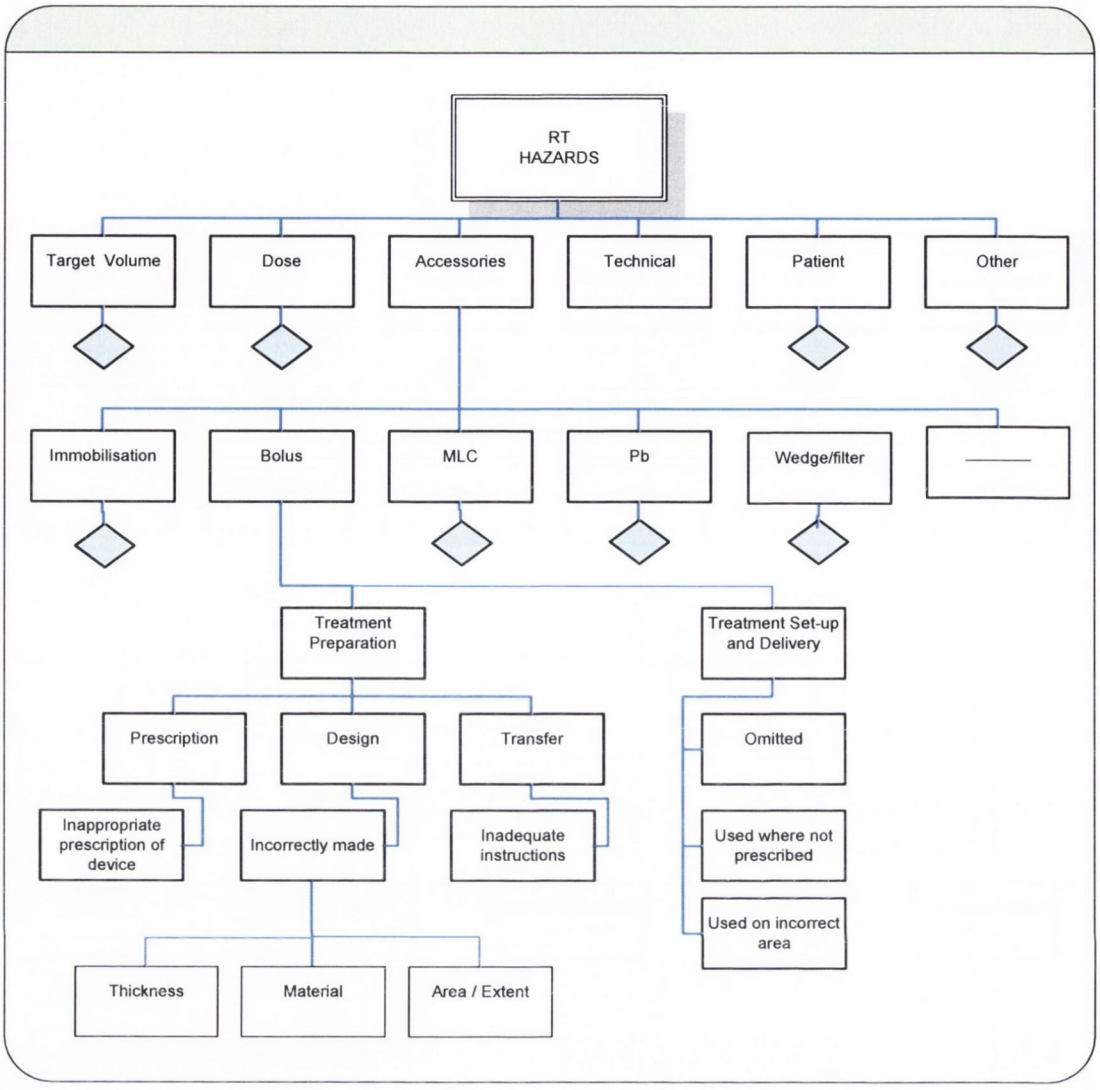

Figure 4-21: Accessory errors - Bolus

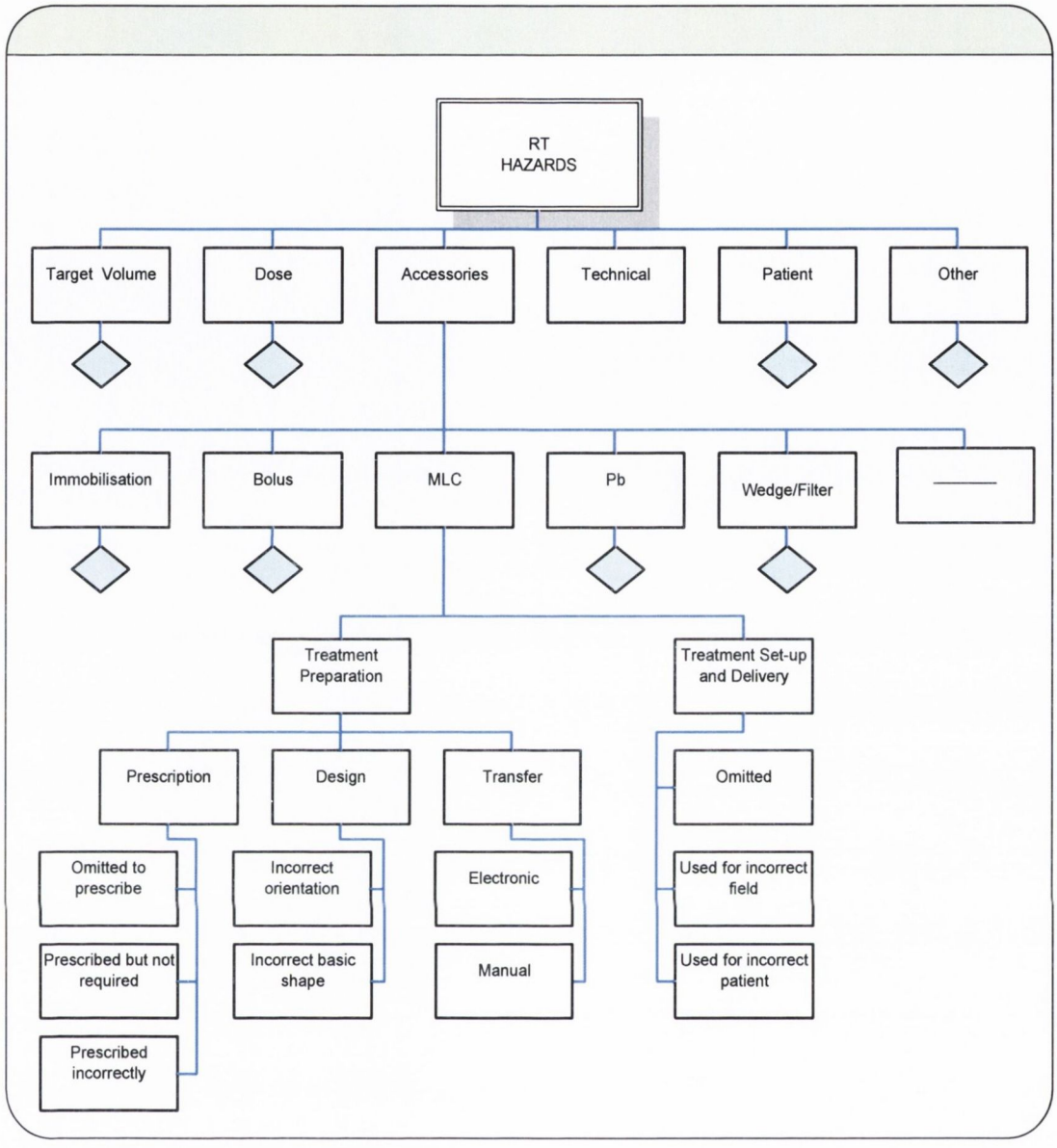

Figure 4-22: Accessory Errors - MLC

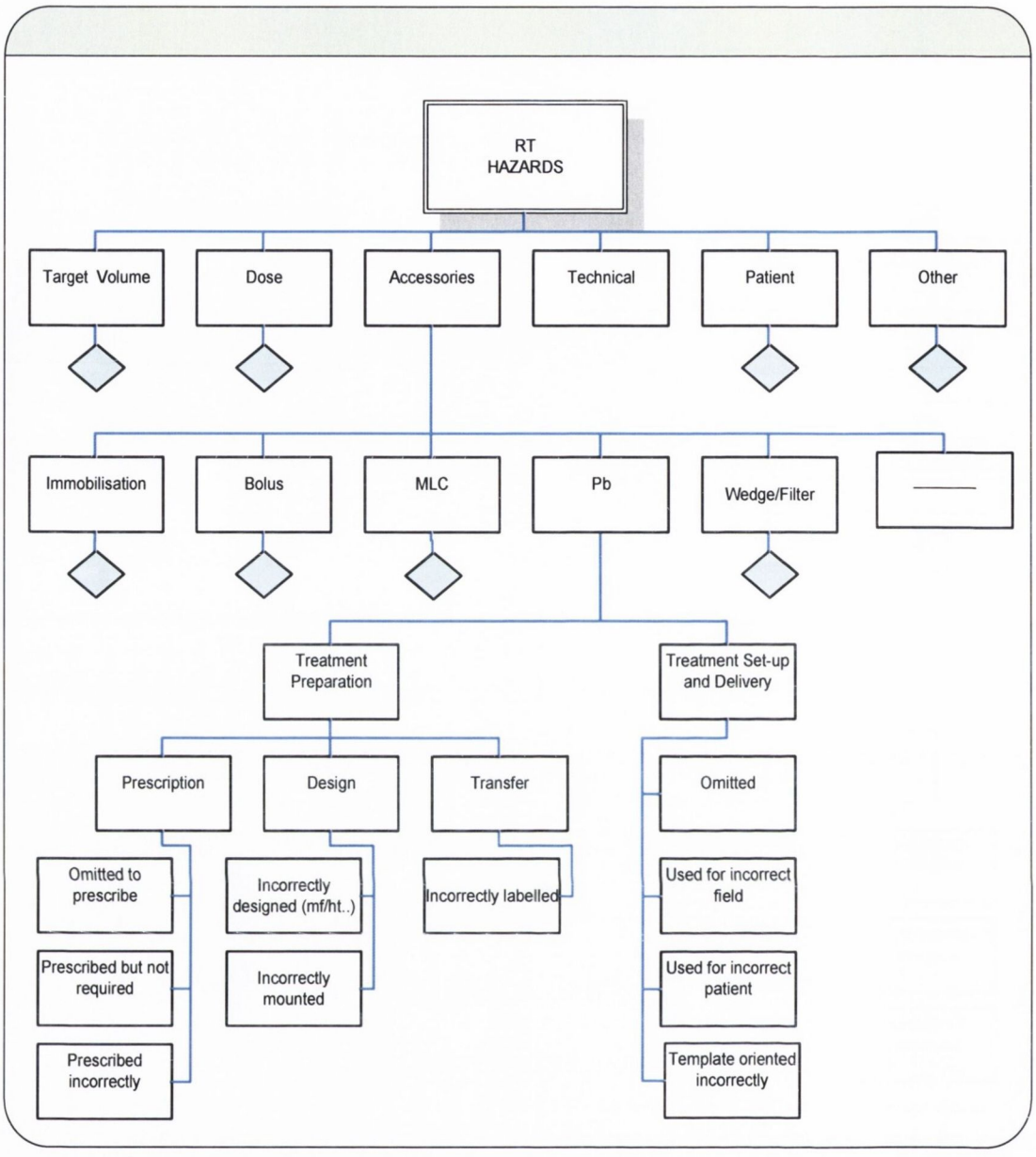

Figure 4-23: Accessory errors - Pb

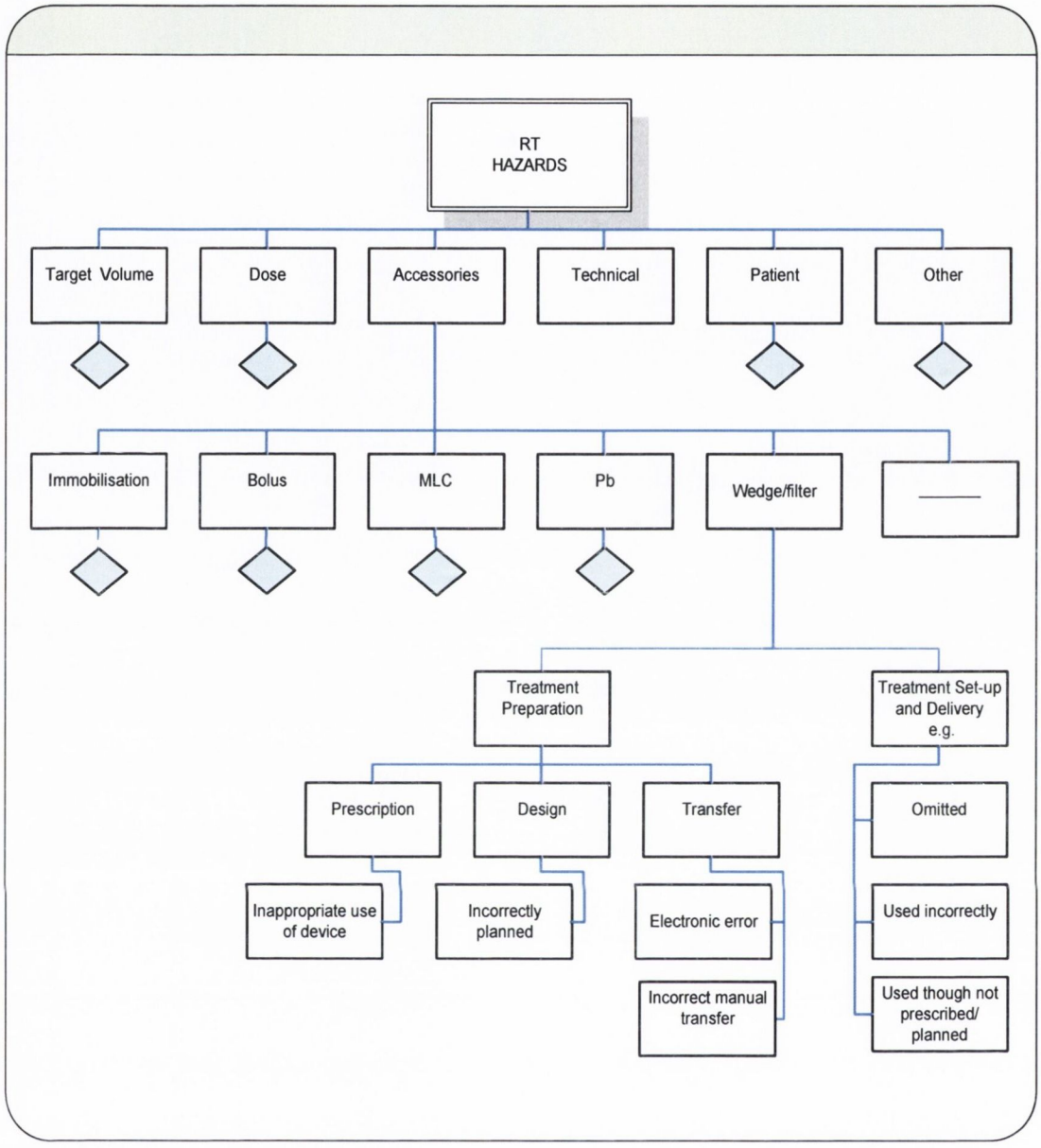

Figure 4-24: Accessory errors – Wedge / filter

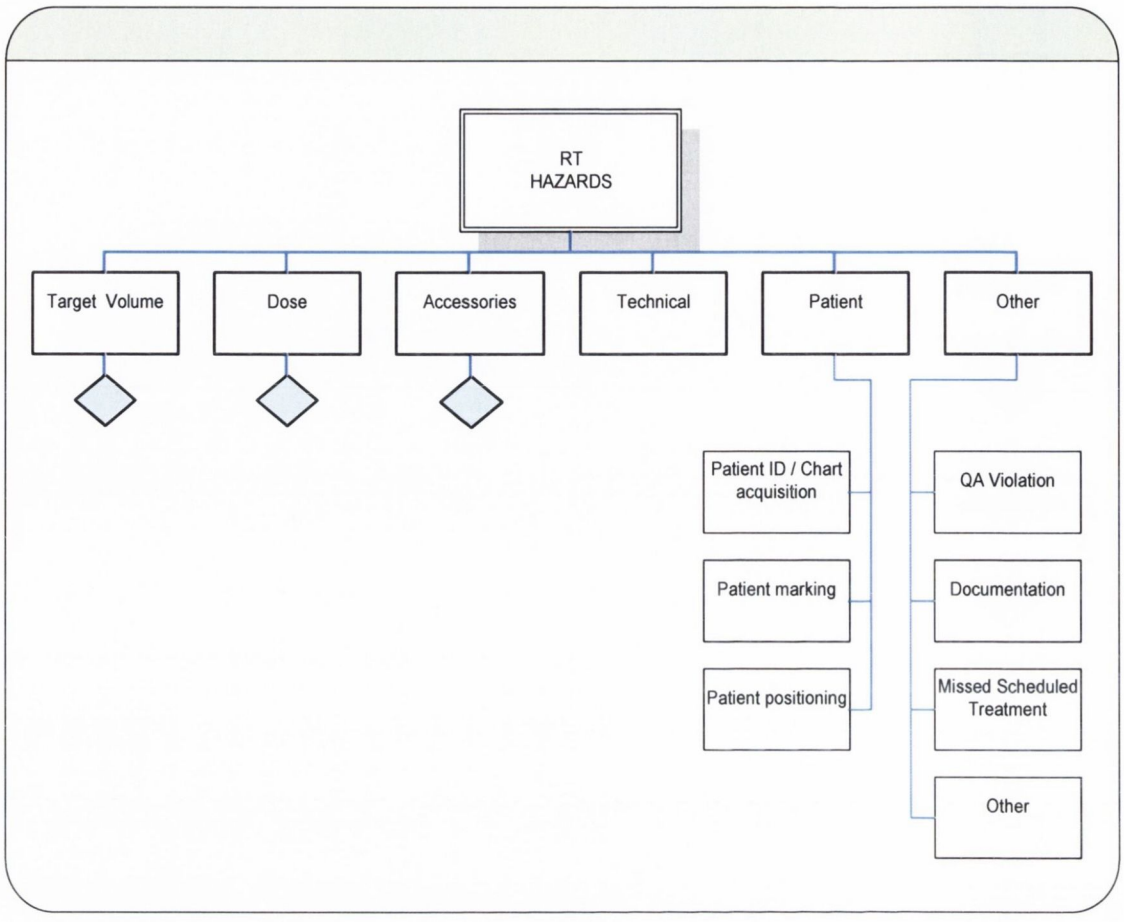

Figure 4-25: Patient errors and Other errors

4.4.2 Hazard Identification Frequency Analysis

A frequency analysis was undertaken using the hazard classification.

Figure 4-26 depicts the relative frequencies of hazards of the first 600 ROSIS reports at Level 1. The frequencies of the Level 2 categories of these hazards are displayed in Table 4-10, while Table 4-11 and Figure 4-27 compare the hazards with the stage of discovery of the incident.

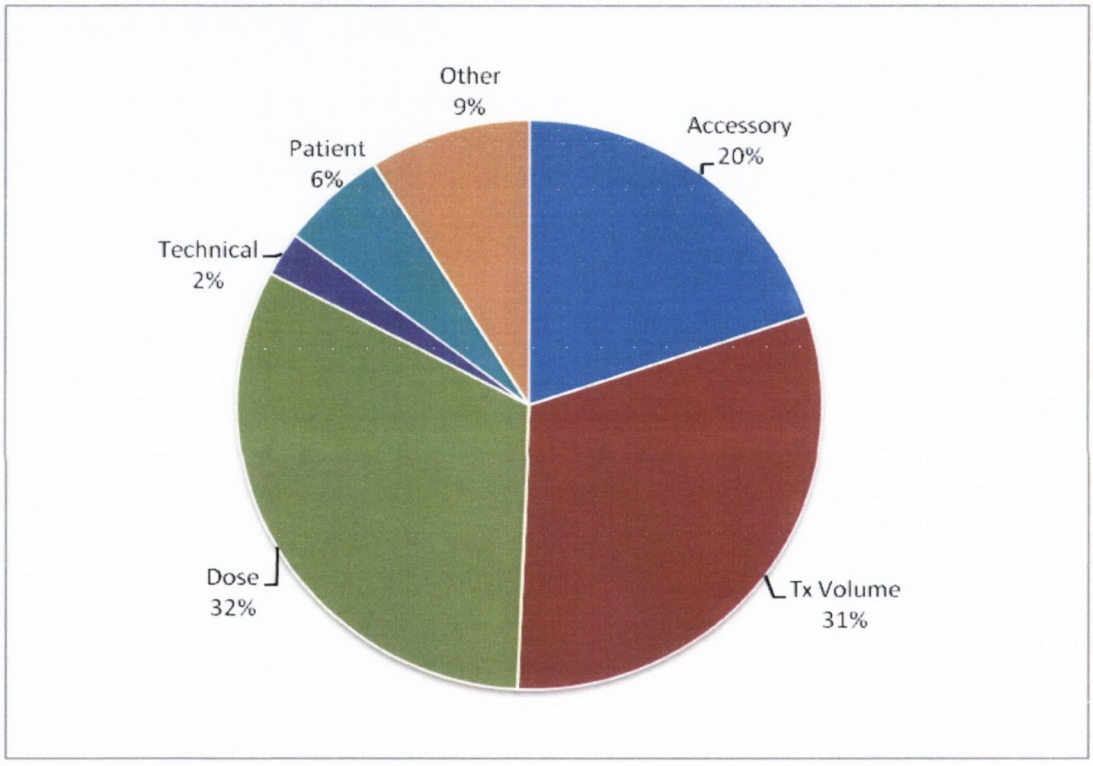

Figure 4-26: Frequency of Hazards of 600 ROSIS Incidents

Table 4-9: Cross-tabulation of Stage of Origin and Stage of Discovery of Incidents

		STAGE OF DISCOVERY			Total
		Pre-Treatment	Treatment	Follow-Up	
STAGE OF ORIGIN	Pre-Treatment	165	197	6	368
	Treatment		135	9	144
Total		165	332	15	512

Table 4-10: Hazard Identification Frequency Analysis of 600 ROSIS Incidents

Categories	Totals	Categories	Totals
ACCESSORY	**119**	**DOSE**	**192**
Treatment Preparation	*58*	Field Matching	6
Bolus	6	MU	61
Compensator	3	Plan	38
Cutouts	2	Prescription	75
Immobilisation Devices	2	Separation	5
MLC	15	Other	7
* Pb	26	**PATIENT**	**35**
Wedge/filter	4	Patient Marking	8
Treatment Set-up and Delivery	*61*	Patient ID / Chart Acquisition	17
Bolus	20	Patient Positioning	10
Compensator	2	**TARGET VOLUME**	**185**
Cutouts	0	Geographical Miss	158
Immobilisation Devices	4	Target Volume Definition	27
MLC	5	**TECHNICAL**	**15**
Pb	16	Computer Bug?	8
Wedge/filter	13	Other	7
Other	1		
OTHER	**54**		
QA	12		
Documentation	21		
Missed treatment	4		
Non-Rt PI	2		
Other	15		

Table 4-11: Cross-tabulation of Hazards with the Discovery of the Incident, based on 350 ROSIS reports.

	Stage of Discovery - Process Related				Non-Process Related		Totals
Stage / Hazards	Pre-planning	Treatment planning	Treatment Delivery	Follow-Up	Equip-ment	Other	
Accessory		5	69		3		77
Patient	1	3	15				19
Tx Volume		9	78		1		88
Dose		16	83	9	4		112
Technical		4	1		10		15
Other		8	20		1	10	39
Totals	1	45	266	9	19	10	350

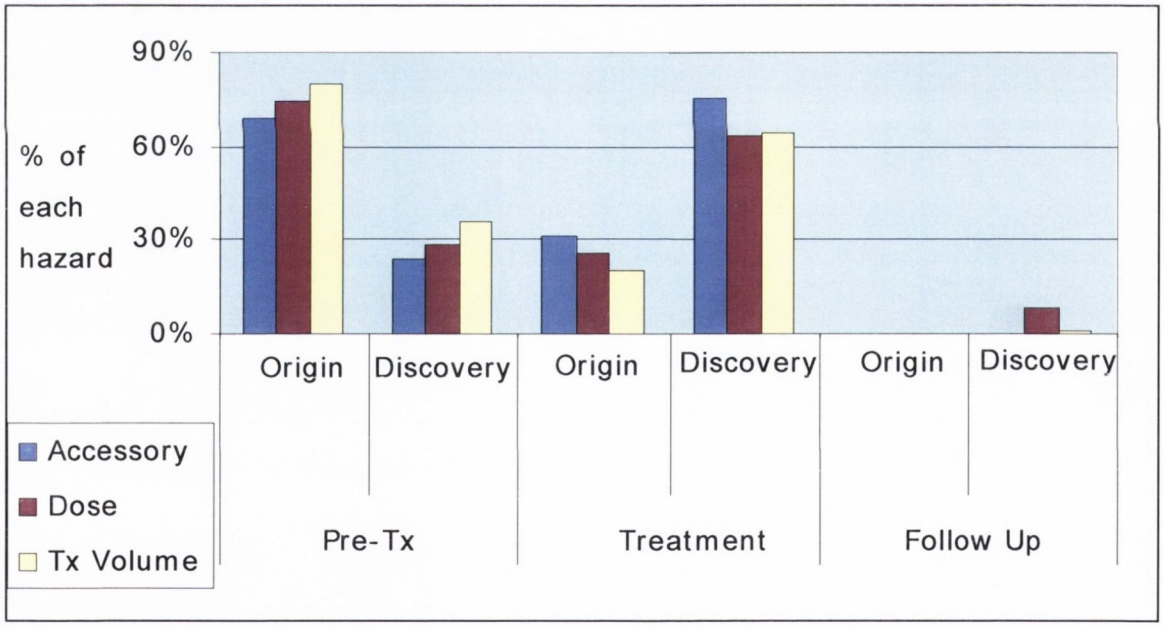

Figure 4-27: Main hazards by stage of origin and discovery

4.4.3 ROSIS Classification

To facilitate collection and analyses of information on incidents in Radiation Oncology, a classification system specific to RO has been developed for ROSIS, with a framework which consists of four classes (Figure 4-28 and Figure 6-8):

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

The relationship between the classes and the situational and investigative information collected is outlined in Table 4-12.

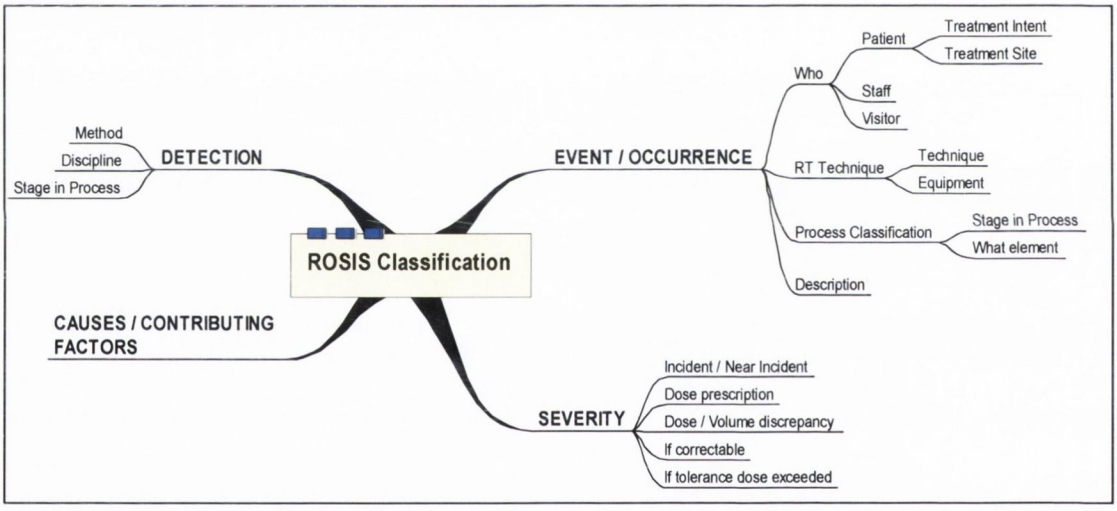

Figure 4-28: Framework of ROSIS Classification

The following sections will describe the Process, Severity, Causes/Contributing Factors, and remaining Classes in more detail.

Table 4-12: Scope of ROSIS Classification System

Title	Element addressed	Addressed through category/categories
1. Event / Occurrence	1.1 Who affected	Who - Patient / Staff / Visitor
	1.2 Where/When occurred	Process classification
	1.3 How occurred	Event Description
	1.4 What occurred	Process classification
		Description
		RT Technique
2. Causes / Contributing factors	2. Why occurred	Causes / Contributing factors
3. Detection	3.1 How Discovered	Method of discovery
	3.2 Where/When Discovered	Stage of process of discovery
	3.3 Who Discovered	Discipline who discovered
4. Severity	4.1 Incident/Near Incident	Treatment delivered incorrectly and number of incorrect fractions
	4.2 Actual harm and potential harm	Dose or volume discrepancy If correctable If tolerance dose exceeded

4.4.3.1 ROSIS Process Classification

A major element of the classification scheme is a process classification under the category "event/occurrence", and which is used to pinpoint the activity where the incident originated, and was discovered, in the RT process.

Four "levels" were defined, with a total of 103 data items, detailed in Table 4-13.

Table 4-13: Number of items per level of process classification

Level of Process Classification	Number of items
Level 1	7
Level 2	20
Level 3	58
Level 4	18

Level 1 outlines the primary activities for the patient/patient information – from imaging to treatment delivery (Figure 4-29). The classification does not consider the earlier stage of the decision to treat with radiotherapy.

Figure 4-30 to Figure 4-36 inclusive illustrate Levels 2 and 3. While Level 1 defines where in the overall process an incident originated, Levels 2 and 3 reflect what element of the process was affected. Each activity from Level 1 is taken and further expanded. Level 2 is comprised of the main branches; Level 3 is their off-shoots. For Level 2, the flow is intended to be from left to right; but again this can be modified without disrupting the data collected. There is no order to items at Level 3.

Level 4 further expands some elements of level 3 – for example if
Level 1 = Dose Calculation, Level 2 = Calculation, and Level 3 = Factors,
then Level 4 could be: omitted / used incorrectly / etc.

The following figures should be read from left to right on the horizontal line, following the position of each node on the horizontal line to give the approximate workflow.
For example, in Imaging (Figure 4-30), the patient is identified, then is positioned/immobilised, following which the position of the imaging isocentre is marked, the scan is taken, and the procedure is documented.

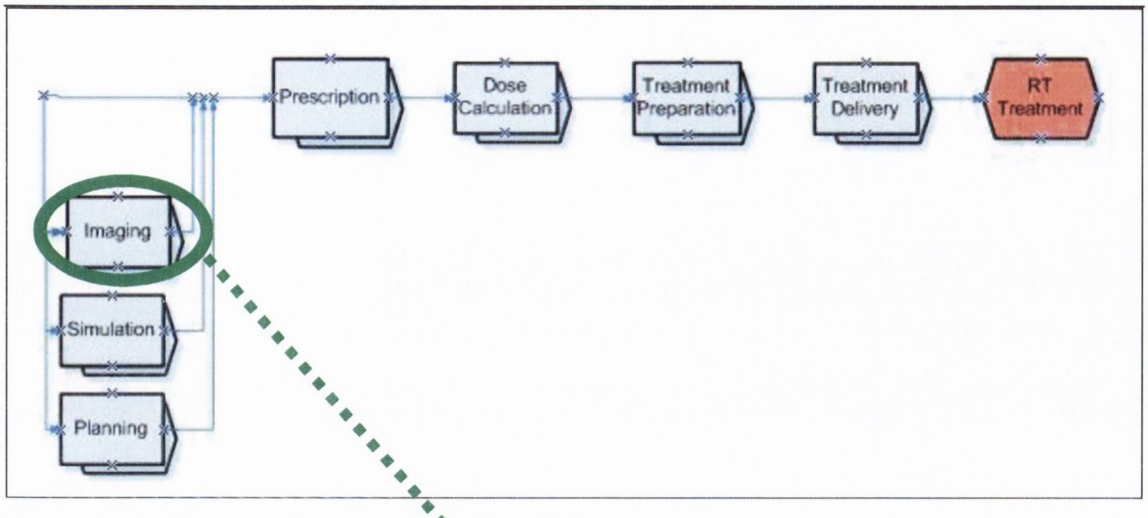

Figure 4-29: Level 1 of Process Classification

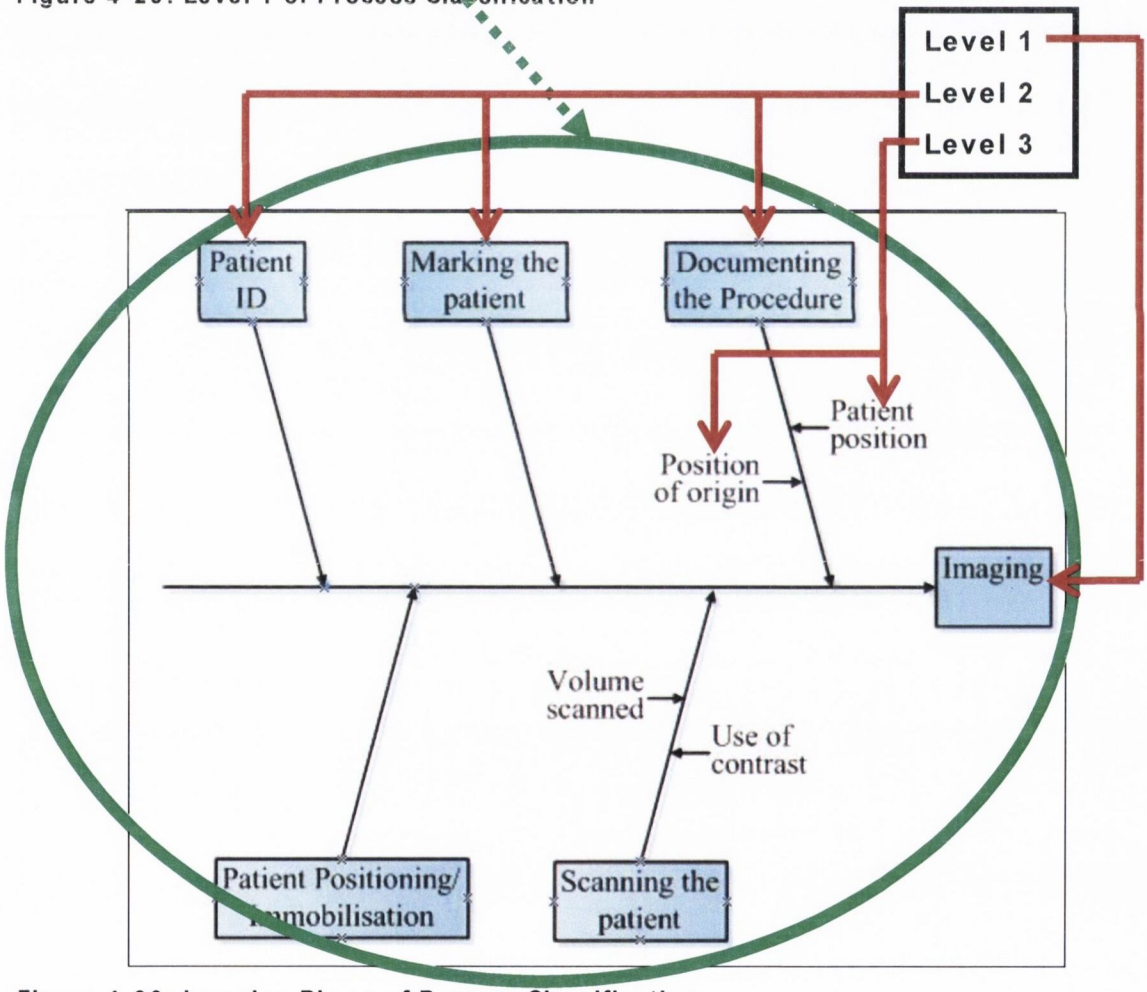

Figure 4-30: Imaging Phase of Process Classification

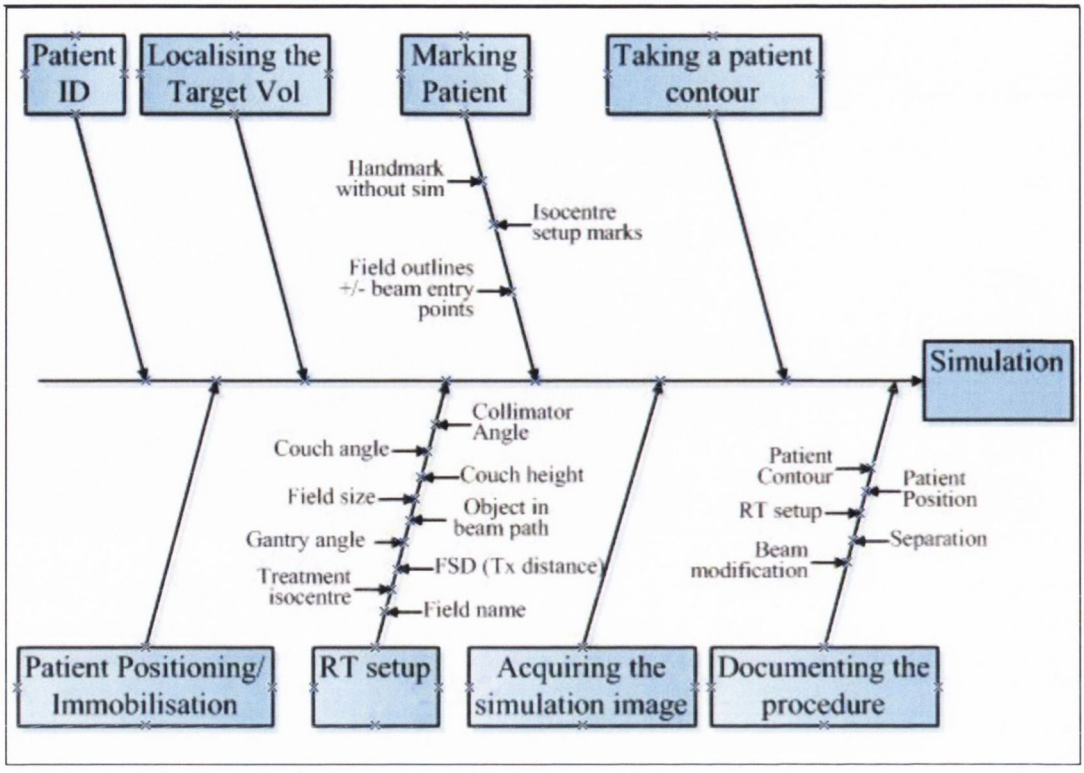

Figure 4-31: Simulation Phase of Process Classification

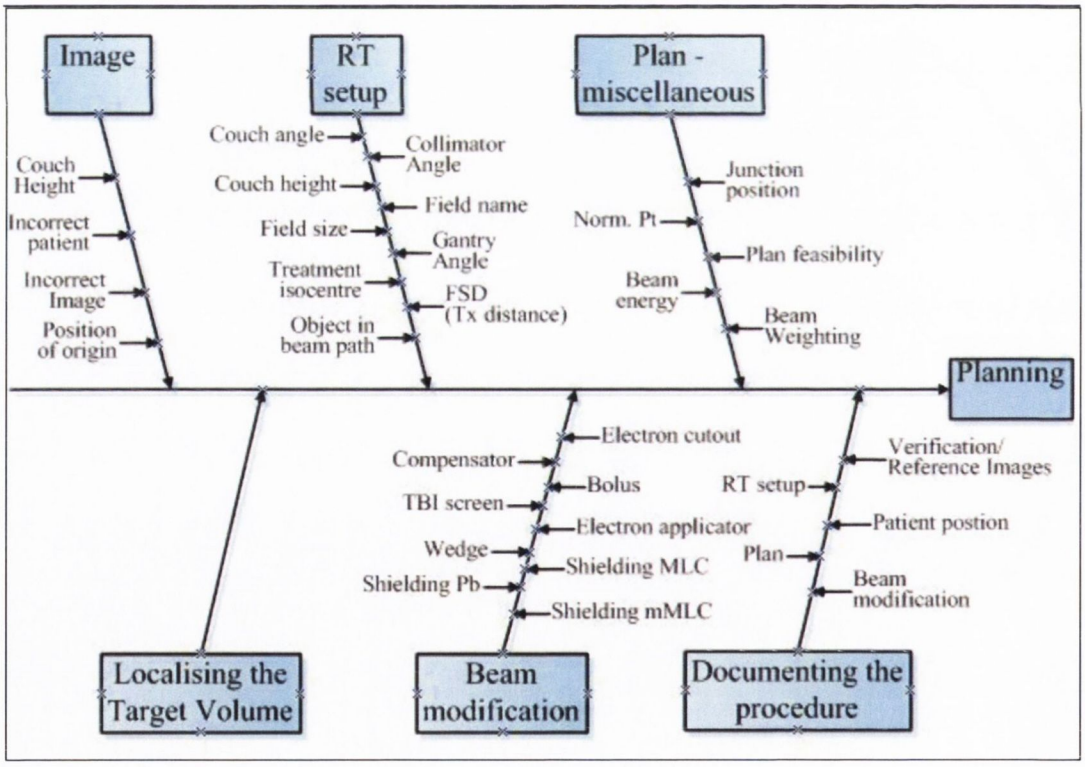

Figure 4-32: Planning Phase of Process Classification

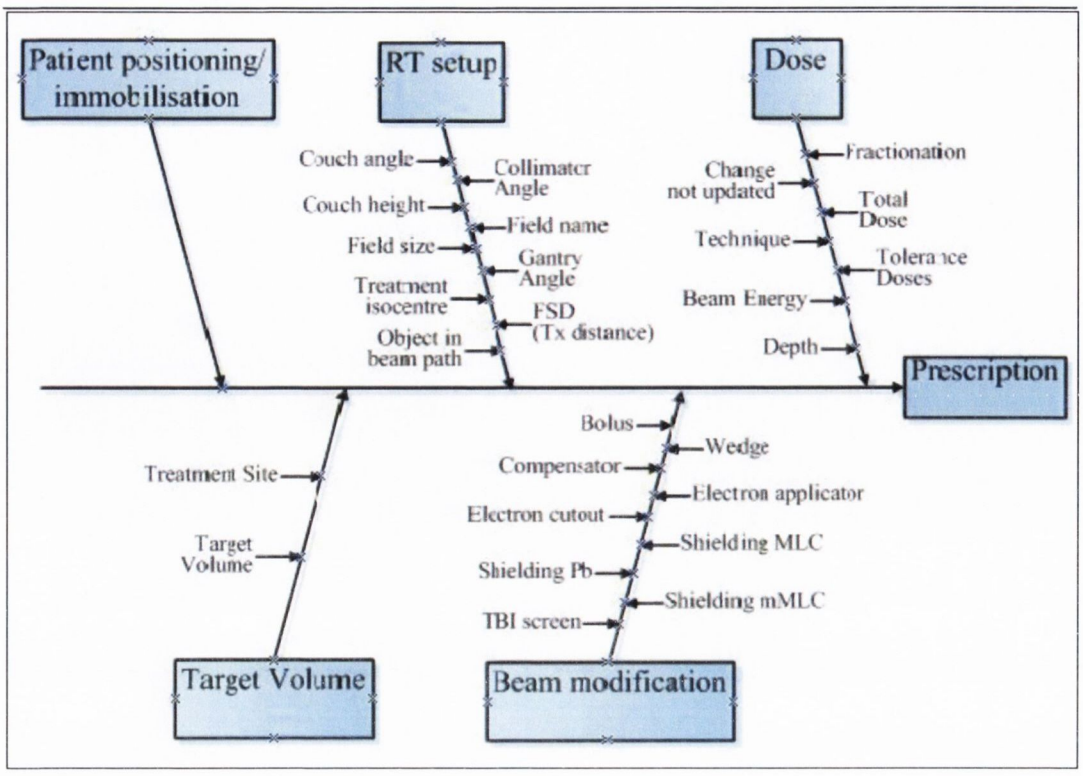

Figure 4-33: Prescription Phase of Process Classification

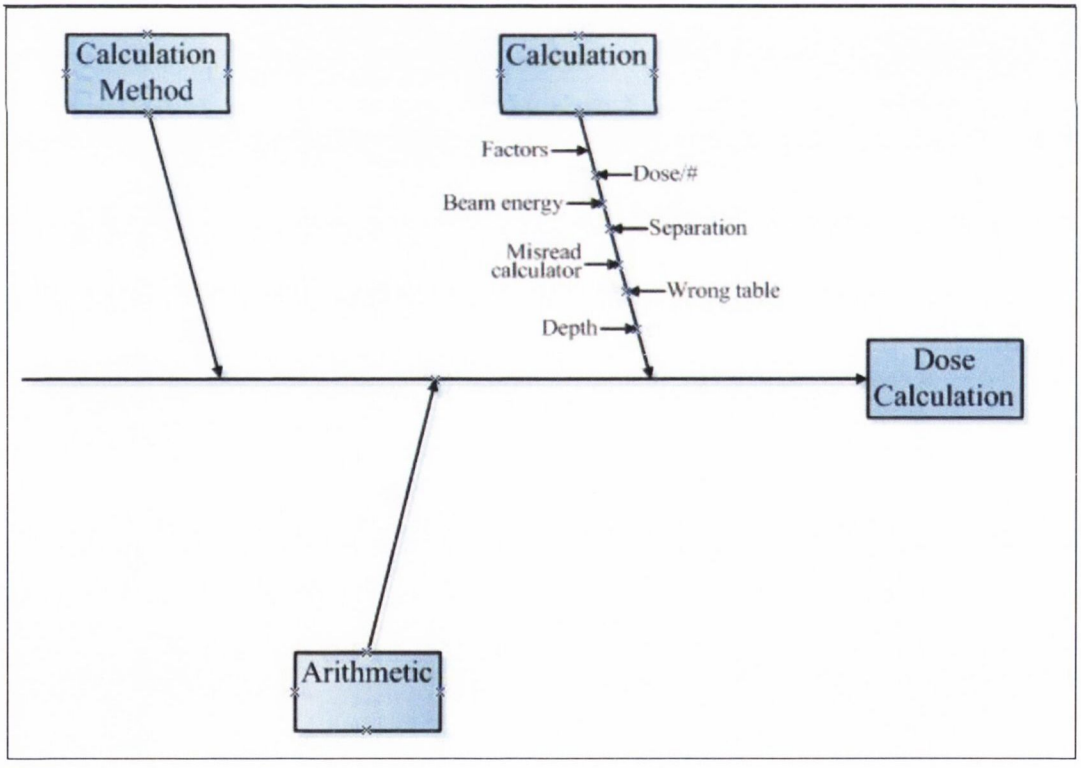

Figure 4-34: Dose Calculation Phase of Process Classification

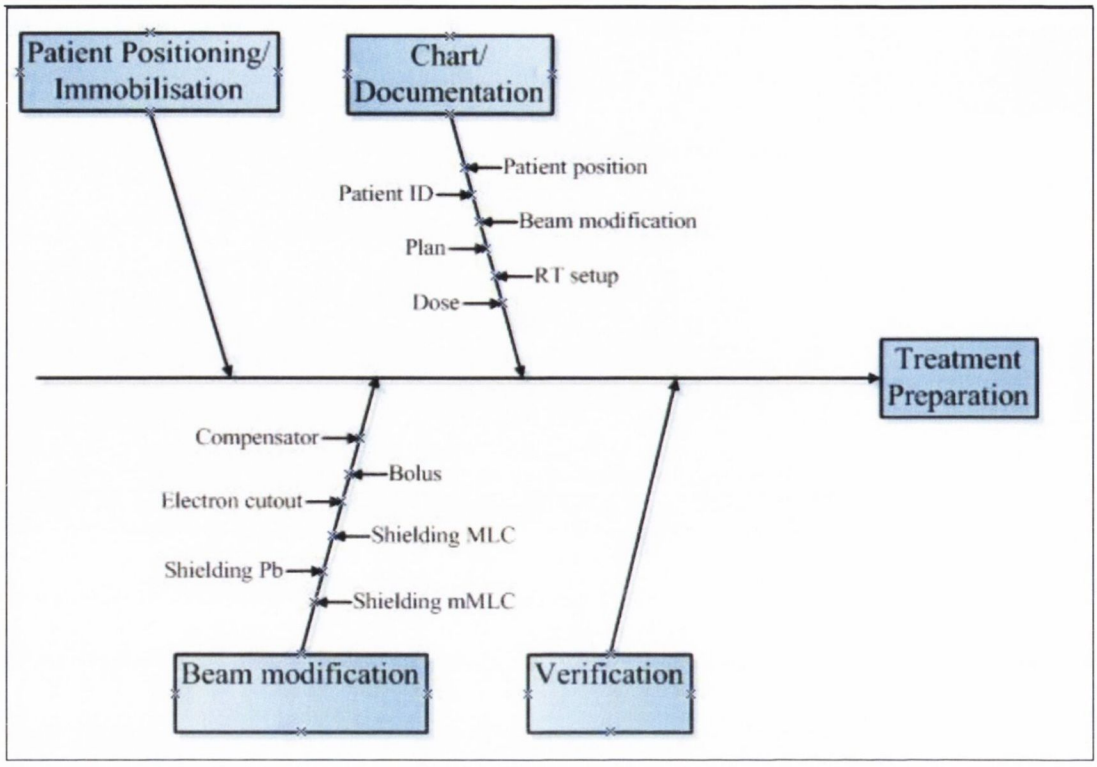

Figure 4-35: Treatment Preparation Phase of Process Classification

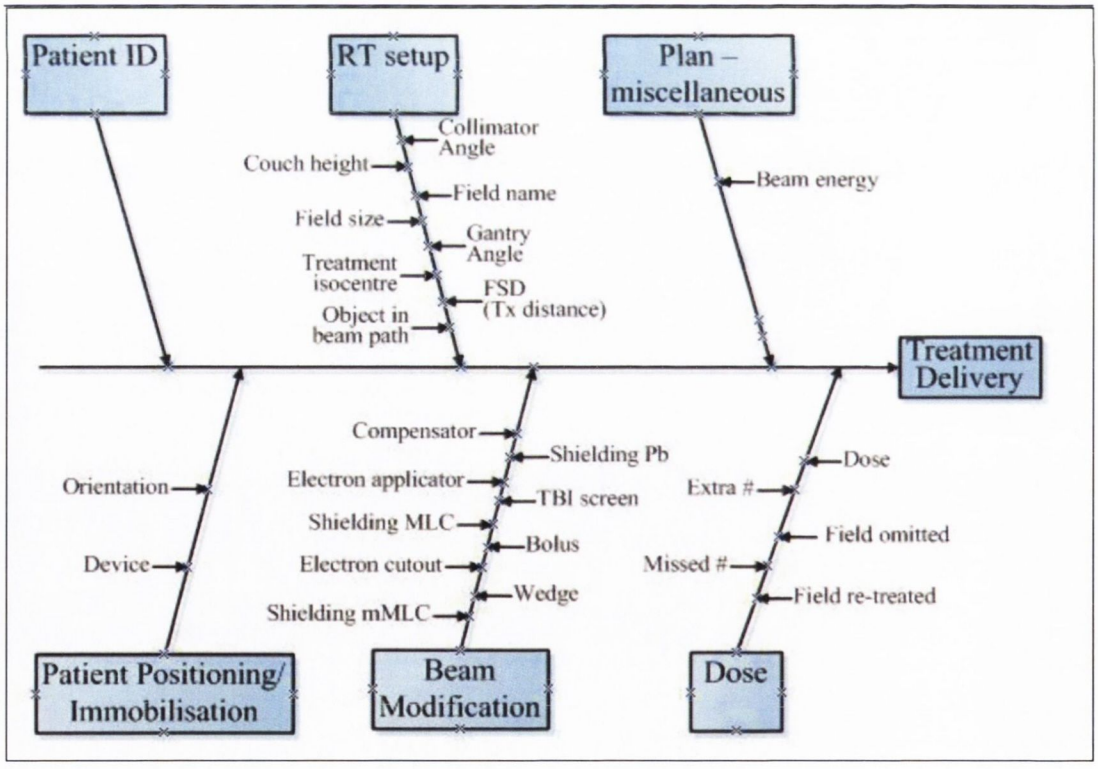

Figure 4-36: Treatment Delivery Phase of Process Classification

4.4.3.2 ROSIS Severity/ Outcome Classification

The data items requested under "severity" are shown in Figure 4-37.

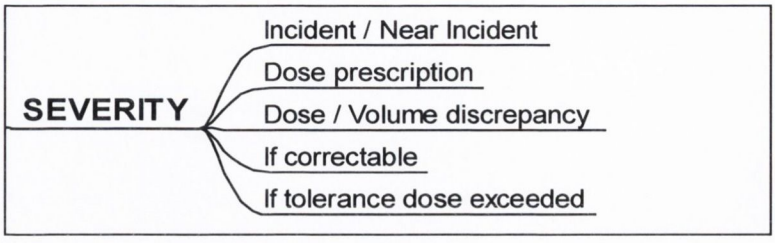

Figure 4-37: ROSIS Severity Classification

Under the category of severity, the questions differ somewhat depending on whether or not there was any irradiation given incorrectly (Table 4-14). In either case, there is a question as to what the dose/volume discrepancy per fraction was or would have been. In the case of incorrect treatment, the prescribed dose, dose per fraction, number of fractions, and treatment schedule are requested. In addition details are sought on whether or not it was corrected/correctable, whether the tolerance of any organ at risk was exceeded, and if so, further details.

When the questions have been answered, a severity score will be automatically assigned to the incident, which idea is generally based on NCC MERP index for categorising medication errors [130]. An example of this can be seen in Table 4-15. In this Table, the ROSIS outcomes are also mapped to the WHO ICPS descriptors described earlier, where ambiguity is visible towards the higher end of the scale based on dose discrepancies.

Table 4-14: ROSIS Questions on Severity

1. Was any part of treatment delivered incorrectly?	a. YES	i. How many fractions were delivered incorrectly?
		ii. How many fractions were prescribed in total?
		iii. What was the prescribed Dose/Fraction (Gy)?
		iv. AND/OR What was the prescribed total dose (Gy)?
		v. How was the treatment scheduled? – *e.g.* once daily, 5 days a week once daily, 7 days a week twice daily, 5 days a week once weekly other
	b. NO	
2. *If from*		
a. *Q 1b* "If the error did reach the patient, what would have been the <u>effect per fraction</u> in terms of dose and/or treated volume?	Select the most appropriate category:	i. Less than 5% per fraction
		ii. Between 5% and 9% per fraction
		iii. Between 10% and 24% per fraction
b. *Q 1a* "What was the <u>effect per fraction</u> in terms of dose and/or treated volume?		iv. Between 25% and 49% per fraction
		v. Between 50 and 99% per fraction
		vi. Greater than 100% per fraction
3. *(If from Q2b)* Was this error corrected?	a. YES	
	b. NO	
	i. Not correctable	
	ii. Not required	
4. Was the tolerance dose of any organ at risk exceeded?	a. YES	i. Name the organ and the dose received.
	b. NO	

Table 4-15: ROSIS Categories of Incident Severity and Outcomes

	Dose discrepancy	ROSIS Outcome	WHO Outcome
A	Error occurred but didn't reach patient	No harm	None
B	Error reached patient, but no harm resulted (< 5% difference in Total dose and/or treated volume)		None
C	Error reached patient & resulted in 5-9% error of total dose and/or treated volume	Slightly increased risk of adverse effects	Mild
D	Error reached patient & resulted in 10-24% error of total dose and/or treated volume	"Moderately" increased risk of adverse effects	Moderate
E	Error reached patient & resulted in 25-49% error of total dose and/or treated volume	Greatly increased risk of adverse effects (leading to serious patient injury or death)	Severe
F	Error reached patient & resulted in 50-99% error of total dose and/or treated volume	Probable serious patient injury / death	Severe / Death
G	Error reached patient & resulted in > 100% error of total dose and/or treated volume		Severe / Death

4.4.3.3 ROSIS Causes and Contributing Factors Classification

Both causes and contributing factors are included here under a combined category.

Initially, a list was derived from a mix of different sources:

- Framework of factors influencing clinical practice [55, 59]
- IAEA Safety Series 17 [34]
- International Taxonomy of errors in primary care

This resulted in another multi-layered system (Table 4-16, for full list see Section 4.5.2.3).

Table 4-16: Number of items per level of Causes/ Contributing factors classification

Level of Classification	Number of items
Level 1	10
Level 2	49
Level 3	20

This was later revised to include only four items (in addition to "Don't Know"), as per the categories of the Eindhoven Classification Model:

- Technical
- Organisational
- Human
- Other

4.4.3.4 ROSIS Event/ Occurrence Classification

Data elements (information) required for this category are outlined in Figure 4-38. The Description is freetext, all other categories have multiple choice answers (see Section 4.5.2). The Process Classification is a major component of this category, and has already been described. Chapter 5 will illustrate how these elements are incorporated into the dynamic reporting system.

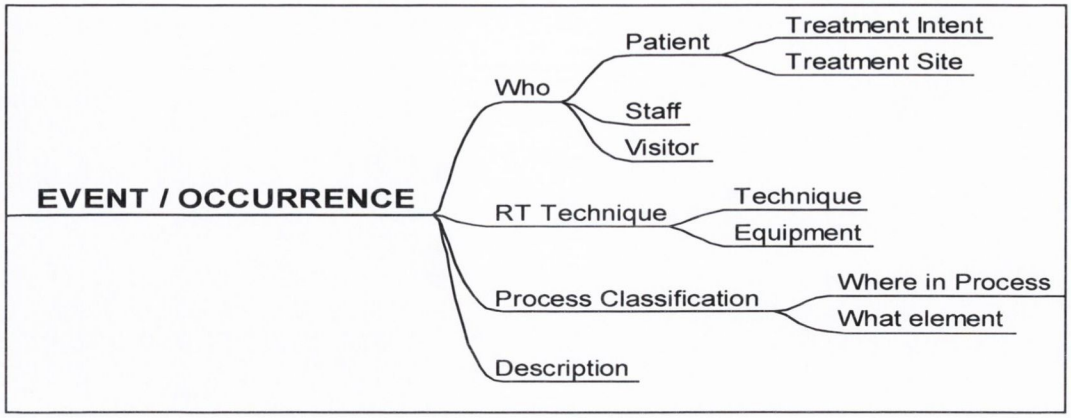

Figure 4-38: ROSIS Category of Event/ Occurrence

4.4.3.5 ROSIS Detection Classification

In the ROSIS classification, information is sought on

- How the error is detected (QA process / other)
- Which discipline detected the error
- At what stage in the process the error was detected

The integration of these elements into the dynamic reporting system is outlined in Chapter 5.

4.4.4 Process Classification Frequency Analysis

In total, 500 ROSIS reports were classified by one individual according to these process classifications. The results can be seen from Figure 4-39 to Figure 4-46, where the numbers allocated to each item represent the number of incidents related to that item. Level 3 items (the items on the branches) are colour-coded so that their position on the branch illustrates the range of reports received per item.

For example, in Figure 4-41 there were 46 reports under the Simulation phase, 29 of these related to Recording Parameters, of which 10-19 were due to recording field design parameters, 5-9 recording the isocentre position, and between 0-4 recording the patient position, accessories, separation or films.

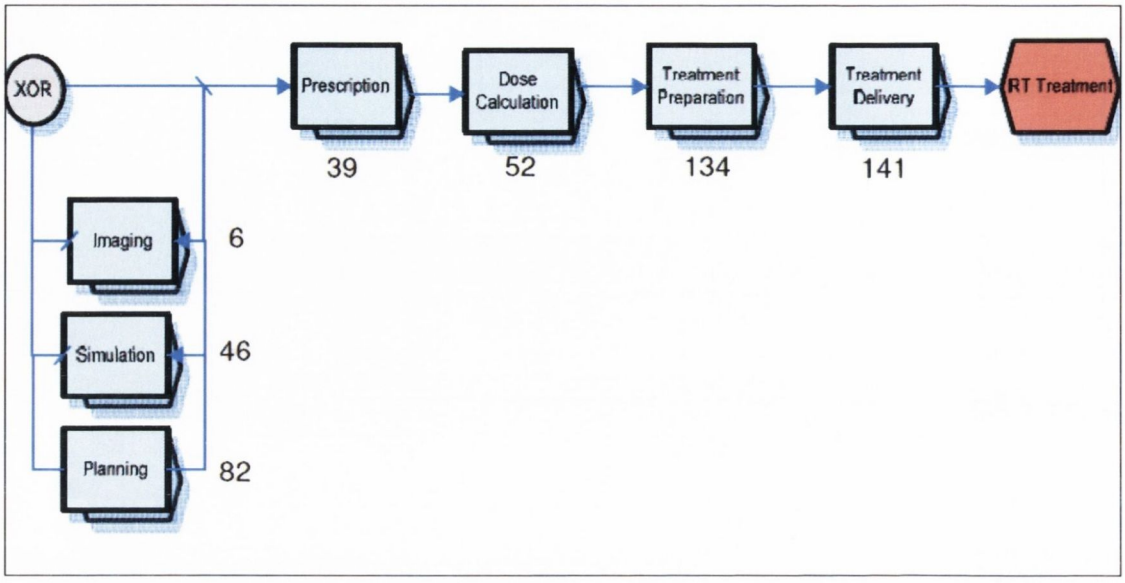

Figure 4-39: ROSIS Process Classification, Level 1. Distribution of 500 incident reports.

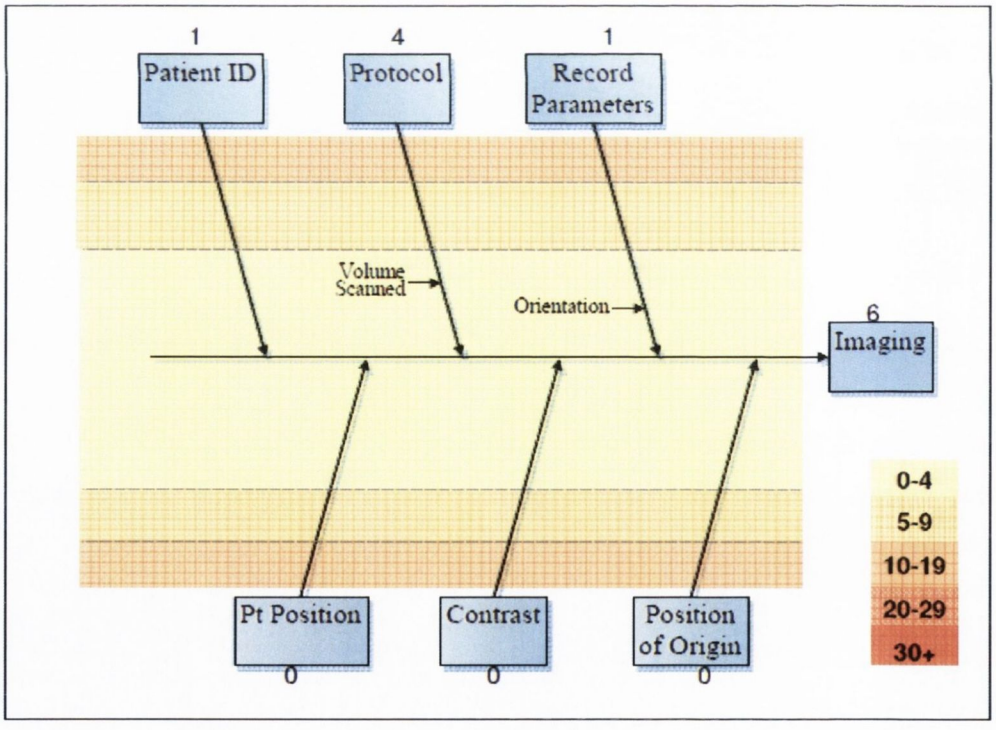

Figure 4-40: Distribution of incidents at Imaging phase of ROSIS Process

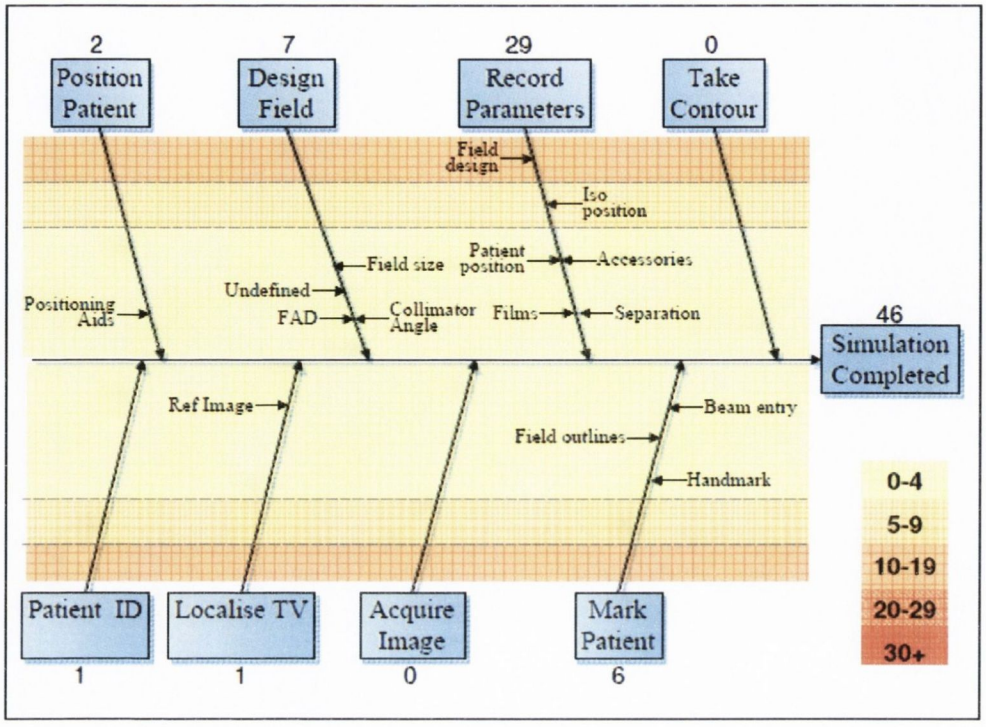

Figure 4-41: Distribution of incidents at Simulation phase of ROSIS Process

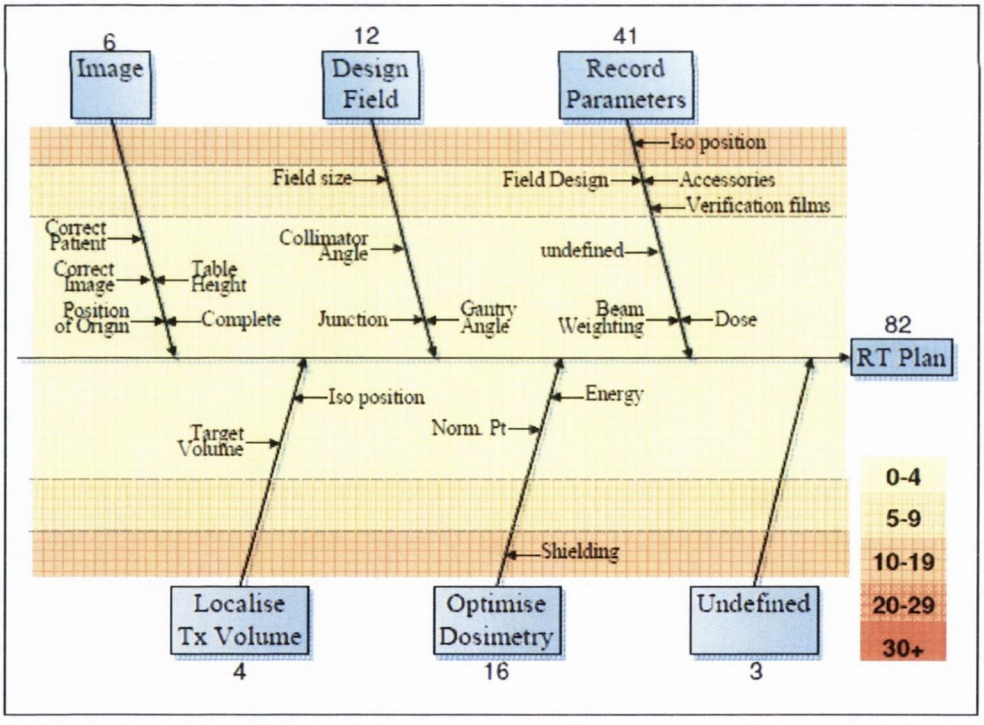

Figure 4-42: Distribution of incidents at RT Planning phase of ROSIS Process

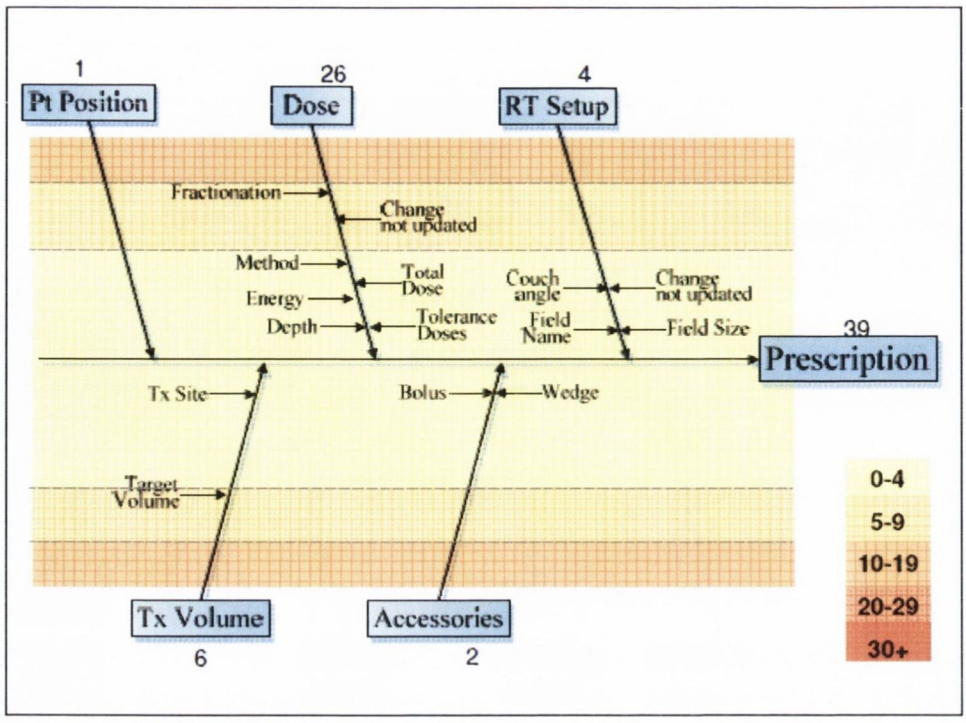

Figure 4-43: Distribution of incidents at Prescription phase of ROSIS Process

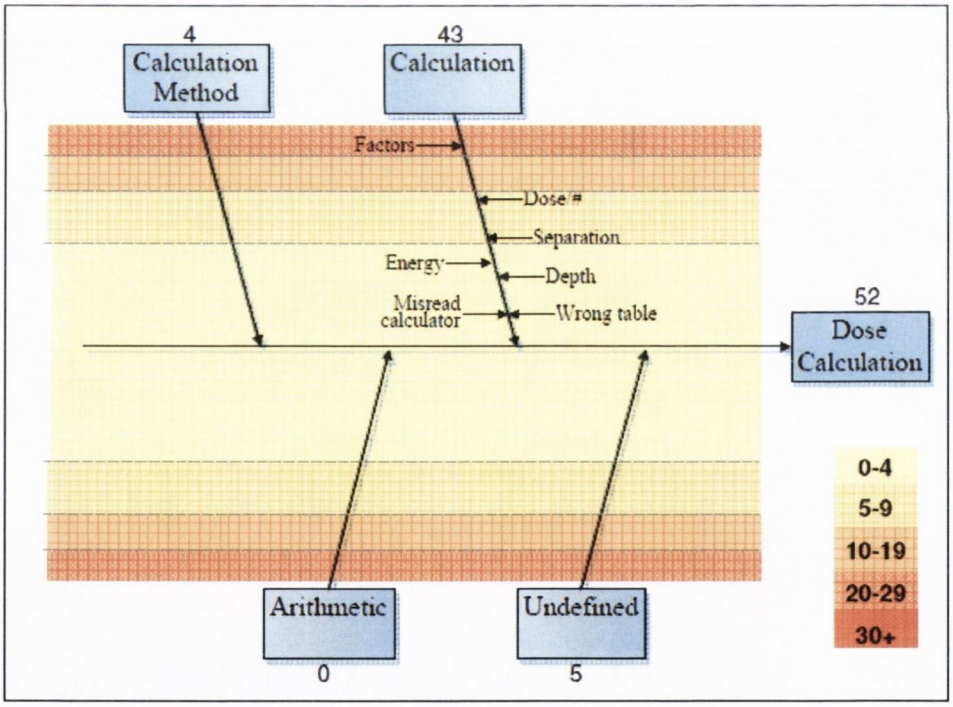

Figure 4-44: Distribution of incidents at Dose Calculation phase of ROSIS Process

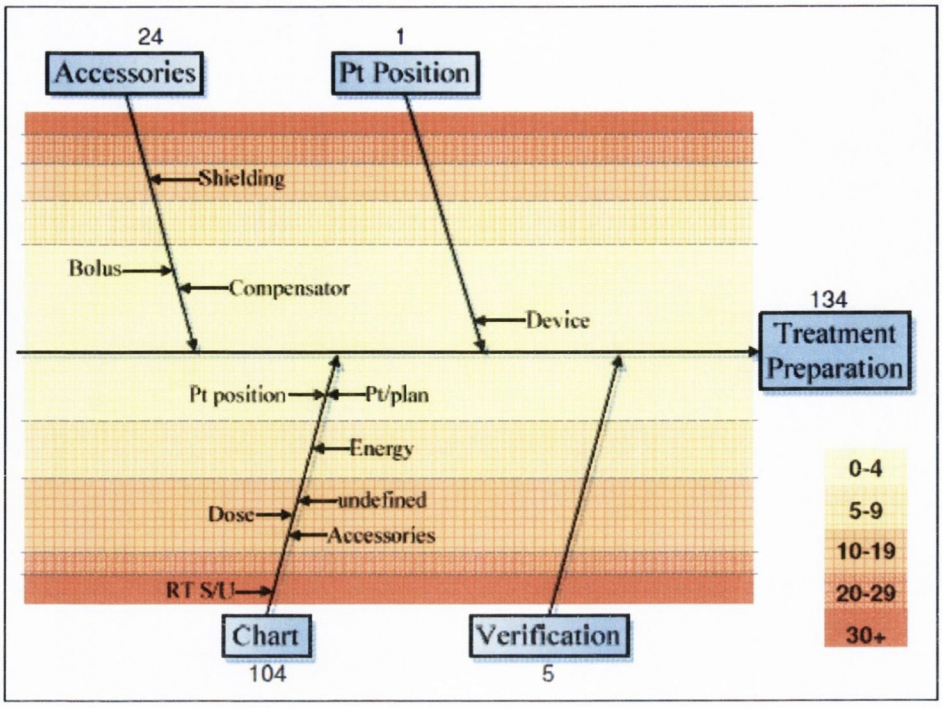

Figure 4-45: Distribution of incidents at Treatment Preparation phase of ROSIS Process

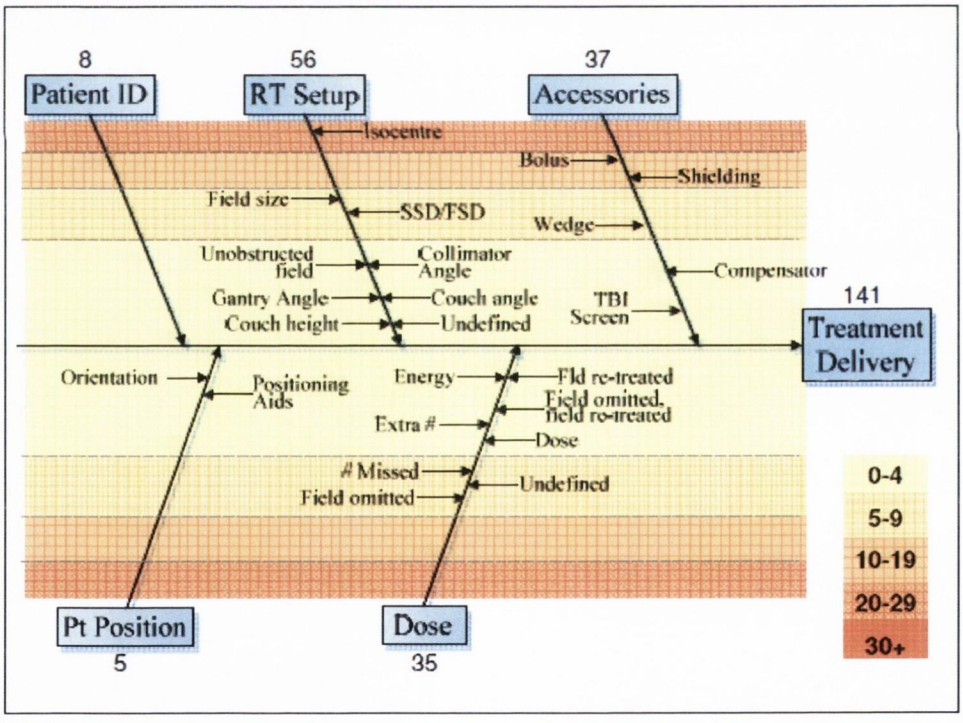

Figure 4-46: Distribution of incidents at Treatment Delivery phase of ROSIS Process

4.5 INTEGRATION OF CLASSIFICATION SYSTEM INTO DEPARTMENT AND INCIDENT FORMS

A dataset was defined based on the Classification. Questions were designed to capture the required information. In some cases, answer options were given; other questions required narrative answers. In order to reduce the number of questions asked of the reporter, dynamic forms were designed, where the next question depends on the answer to a previous question.

The questions and their possible answers and answer formats are given in the following pages.

The department dataset begins on page 149.
The incident dataset begins on page 154;

- Questions eliciting the origin of the incident in the RO process - page 158;
- Questions eliciting the severity of the incident - page 167;
- Questions eliciting the cause/contributing factor of the incident - page 169.

An illustration of how these questions work in practice can be seen in Appendix I (p301), where the information from three existing ROSIS Incident Reports have been used to answer the questions of this revised ROSIS Dataset.

4.5.1 Dataset for Department Form

Contact details

Dept/Hospital name and address	Freetext
Name of contact person	Freetext
Email of contact person	Freetext
Phone number of contact person	Freetext

Department Infrastructure

Approximate number of patients per year: (New patients receiving radiotherapy)		*Number*		
Estimate proportion of CT based treatment plans		*Number(%)*		
Type and number of equipment in your department	Select multiple options	CT	How many units?	*Number*
		MRI	How many units?	*Number*
		PET	How many units?	*Number*
		Ultrasound	How many units?	*Number*
		Conventional simulator	How many units?	*Number*
		Cone-beam simulator	How many units?	*Number*
		Virtual CT-Simulator	How many units?	*Number*
		Other (specify)	How many units?	*Number*
		LA (photons/electrons)	How many units?	*Number*
		Orthovoltage	How many units?	*Number*
		Co-60	How many units?	*Number*
		Brachytherapy	How many units?	*Number*

		Intraoperative RT	How many units?	*Number*
		Radio-isotopes	How many units?	*Number*
		Gammaknife	How many units?	*Number*
		Cyberknife	How many units?	*Number*
		Other (specify) (e.g.neutrons/protons/light ions)	How many units?	*Number*
Network	Tick one or several boxes that best describes your department	None		
		Treatment planning system sends RT parameters to treatment unit		
		Simulator sends RT parameters to treatment unit		
		Full networking of RT parameters (i.e. field size settings, MU etc.)		
		Full networking of RT images (i.e. electronic portal images, DRR etc.)		
Record and verify system (R&V):	Select the most appropriate alternative.	No treatment unit has R&V		
		Some treatment units have R&V		
		All treatment units have R&V		
Staffing (FTEs)	Please specify how many FTE of each staff are in your dept	Radiation Oncologist (physician)	*Number*	
		medical physicist	*Number*	
		radiation therapist at treatment unit	*Number*	
		radiation therapist at simulator and/or in-house Ct	*Number*	
		staff doing dosimetry	*Number*	
		staff doing technical maintenance	*Number*	
		other *(please specify category----freetext-----)*	*Number*	
Maintenance	How is the majority of your maintenance of the equipment performed		*select one*	inhouse service service contract

Department Treatment modalities / techniques

What treatment modalities / techniques are you currently using? *(multiple selection possible)*	LA - Photons	2-D RT		
		2.5D RT		
		3-D CRT		
		4-D / Gating	*freetext for details of method*	
		IMRT	Dynamic	*one selection possible*
			Static	
		Stereotactic	Radiosurgery	*multiple selections possible*
			Radiotherapy	
			Intra-cranial	
			Extra-cranial	
		TBI		
		HBI		
	LA- Electrons	TSEI		
		Skin Apposition		
	Orthovoltage			
	Co-60			
	Brachytherapy	HDR	*multiple selections possible*	
		LDR		
		2-D		
		3-D		
		4-D		
	Intraoperative RT			
	Radio-isotopes			
	Protons			
	Neutrons			

	Light ions		
	Gammaknife		
	Cyberknife		
	Other (give details --- *freetext*----)		

Quality Assurance procedures in the department

QA / Defences	*Select the options that best describe the QA system at your department*	Treatment charts are independently checked before treatment begins
		Treatment charts are routinely checked during treatment
		Data entry into record and verify is independently checked
		In-vivo dosimetry is used for most new patients
		Peer-review (planning conference) is done for most new patient prescriptions (dose and location)
		Portal or volumetric images are taken for most new patients (films or electronic)
		Regular clinical review (of side effects etc.) of most patients
		Written quality control procedures and records for most treatment unit checks
		Written procedures for most of the clinical processes
		Formal quality management system (ISO etc.)
		Regular QC of treatment units
		External dosimetry audit by EQUAL or by other, please specify *---freetext---*
		Other QA, please specify *---freetext---*

Local Risk Management

Do you have a dedicated member of staff for risk management / quality assurance			*Y/N*
Reporting system	Is your reporting system:	*select one*	Mandatory
			Voluntary
		select one	Confidential

			Anonymous		
	Copy of report form		*request to be sent*		
Feedback to staff	Is feedback given to staff?		*Y/N*	If Yes, Give details …	*freetext*
Committee	Do you have a risk management committee?		*Y/N*		
	Composition of committee		*freetext*		
	How long in existence		*number (years)*		
	How often does the committee meet		*freetext*		
	Methods of analysis / investigation		*freetext*		

4.5.2 Dataset for Incident Form

Incident	Description / Keyword	*freetext*			
	Who did it affect?	*Select option(s)*	One patient		
			Several patients	How many?	*Number*
			Staff	How many?	*Number*
			Visitor(s)	How many?	*Number*
		If patient(s), what was the treament intent?	*Select option*	Radical	*one option possible*
				Palliative	
				Prophyllactic	
				Benign disease	
Occurrence	Treatment Technique	*select option (one only)*	LA - Photons	2-D RT	
				2.5D RT	
				3-D CRT	
				4-D / Gating	*freetext for details of method*
				IMRT	Dynamic *one selection possible*
					Static
				Stereotactic	Radiosurgery *multiple selections possible*
					Radiotherapy
					Intra-cranial
					Extra-cranial
				TBI	
				HBI	
			LA- Electrons	TSEI	
				Skin Apposition	
			Orthovoltage		
			Co-60		
			Brachytherapy	HDR	*multiple selections*
				LDR	

				2-D	possible
				3-D	
				4-D	
			Intraoperative RT		
			Radio-isotopes		
			Protons		
			Neutrons		
			Light ions		
			Gammaknife		
			Cyberknife		
			Other (give details --- *freetext*----)		
	Treatment Site	*select option*	Brain	*one selection possible*	
			Head and Neck		
			Thorax		
			Breast		
			Abdomen		
			Pelvis		
			Extremity		
			TBI		
			HBI		
	Where/when in process	*select from lists*	*Pick activity from sheet **"process"***	*one "tree" possible*	
	Description *(the details)*	*freetext*			
	Cause	*freetext*			
	How / why	*select option(s)*	*Pick from sheet "Causes_Contributing factors"*	*multiple selections possible*	
	Hardware (if involved)	*freetext*			
	Who - what discipline	*select option(s)*	Radiation Oncologist (physician)	*multiple selections possible*	
			medical physicist		
			radiation therapist at treatment unit		

			radiation therapist at simulator and/or in-house Ct	
			staff doing dosimetry	
			staff doing technical maintenance	
			other *(please specify -------freetext-----)*	
Detection	Where/when in process	*select from list*	Imaging	*one selection possible*
			Simulation	
			Planning	
			Prescription	
			Dose calculation	
			Treatment Preparation	
			Treament Delivery	
	How / why	*Select option(s)*	Chart-check - pre-treatment	*multiple selections possible*
			Chart-check - during treatment	
			in-vivo dosimetry	
			portal imaging	
			volumetric imaging	
			clinical review of patient	
			quality control of equipment	
			found at time of 1st patient treatment during regular checks	
			found at later stage during patient treatment	
			external audit	
			other (please specify -------freetext-----)	
	Who - what discipline	*select option(s)*	Radiation Oncologist (physician)	*multiple selections possible*
			medical physicist	
			radiation therapist at treatment unit	

			radiation therapist at simulator and/or in-house Ct	
			staff doing dosimetry	
			staff doing technical maintenance	
			other *(please specify -------freetext-----)*	
Severity	*See sheet "severity"*	potentially 5 questions		
Suggestions for future prevention	freetext			

4.5.2.1 Dataset for Process Classification

During which activity did the error occur?					
Imaging	What activity of imaging did it involve?	Identifying the patient			*... give details*
		Positioning the patient			*... give details*
		Scanning the patient	Did the error involve:	volume scanned?	*... give details*
				use of contrast?	*... give details*
		Marking the patient			*... give details*
		Documenting the procedure	Which parameter was affected?	patient position	*... give details*
				position of origin	*... give details*
		Other			*... give details*
Simulation *(including handmark)*	What activity of simulation did it involve?	Identifying the patient			*... give details*
		Positioning the patient			*... give details*
		Localising the target volume			*... give details*
		Designing the RT Set-Up	Which parameter was affected?	Collimator angle	*... give details*
				Couch angle	*... give details*
				Couch height	*... give details*
				Field size	*... give details*
				Gantry angle	*... give details*
				Object in beam path	*... give details*
				FSD (Tx distance)	*... give details*
				Treatment isocentre	*... give details*

		Acquiring the simulation image	What modality was used?	Conventional 2D simulation			… *give details*
				Cone-beam simulation			… *give details*
				Virtual (CT) simulation			… *give details*
				Other			… *give details*
		Marking the patient	Did the error involve …	Handmarking patient without simulation?			… *give details*
				Marking on the treatment set-up marks?			… *give details*
				Marking on the field outlines and/or beam entry points at simulation?			… *give details*
		Taking a patient contour					… *give details*
		Documenting the procedure	Which parameter was affected?	Patient position			
				RT Set-up	What was incorrectly documented / omitted?	Collimator angle	… *give details including where to be recorded to*
						Couch angle	
						Couch height	
						Field size	
						Field name	
						Gantry angle	
						Object in beam path	
						FSD (tx distance)	
						Treatment isocentre	
						Other	
				Details of any beam modification	What was incorrectly documented / omitted?	Bolus	
						Wedge	
						Shielding	
						Compensator	

					TBI Screen
					Electron applicator
					Electron cutout
					Other
				Patient separation	*... give details including where to be recorded to*
				Patient contour	*... give details including where to be recorded to*
		Other			*... give details*
Planning	What activity of planning was affected?	Retrieving and preparing the image for planning	Which parameter was affected?	Incorrect patient	*... give details*
				Incorrect image for correct patient	*... give details*
				table height	*... give details*
				position of origin / zero slice	*... give details*
		Localising the target volume			*... give details*
		RT set-up	Which parameter was affected?	collimator angle	*... give details*
				Couch angle	*... give details*
				couch height	*... give details*
				field name	*... give details*
				field size	*... give details*
				gantry angle	*... give details*
				object in beam path	*... give details*
				FSD (tx distance)	*... give details*
				Treatment isocentre	*... give details*
		Plan - miscellaneous	Which parameter was affected?	beam energy	*... give details*
				Beam weighting	*... give details*
				junction position	*... give details*
				normalisation point	*... give details*
				plan feasibility (Space/collision)	*... give details*
		Beam modification	Which parameter	Bolus	*... give details*

			was affected?	Compensator			… give details
				Electron applicator			… give details
				Electron cutout			… give details
				Shielding - MLC			… give details
				Shielding - mMLC			… give details
				Shielding - Pb			… give details
				TBI Screen			… give details
				Wedge			… give details
		Documenting the procedure	Which parameter was affected?	Patient position			… for all of these "give details including where to be recorded to"
				RT Set-up	What was incorrectly documented / omitted?	collimator angle	
						Couch angle	
						couch height	
						field name	
						field size	
						gantry angle	
						object in beam path	
						FSD (tx distance)	
						Treatment isocentre	
				Plan - miscellaneous	What was incorrectly documented / omitted?	beam energy	
						Beam weighting	
						junction position	
						normalisation point	
				Beam modification	What was incorrectly documented / omitted?	Bolus	
						Compensator	
						Electron applicator	
						Electron cutout	
						Shielding - MLC	
						Shielding - mMLC	
						Shielding - Pb	

					TBI Screen	
					Wedge	
					Other	
				Verification films/DRRs		
				Other		
		Other				*... give details*
Prescription	What activity of prescribing was affected?	Patient position				*... give details*
		Target volume	What was incorrect about the target volume?	Treatment site (e.g. wrong side)		*... give details*
				Extent of target volume (extent)		*... give details*
				Other		*... give details*
		Dose	What was incorrect about the dose?	fractionation		*... give details*
				change not updated		*... give details*
				method		*... give details*
				total dose		*... give details*
				tolerance doses		*... give details*
				energy of beam		*... give details*
				depth		*... give details*
				Other		*... give details*
		Beam modification	Which accessory was affected?	Bolus		*... give details*
				Compensator		*... give details*
				Electron applicator		*... give details*
				Electron cutout		*... give details*
				Shielding - MLC		*... give details*
				Shielding - mMLC		*... give details*
				Shielding - Pb		*... give details*
				TBI Screen		*... give details*
				Wedge		*... give details*
				Other		*... give details*
		RT Setup	What was	Collimator angle		*... give details*

			incorrect about the RT Set-up parameters?	Couch angle		… give details
				Couch height		… give details
				Field size		… give details
				Field name		… give details
				Gantry angle		… give details
				Object in beam path		… give details
				FSD (tx distance)		… give details
				Treatment isocentre		… give details
				Other		… give details
		Other				… give details
Dose Calculation	What activity of dose calculation was affected?	Calculation method				… give details
		Arithmetic				… give details
		Calculation	What was incorrect about the calculation?	Use of factors	Incorrect factor (value)	… give details
					Omitted factor	… give details
					Used factor where not required	… give details
				Dose per fraction		… give details
				Separation		… give details
				Energy		… give details
				Depth		… give details
				Misread calculator		… give details
				Wrong tables		… give details
				Other		… give details
		Other				… give details
Treatment Preparation *(including verification)*	What activity of treatment preparation was affected?	Beam modification	Which accessory was affected?	Bolus		… give details
				Wedge		… give details
				Compensator		… give details
				Other		… give details
		Chart (paper /	**1. Was the error**	Patient position		… for all

		electronic)	**in:** i. the paper chart, ii. the electronic chart, or iii. both? **2. What parameter was incorrect?**	RT Set-up	What was incorrectly documented / omitted?	collimator angle	*of these "give details including where to be recorded to"*
						Couch angle	
						couch height	
						field name	
						field size	
						gantry angle	
						object in beam path	
						FSD (tx distance)	
						Treatment isocentre	
				Plan - miscellaneous	What was incorrectly documented / omitted?	beam energy	
						Field matching	
						Beam weighting	
				Beam modification	What was incorrectly documented / omitted?	Bolus	
						Compensator	
						Electron applicator	
						Electron cutout	
						Shielding - MLC	
						Shielding - mMLC	
						Shielding - Pb	
						TBI Screen	
						Wedge	
						Other	
				Dose	What was incorrectly documented / omitted?	fractionation	
						change not updated	
						total dose	
						tolerance doses	

				Other		Other	
		Pt positioning device					... give details
		Verification					... give details
		Other					... give details
Treatment Delivery	What activity of treatment delivery was affected?	Patient identification					... give details
		Patient positioning	what was incorrect	Patient orientation relative to machine			... give details
				Positioning aid incorrectly used			... give details
		RT set-up	Which parameter was affected?	collimator angle			... give details
				Couch angle			... give details
				couch height			... give details
				field name			... give details
				field size			... give details
				gantry angle			... give details
				object in beam path			... give details
				SSD / FSD (tx distance)			... give details
				Treatment isocentre			... give details
		Plan - miscellaneous	Which parameter was affected?	beam energy			... give details
		Beam modification	Which parameter was affected?	Bolus			... give details
				Compensator			... give details
				Electron applicator			... give details
				Electron cutout			... give details
				Shielding - MLC			... give details
				Shielding - mMLC			... give details
				Shielding - Pb			... give details
				TBI Screen			... give details

				Wedge	*... give details*
		Dose	what was incorrect?	field was omitted	*... give details*
				field was re-treated	*... give details*
				fraction was missed	*... give details*
				extra fraction was given	*... give details*
				dose (value) was incorrect	*... give details*
		Other			*... give details*

4.5.2.2 Initial Dataset for Severity / Outcome Classification

1. Was any part of treatment delivered incorrectly?	a. YES	i. How many fractions were delivered incorrectly?	
		ii. How many fractions were prescribed in total?	
		iii. What was the prescribed Dose/Fraction(Gy)?	
		iv. ?AND/OR What was the prescribed total dose (Gy)?	
		v. How was the treatment scheduled? – *select as applicable*	1. 1 fraction per day
			2. 2 fractions per day
			3. 3 fractions per day
			4. 2 fractions per week
			5. 1 fraction per week
			6. Treatment on weekdays
			7. Treatment on Saturday
			8. Treatment on Saturday
			9. Other _____*(details)*
	b. NO		
2. *If from*			
a. *Q 1b* **"If the error did reach the patient, what would have been the <u>effect per fraction</u> in terms of dose and/or treated volume?**	**Select the most appropriate category:**	i. Less than 5% per fraction	
		ii. Between 5% and 9% per fraction	
		iii. Between 10% and 24% per fraction	
b. *Q 1a* **"What was the <u>effect per fraction</u> in terms of dose and/or**		iv. Between 25% and 49% per fraction	
		v. between 50 and 99% per fraction	

treated volume?		vi. Greater than 100% per fraction	
3. *(If from Q2b)* **Was this error corrected?**	a. YES		*Q 3 – include free-text box for Details*
	b. NO		
	i. Not correctable		
	ii. Not required		
4. Was the tolerance dose of any organ at risk exceeded?	a. YES	i. Name the organ and the dose received.	Q4 – free-text box
	b. NO		
5. Could this error have been detected by ***(tick all that apply)***	a. Portal imaging?		
	b. Volumetric imaging?		
	c. Central axis in-vivo dosimetry?		
	d. Off-axis in-vivo dosimetry?		
	e. Thorough chart check?		

Other possible questions, depending on Severity:

What symptoms had patient? How did you manage these?

#what measurements - chromosome abberations etc…

4.5.2.3 Initial Dataset for Causes/Contributing Classification

Reporter instructions:

Please choose the factors below that may have caused and/or contributed to the error

Please tick all that apply

A box is provided for further details

1. Don't Know		
2. Organisational / Management factors	a. Financial resources	
	b. Lack of emphasis on safety or a safety culture	
	c. Lack of or outdated procedures / protocols	
	d. Lack of quality assurance or defence in depth	
	e. Other	
3. Work environment factors	a. Heavy workload	
	b. Inadequate staffing level / Inadequate skills mix	
	c. Assignment or placement of inexperienced personnel	
	d. Patient treated after-hours (weekdays) or at weekend	
	e. Equipment: design, availability and maintenance (ii – v taken from IAEA)	i. Old/inadequate equipment
		ii. Insufficient redundancy in the design of equipment *(e.g. single fault criterion, interlock failure);*
		iii. Software problems;
		iv. Hardware incompatibilities in equipment and accessories *(e.g.wedge or shielding block incompatible with coding system, or ionization chamber that does not fit an electrometer);*

		v. Possibility of operating the equipment in a 'non-clinical mode' with the key in the usual 'beam-on' position
		vi. Computers not linked/networked for electronic transfer
		vii. Other
	f. Distracting work conditions leading to loss of concentration	
	g. Missing or inconsistent information (e.g. documentation insufficient)	
	h. Boring/monotonous task – loss of concentration	
	i. Not enough physical working space	
	j. Noise	
	k. Lighting	
	l. Other	
4. Task factors	a. Task design inappropriate	
	b. No, unclear, or unknown protocol for task	
	c. New technique	
	d. Change in regular routine	
	e. Human-machine problems *(from IAEA)*	i. Problems of human-machine interface
		ii. Bypassing of interlocks and operation in a 'non-clinical mode'
		iii. Maintenance problems
		iv. Other
	f. Other	
5. Human Factors	a. Lack of attention to detail	

	b. Failure to follow procedures / protocols	
	c. Failure to check or read documentation	
	d. Other	
6. Individual (Staff) factors (including Training and education)	a. Inadequate knowledge	i. Lack of clinical knowledge
		ii. Lack of physics knowledge
		iii. Lack of knowledge about equipment / software
		iv. Other
	b. Inadequate experience	i. Staff member in training
		ii. Performing an unfamiliar task
		iii. Unfamiliar technique / dose
		iv. Other
	c. Staff physical and/or mental health	
	d. Other	
7. Teamwork	a. Lack of leadership	
	b. Lack of delegation	
	c. Roles and responsibilities confused	
	d. Inadequate supervision of staff or student	
	e. Senior/Experienced staff unavailable for advice	
	f. Team unfamiliar with working together	
	g. New staff or Temporary staff	
	h. Interpersonal problems among staff	
	i. Other	
8. Communication (including documentation)	a. Verbal miscommunication	
	b. Written miscommunication	i. Misread or didn't read
		ii. Illegible handwriting

		iii. Use of Abbreviations or acronyms not understood by all
		iv. Number - Trailing zero(2.0), Leading zero(02), or Decimal point
		v. Other
	c. Non-metric use of measurement	
	d. Mistakes in reading or transferring information (paper or electronic)	
	e. Failure to update documentation (paper or electronic)	
	f. Incomplete or poorly written instruction manuals	
	g. Communication within one discipline/department	
	h. Communication with staff from other disciplines/departments	
	i. Communication with patient	
	j. Misunderstanding of communication in a foreign language (verbal or written)	
	k. Other	
9. Patient factors	a. Patients with same /similar names	
	b. Patient unable to co-operate (due to condition)	
	c. Patient distressed and/or very anxious	
	d. Difficulty communicating with patient (language, speech, hearing, level of consciousness etc)	
	e. Other	
10. Other		

+ BOX FOR FURTHER DETAILS

5 Chapter 5: Discussion

5.1 INTRODUCTION

This thesis aims to

1. Describe the development of ROSIS – a voluntary external online reporting and learning system in radiation oncology
2. Analyse the data collected by ROSIS from 2003-2008
3. Define a classification system for the collection and analysis of information on incidents in RO
4. Develop a revised reporting and learning system and make recommendations for further development of this

The discussion will consider the department and incident information in the ROSIS database, and what lessons can be learned for RO safety. It will then explore the collection of a more detailed dataset through the proposed classification, and the revision of the initial reporting and learning system to enhance the lessons learned and methods of dissemination.

Care must be taken in interpreting data from reporting systems. Since reporting systems are dependent on people to report (and initially, to identify) incidents, they may not reflect the true scenario. Therefore, it must be remembered that voluntary incident reporting may not reveal the true cross-section of incidents (although it is likely that neither does most mandatory reporting) [107]; and that all reporting is subject to biases – not all types of incidents might be reported, nor the true frequency of each incident type, nor the absolute relative frequency of the incidents [107].

Nonetheless, incident data can be used to

- "prove the existence of a safety issue,
- understand its possible causes,
- define potential intervention strategies, and
- track the safety consequences once intervention has begun" [107]

According to Chappell, "caution should always be used when employing incident data to determine the prevalence of a safety problem . . . [as] the relationship between incidents that are reported and those that occur is not known". From the

ROSIS reports we know that particular types of mistakes occur in RO – but we don't have information about their magnitude. We know some of the forms it can take, but we can't say we know them all. Nonetheless, we can prove that mistakes still exist in RT – meaning that at a local level, preventative strategies may be implemented or reviewed. Further research using different methodologies may be required to investigate specific details of incident occurrence, or to verify report data.

Percentages are used here to compare incident occurrence, and the term "reported" is used to convey the fact that the above biases may be inherent in the data.

5.2 ROSIS DEPARTMENTS AND REPORTS

A major strength of ROSIS is that it enables direct analysis of reports from different departments and clinical situations internationally; this current analysis includes 101 departments and 1074 reports.

Recruitment of departments was initially focussed within Europe, but over time has become more international. As of early 2009, 101 departments have registered with ROSIS; initially registered departments were located mainly within Europe, but there is now a more diverse global distribution of departments in ROSIS. Based on new patient numbers, the potential patient population covered by ROSIS is 150,000. According to the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) [61] approximately 0.9 per 1,000 inhabitants receive radiotherapy annually. With a world population of seven billion, this means that ROSIS covers approximately 2.4% of all radiotherapy patients.

Infrastructure and resources are identified as important contributors to patient safety. Within the departments reporting to ROSIS, there is substantial variation in terms of infrastructure, and resources, both overall, and per patient population. The patient population of 150,000 is served by a total of 343 Megavoltage (MV) units (Linac and Co-60), and an average of 437 patient treatments per MV unit per year. This is slightly less than the QUARTS (QUAntification of Radiation Therapy Infrastructure and Staffing Needs) recommendation of 450 treatments per MV unit[†] per year for European countries [62], but does mask major differences between departments. Within the subset of ten departments with a minimum of 20 reports (all of which are European departments), there is an average of 564 patient treatments per MV unit, which is in excess of the QUARTS recommendation.

Most departments (75) have both Linacs and brachytherapy equipment, at present the specific capabilities of these are unknown but will be sought in future department forms. Some techniques and technologies are more resource-intensive. At the moment, complexity is measured by the percentage of CT planned treatments. ROSIS departments cover a range of 0-100% CT planned treatments. However, capturing complexity based on CT planning is not representative of modern-day technology and techniques. Additional information to

[†] The QUARTS Model considered patient throughput on Co-60 to be equivalent to that of a Linac

be captured in future includes details on IMRT, stereotactic, and gating capabilities (Section 4.5.1).

It is difficult to compare staffing levels across different countries, due to the differing roles and responsibilities per discipline, different patterns of disease occurrence and detection, and varying complexities of treatments. The QUARTS project [153] reviewed radiotherapy staffing in 41 countries across Europe, 40% of which had guidelines for staffing. ROSIS departments have an average of 281 patients per Oncologist; and 387 per Physicist; these compare well with the QUARTS data (suggestion of 200-250 patients per Radiation Oncologist and 450-500 per Physicist). However, these figures again mask a higher workload amongst the subset of ten departments, particularly for oncologists. It is difficult to compare these figures across different departments and countries; the data on the remaining disciplines (Radiation Therapists (RTs/RTTs), Dosimetrists and Technical Maintenance) are extremely dependent on factors such as roles and responsibilities, and treatment complexity. Recommended infrastructure per department is subject to large variation depending on case mix, roles and responsibilities, techniques and procedures. Adequate staffing with appropriately trained personnel is a recurrent topic in the literature as a pre-requisite for patient safety. [34, 44, 53, 154-155].

Data transfer is a safety critical step in the treatment chain, and electronic transfer can reduce the human error contribution to data transfer errors. In this respect the ideal is for a department to transfer all data electronically. Networking capabilities are varied between and within departments; whilst ten departments have no network, typically departments have a mix of electronic data transfer options. This is also typical of the subset of ten departments. It is noteworthy that only 14 departments are fully networked throughout, including images. It is likely that including an element of human data transfer at any stage in the process will lead to an increase in data transfer errors. Where a subsequent part of the process is electronic, staff may be overconfident in the integrity of the data, forgetting that the original data was manually input. One may also note that many electronic systems are not completely integrated, and transfer between e.g. treatment planning system and R&V systems may be manually performed; such import/export functions where human interaction is involved may result in transfer errors. However, neither is electronic data transfer completely dependable [156]. As treatment complexity increases, we are more reliant on electronic data transfer, and must be vigilant as to its inherent risks. Information transfer with redundancy

is one of nine safety processes identified by the WHO as relevant throughout the RO process [44].

A generally encouraging finding is the use of multiple QA methods in departments, with a reported average of seven methods per department (Table 4-3). The subset of ten departments have a higher average of eight methods per department, and also exhibit more consistency, with the same five methods being used in all departments, and a further two methods in nine of the ten departments (Table 4-5). The International Basic Safety Standards recommend an approach which encompasses multiple layers of defences [74], and these methods can be seen as filter levels in a defence at depth or a multi-layered defence system. The least utilized QA methods among the 101 departments were In-Vivo Dosimetry and Formal Quality Management System (QMS); the most utilized was a Regular QC of Treatment Units. Nonetheless, three of 101 departments do not perform Regular QC of Treatment Units which is cause for concern, and is inconsistent with general guidelines [69, 84, 157-158]. This latter could also have been a misinterpretation in reporting the departmental status.

The existence of defence-in-depth is an important aspect of detecting mistakes and preventing adverse events. In the ROSIS database, treatment was delivered incorrectly in just over one half of the reports. Most of these incidents were detected at an early stage (1-3 fractions), with a minority affecting 4 or more fractions. Without knowing the total number of fractions prescribed, it is difficult to put this into the context of severity of the incident. For those incidents where the total fractionation prescribed is known (199), the reports represented a mistake in an average 22% of prescribed treatment fractions (Figure 4-5). Depending on the type and extent of the mistake, this could represent a very significant impact on treatment outcome and/or incidence of adverse events.

A difference is observed in the ratio of reported incidents versus near-incident depending on the quality control method used (Table 4-6), e.g. "Found by chart check" results in proportionally more near-incidents than "Found at later patient treatment" and "In-vivo dosimetry". This is sensible since chart checking may be more likely to identify mistakes pre-treatment. There is also the contra-intuitive result that "Found at first patient treatment" seemed to incur more severity than when "Found at later patient treatment" (average 25% vs. 15% of prescribed fractions treated incorrectly). This is probably an artefact of the reports (e.g. there was an average of 15 prescribed fractions per treatment for "Found at first patient

treatment" vs. 20 prescribed fractions per treatment for "Found at later patient treatment").

The literature has mainly focussed on the value of chart-checking [31, 42, 80-81, 84-86], in-vivo dosimetry [27, 80-84], and portal imaging [81, 84] as the most valuable quality control tools.

Chart checks constitute a major method of detection of incidents reported to ROSIS. Detection of incidents through chart checks is more multidisciplinary compared to the overall database (Figure 4-13 vs Figure 4-2). Figure 4-6 shows the majority of incidents detected in pre-treatment stages were discovered by chart checking. In general, chart checks provide an excellent opportunity to detect incidents *pre-treatment*. However, the reported incidents detected by chart check are evenly distributed between being detected pre-treatment and once treatment has begun. Rather than a reflection of the true ratio of detection, it is likely that this is a reporting bias with more reports being made where treatment has been delivered incorrectly. Nonetheless, it does suggest that a modification of the checking process in these departments may enable more incidents to be detected pre-treatment (Figure 4-7, Figure 4-9, Figure 4-10, Table 4-6). Where an incident was discovered by a chart check during treatment, an average of two fractions were delivered incorrectly, though the number ranged from one to 20 fractions. In "Lessons learned from accidental exposures in radiotherapy", the IAEA note that "in some of the accidents, even the review of charts and calculations failed to detect a mistake."[34]. The importance of, and sometimes failure of, chart checking is a common feature in the literature [27, 31, 42, 45, 67, 80-81]. For future design of a QA system one has to consider this finding especially when departments are going "paper-less" using electronic patient files. It would be interesting to have more information on the scope, purpose and stage of the chart checks reported by departments.

In 1992, Leunens [81] reported that combining in-vivo dosimetry and portal imaging would detect 95% of incidents in their study; in the present dataset these methods are responsible for the detection of approximately 10% of incidents reported (a total of 110). Portal imaging is reported as detecting 104 process-related incidents; interestingly this is one area where oncologists as well as RTs play a major role in the discovery of these incidents (33% and 38% respectively).

Although portal imaging is almost universally routinely used, in-vivo dosimetry is not used routinely in most departments (Table 4-3 and Table 4-5). The routine use of in-vivo dosimetry at first fraction of treatment / phase of treatment, for all patients is quite controversial. There is general agreement as to its overall worth in the context of patient safety, particularly when used as a truly independent check of delivered dose, and the WHO Radiotherapy Risk Profile identified that it could mitigate 24 of the 81 risks identified [44]. In terms of practicalities, its value is however moderated by its cost, and there is a lack of consensus with regard to its value in the context of its cost-benefit [27, 86, 93-95]. It is suggested that the value of in-vivo dosimetry may be indirectly related to the comprehensiveness of checks prior to treatment.[67] Although it is not a primary method of detection in the ROSIS database, with just seven reports, it must be considered that it is routinely used in only 33% of departments (Table 4-3 and Figure 4-3) (and in only one of the subset of ten departments (Table 4-5)), leading to less opportunities for detection of incidents using this method.

Mistakes in data transfer may be a factor in as many as 50% of ROSIS reports. These incidents were significantly more likely than non-data transfer errors to have originated pre-treatment (Figure 4-8; $p < 0.001$, Pearson Chi-Squared), although there is no real difference in their stage of detection. The detection of data transfer incidents is more reliant on chart checking, compared with non-data transfer incidents which are more likely to be found at the time of patient treatment (Figure 4-9).

Mistakes made in the transfer of the data are often missed where adequate checking procedures are not in place, or where they are in place but have not been used properly or were rushed etc. In these instances, it is common for some of the patient's treatment to be delivered incorrectly before the mistake is found. This is seen in the ROSIS database where, despite the increased opportunity for detection of the data transfer incidents as a result of their earlier occurrence in the RO process, 45% still resulted in incorrect treatment being delivered. This equates to 22% of the 600 ROSIS reports evaluated, and means that over one-fifth of the ROSIS database may describe incorrect delivery of radiotherapy due to an error in data transfer.

Record and verify systems (R&V systems), or check and confirm systems, have been a crucial part of the technological advancement in Radiation Oncology – enabling the delivery of more sophisticated and complex treatments. However,

although the implementation of R&V systems has reduced some types of "random" mistakes, new risks were also introduced. [81, 87, 90] Many R&V-related mistakes arise during manual input of data – this is seen in the ROSIS database where the most common R&V error is incorrect data input into R&V, mainly affecting field parameters, isocentre position, and equipment position, as well as dose parameters. Despite the above-mentioned recommendation for redundancy in data transfer checks, half of these errors resulted in some incorrect treatment being delivered prior to detection.

Reliance on computers often leads to operators trusting the information they contain – forgetting that the information could either be electronically corrupted, or that often the information has been manually input into the computer. Instances where much of the data is electronically transferred, but some is manually input can also give rise to a false sense of security. As this data forms the basis of the patient's treatment, it is imperative that it is always correct. It is clear from the department data that often a combination of network options exist in a department, implying that there is partial electronic transfer of data. Comprehensive checking procedures prior to the use of any data in the R&V system, and appropriate independent checks during the first treatments (or when using any new data) should ensure that most mistakes are detected at an early stage.[39]

As with any other area, it is important that the checking procedures are appropriate. For example – checking data on a R&V system computer screen against original data on paper can itself be very error prone. The data is presented on different media (on-screen vs paper), is probably also in a different layout, and the sequence of data may be different. The checker must be careful to avoid an "expectation bias" – e.g. where he/she sees a gantry angle of "0" on the paper, and looks to find a "0" on the screen, without also consciously checking that it corresponds to the value for the gantry angle given on the screen.

A solution for this problem does exist. In 1995, De Graaff and van Kleffens [88] described a system they developed to minimize manual data entry errors. This system was based on a programme, which automatically checked two independent manual data inputs, and highlighted any inconsistencies to the second inputter. They found that the "introduction of this system has shown a remarkable decrease in data entry errors on our machines." Although this was described fifteen years

ago, and should not take more staff time than a visual chart check, this system has not been adapted for common or commercial use in RO.

Errors in data transfer will be influenced by specific departmental procedures and equipment. To date, ROSIS has not had the capability to explore issues associated with the use of particular R&V systems, or in particular environments; this could be an area for future investigation. In fact, the main purpose in collecting information about the department infrastructure is to enable future investigation into whether or not these variables in infrastructure affect the occurrence or detection of incidents. The department form has therefore been revised to capture more information on the department, particularly the department's equipment and technology (Section 4.5.1). A limitation of the current system is that departmental infrastructure is not updated – however, an annual check is being introduced to confirm departmental infrastructure.

Most departments participate in an audit programme, although none of the reported ROSIS incidents were detected by external audit. External audits could focus on purely physical and technical aspects (dosimetry audit), or could focus on clinical and procedural aspects of treatment (clinical audit). Where information is given on the nature of the audit, many seem to be dosimetry audits. External audits – physical and clinical - are extremely valuable activities, and although not yet reported to ROSIS as detecting incidents, are well-documented as an essential activity to complement internal quality assurance programmes.[68-69, 159]

Most reported incidents were detected by Therapists at the treatment unit (RTs/RTTs); however, it must be stressed that it does not follow that most incidents occur during treatment. Probably the most likely explanation for more incident detection by RTs during treatment is simply that this is the most likely time for a mistake to be detected, as all the various aspects are combined for treatment delivery. It was previously reported [101] that most reported incidents arise pre-treatment, but are passing pre-treatment checks and are not detected until the patient is on treatment, or at follow-up. This is supported by data from the process classification which identifies the origin of less than one quarter of reported incidents as being during treatment (23.5%; 141/600). Figure 4-7 illustrates varying patterns of incident occurrence and detection between departments, possibly due to actual differences, but it is also likely to be an artefact of differing reporting practices between departments. Another explanation is reporting bias. Reporting bias may be as a result of differences between health

care professionals – for example, doctors are allegedly less likely to report incidents [160]; or it could be due to failure to report near-incidents – this could explain the high proportion of errors that actually affect the patients. In RO, a near-incident to incident ratio of 13.8 to 1 was detected for errors originating in the treatment preparation chain [31].

In the pre-treatment activities of the process classification, errors in treatment planning and dose calculation account for 22% of incidents; if prescription errors are included this rises to 29% - a similar proportion as that identified with the hazard classification ("Dose" 32%; Figure 4-26)[‡]. The literature [31, 80, 85] reports data transfer errors as being the most common type of mistake here; the ROSIS dataset is consistent with this and reveals data transfer as a factor in almost 50% of these incidents.

Patient mis-identification is normally regarded as a serious incident among regulators [74]. There are ten reports among the 600 process classification where the patient was incorrectly identified; this is a mistake common to all areas of health care and has received considerable attention in the literature and in governmental and organisational safety strategies. It is recommended that two to three independent techniques are simultaneously used to verify the patient's identity – these could be the patients first and last names, their date of birth and their address.[147] One of the ROSIS incidents on patient identification describes confusion between two patients, who have the same forenames and surnames, who live on the same street, and who were born on the same day and month, just one year apart (ROSIS Incident ID = 35). A common suggestion for eliminating this type of incident is to have patient photographs in the chart / R&V system, however, there are at least two reports of this incident occurring even in departments where patient photographs are available to verify identity (ROSIS Incident ID 312 and 996). Photographs, barcodes, fingerprints are all presented as methods of reducing this incident, but adherence to protocols and working with awareness are crucial, with or without these additional aids.

Another worrying theme across the various Process Classification Level 1 activities is the failure to correctly record parameters – this accounted for 71 of 134 mistakes in Imaging, Simulation and Planning, and a further 104 of 134 mistakes in

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[‡] It should be noted that this 32% masks proportionally more prescription errors, and some due to incorrect execution of the prescription at treatment delivery)

preparing the treatment chart (whether electronic or paper) during Treatment Preparation. The occurrence and significance of data transfer errors has already been discussed. The most commonly incorrectly recorded parameters were those of the isocentre position, and field geometrical parameters. These were also the most common incorrectly executed parameters during treatment delivery. Where daily image guidance is used, it is likely that most of these incidents are detected prior to treatment, but without routine daily imaging these are still preventable incidents, and awareness should be raised about their occurrence and frequency. Other forms of technology can assist in reducing the occurrence of isocentre positioning errors, for example, couches with bed zeroing facilities reduce reliance on memory and daily on-the-spot calculations incorporating vectors.

Although specific remedies can be suggested for every mistake, the importance of a safety culture in contributing to the overall safety record is recognised. A safety culture should create a situation where *"all duties important to safety should be carried out correctly, with due thought and full knowledge, sound judgment and a proper sense of accountability"*.[14] The outcome of a safety culture should be that *"safety issues receive the attention warranted by their significance"*[14]; the success of this depends on both organisational and individual efforts.

This raises the question of how an objective of safety can be embedded in all activities of an organisation, and its people. There is consensus that there must be a visible management commitment to safety and safety must be proclaimed to be the responsibility of all staff [3, 7, 14-15, 19-20]. Whilst the impetus for safety should come from management, it is important to delegate some control of the safety programme to those on the front line, so they are responsible for and involved in its day-to-day execution. For example, where a reporting system is to be initiated, it might be useful to focus on e.g. ten particular types of events to be reported. The decision as to which ten events are the most important to report may be made by front line staff; they will know their input on safety is valued, they will be able to act on issues they are concerned about, and it gives them a sense of ownership of the system. Since they have invested in the programme it is likely that they will have an interest in its success, and will use it to report their safety concerns. It will then fall to management to support their efforts in reporting, by following up on reports, evaluating systems, and introducing improvements if necessary. Communication and feedback from management at all stages will be crucial. Similarly, if a prospective FMEA is proposed, then it is important that the team includes managerial and front line staff exploring the FMEA topic together.

It is possible that local safety improvement could be a grass roots movement, but to succeed this must obtain unequivocal management support at an early stage in its development.

Ideally, organisations would strive for safety; given the lack of visible results from investing in safety, it may be necessary for governments to mandate implementation of safety programmes in their health systems. Even if management only implements safety programmes under mandate, it is still important for the success of the programme that it is a collaborative effort between management and front-line staff, is seen as a positive worthwhile activity, and a priority for the organisation. A clear message must always be sent that safety is everybody's business. The success of such an approach can be seen in the *Experience feed back committee in radiotherapy (CREx)*, tested in Angers, Lille and Villejuif and now in more than 50 radiotherapy departments in France. {Lartigau, 2008 #99;Mazeron, 2008 #53;Mazeron, 2008 #100;Woynar, 2007 #75}

Once the framework is in place, some challenges still remain. One is the question of how to keep safety a priority for the organisation. Another is how to make and keep safety a priority for the individual. Setting targets, to be reviewed and updated regularly, is one method for organisations to keep focussed on safety. Involving front-line staff in setting and attaining these targets, and rewarding successes may stimulate the individual. Supporting staff to constantly evaluate and improve working practices so as to improve reliability and safety would also be beneficial.

Working with awareness is one component of a safety culture documented in the literature [34, 150]. The ability of staff to be ever-vigilant will depend on their education and training, including training on new equipment and techniques. Reinforcement for working with awareness should come from management, and be facilitated by appropriate training and working arrangements (e.g. quiet areas for concentration, suitable workload).[14, 150].

The category "Found at time of patient treatment" (Table 4-6) highlights the importance of working with awareness – but this safety layer has not generally been evaluated in the literature. Working with awareness is a less tangible "safety layer", but based on ROSIS reports, it is a major contributor to patient safety, resulting in as much detection as the sum of chart checking, in-vivo dosimetry and

portal imaging. A distinction has been made between incidents discovered during the first patient treatment, and those discovered at a later patient treatment. To date, the numbers collected under the sub-category of "First patient treatment" are consistent with the rest of the data where many reported incidents occur pre-treatment, and could therefore be detected at the critical first treatment. This reinforces the fact that the first patient treatment is a step where careful consideration of all the components of treatment by the treatment team is constructive to patient safety.

A vital question for safety is how well can individuals maintain concentration and awareness? Automaticity is defined as the *'property of a process that takes place largely independent of conscious control and attention'* ([161] as cited by [64]) and is recognised as an important tool in performing tasks using less cognitive effort. A typical example is driving a car – a person learning to drive needs to think of each task, whilst an experienced driver will automatically and fluidly perform the required tasks to drive. Normally a desired state, automaticity carries risks for safety procedures which require attention. According to Toft and Mascie-Taylor [64], involuntary automaticity may occur when tasks are commonly repeated, with the result that a person may automatically make expected responses e.g. to a checklist, without consciously checking the required parameters. Toft and Mascie-Taylor call for more awareness of and emphasis on the effects of automaticity in health care. This is similar to the observations by the INSAG that *"sound procedures and good practices are not fully adequate if merely practised mechanically"* and therefore that *"Safety Culture requires all duties important to safety to be carried out correctly, with alertness, due thought and full knowledge, sound judgement and a proper sense of accountability"[14].*

In practical terms, this must translate to several factors being in place:

1. Appropriate training and education of staff
2. Appropriate workload
3. Good systems of communication
4. Recognition of safety as an organisational priority
5. Provision of appropriate environment in which to carry out duties important to safety, without distractions
6. Promotion of reflective practice by staff, including recognition of unfavourable conditions (e.g. stress / fatigue)
7. Evaluation of systems of working so as to promote stimulation and reduce involuntary automaticity

5.2.1 Summary

An international cross-organisational reporting system has been developed and implemented, yielding opportunities for learning from mistakes in Radiation Oncology. ROSIS covers a broad patient population and varying infrastructures, but with reasonable averages of Patients per MV unit, per Oncologist, and per Physicist. It is difficult to draw conclusions from the number of Patients per RT/RTT. Some level of defence-in-depth is apparent in most departments.

The majority of ROSIS reports relate to external beam radiation treatment; half of the events reported resulted in some treatment delivered incorrectly. The results from reporting systems need to be carefully interpreted and not over-analysed; however, areas for improvement can be identified since many incidents appear to arise pre-treatment, but are not detected until later in the treatment process. The most commonly reported detection methods were "found at time of patient treatment" and "chart-check", with a higher proportion of near-incidents detected by chart-check. While the majority of the incidents reported are of minor dosimetric consequence, they affect on average more than 20% of the patient's treatment fractions. The most common parameters reported as being incorrect were isocentre position and field geometrical parameters. Data transfer was consistent with the literature in being implicated in almost half of the incidents evaluated.

"Working with Awareness" is an essential element of a safety culture, and is seen in ROSIS reports to actively contribute to patient safety.

5.3 ROSIS CLASSIFICATION

This section considers the ROSIS Classification; its various classes, how it is prospectively integrated into the reporting system, and how it may integrate with other classification systems. Finally, the classification is examined using the WHO framework for analysing classification methods.

5.3.1 The ROSIS Classification

The primary purpose of classification is the provision of aggregated data in a form amenable to analysis and learning [121-124]. Feedback is a crucial component of any reporting system, and is the core component of a voluntary system such as ROSIS. The primary users of ROSIS are the professional RO Community. In the past, feedback from ROSIS to the RO community has been in the form of the original (de-identified) reports, spotlight cases, a short course in RM, presentations at courses, meeting and conferences, and provision of preset and user-defined searches of the online database. Detailed analysis of the data was not feasible, due to the nature of the data collected. The ROSIS reporting system lacked detail in specific areas, and it was felt that improved learning could be achieved with the collection of further detail on each incident.

It is desirable to have a classification system to facilitate the standardized collection of information, allowing comparisons across place and time. A classification system which is used universally is ideal; the WHO has published an International Classification for Patient Safety [47]. This should be incorporated into ROSIS where possible. As the WHO acknowledge however, it is impossible for one classification to be used universally within health care, and different disciplines may require their own versions [47]. The IOM specifically recommend that discipline-specific systems be used to allow maximal learning.[10]

Retrospectively classifying reports based on the information in the reports is one option. A hazard identification was begun using retrospective reports, and later refined using ROSIS reports. This classification of hazards proved useful in organising reports and comparing incident occurrence. Interestingly, analysis of the 910 retrospective reports and the 600 ROSIS reports yielded a similar relative distribution of hazards (Figure 2-1 and Figure 4-26). However, experience showed

that because of the detail required for classification, it could be difficult to retrospectively organise reports into these categories, depending on the amount and type of information given in the report forms [145]. For many reports this approach was felt to be either not feasible, or to lack reliability.

ROSIS has developed a classification system to assist in prospectively collecting and collating incidents in external beam RO in order to maximise learning. The RO classification proposed has been designed for ROSIS and, given the international participation in ROSIS, has been designed with the intention of having global applicability within RO. The aim is to provide lessons that are clinically relevant and meaningful, through requesting more comprehensive data, based on a customised classification.

Whereas the original forms are predominantly narrative, collecting more contextualised information about the incident would

1. Obtain more detailed / required information on incidents
2. Facilitate data classification at source by reporter
3. Generate clinically relevant lessons for the RO community
4. Facilitate provision of the system in other languages

There were three main requirements of the classification:

1. Effective tool for analysis and learning
2. Flexible
    a. Applied to different departments and processes
    b. Translated into different languages
3. Incorporated into the reporting system

The analysis of incident and near-incident data in order to learn lessons is not an exact science. This classification scheme has been developed as a means of collecting, collating, and analysing data in order to identify trends and to learn from mistakes. The classification system encompasses both incidents and near-misses, and underdoses as well as overdoses, thus maximising opportunities for learning, and also provides a means of evaluating preventative and/or recovery actions.

It is crucial that the correct conclusions are drawn; to that extent the classification must be tested for reliability and validity [121]. Nonetheless, there are many systems in place in health care that have not been tested. To date, the process

classification of the ROSIS classification has been retrospectively tested; this and the remaining elements should also be prospectively tested, ideally in the field.

The classification includes elements under four main classes, each of which will be discussed individually in the following sections.

5.3.2 Event / Occurrence Class

This class covers many key contextual aspects of the incident, including who was affected, where, when and how the incident occurred, and what occurred. Through the process classification, specific detail is captured on where in the process the incident originated, and what aspect of the overall radiotherapy prescription it affected (shielding / dose / isocentre position etc).

Further contextual information in terms of the radiotherapy technique and the treatment site are also captured under this class. If the incident is related to an equipment failure, details are requested of the make and model involved.

Different levels of analysis will be possible depending on the amount and detail of reports collected under these headings. Analyses would include:

- whether particular incidents are more likely with specific techniques
- whether particular incidents are more likely with specific treatment sites
- which activities of the RO process are particularly error-prone
    - also with sub-analyses per technique and per treatment site

These analyses can be on the basis of the full dataset, or the dataset belonging to an individual department, or from a sub-set of departments with similar infrastructures.

A major aspect of the event class is the process classification.

5.3.2.1 Process Class

The process classification is designed for conventional external beam irradiation. The seven activities at level 1 of this classification are broadly similar to those used by the WHO in the Radiotherapy Risk Profile [44], and include:

1. Imaging

2. Simulation
3. Planning
4. Prescription
5. Dose Calculation
6. Treatment Preparation
7. Treatment Delivery (first and subsequent)

The aim with this classification was to define discrete activities which overall describe the process of treatment preparation and delivery, and therefore to locate "where" in the process the incident originated. These activities may be undertaken in different sequences in different departments or for different treatment techniques; or some of the activities may be omitted. Although it is recognised that processes will differ between and within each and every department, the process classification is intended to be generic and applicable to all EBRT processes. Used in this manner, results using the process classification could be applicable to any department. A future element may be to work with individual departments to define their specific processes, and when giving them feedback, to re-arrange the activities to accurately reflect that department's processes. This would allow ROSIS to tailor individual feedback reports to highlight specific areas for attention/improvement. This would also involve looking at checks/detection methods in place, and how effective they are.

The same level 1 activities are used to capture the stage of detection of the incident – one purpose of this is to monitor the number of steps between incident origin and detection, and thereby to evaluate the effectiveness of existing quality control methods.

The same element at level 2/3/4 can occur at different phases throughout level 1; this allows for comparison of all cases of "what" occurred e.g. the patient could be identified incorrectly (level 2) at simulation, or at treatment delivery (both level 1). It is important to be able to link the two occurrences, although they occurred at different phases.

An aspect of level 4 which is less satisfactory is that it can repeat some of the elements of level 3. For example "*RT Set-up*" is typically a level 2 element, and therefore its sub-elements are normally level 3. However, in some instances, it is a level 3 element, and therefore its sub-elements also exist at level 4. While this

scenario is manageable, and amenable to analysis, it would be preferable to simplify this in the future.

The process classification needs to be used by different individuals in different organisations. It was devised by one individual, but was tested for inter-rater reliability. This testing, using a retrospective methodology and three individual classifiers, showed a good level of agreement, as well as identifying a weakness in a level 1 category. A recognized limitation of classification schemes in practice is overlap between categories, and this is no different.

Overall, categories at level 1 are occurring with similar relative frequencies between classifiers. Some activities were more troublesome – representing individual differences in categories chosen, and the most variation occurred within the activity of Treatment preparation. In retrospect, this was understandable, as this was the most indistinct and least well defined category, and could be said to cover all aspects prior to treatment delivery. Either clearer instructions or an interim meeting and review of inter-rater agreement at e.g. 50 reports (25%) may have highlighted this discrepancy, and improved the overall result. Nonetheless, when this activity was excluded from the analysis, there was good agreement amongst the remaining activities.

These results are quite encouraging, since there were a number of additional limitations in methodology. In the first case, classifiers were asked to classify by origin of mistake. This can be difficult in any event; but is particularly difficult when a classifier can rely only on the incident report (which may not be very informative), and is not familiar with the specific department procedures and processes. For a number of the reports, it was difficult to judge from the information in the report under which activity the incident originated. Another difficulty that arose was that occasionally, multiple mistakes could be reported in one report. For the most part, these are limitations of the retrospective methodology used here, and the system should also be validated prospectively.

Determining what element of treatment was affected (normally at Level 3 or Level 4 of the classification) was more successful, with 77% agreement. This is probably because for most cases, this is independent of the origin of the incident, since the same element affected is represented at many stages – e.g. shielding. Knowing what element of treatment was affected is valuable by itself (and is a success of

the classification), but leads to greater learning when combined with the activity where it originated and where it was detected.

The process classification trees may also prove useful in providing feedback to users as a visual representation of incident occurrence and detection.

Knowing that a hazard can occur (and recur with a certain frequency) is one aspect of risk assessment; a further essential aspect is assessing the likely outcome of the hazard.

5.3.3 Outcome Class

Safety management should initially focus resources on preventing the most harmful incidents. This is typically decided based on a risk rating – a factor of the likelihood of occurrence of an incident, its potential outcome, and sometimes also the likelihood of detection of the incident.

Experience with the ROSIS system from 2003 indicated that the responses to the question on severity were highly subjective, as reported previously [25, 101, 108]. The main difficulty lay in the definition of the actual and potential harm that may have occurred to the patient. This is best illustrated through the responses where a near-incident is reported, and the reporter is ambiguously asked *"What was the severity or potential severity?"* In many cases, *"None"* was selected. An interim revision was made, where the number of fractions affected and the total fractionation was requested – to differentiate actual incidents from near misses and to begin to more objectively quantify severity.

Subsequently, this question was again redesigned to capture actual and potential severity separately. The reporter was still asked how many fractions were delivered incorrectly, and how many were prescribed in total. The purpose of this was twofold:

1. To evaluate how long the incident existed before it was detected
2. To obtain another (crude) measure of the possible severity

This seemed to be working well, but it was felt that it might be possible to collect more objective data, and a new classification was devised. The aim of the proposed outcome classification is to collect information in an objective manner,

which can then be sorted according to a "behind-screen" classification into pre-defined levels of severity. Data to be collected is as follows:

1. Number of fractions treated incorrectly (if any)
2. Total number of fractions prescribed
3. Total dose prescribed
4. Percentage dose discrepancy
    a. Actual
    b. Potential
5. Treatment schedule (e.g. once daily, five days a week)
6. Whether or not the error was correctable
7. Whether the tolerance dose of any organ was exceeded.

The main influences in this classification at the time of its design were the NCC MERP [130] and Klein et al[37].

This new severity classification is also scaleable, however this time there are a number of data items which combine to provide an overall severity score (similar to the NCC MERP). This constitutes a more objective means of defining the outcome for the patient than the initial version. It is envisaged that it may be possible to update outcome information on individual patients/incidents, perhaps combined with an objective measurement for more serious incidents (e.g. chromosome aberrations) so that a record of injury related to incident-type, dose/volume error etc may be created.

A limitation of this classification is the detail required – even with the previous question on severity, often the number of fractions treated incorrectly or the prescribed number of fractions were omitted. The proposed classification includes more onerous data elements than these; this data may not be readily available to the reporter, and these questions may not be answered.

5.3.4 Causes and Contributing factors Class

Both causes and contributing factors, although different in their own rights, are combined into a single category for the current classification. It may not be possible to correctly define the cause of an incident without a proper investigation. Without such an investigation, it is also possible that biases would play a role in the selection of these factors. Attributing the wrong cause/contributing factor to an incident is undesirable and may lead to incorrect conclusions being made, and

missed opportunities to learn from mistakes. Since the majority of incidents/near incidents reported to ROSIS are minor, it was felt that although in an ideal world it might be optimal, it would be unrealistic to request that a root cause be identified for each mistake, or a full systems analysis undertaken [162]. It would be inappropriate to collect information on this if the data was of questionable integrity, and could lead to incorrect conclusions being drawn. As the WHO emphasise "the appropriate balance to strike between the detail and accuracy required and the effort of collecting it must be clearly delineated."[47] For this reason, causes and contributing factors are considered under the same heading; as each are significant in the occurrence/development of the incident, and in future prevention [162]. Where investigations are undertaken, it is possible to provide detailed results of these in a freetext section of the incident report form.

Initially a multi-level list was prepared, based on the Framework of Factors Influencing Clinical Practice [162], and incorporating RO specific issues based on the IAEA and ICRP reports [24, 34]. On reflection and discussion among the ROSIS group, this list was too large and unwieldy for reporters. Another consideration was that since most reports relate to minor or near-incidents, there may not be a full investigation and discovery of causes and contributing factors. It was felt that it would be preferable to keep this element as simple as possible, and to initially include the headings of the Eindhoven Classification Model:

1. Technical factors
2. Organisational factors
3. Human factors
4. Other factors

As well as an option of "Don't know" and "Patient factors".

The ECM categories are already in use in RO in the Netherlands in the PRISMA-RT system, and since it is likely that the ICPS will eventually adopt the Eindhoven or a similar model, beginning with these categories would give the option of harmonising ROSIS data with that of others. At a later stage, ROSIS could expand the above headings to incorporate a causal analysis such as is undertaken in PRISMA. This also requires training reporters to ensure that they can classify causes and contributing factors reliably and validly.

A recent survey of ROSIS departments on what they want from a reporting and learning system showed that they felt the most important aspect in learning from incident is to know the cause of the incident (Figure 2-9) [116]. This area of the

ROSIS classification is quite basic, and will not yield many lessons or recommendations on prevention.

It is anticipated that this class will need to evolve to meet the needs of the users, but this should not be undertaken at the expense of valid and reliable information.

This area will be closely monitored in terms of usage, and future literature.

5.3.5 Detection Class

Clearly, detection of potential incidents is a crucial aspect of safety in RT. Detection can lead to either secondary prevention (incident recovery as per the WHO) or tertiary prevention (ameliorating actions as per the WHO [47]).

The class Detection captures information on the stage of detection of the incident, who detected the incident, and how it was detected.

The stage of detection of the incident is captured using Level 1 of the Process Classification – this allows comparison with the occurrence of the same incident, and an appreciation of the length of time of existence of the incident in the process.

This information is also combined with the method and discipline of detection of the incident; some incidents have been shown in the current results to be more likely to be detected by a specific quality control method or discipline. The main addition in this area from the original forms is the incorporation of the process classification for stage of discovery.

One aim of collecting information on detection is to highlight effective detection methods, and systems of defence in depth. Collecting this data will also highlight the failure of specific detection methods – in general or within individual departments – and encourage reflection on the correct implementation of and continued good practice in ensuring quality and detecting mistakes. This is in keeping with the WHO recommendation [124] that data should be used to highlight priorities and strategies for the prevention of errors and/or mitigation of their effects.

5.3.6 Integration of Classification into Reporting System

The classification outlined contains some new data elements, which need to be collected prospectively. This required the development of a new report form for ROSIS. The main criteria for the new report form were that it would incorporate the classification in such a way that no additional training was required to use the classification, and that it would not take substantially longer to complete than the current form. The initial ROSIS report form was broadly based on the information typically collected by departmental report forms; redesigning the report form based on the classification requirements meant incorporating some elements which are not typically collected. This entailed a conceptual shift in that ROSIS might stimulate the collection of data not normally documented. However, against that is the risk of complicating the reporting process. Some redistribution of priorities had to be managed based on the trade-off between obtaining detailed data for analysis, but also keeping the reporting process simple and straightforward. This resulted in simplification of the outcome section of the report form, compared to that originally proposed. This section was deemed to be potentially difficult for reporters, since it could be difficult to define e.g. a % dose / volume discrepancy. A format closer to the current report form was chosen, and the ASN-SFRO scale was introduced as a good model and for consistency between systems. This scale will need to be modified to also incorporate underdose situations.

The revised system is explained in Chapter 6, Section 6.2, and the new report form can be seen in Section 6.2.2.2, page 225.

5.3.7 Integration with other classification systems

Ultimately, learning can be enhanced by sharing data among interdisciplinary as well as intradisciplinary systems. This requires a common language.

The ideal situation is that proposed by the WHO ICPS [47] – where systems are based on the same pre-defined classifications. The ROSIS classification has been developed to align with this where possible, and ROSIS has encouraged

collaboration with other groups developing reporting systems in RO in order to standardise data collection. For example, the Swiss CIRS system (c.f. www.rosis.ch) is based on ROSIS, and was developed in such a way as to be able to directly combine data from the two systems. The classification outlined here has been discussed with representatives from the American Association of Physicists in Medicine (AAPM), and a revised classification agreed. (Appendix J) In principle, it is agreed among ROSIS and the UK NRLS that where possible, data should be collected in a comparable format.

The severity scales of the WHO ICPS, the original ROSIS scale, and the ASN-SFRO scale are broadly comparable – as illustrated in Table B-ii, p250.

The causes / contributing factors section follows the headings of the Eindhoven Classification Model (ECM), and can be expanded to fully incorporate the ECM. This would provide a link between ROSIS and PRISMA-RT. The ECM may also be used by the WHO ICPS in the future; if so, this would provide other linkages for ROSIS.

Although the framework of classification systems should remain stable, the content of the systems themselves should be adaptable to changes and advances in practice. This will create practical difficulties in maintaining comparable systems, and will be a significant challenge to all parties.

5.3.8 Summary: Analysis of Classification Methods

A summary of the key features of the ROSIS Classification is given in Figure 5-1.

Key Features of the ROSIS Classification

- Radiation Oncology Specific
- Method
  - Literature review
  - RT incident-types from ROSIS database
- Purpose
  - Organise reports
  - Facilitate analysis
  - Improve safety
- Scope
  - All incidents and near-incidents relevant to an RO dept
  - Preventative & corrective factors
- Intent
  - Maximise learning - Collect detailed information
- Feasibility
  - Incorporated into online Reporting System
- To be evaluated:
  - Analysis
  - Sensitivity
  - Reliability and Validity

Figure 5-1: Key Features of the ROSIS Classification

A framework for analysing classification methods is put forward by the WHO [125]. The text below contains the questions of this framework (italics), and the answers (non-italicised) of this author when applying it to the ROSIS classification.

"In analyzing the technical merit of the various extant classification methods, the following characteristics or attributes of a classification should be considered:"[125]

- *"Is the purpose of the classification fully explained and is it appropriate for its intended use? Preferably, the classification should have been tested on the types of incidents and adverse events to which it will be applied.*
    - The purpose of the classification is given in Section 0, and it is believed to be appropriate. The classification has not been fully field tested, but has derived from analysis of incident reports in RO, and as such is felt to encompass these.
- *Is the classification broad enough for the application, neither capturing too many nor too few data elements? Is it capable of identifying preventative and corrective strategies where this is relevant?*
    - The classification on severity may be too broad, and has been reduced for reporting purposes. Early analysis of data collected will give more insight into this question. A limitation of the process classification is its restriction to external beam RT. The system does identify preventative and corrective strategies.
- *What is the conceptual approach to the classification framework? In other words, which theory in the science of human factors and error and systems failure does it reflect, if any, and is this approach consonant with the orientation of the purpose? Is the theory well established (e.g. Reason's human error) or is it an idiosyncratic notion that may not correspond to a broader body of knowledge?*
    - Broadly, the framework is based on a systems theory of organisational accidents. The Human factors aspect of the ECM as used in the causes and contributing factors classification is based on Rasmussen's model of human error.
- *How feasible is the classification to implement? Can it be implemented as a paper-based and electronic on-line incident monitoring system or mapped to data collected from existing reporting systems? Is professional expertise required to apply or interpret the classification instrument? Does it use readily available data (e.g. information already contained in medical records, medicolegal files, complaints, morbidity and mortality data) and will it be readily acceptable to patient safety stakeholders? What useful purposes have been achieved using the classification? Is the classification instrument readily available and is there a cost involved? Above all, are there clear instructions that specify how the data elements are codified?*
    - The classification has been incorporated into an electronic on-line dynamic incident report form to enable prospective data collection. Additional training or professional expertise are not required to use

the report form. It relies mainly on data which is normally available on local report forms or treatment sheets. The process classification has been retrospectively applied to ROSIS reports, and has highlighted the occurrence of specific incidents. The classification is readily available and has been shared with other groups in the interest of developing comparable systems. The report form does not code the data.

- *Is it clear how data derived from the classification are analyzed?*
    - Analysis will be undertaken on all possible aspects of incident occurrence and detection, but attention will be drawn to biases which may exist within the data.
- *Is it sufficiently sensitive to differentiate similar adverse events with different contributing factors, and is this adequate for the purpose? Is it suitable for recording and tracking errors only, or can it provide detailed information to inform the development of preventative and corrective strategies?*
    - The classification on causes and contributing factors is currently very weak, and will need to be expanded to the full ECM or equivalent to provide useful information on causes / contributing factors. However, the classification overall has been developed to facilitate analysis and learning, and it is hoped that in its current format it will provide detailed information for the development of preventative and corrective strategies. Case based reasoning models will be investigated to explore linkages not directly observed using the classification.
- *How strong is the available evidence for reliability and validity of the classification instrument? Has it been field tested in the "real world?" How many different incident reporting systems has it been compared with? How many different users have tested the classification instrument, and did they obtain similar results?"*
    - The process classification has shown good inter-rater reliability retrospectively; however, the full classification remains to be tested prospectively for reliability and validity.

The overall structure of the classification is stable, but it is anticipated that data elements and options under classes may need to evolve with clinical practice and taking into account incident occurrence and detection.

5.4 LEARNING FROM ROSIS

The *raison d'être* for ROSIS is to improve patient safety; this could be achieved by raising awareness of safety within RO, by contributing to the development of a safety culture, and by providing evidence on systems design for patient safety. Lessons must be learned and changes implemented in order to close the learning loop. Figure 5-3 illustrates the various aspects of learning from ROSIS.

ROSIS is primarily a reporting and learning system, whose primary users are individual professionals within radiotherapy departments. However, there are a number of additional stakeholders who can be identified (Figure 5-3). The system is driven by users; therefore the analyses and learning should also be directed at their needs, and should be user-friendly.

As a cross-organisational reporting system, ROSIS offers a unique opportunity for learning, compared to local systems. In a true epidemiological sense, comparisons can be based on similarities and differences between departments and organisational cultures; though particularly this latter would require significant resources to investigate and capture.

Lessons can be learned from different sources, and at various levels of detail. Reading the incident reports in their original format is probably the most basic form of learning, but the narratives can be very effective at proving the existence of mistakes and how easily they can occur in any department. Individuals can also search the online database for specific items across all incident reports, and can draw their own conclusions from the sample retrieved. Standard and customisable report outputs can be made available on the ROSIS website for the interactive online database. A moderated discussion board does not exist at present, but would facilitate exchange of opinions on specific reports or themes, and would also be useful in promoting open discussion and safety awareness within the RO community.

ROSIS can provide themed / tailored lessons through database analysis leading to the publication of spotlight cases or newsletters, and scientific publications and presentations. Where feasible, these analyses should also give rise to recommendations on best practice. [99]

The reporting system captures narrative data, giving the possibility that data mining / cluster analysis can be used (as a means of analysing the data, and/or as a method of validating the classification system). Database analysis can take the form of standard database retrieval or case based reasoning. Standard database retrieval will only access incident reports that contain identical descriptions, not incidents that share a common characteristic. It is reported that the integration of case based reasoning and information retrieval improves the identification of clusters of similar incident reports. [163] Data mining and case based reasoning methods should be tested to ascertain if they can identify trends and hazards and predict future failures.

Individual incident reports could give cause for issuing alerts to the RO community, particularly relating to the identification of new hazards, or the function of hardware or software. Manufacturers could be included in all ROSIS dissemination activities, to ensure that they are aware of design and operational issues which they have a duty to improve.

It appears that departments should play a larger role in promoting patient safety. In a recent survey [116], most respondents replied that their main source of information on safety in RT was from the internet (68%), with 64% also accessing such information at meetings and courses, and only 32% reporting that they get this information from their department. Individual RO departments, as well as using data from ROSIS in a managerial sense, could also use it to promote a safety culture amongst their staff. Using ROSIS as an example and motivator to staff could be useful when introducing a reporting system where none exists, by creating a learning environment and promoting a just culture. Perhaps the provision by ROSIS of more spotlight cases and analyses might encourage this.

Individual departments should be offered a tailored analysis for their own data; this could be benchmarked against the aggregate ROSIS data. It may prove valuable if used by RO departments in negotiations with hospital administration to demonstrate the effectiveness of safety measures, or the need for resources to improve safety. It can also act as a motivator to improve safety compared to others, or compared to own performance year-on-year. Benchmarking based on incident reports is not an exact science, and caution must be used in interpreting the relative performance between departments and/or over time, since there are many biases inherent in the data.

ROSIS is an independent, voluntary reporting and learning system; nonetheless lessons from ROSIS can be noted by policy makers and regulators. Over the past year, publications by international organisations (WHO, UNSCEAR, ICRP) have used ROSIS reports to highlight particular issues or to learn from incidents in RO. Safety measures and improvements could be enforced by regulators at a national level.

ROSIS depends on individual departments (and therefore their staff) to identify and report incidents, and to report their lessons learned, ideally following an investigation of the causes. The learning facilitated by ROSIS is therefore completely reliant on the quality and quantity of information provided by departments. As discussed in Section 2.2.1, some countries require incidents (in some cases also near-incidents) to be reported, and therefore a culture and practice of reporting will already exist there. In order to encourage reporting, the following should be taken into account: [55, 112, 160, 164]

- Definitions – to provide guidance on what is reportable
- Training – on what and how to report, ideally at commencement of employment and with refresher talks or leaflets. This can be incorporated into induction health and safety training
- Workload – ensure that reporting can be undertaken as part of routine activities, and that it is a simple process
- Severity of incidents – specifying if there is a minimum level for reporting incidents
- Discipline and seniority of individual reporting – emphasise that reporting is everybody's responsibility
- Foster a sense of ownership so that reporters see themselves as vital stakeholders in the system, and see the system both as an indicator of the quality of their work and as a tool to improve the quality
- Fear of blame – ensure that the managerial response to incidents is fair to individuals, and support individuals involved in mistakes
- Resources – a dedicated risk manager (who has sufficient time to follow-up on reports) can greatly influence reporting rates
- Audit reporting – for example, compare incident rates reported against rates observed, or detected through retrospective case review.
- Respond and improve – beware of reporters developing a sense that reporting is not required, or hat it will not lead to quality improvement. Feedback is important. Specifically targeting an incident-type to be reported (maybe based on prospective analysis) in order to learn about its occurrence and try to prevent it in future is another way of using resources

well, whilst highlighting that reporting is important and can lead to improvement.

- Feedback is essential, and can take various guises – from paper/electronic newsletters, to case reviews, learning opportunities, lunchtime series, morbidity and mortality rounds, etc.

A synergistic relationship should exist between individual RO departments and ROSIS, where both parties are working together and helping each other to promote and enhance patient safety.

This highlights another dimension of ROSIS users, and necessitates a distinction between departments who are actively reporting to ROSIS, and those who do not report but who do use the system for learning. A central thesis of ROSIS is that lessons learned should be disseminated as widely as possible; however, this relies completely on altruistic contributions. There should probably be an extra incentive for departments to become active members of ROSIS – this could be facilitated through additional features provided for those who are actively reporting, e.g. benchmarking, and analysis on an individual departmental basis of incident occurrence and detection.

The learning aspect of ROSIS can be improved. One aspect worth more attention is an aspect highlighted by Leape [99] as one of four main methods by which voluntary reporting can lead to improved safety, i.e. "the dissemination of individual experiences in safety improvement methods". This was also volunteered by participants in a recent survey carried out by ROSIS. [116] Case reports and studies from individual departments on tried and tested methods of improving safety could be both practical and inspirational for others to view, could promote discussion, and exchange of information, experience, and knowledge on safety management in RO.

Finally, a reporting and learning system can yield interesting lessons; this is of value in itself, but may give further leads when combined with prospective methods. Data from prospective methods could be used to focus reporting on particular incidents, in order to obtain specific causative information. It can also be used as an estimate of how many such incidents/near-incidents could reasonably be expected to be reported, and as such could indicate the health of a reporting system.

A reporting system may highlight particular incidents and/or procedures/processes which are error-prone, and potential failures can then be hypothesised and investigated using prospective methods.

ROSIS needs to approach learning from incident reports from an epidemiological perspective – exploring all the variables to develop hypotheses about incident occurrence and prevention. These hypotheses should then be tested using other methodologies, since the biases inherent in incident reporting should normally preclude evidence for a causal link. However, to again draw parallels with epidemiology, it is often not necessary to know the actual cause to enable prevention – substantial learning including recommendations for safety improvement may be achieved on the basis of report analyses.

5.4.1 Recommendations for Safety

The following general recommendations for safety are based on the literature and on the ROSIS dataset, and could be used by departments to improve safety:

As part of the quality assurance programme, departments should map at least at a basic level the entire process for each technique, using a multidisciplinary group who are involved in the day-to-day preparation and delivery of treatment. Safety critical steps should be identified, the entire process analysed for weaknesses, and the comprehensiveness and appropriateness of quality controls determined. Policies and procedures should be reviewed, and revised as necessary. The ROSIS database could be consulted for examples of incidents which may occur and for which controls should exist.

Personnel

Safety in a complex environment like health care will depend to a large extent on the personnel.

- Ensure the education and training of personnel is sufficient:
  - for roles and responsibilities expected of them
  - to recognise unsafe practices and mistakes.
  - to realise own limits
- Ensure adequate supervision exists where appropriate.
- Ensure personnel have clear protocols to follow for specific tasks and situations.

- Ensure a system of peer review exists and operates satisfactorily.
- Raise awareness of automaticity, where routine tasks are undertaken automatically, without full attention.
- Encourage Mindfulness / Working with awareness, and design systems of working and a culture to promote and reward this.
- Ensure that personnel are motivated for safety, and feel empowered to bring their safety concerns to the attention of management.
- Place an emphasis on working within teams, rather than as disciplines. This may help to promote healthy communication amongst the entire team, and encourage a co-operative approach. Communication is probably more difficult for individuals when viewed as disciplines in a hierarchical model.

Quality controls

Quality controls are an essential component of a safety system. A quality assurance programme should include layers of quality controls (defence-in-depth) to ensure that an acceptable level of risk is achieved. It is important in designing the quality assurance programme to ensure that controls are fit for purpose and are carried out appropriately. Controls should be complementary to each other. Calculation or data controls must be conducted by a person other than he who performed the calculation or data transfer; ideally, a different methodology would be used.

Where possible, controls should be made in a non-pressurised and peaceful environment, without distractions. Some pre-treatment checks may be carried out on the machine without the patient present.

Checklists are a useful tool in ensuring that nothing is inadvertently omitted from the control. However, there is a risk of checklists being used automatically, without due attention.

Another aspect of checking which may weaken the defence is that of "ambiguous accountability" – where two people performing the same task each assume that the other person will be rigorous, with the result that neither person gives the task their full attention, and ultimately compromises safety. [64]

Individuals performing controls should aim to find a mistake. They are responsible for the check; to this end their signature should be recorded. Thoroughly checking Person A's work should not be seen as a lack of faith – it should be recognised that anyone can make a mistake, and it is the role of the checker to detect that mistake. This approach should be communicated from and supported by management.

Data transfer

Incorrect data transfer is one of the single largest causative factors in incidents. Documenting the procedure correctly is as important as correctly performing the procedure, particularly for pre-treatment activities. Sufficient time should be allocated for documentation and data transfer. Safety-critical information should never depend on transfer by one individual without being checked by another. When checking data transfer, the primary data source must always be used as the reference. A difficulty in detecting errors in data transfer is that visual and verbal checklists are subject to expectation bias. Typically, checking procedures include checking across different media (e,g, paper to visual display unit), each with a different sequence of data. A double data entry system should be preferred, where data is entered by two different individuals from the primary data source, and consistency between the different inputs is checked internally by the computer; if differences are detected, verification is sought by the computer.

Data transfer is complicated where different equipment and co-ordination systems are used.

Electronic data transfer is to be preferred over manual; however, checks are still required as the integrity of the data cannot be assured.

Patient identification

Patient identification is a recurrent problem across different departments (see ROSIS Newsletter "Spotlight on Patient Identification" – Appendix H). At a minimum, a system should be in place where patients are identified by three items – their name (first and last), their date of birth, and their address. The patient should be asked to state this information, rather than to verify it. The addition of a photograph, barcoding, fingerprinting, or other identification technique may be beneficial, but should not be necessary if sufficient emphasis is placed on routine patient identification procedures. Patients should be informed that their treatment is specifically designed for them, and is not suitable for anyone else. If there are patients on treatment with similar names the patients should be informed that there is someone else attending with a similar name, and that they should be extra vigilant when called.

Conducting spot-checks may be a method of maintaining focus on this tedious topic.

Geographic misses

The most common manifestation of incidents in RO is as a geographic miss. The following measures are recommended to prevent geographic misses during treatment

- Draw one field outline on skin to be checked daily (or check beam light against image of field outline on skin)
- Verify the table position, using indexed immobilisation systems to limit the tolerance range
- Perform isocentre checks (through imaging or trigonometrically)
- Provide a zero function on treatment couch to simplify moves
- Refer to a photograph of patient position during imaging for treatment planning
- Ensure treatment marks/tattoos cannot be confused with inherent skin markings

In-vivo dosimetry

In-vivo dosimetry should be used as a standard safety layer in all departments. An exception might be made if the department has a proven safety record and can show that in-vivo dosimetry has not detected a proportionate amount of mistakes over a reasonable time frame (e.g. 2 years minimum). In these cases, it could be shown that almost all mistakes are detected prior to the first treatment, and the use of in-vivo dosimetry might be omitted on the basis of a cost/benefit analysis. Even in departments where is omitted, it should be re-introduced for new techniques and procedures until the same safety record can be shown for them.

Overall, departments should adopt a policy for preventing hazards, such as that provided in Schedule 3 of the Irish Safety Health and Welfare at Work Act, 2005, and reproduced here in Figure 5-2.

Schedule 3: General Principles of Prevention

1. The avoidance of risks.
2. The evaluation of unavoidable risks.
3. The combating of risks at source.
4. The adaptation of work to the individual, especially as regards the design of places of work, the choice of work equipment and the choice of systems of work, with a view, in particular, to alleviating monotonous work and work at a predetermined work rate and to reducing the effect of this work on health.
5. The adaptation of the place of work to technical progress.
6. The replacement of dangerous articles, substances or systems of work by safe or less dangerous articles, substances or systems of work.
7. The giving of priority to collective protective measures over individual protective measures.
8. The development of an adequate prevention policy in relation to safety, health and welfare at work, which takes account of technology, organisation of work, working conditions, social factors and the influence of factors related to the working environment.
9. The giving of appropriate training and instructions to employees.

Figure 5-2: General Principles of Prevention, Schedule 3, (Irish) Safety, Health and Welfare at Work Act, 2005

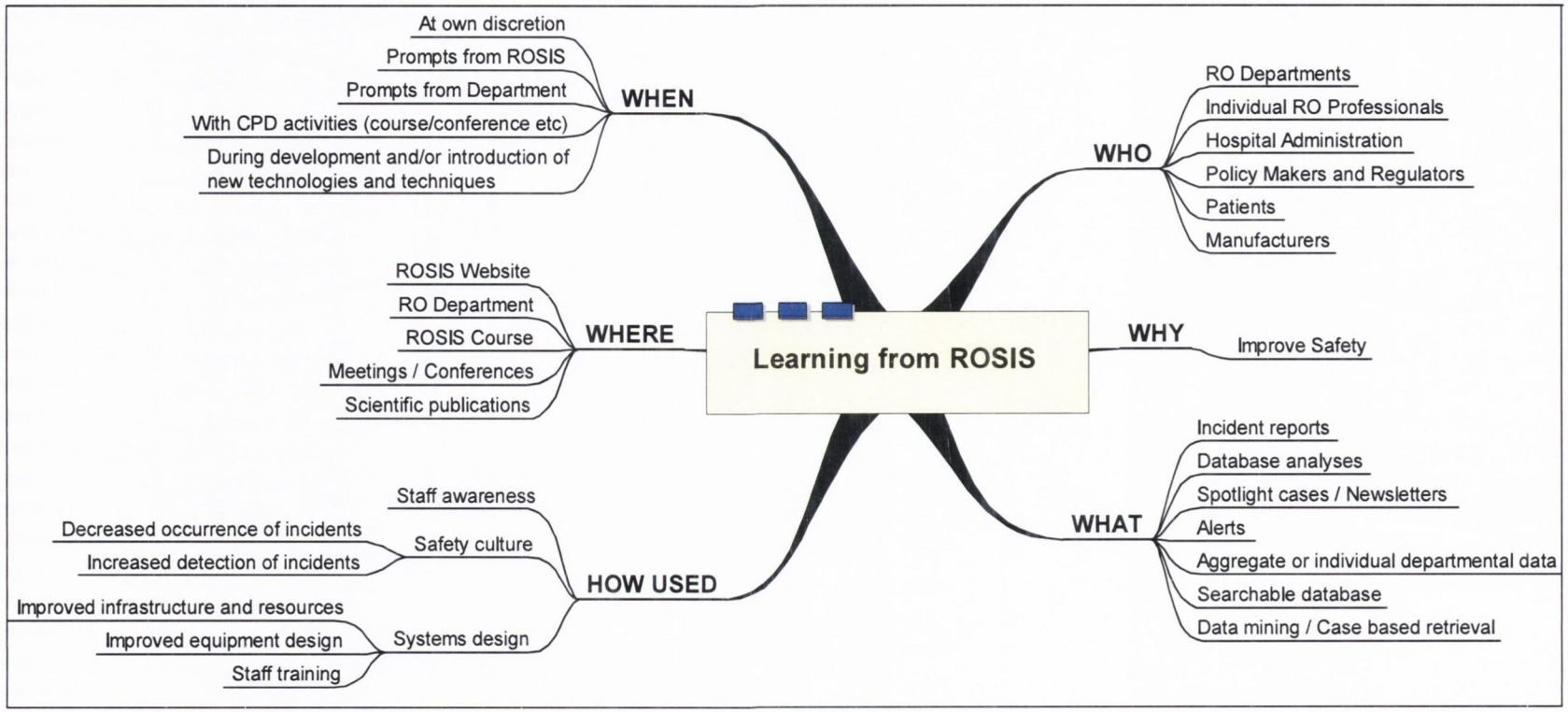

Figure 5-3: Schematic Representation of Learning from ROSIS

6 Chapter 6: Current Limitations and Further Development of ROSIS

This chapter describes some of the limitations of ROSIS, and how these might be overcome. It presents the revised webforms and website, and makes recommendations on how ROSIS might develop further.

6.1 LIMITATIONS OF ROSIS

There are a number of limitations in the ROSIS system, many of which will be addressed by future developments of the system.

Some of the limitations have been outlined in the first evaluation by ROSIS departments [152], including language, time constraints, duplicate data entry, and lack of provision to update departmental information. Limitations in learning have been highlighted by a more recent survey [163]. This feedback is highly significant for ROSIS, as the system is only as valuable as the information it provides. These observations are addressed in the current revision of the website and reporting system.

Language is seen as a major limitation; to date, ROSIS is available in English only. The current ROSIS forms depend mainly on free-text answers, and it is not feasible without considerable resources to translate and analyse answers. The revised department and incident report forms capture most information in standardised format. The language barrier can be reduced if the forms are mainly based on pre-selected alternatives and texts. Some free-text boxes will also be retained, as the narrative of the incident is important for understanding. This will enable report forms to be translated and will allow for data analysis to be undertaken regardless of the language of the report. Results of data analysis can be generated in different languages, and importantly, narratives (as one of the most enlightening aspects of the individual reports) will be retained in their original (reported) language.

Lack of ability to easily update information on changes in department infrastructure and also to make amendments to incident reports are further limitations of the system that are being addressed in the revision of the ROSIS website.

A limitation of ROSIS analyses and feedback at the moment is the generalised nature of the incident forms, which were developed to be similar to incident report forms in use in departments. It is hoped that the revised forms will give more flexibility and options for analysis. For example, they will capture information on the stage of origin and detection of the incident within the treatment process. Evaluating incident occurrence and detection in the context of quality control measures may highlight patterns where a change in processes/use of quality control might enable these incidents to be detected prior to treatment delivery.

Feedback is an extremely important aspect of a reporting and learning system. ROSIS can make considerable improvements in this area, as has been discussed in the previous chapter. Suggestions are also given in Section 6.2. One area which should be addressed is providing incentives for reporting beyond altruism, for example, by preparing specific lessons for individual departments based on their own report set.

The existence of ROSIS alongside departmental and/or national reporting requirements means that a report to ROSIS is maybe the second, or third report made, this is time-consuming and impractical in many instances. However, innovative departmental[100] and national[165-166] systems have been developed to be compatible with the ROSIS system.

While ROSIS standardises information collected on incidents in RO; this standardisation is often a secondary activity, since the primary method of data collection – the local incident report form – is normally different to the ROSIS forms. A solution to this and to duplicate reporting (locally and to ROSIS) is for ROSIS to develop a local reporting and learning system which can be used by departments for their own risk management purposes, and which will also export reports to the international ROSIS reporting and learning system. This "local ROSIS" would include more fields than the ROSIS forms, since additional information (e.g. patient name, hospital number, location of incident, reporter name) would be required for local risk management purposes. Only fields needed by the international ROSIS would be exported. The export function would ideally

be automatic, but it could be decided on a report by report basis by the local department if wished.

An ongoing hindrance to development of ROSIS is the lack of resources; limited resources are generated through the risk management course, but in the main the development of ROSIS since 2003 has been non-funded.

6.2 REVISIONS TO ROSIS

Revisions to ROSIS will be discussed under the headings of

- Revised Website
- Revised Department and Incident Report Forms
- Recommended Analyses for Website

6.2.1 Revised Website structure

The website was revised. A major change was the creation of a members area log-in, with two levels – one for administrator, and one for ROSIS member (user).

This means that only ROSIS members can submit a report, and there can be multiple members registered per department. This is also where the new interactive database can be accessed – meaning that the new raw data can only be accessed by ROSIS members. At log-in, members are identified as belonging to a particular centre, and therefore can view interactive analyses specific to their centre. The old database will still be available on the general home page, as will old and new spotlight cases, recommendations and lessons learned. Researchers could be granted a user log-in to access the database.

There is now also an administrator log-in – this has the additional functionalities of reviewing and approving the content of reported incidents before they are automatically inserted into the live database. It also provides a spreadsheet of the database incidents for off-line analysis by ROSIS.

Menus were defined for the homepage and general website (Figure 6-1), and the left-hand menu was customised for the log-in areas for users and administrators respectively to reflect additional functionality (Figure 6-2).

Figure 6-3 and Figure 6-4 illustrate the preferred position of these menus relative to the homepage on the www.rosis.info website, and on the www.rosis-info.org, which has a slightly different structural layout.

Top of page:

- Home
- About ROSIS
- ROSIS Safety Information *(-> from old report forms)*
- Learn about Safety in RO *(-> Link to ROSIS Course)*
- Spotlight Cases
- ROSIS Publications

Left hand side:

- Register Clinic
- Submit a Report
- Members Corner
    - o Username _____ Password _____

Bottom of page:

- Disclaimer
- Copyright
- Terms and Conditions
- Contact
- Useful Links & Resources

Figure 6-1: Website menus for the homepage and associated pages

User Login

Replace left hand side menu with the following:

- Send a Report
- Your Reports
- All Reports
- Logout

Top and bottom menu bars remain the same

Administrator Login

Add the following to the user left hand side menu

- Approve Reports
- Register User
- Incident Spreadsheet / Download incidents

Top and bottom menu bars remain the same

Figure 6-2: Website menus for the log-in areas for users, and administrators

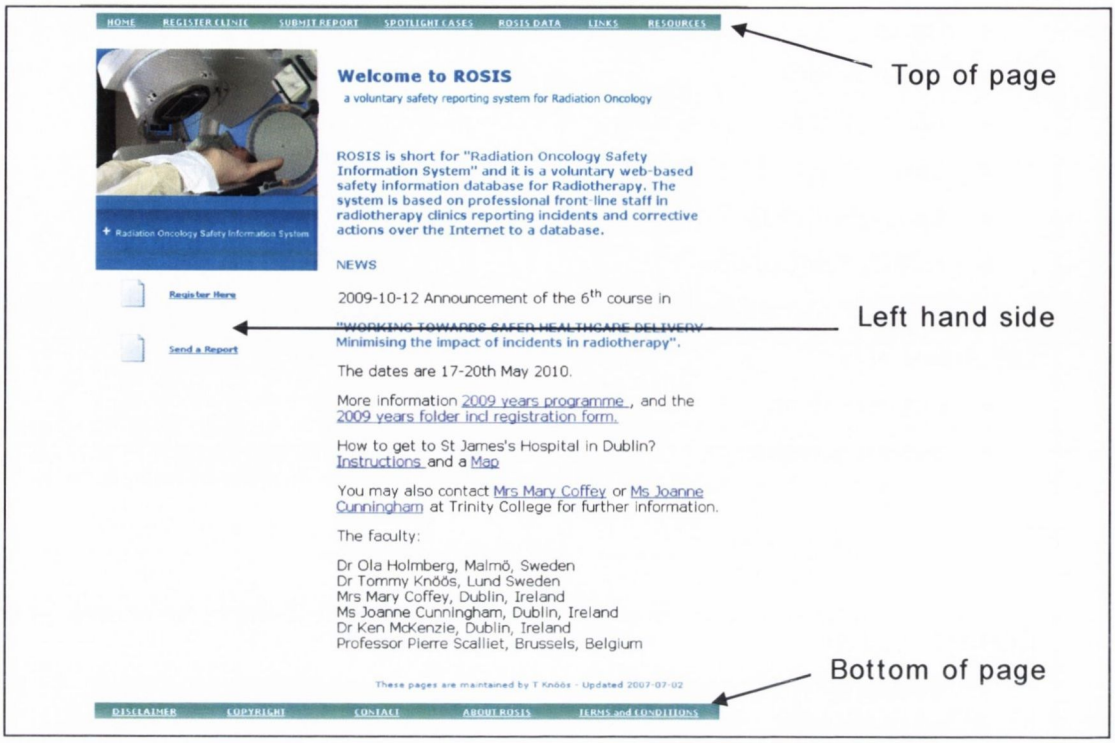

Figure 6-3: Menu positions applied to www.rosis.info web layout

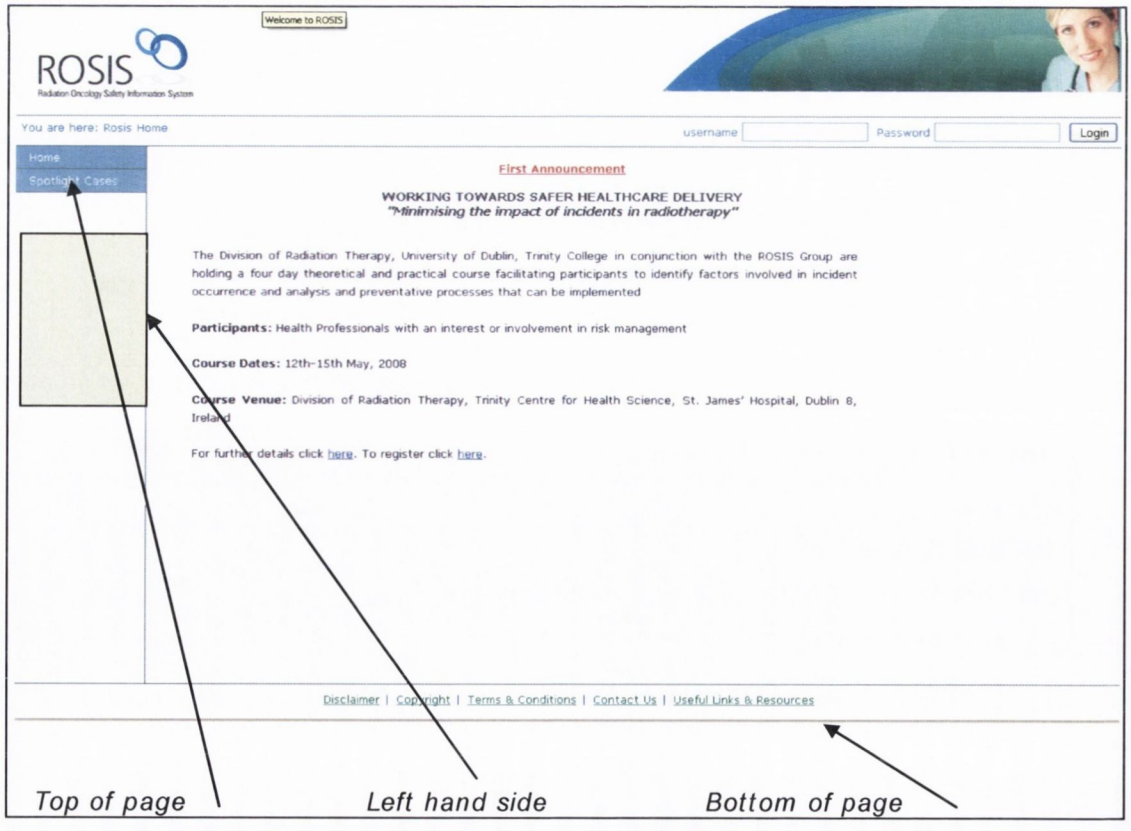

Figure 6-4: Menu positions applied to www.rosis-info.org web layout

6.2.2 Revised Department and Incident Report Forms

The optimal implementation of the classification system was by incorporating it into the report forms; in this way the reporter, who is familiar with the local procedures, processes and equipment, would be able to most accurately report the incident using the classification.

A relational database was created in MS Access; and dynamic report forms, and a web platform in xml was created through collaboration with the School of Computer Science in Trinity College Dublin. Margaret Forrest initially developed a prototype relational database in MS Access, and Graham Woods has developed an xml website, and dynamic forms for ROSIS which insert directly into a MySQL database. MySQL was eventually chosen as an optimal database since there are size and user limitations with MS Access. Although a dynamic department form was prepared, ultimately it was felt that it would be more secure not to have this information electronically sent and automatically inserted into a live online database, and that it would be best to keep this area offline and to use a downloadable form in a Portable Document Format (pdf). When received, these forms will be manually input into an offline database, and a department code assigned which will be used to identify reports from this department in the online database.

The revised Department form is given from page 220; the content of the incident form from page 225.

Since the incident form deviates from the initially proposed classification on severity and causes/contributing factors, a text outline of the classification content of the form is given in Figure 6-8.

The operation of the dynamic form will be illustrated here through the incorporation of the process classification into the incident report form.

The process classification will be incorporated into the dynamic reporting forms in a language guided process as shown in Figure 6-5, Figure 6-6, and Figure 6-7. First, the reporter is asked "During which activity did the error originate?" and is presented with the process classification level 1 options (Figure 6-5).

One the level 1 activity is chosen (in this example, "Treatment Delivery"), the corresponding process image will also be shown to assist in selecting appropriate activities (Figure 6-6). In this example, the field size was incorrect, so the reporter will select the level 2 activity of "RT set-up" (Figure 6-6); then they will have the option of selecting the level 3 parameter of "Field Size" (Figure 6-7).

Any additional information on the incident can be given in freetext under "Please give any further details on incident". For example, a reporter might say that an incorrect field size was set for this patient, or more informatively, that the field size used was that of another field for this patient; or of the last field for the previous patient, etc.

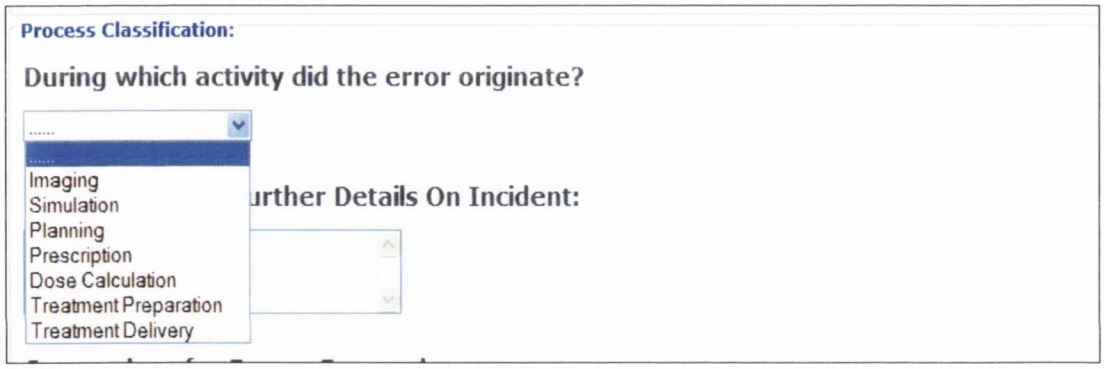

Figure 6-5: First question in dynamic process classification

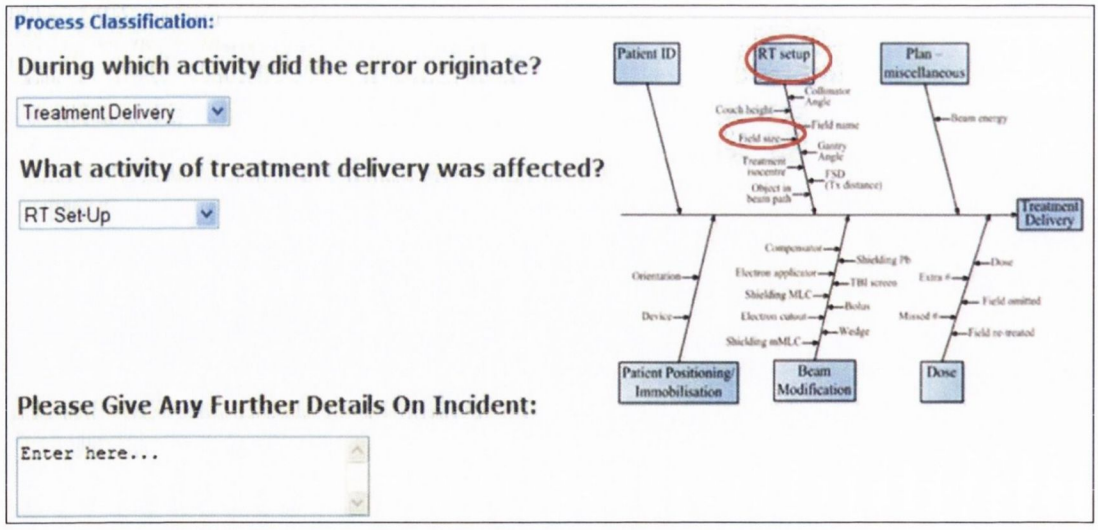

Figure 6-6: Second question in dynamic process classification

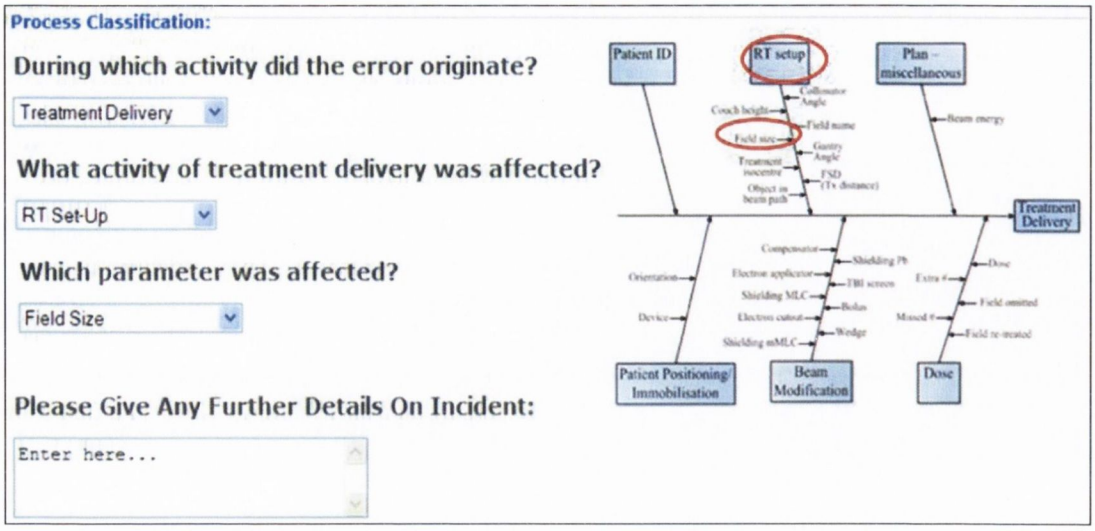

Figure 6-7: Third question in dynamic process classification

6.2.2.1 ROSIS Department Form

DEPARTMENT REGISTRATION FORM

Radiation Oncology Safety Information System
– a voluntary reporting system for radiation oncology

The first step in becoming an active ROSIS participant is registration.

This means that you must first complete and return this registration form giving details of your clinic and the local contact person/people who will be responsible for submitting reports. This will be the only time that you will be asked for this information.

On receipt of the submission you will be sent a clinic ID number which will be your unique identifier. You will use only this number in all subsequent communication. All information submitted thereafter will be anonymised. Your clinic details will be confidential and cannot be accessed by users of this website.

The registration form includes details of the equipment, staff and environment in your centre. This information relates to the complexity of the processes within departments and will be used by the ROSIS group to carry out in-depth trend analysis of incidents in relation to complexity of practice, working environment and educational background of professional staff in a range of clinic types.

PLEASE RETURN THIS FORM TO:

ROSIS
FAO Joanne Cunningham
Division of Radiation Therapy
Trinity Centre for Health Sciences
St James' Hospital, Dublin 8, Ireland

Department Information

Hospital Name: _____

Address: _____

_____

_____

_____

Contact Person(s): _____

Position: _____

Email: _____

Phone number: _____

Department Infrastructure

Approximate number of patients per year: (New patients receiving radiotherapy)

_____

Estimate proportion of CT based treatment plans

_____

Select one or more options that best describes your network:

- □ None
- □ Treatment planning system sends RT parameters to treatment unit
- □ Simulator sends RT parameters to treatment unit
- □ Full networking of RT parameters (i.e. field size settings, M.U. etc)
- □ Full networking of RT images (i.e. electronic portal images, D.R.R. etc)

Select the most appropriate description of your record and verify system:

- □ No machines have record and verify
- □ Some machines have record and verify
- □ All machines have record and verify

Please specify how many FTE of each staff are in your department:

_____ Radiation Oncologist (physician)

_____ Medical Physicist

_____ Radiation Therapist (RTT) at treatment unit

_____ Radiation Therapist (RTT) at simulator and/or in house CT

_____ Staff doing dosimetry

_____ Staff doing technical maintenance

_____ Other – *Please give details:*

_____

Which of the following treatment modalities and/or techniques are you currently using?

- □ **LA – Photons**
  - □ 2-D RT
  - □ 2.5D RT
  - □ 3-D CRT
  - □ 4-D / Gating *please specify technique* _____
  - □ IMRT …
    - □ Dynamic
    - □ Static
  - □ Stereotactic …
    - □ Radiosurgery
    - □ Radiotherapy
    - □ Intra-cranial
    - □ Extra-cranial
  - □ TBI (total body irradiation)
  - □ HBI (hemi-body irradiation)
- □ **LA – Electrons**
  - □ TSEI (total skin electron irradiation)
  - □ Skin Apposition
- □ **Orthovoltage**
- □ **Co-60**
- □ **Brachytherapy**

- □ HDR
- □ LDR
- □ 2-D
- □ 3-D
- □ 4-D

□ **Intraoperative RT**

□ **Gammaknife**

□ **Cyberknife**

□ **Radio-isotopes**

□ **Other -** *Please give details:* _____

_____

_____

Type and number of equipment in your department:

_____ CT

_____ MRI

_____ PET

_____ Ultrasound

_____ Conventional Simulator

_____ Conebeam Simulator

_____ Virtual CT-Simulator

_____ LA (Photons/Electrons)

_____ Orthovoltage

_____ Co-60

_____ Brachytherapy

- _____LDR
- _____MDR
- _____HDR

_____ Intraoperative RT

_____ Radio-isotopes

_____ Gammaknife

_____ Cyberknife

_____ Other

How is the majority of your maintenance of the equipment performed?

□ Service Contract

□ Inhouse**Quality Assurance Procedures in the Department**

Select the options that best describe the QA system at your department

- □ Treatment charts are independently checked before treatment begins
- □ Treatment charts are routinely checked during treatment
- □ Data entry into record and verify is independently checked
- □ In-vivo dosimetry is used for most new patients
- □ Peer-review (planning conference) is done for most new patient prescriptions (dose and location)
- □ Portal or volumetric images are taken for most new patients (films or electronic)
- □ The patients identity is formally checked using a minimum of two identification methods prior to each daily treatment
- □ Regular clinical review (of side effects etc.) of most patients
- □ Written quality control procedures and records for most treatment unit checks
- □ Written procedures for most of the clinical processes
- □ Formal quality management system (ISO etc.)
- □ Regular QC of treatment units
- □ External dosimetry audit by EQUAL or by other - *please specify who conducts this audit*

  _____
- □ Other QA, *Please give details:*

  _____

Risk Management Procedures in the Department

Do you have a dedicated member of staff for Risk Management /Quality Assurance activities?

□ Yes □ No

Do you have a reporting system?

□ Yes □ No

- □ General hospital-wide report form
- □ Radiotherapy-specific report form

Is your reporting system:

□ Mandatory or □ Voluntary

□ Anonymous or □ Confidential

Is feedback given to staff?

□ Yes □ No

Do you have a risk management committee?

□ Yes □ No

How long has this committee been in existence (years)?

_____ **years**

6.2.2.2 ROSIS incident report form

Since this is a dynamic form, it is represented statically here by showing the questions and the answer options and format.

EVENT SUMMARY				
Please state the number of persons affected?				*freetext box, number for each option*
	Patients			
	Staff			
	Visitors			
INTENDED TREATMENT TECHNIQUE				*dynamic dropdown options:*
	LA - Photons	2-D RT		
		2.5D RT		
		3-D CRT		
		4-D / Gating		*freetext for details of method*
		IMRT	Dynamic	*one selection possible*
			Static	
		Stereotactic	Radiosurgery	*multiple selections possible*
			Radiotherapy	
			Intra-cranial	
			Extra-cranial	
		TBI		
		HBI		
	LA- Electrons	TSEI		
		Skin Apposition		
	Orthovoltage			
	Co-60			
	Brachytherapy	HDR		*multiple selections possible*
		LDR		
		2-D		
		3-D		
		4-D		
	Intraoperative RT			
	Radio-isotopes			
	Protons			
	Neutrons			
	Light ions			
	Gammaknife			
	Cyberknife			
	Other			

INTENDED TREATMENT SITE			*dropdown options, select one*
	Brain		
	Head and Neck		
	Thorax		
	Breast		
	Abdomen		
	Pelvis		
	Extremity		
	TBI		
	HBI		

EQUIPMENT			
If the incident cause is related to equipment (h/w or s/w), please specify the make and model including version number:			
	Make and Model		*freetext box*

INCIDENT DESCRIPTION		
Please describe the incident/near incident in detail		*freetext box*

CAUSE / CONTRIBUTING FACTORS			
Please choose the factors below that may have caused and/or contributed to the error			*list, multiple selections possible*
	Don't know		
	Technical Factors		
	Organisational Factors		
	Human Factors		
	Patient Factors		
	Other		

SEVERITY			
Was any part of the treatment delivered incorrectly			*radio buttons*
	Yes		
	No		
How many fractions were delivered incorrectly?			*freetext box, number*
How many fractins were prescribed in total?			*freetext box, number*
Outcome for the patient(s)/person(s) affected			

		radio buttons
	0. None: Event without consequence	
	1. Light: Event with dosimetric consequences but no expected clinical consequence (grade 1) - *No expected symptom*	
	2. Moderate: Event leading to or liable to lead to a moderate impairment of an organ or function (grade 2) - *Dose higher than recommended doses liable to lead to unexpected but moderate complications*	
	3. High: Event leading to a severe impairment of one or more organs or functions (grade 3) - *Dose or irradiated volume higher than tolerable doses or volume*	
	4. Severe: Serious life-threatening event, disabling complication or sequelae (grade 4) - *Dose or irradiated volume far higher than tolerable doses or volumes*	
	5. Death (grade 5) - *Dose or irradiated volume far higher than normal leading to fatal complications or sequelae*	
Comments regarding actual outcome		*freetext box*
Potential outcome for the patient(s)/person(s) if the incident was not detected/corrected		*radio buttons*
	0. None: Event without consequence	
	1. Light: Event with dosimetric consequences but no expected clinical consequence (grade 1) - *No expected symptom*	
	2. Moderate: Event leading to or liable to lead to a moderate impairment of an organ or function (grade 2) - *Dose higher than recommended doses liable to lead to unexpected but moderate complications*	
	3. High: Event leading to a severe impairment of one or more organs or functions (grade 3) - *Dose or irradiated volume higher than tolerable doses or volume*	
	4. Severe: Serious life-threatening event, disabling complication or sequelae (grade 4) - *Dose or irradiated volume far higher than tolerable doses or volumes*	
	5. Death (grade 5) - *Dose or irradiated volume far higher than normal leading to fatal complications or sequelae*	
Comments regarding potential outcome		*freetext box*

DETECTION		
When in the process was the error detected		*dropdown options, select one*
	Imaging	
	Simulation	
	Planning	
	Prescription	
	Dose calculation	
	Treatment Preparation	
	Treatment Delivery	
Detection Method		*dropdown options, multiple selection possible*
	Chart-check - pre-treatment	
	Chart-check - during treatment	
	in-vivo dosimetry	
	portal imaging	
	volumetric imaging	

	clinical review of patient	
	quality control of equipment	
	found at time of 1st patient treatment during regular checks	
	found at later stage during patient treatment	
	external audit	
	other	
Detection - Staff Type:		*dropdown options, multiple selection possible*
	Radiation Oncologist (physician)	
	medical physicist	
	radiation therapist at treatment unit	
	radiation therapist at simulator and/or in-house Ct	
	staff doing dosimetry	
	staff doing technical maintenance	
	other	

PROCESS CLASSIFICATION		
During which activitiy did the error originate		*dynamic dropdown options, select one, + two subsequent levels are possible,*
	Imaging	
	Simulation	
	Planning	
	Prescription	
	Dose calculation	
	Treatment Preparation	
	Treatment Delivery	
Box for any further information		*freetext box*

Suggestions for future prevention	*freetext box*

ROSIS Classification

1. EVENT / OCCURRENCE

1.1 Who

1.1.1 Patient

1.1.1.1. Treatment Intent

1.1.1.2. Treatment Site

1.1.2 Staff

1.1.3 Visitor

1.2 RT Technique

1.2.1 Technique

1.2.2 Equipment

1.3 Process Classification

1.3.1 Stage in Process

1.3.2 What element

1.4 Description

2. SEVERITY

2.1 Incident / Near Incident

2.2 Actual harm

2.3 Potential harm

3. CAUSES / CONTRIBUTING FACTORS

3.1 Don't know

3.2 Technical

3.2 Organisational

3.3 Human

3.4 Patient

3.5 Other

4. DETECTION

4.1 Method

4.2 Discipline

4.3 Stage in Process

Figure 6-8: Text outline of ROSIS Classification, 2010

6.2.3 Recommendations for additional analyses to be provided on website

At log-in, each user should be able to access:

- A list of the incidents that have been reported since their last log-in
- A list of incidents reported by their department
- Individual incident reports
- Pre-defined searches on the interactive database
    - Treatment technique
    - Treatment site
    - Factors that may have caused the error (Human Factors, Patient Factors, Organisational Factors, Technical Factors)
    - Severity of treatment delivered incorrectly (number of fractions delivered incorrectly)
- User-defined searches on the interactive database
    - The user should be able to select criteria on which to search the database. This could be a single field – e.g. Incidents that occur during Treatment Delivery, or could be further refined by the addition of additional fields, e.g. Incidents that occur during Treatment Delivery to the Head and Neck using IMRT.
- Each ROSIS department should be able to view its performance against the rest of the incidents in the database

The redesign of the database and website has been undertaken to facilitate the provision of these analyses.

Spotlight cases (or expert analyses) should be prepared by ROSIS to answer the following questions:

- *Which stages of the RT process are most likely for mistakes to occur / be detected?*
- *Are some mistakes more common to certain techniques / treatment sites / stage in process?*
    - *e.g. IMRT of H&N at treatment delivery*
- *Are some mistakes more serious?*
- *Are there similar types/frequencies/severities of mistakes in similar departments (size, equipment, technology, personnel, QA/QC) ?*
- *Are incidents by-passing particular QA/QC methods*

- *Are there activities which are especially error-prone?*

These analyses should be published and made available to the general RO Community; but added value can be given to ROSIS Departments in terms of also providing these analyses on an individual basis for each ROSIS department.

6.3 FURTHER DEVELOPMENT OF ROSIS

The history of ROSIS proves that there is a need for such an international reporting and learning system in RO.

As an independent and voluntary system, the name ROSIS appears to have garnered a good reputation among the RO Community.

ROSIS has proven that it is a viable concept, but a severe limitation to its development and meeting its potential has always been funding.

ROSIS now needs to build on the successes of the past years, and to ensure that it can exist into the future and meet the needs of users by taking a more structured approach to its management.

ROSIS can develop a social entrepreneurship business model, by establishing a Company Limited by Guarantee, and carefully composing Articles of Association to ensure that the not-for-profit, open and sharing ethos of ROSIS is maintained in the business world. ROSIS is still very abstract, and should become a legal entity in order to develop and evolve as a respected international reporting and learning system. As a legal entity, ROSIS could develop partnerships with research institutions and/or industry, and would be eligible for funding applications. Being a company limited by guarantee with a social mission might also be appealing for industry partners many of who now address their "Corporate Social Responsibility" through partnerships with non-profit subsidiaries or partners.

Beginning to "market" ROSIS also entails protecting the brand of "ROSIS" – a step which has begun with the national and international trade-marking of ROSIS (Appendix K), and creating information leaflets aimed at possible partnerships (Appendix L).

A major area for expansion of ROSIS is to develop local departmental reporting and learning systems, based on the cross-organisational system. This should facilitate departmental risk management procedures by having a system tailor-made for RO, would greatly enhance the penetration of ROSIS, would make reporting to the international ROSIS very straightforward, and as an end-point will capture more information on incidents – yielding more learning. The idea was based on requests by ROSIS departments to be able to copy the forms and database of ROSIS in their

own department, and was discussed with the Computer Science department in TCD, who cautioned on the contractual aspects such a system would bring. It has also been an element of funding applications by ROSIS. One possibility which is currently being explored is partnership with industry in order to enable the development, distribution and ongoing support required of such a system. It is hoped that any such partnership would result in the provision of resources (monetary or personnel) for ROSIS which can then be used to maintain the international system, perform data analysis, and ensure that the communication and dissemination aspects of ROSIS are optimal.

In the short to medium term, it is essential that ROSIS acts on the highlighted weaknesses in learning and communication – the revision of the website has addressed some of these issues, and further feedback will be sought from the users once it is live. More expert analyses of the database is needed, and a stronger role in alerting the RO Community of new hazards or equipment failures. Being able to view raw incident reports is no longer sufficient, and expert analyses are vital to ensure the continued contribution of ROSIS Departments and regard for ROSIS as an international reporting and learning system.

ROSIS could certify to a clinical audit process that a department participates in reporting and learning, based on meeting specified quota. Quality has long been recognised as an essential component of healthcare, and clinical audit has developed as a means of assessing quality of health care delivery at the point of care. The outcome of treatment may depend on the quality of treatment, and the quality of treatment might predict outcomes. Auditors of quality must be primarily concerned with ensuring optimal outcomes for patients. Mistakes in treatment have the potential to compromise the outcome. Incident reporting and learning systems must be a component of any clinical environment, and should be evaluated alongside other quality indicators. Departments should demonstrate a commitment to reporting and learning, and participation in a system such as ROSIS should be a requirement. ROSIS should lobby policymakers to ensure that departments participating in clinical audit must demonstrate a commitment to safety which includes a healthy reporting and learning system, which could be "certified" through benchmarking their participation in an international system such as ROSIS.

7 Chapter 7: Conclusion

An international cross-organisational reporting system has been developed and implemented, yielding opportunities for learning from mistakes in Radiation Oncology. Feasibility of the system is clearly demonstrated in the recruitment of ROSIS departments, the volume of reports submitted, and the system's growing international recognition and impact. ROSIS covers a broad patient population, with reasonable averages of Patients per MV unit, per Oncologist, and per Physicist. It is difficult to draw conclusions from the number of Patients per RT/RTT. Some level of defence-in-depth is apparent in most departments.

The majority of ROSIS reports relate to external beam radiation treatment; half of the events reported resulted in incorrect treatment delivery. The results from reporting systems need to be carefully interpreted and not over-analysed; however, areas for improvement can be identified since many incidents appear to arise pre-treatment, but are not detected until later in the treatment process. The most commonly reported detection methods were "found at time of patient treatment" and "chart-check", with a higher proportion of near-incidents detected by chart-check. While the majority of the incidents reported are of minor dosimetric consequence, they affect on average more than 20% of the patient's treatment fractions. Recommendations are made on how to improve safety and avoid (or detect) the most common incidents.

A comprehensive classification system has been devised to enable improved learning from radiotherapy incidents. This is the first version of the ROSIS Classification System; it will be reviewed on a regular basis, and modified to include new information or terms when necessary. The classification elements have been defined in terms of a dataset, and through dynamic webforms are incorporated into a revised ROSIS reporting system and website. Most dataset elements are suitable for local, national and international data collection; however, in the case of local application, there are modifications needed to ensure that additional local management and learning can take place. ROSIS aims to develop these local applications, but needs support.

Information reported to ROSIS can be used to investigate incident occurrence and detection. The information gained from the project can also be used for more process-oriented risk management approaches to increase the accuracy in delivery of radiation therapy as well as an increased safety for the patients. Reports based

on the new dataset will give more potential for data analysis. Since the new report forms are based on more standardised information and answer options, it will be possible to translate the form and accept reports in various languages, whilst still being able to code and analyse the full dataset. Learning lessons has been identified as an area for improvement for ROSIS, and recommendations are made in this respect.

ROSIS has established itself as an international safety information system since its inception at the beginning of this millennium; yet there are expectations of the system which are not currently being realised. The system is severely limited due to lack of resources of personnel, and finance, and cannot progress much further without these. Resources are required to carry out data analyses (of the entire database, and for subsets e.g. individual departments; to perform benchmarking; to compile spotlight cases; to further develop classification etc), to develop a social entrepreneurship business model and to promote ROSIS, to develop and maintain the database website, to liaise with stakeholders, to lobby policymakers, and to develop local systems.

Further development and promotion of ROSIS are required to meet its full potential and for its ongoing and increasing contribution to patient safety in radiation oncology. Funding is being sought as a matter of priority. In the meantime, ROSIS will launch the revised website and forms, and continue data collection, feedback and education based on these.

APPENDIX A

A. ROSIS 1074

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Radiation safety

Radiation Oncology Safety Information System (ROSIS) – Profiles of participants and the first 1074 incident reports

Joanne Cunningham [a,*], Mary Coffey [a], Tommy Knöös [b], Ola Holmberg [c]

[a] Discipline of Radiation Therapy, School of Medicine, Trinity College, Dublin, Ireland; [b] Radiation Physics, Skåne University Hospital and Medical Radiation Physics, Lund University, Sweden; [c] Radiation Protection of Patients Unit, Radiation Safety and Monitoring Section, Division of Radiation, Transport and Waste Safety, International Atomic Energy Agency, Vienna, Austria

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ABSTRACT

Background and purpose: The Radiation Oncology Safety Information System (ROSIS) was established in 2001. The aim of ROSIS is to collate and share information on incidents and near-incidents in radiotherapy, and to learn from these incidents in the context of departmental infrastructure and procedures.

Materials and methods: A voluntary web-based cross-organisational and international reporting and learning system was developed (cf. the www.rosis.info website). Data is collected via online Department Description and Incident Report Forms. A total of 101 departments, and 1074 incident reports are reviewed.

Results: The ROSIS departments represent about 150,000 patients, 343 megavoltage (MV) units, and 114 brachytherapy units. On average, there are 437 patients per MV unit, 281 per radiation oncologist, 387 per physicist and 353 per radiation therapy technologist (RT/RTT). Only 14 departments have a completely networked system of electronic data transfer, while 10 departments have no electronic data transfer. On average seven quality assurance (QA) or quality control (QC) methods are used at each department. A total of 1074 ROSIS reports are analysed; 97.7% relate to external beam radiation treatment and 50% resulted in incorrect irradiation. Many incidents arise during pre-treatment but are not detected until later in the treatment process. Where an incident is not detected prior to treatment, an average of 22% of the prescribed treatment fractions were delivered incorrectly. The most commonly reported detection methods were "found at time of patient treatment" and during "chart-check".

Conclusion: While the majority of the incidents that reported to this international cross-organisational reporting system are of minor dosimetric consequence, they affect on average more than 20% of the patient's treatment fractions. Nonetheless, defence-in-depth is apparent in departments registered with ROSIS. This indicates a need for further evaluation of the effectiveness of quality controls.

 Radiotherapy and Oncology 97 (2010) 601–607

Safety is a vital aspect of radiation oncology (RO); past events highlight the need for ongoing vigilance and increased focus on the identification and management of real and potential dangers associated with this medical specialty [1–6].

Safety management in an organisation should encompass both proactive and reactive measures [7–8]. Data from reactive measures can also be used in a feedback process to enhance proactive safety management actions [9]. Proactive measures aim to identify potential hazards and prevent errors from occurring. These include process mapping, statistical process control and analytical methods e.g. Fault tree analysis, Failure modes and effects analysis (FMEA). Reactive measures focus on errors once an incident has occurred; e.g. root cause analysis among other methods but also incident reporting and investigation.

Although reporting of incidents and near-incidents is subject to biases, it reveals valuable information on the types, causes and detection of mistakes which occur [10]. A complication of using near-incident data to identify causes is that the relationship between causal factors in the occurrence of incidents and in the occurrence of near-incidents is not yet known for radiotherapy, although in the railway domain the common causes hypothesis is supported [11].

Effective learning from national and international incident reporting systems leading to safety promotion has been illustrated in other areas by systems such as the Aviation Safety Reporting System [12], and the Advanced Incident Monitoring System [13]. For example, Leape [14] identifies four methods by which external reporting (voluntary or mandatory) can promote safety:

- Alerts about new hazards
- Shared experience on prevention of errors
- Analysis of many reports to reveal trends and specific hazards

* Corresponding author. Address: Discipline of Radiation Therapy, School of Medicine, Trinity Centre for Health Sciences, St. James Hospital, Dublin 8, Ireland.
E-mail address: snichuin@tcd.ie (J. Cunningham).

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- Recommendation of "best practices" based on analyses

Mandatory reporting of incidents in RO at a national level is common practice in Europe, existing in several countries for decades under regulations deriving from radiation protection and/or health legislation. Departments in several countries have well developed local reporting systems for incidents and near-incidents. However information from these systems is not extensively shared. With a vision to reduce the potential for repetition of incidents in other settings by sharing information on local incidents and near-incidents with the wider community, the Radiation Oncology Safety Information System – ROSIS – was created as a learning tool. ROSIS is a voluntary, web-based reporting system which aims to:

- Establish an international reporting system in RO, and
- Use the system to reduce the occurrence of incidents in RO by
  - enabling RO departments to share reports on incidents with other departments as well as with other stakeholders such as scientific and professional bodies
  - collecting and analysing information on the occurrence, detection, severity and correction of RO incidents
  - disseminating these results and generally promoting awareness of incidents and a safety culture in RO

ROSIS was established in 2001. ROSIS reports have been a subject of, or have been recognised in, a number of scientific publications [1,15–20,22,46]. This paper reports on the profiles of 101 participating departments and 1074 ROSIS incident reports (separately).

Materials and methods

ROSIS has been designed to collect information on incidents and near-incidents, and to put these in the context of the infrastructure and procedures of the department.

Two distinct forms are used for data collection:

- A Department Form – to collect information on the department infrastructure and procedures
- An Incident Report Form – to collect information on the incident/near-incident

These forms were put on the Internet in January 2003, initially hosted by the ESTRO web-server. An outline of the basic topics in these forms can be seen in Table 1; the full forms can be viewed online at www.rosis.info.

A dedicated ROSIS website was developed under the domain name: www.rosis.info, and put on the Internet in October 2004. All anonymised incident reports are stored in an online searchable database and made available on the website in their original text.

Table 1
Basic topics of the ROSIS Department form and ROSIS Incident form.

Department form	Incident form
Dept. name and location; contact person	Modality
Type and number of machines	Who detected
No of patients treated/year	Error/near miss
Record and verify system	Who and how many involved
Integration of network/areas	How detected
Full time equivalent per category of staff	Outcome/potential outcome
Service contract	Description, cause, suggestion for prevention
QA methods	Comments

For the purposes of reporting, an incident is defined as any incorrect delivery of radiation. The magnitude of the incorrect delivery is defined by the local user. A near-incident is considered to be any event, which may have resulted in an incident. For the latter type, however, the responsibility of identification relies strongly on the local reporter.

In this paper, the focus will be on the existence, types, causes and detection of mistakes in the radiotherapy process, which have been reported to ROSIS.

Information from Department Forms and Incident Reports are entered into an MS Access Database, and data analysis is undertaken in MS Access and MS Excel. Each incident report is retrospectively examined to identify the most likely stage of incident occurrence. All other data are reported directly. In keeping with best practice on reporting systems, simple descriptive statistics are used to evaluate the ROSIS department and incident data.

Results

Results are divided into two sections:

1. Profiles of departments participating in ROSIS
2. Incident data reported to ROSIS

Profiles of departments participating in ROSIS

Registration of departments has grown steadily since the ROSIS reporting system was introduced. In early 2009, there were 101 departments registered; 70 from Europe and between 2 and 12 from each of the following regions:

- Africa
- Asia
- Australia and the Pacific
- North America
- South and Central America.

With respect to infrastructure, the departments represent a total of

- 309 Linear Accelerators (Linacs) (avg 3 per dept)
- 34 Cobalt Machines (avg 0.3 per dept)
- 114 Brachytherapy Machines (avg 1.1 per dept)
- and a patient population of over 150,000 new patients per year (average 1497 per dept; range 50–6500)

Twenty-three departments are equipped with Linacs alone, while 23 have a minimum of one Co-60 unit, and 76 have at least one brachytherapy machine. The complexity of treatments within departments varies greatly, with an average of 74% CT planned treatments (range 0–100%).

While most departments have at minimum a method of networked data transfer from simulator or treatment planning system to treatment unit, 11 do not have any electronic data transfer (10%). There is considerable variation in the level of networking within the group as a whole, with only 24 departments having a single form of network throughout their department. It is also noteworthy that there are often several networking arrangements within one department – from four possible options, 2.4 options were selected on average. The network options and distribution are shown in Table 2.

A record and verify system is used on all units in 67 departments (68%), on some units in 26 departments (26%), and six departments have no R&V system in the department at all. This information is unknown for two departments.

Table 2
Networking capabilities available in departments. Multiple selections may be made by each department.

Network options	Number of departments
None (no network between units or treatment planning system, or record and verify system	10
Treatment planning system sends radiotherapy (RT) parameters to treatment unit	55
Simulator sends RT parameters to treatment unit	28
Full networking of RT parameters (i.e. field size settings, monitor units etc.)	69
Full networking of RT images (i.e. electronic portal images, digitally reconstructed radiographs etc.)	69

Table 3
Number of patients per FTE member of staff.

Discipline	Average	Median
Oncologists	281	250
Physicists	387	320
Radiation therapists at treatment units	159	125
Radiation therapists at simulator/CT	546	450
Dosimetrists	549	467
Technical maintenance	833	667

The average number of patients per member of staff is displayed in Table 3.

Of the participating departments, 54 have contracts for equipment service/maintenance, whereas for 40 this is performed in-house. One department has a 50:50 mix between contracts and in-house, and there is no data for two departments.

Participants were asked to report quality assurance procedures present in their department (Table 4). This list encompasses the quality assurance (QA) planning and managerial activities, (e.g. formal quality management systems) as well as routine quality control (QC) monitoring activities (e.g. chart checking, portal imaging, in-vivo dosimetry). The most common procedures are regular quality control of treatment units (98 departments), portal imaging (94), chart checking (90), and quality control procedures (91). In-vivo dosimetry and formal quality management systems are the least common (34 and 35 departments, respectively).

The majority of departments (69) participate in at least one dosimetric audit programme:

- IAEA (International Atomic Energy Agency) – 10 departments
- EQUAL (ESTRO) – 18 departments
- RPC (Radiological Physics Center at MD Anderson) – 7 departments
- Other Regional/National – 23 departments
- Specific audit programme not specified – 24 departments

Most departments have a system of QA or QC that monitors the radiotherapy process at several steps. Thus, a defence-in-depth system is implemented to various degrees at different hospitals. Defence-in-depth is defined by the International Basic Safety Standards (BSS) as "the application of more than a single protective measure for a given safety objective such that the objective is achieved even if one protective measure fails" [21]. If the category "Other QA" is excluded, the minimum number of remaining QA methods used in any one department is three; the maximum is 10. Both the average and median of number of methods used is seven.

Table 4
Departmental Quality Assurance (QA)/Quality Control (QC) procedures.

QA/QC activity	Total (%)
Chart check	90 (89)
In-vivo dosimetry	34 (34)
Peer review	56 (55)
Portal images	94 (93)
Regular clinical review	73 (72)
Quality control procedures	91 (90)
Procedures for clinical processes	69 (68)
Formal Quality Management System	35 (35)
Regular QA of treatment units	98 (97)
Audit programme	69 (68)
Other QA	28 (28)

Incident data reported to ROSIS

Of the 1074 reports submitted to ROSIS between January 2003 and August 2008, 1049 (97.7%) are on the use of external beam radiation, 20 (1.9%) on brachytherapy, and five (0.5%) on other occurrences (mainly non-process). Incidents are classified as being either process-related, where the occurrence of the incident is related to a failure in the process, or non-process related, where the process had no real bearing on the occurrence of the incident (e.g. hardware or software failures, slips/trips/falls). Process-related incidents are classified as pre-treatment/treatment/follow-up, or into activity related processes (e.g. imaging/simulation/planning/treatment).

Only 258 of the reported process-related incidents were detected prior to treatment. Most reported incidents (754) were detected at the treatment sub-process of the radiotherapy process, and 23 were detected at follow-up. The remaining 39 reports were either non-process, or not classifiable.

The majority of the reported incidents were detected by radiation therapists at the treatment unit (RTs/RTTs) (Fig. 1), and were found during a patient treatment appointment i.e. "found at the time of patient treatment" (457/43%) (Fig. 2). Detection by the QC process chart check was the next most common method of detection (350/33%) (Fig. 2). Of these chart check detections, 168 were detected during pre-treatment, whereas the other half (167) were found when chart checks were performed during the treatment (151) or at follow-up (16 – from one centre).

Two reports relate to an incident involving staff or non-patient. A minor number of reports, 21, relate to incidents involving several patients (range: 2–7 patients).

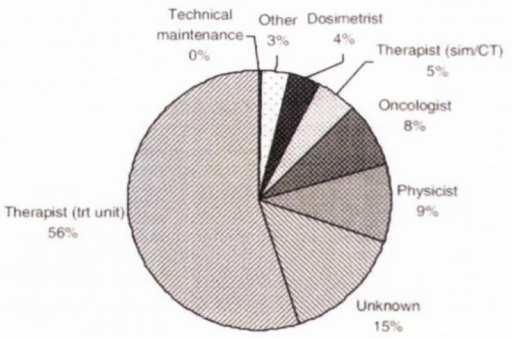

Fig. 1. Discipline who detected the incident.

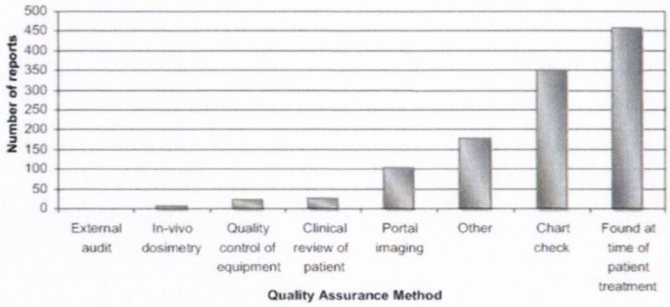

Fig. 2. Quality assurance method by which the incident was detected.

Treatment was delivered incorrectly in 546 of the reports (51%). This refers to any incorrect delivery of radiation, and is an incident as defined by ROSIS. For 473 of these 546 reports, the number of fractions treated incorrectly is known:

- 1–3 fractions incorrect = 408 reports (86% of 473)
- 4–10 fractions incorrect = 53 reports (11% of 473)
- 11–24 fractions incorrect = 12 reports (3% of 473)

For 199 of these reports (42% of 473), the total number of fractions prescribed is also known. Using this information, the reported incidents range from 3% to 100% of the treatment delivered incorrectly, with an average of 22% of the prescribed treatment fractions incorrect (Fig. 3).

Table 5 gives the relationship between the incident and the QA method by which it was detected. Where data is available, this table also illustrates the number of fractions where the treatment was given incorrectly. Chart-checking was the most common detection method of incidents in five of the eight activity related processes.

Discussion

A major strength of ROSIS is that it enables direct analysis of reports from different departments and clinical situations internationally; this current review includes 101 departments and 1074 reports.

In considering incident reports, it must be remembered that

1. Voluntary incident reporting may not reveal the true cross-section of incidents (although it is likely that neither does most mandatory reporting) [10]; and that
2. All reporting is subject to biases: not all types of incidents might be reported, nor the true frequency of each incident type, nor the absolute relative frequency of the incidents [10].

For these reasons, it is important that incident data from reporting systems is interpreted carefully and not over-analysed.

As of early 2009, 101 departments have registered with ROSIS; initially registered departments were located within Europe, but there is now a more diverse global distribution of departments in ROSIS. Based on new patient numbers, the potential patient population covered by ROSIS is 150,000. According to the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) [22] 5.1 million people receive radiotherapy annually; this means that ROSIS covers approximately 3% of all radiotherapy patients.

Within the departments reporting to ROSIS, there is substantial variation in terms of infrastructure, and resources – overall, and per patient population. The patient population of 150,000 is served by a total of 343 Megavoltage (MV) units (Linac and Co-60), and an average of 437 patient treatments per MV unit per year. This is slightly less than the QUARTS recommendation of 450 treatments per MV unit per year for European countries [23], but does mask major differences between departments. [QUARTS stands for Quantification of Radiation Therapy Infrastructure and Staffing Needs].

Most departments (75) have both Linacs and brachytherapy equipment, at present the specific capabilities of these are unknown. Complexity is measured by the percentage of CT planned treatments. ROSIS departments cover a range of 0–100% CT planned treatments. This might not be representative of modern-day technology and complexity.

Data transfer is a safety critical step in the treatment chain. Electronic transfer can reduce the human error contribution to data transfer errors; ideally a department would transfer all data electronically. Networking capabilities are varied between and within departments; while 10 departments have no network, typically departments have a mix of electronic data transfer options. It is noteworthy that only 14 departments are fully networked throughout, including images. It is likely that including an element of human data transfer at any stage in the process will lead to an increase in data transfer errors [24,49–51]. Where a subsequent part of the process is electronic, it can give rise to a false sense of security. One may also note that many electronic systems are not completely integrated, thus transfer between e.g. treatment planning system and R&V systems is performed, and import/export functions where human interaction is involved may still lead to transfer errors. However, neither is electronic data transfer completely dependable [25]. As the treatment complexity increases, we are more reliant on electronic data transfer, and must be vigilant as to its inherent risks.

It is difficult to compare staffing levels across different countries, due to the differing roles and responsibilities per discipline, different patterns of disease occurrence and detection, and varying complexities of treatments. The QUARTS project [26] reviewed radiotherapy staffing in 41 countries across Europe, 40% of which had guidelines for staffing. ROSIS departments have an average of 281 patients per Oncologist; and 387 per Physicist; these compare well with the QUARTS data (suggestion of 200–250 patients per Radiation Oncologist and 450–500 per Physicist). The data on the remaining disciplines (Radiation Therapists (RTs/RTTs), Dosimetrists and Technical Maintenance) are extremely dependent on such factors as mentioned above.

The main purpose in collecting information about the department infrastructure is to enable investigation into whether or not these variables in infrastructure affect the occurrence or detection of incidents. This is not yet possible with the amount and type of

Table 5
Cross-tabulation of reports where treatment has been delivered incorrectly with the eventual detection method.

	Chart check	Found at time of patient treatment	In-vivo dosimetry	Portal Imaging	Clinical review of patient	Quality control of equipment	Other	External audit
Total number of reports per detection method	335	451	7	103	22	20	164	0
Number of reports where treatment was delivered incorrectly (% of all reports for this detection method)	124 (37.0)	302 (67.0)	5 (71.4)	68 (66.0)	11 (50.0)	13 (65.0)	62 (37.8)	0
Range of number of fractions treated incorrectly per detection method	1–24# (n = 107)	1–24# (n = 262)	1–8# (n = 4)	1–10# (n = 56)	2–18# (n = 11)	1–6# (n = 12)	1–13# (n = 56)	0
Average number of fractions treated incorrectly per detection method	3 (n = 107)	2 (n = 262)	3 (n = 4)	2.2 (n = 56)	3.7 (n = 11)	2.4 (n = 12)	2.4 (n = 56)	0

information in the database, but modifications are being made to capture more information on the department's equipment and technology; this will include an annual check to confirm the infrastructure of the participating departments.

A generally encouraging finding is the use of multiple QA methods in departments, with a reported average of seven methods per department. The International BSS recommends an approach which encompasses multiple layers of defences [21], and these methods can be seen as filter levels in a defence at depth or a multi-layered defence system. The least utilized QA methods were in-vivo dosimetry and formal quality management system (QMS); the most utilized was a Regular QA of Treatment Units. Nonetheless, three departments do not perform Regular QA of Treatment Units – this is cause for concern, and is inconsistent with general guidelines [27–30]. Alternatively, this result could be a misinterpretation of the department form leading to a failure to select the option "Regular QA of Treatment Units" when reporting the departmental status.

The existence of defence-in-depth is an important aspect of detecting mistakes and preventing adverse events. In the ROSIS database, the treatment was delivered incorrectly in just over one half of the reports. Most of these incidents were detected at an early stage (1–3 fractions), with a minority affecting 4 or more fractions (Fig. 3). Without knowing the total number of fractions prescribed, it is difficult to put this into the context of severity of the incident. For those incidents where the total fractionation prescribed is known (199), the reports represented a mistake in an average 22% of prescribed treatment fractions. Depending on the type and extent of the mistake, this could represent a very significant impact on the treatment outcome and/or incidence of adverse events.

A difference is observed in the ratio of reported incidents versus near-incident depending on the quality control method used (Table 5), e.g. "Found by chart check" results in proportionally more near-incidents than "Found at later patient treatment" and "in-vivo dosimetry". "Found at first patient treatment" seemed to incur more severity than when "Found at later patient treatment" (average 25% vs. 15% of the prescribed fractions treated incorrectly). This is probably an artefact of the reports (e.g. there was an average of 15 prescribed fractions per treatment for "Found at first patient treatment" vs. 20 for "Found at later patient treatment").

The literature has mainly focussed on the value of chart-checking [24,30–35], in-vivo dosimetry [24,30,32,36–38], and portal imaging [24,30] as the most valuable tools. In 1992, Leunens [24] reported that combining in-vivo dosimetry and portal imaging would detect 95% of incidents in their study; in the present dataset these methods are responsible for the detection of approximately 10% of incidents reported (a total of 110). Although portal imaging is almost universally routinely used, in-vivo dosimetry is not used routinely in most departments (Table 4). The added value of routine use of in-vivo dosimetry at first fraction of treatment/phase of treatment, for all patients is quite controversial. There is general agreement as to its overall worth in the context of patient safety, particularly when used as a truly independent check of delivered dose, and the WHO Radiotherapy Risk Profile identified that it could mitigate 24 of the 81 risks identified [1]. It is suggested that the value of in-vivo dosimetry may be indirectly related to the comprehensiveness of checks prior to the treatment [39]. In terms of practicalities, its value is however moderated by its cost, and there is a lack of consensus with regard to its value in the context of its cost-benefit [33,36,40–42]. Although it is not a primary method of detection in the ROSIS database, one reason for this is that it is routinely used in a small minority of departments, leading to less opportunity for it to have detected incidents in the ROSIS departments.

Most departments participate in an audit programme, although none of the reported ROSIS incidents were detected by external

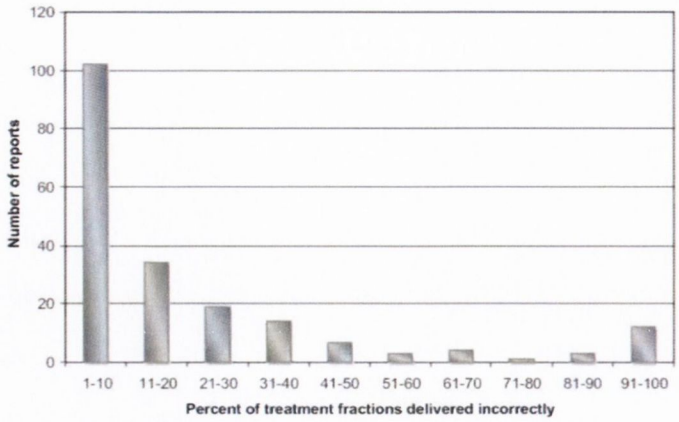

Fig. 3. Percent of treatment fractions delivered incorrectly ($N = 199$ reports).

audit. The extent of the audit programmes in which the ROSIS departments participated is unknown: whether it related to purely physical and technical aspects, or also incorporated procedural aspects of the treatment. External audit is an extremely valuable activity, and although it is not yet reported to ROSIS as detecting incidents, it is well-documented as an essential activity to complement internal quality assurance programmes [27,43–44].

The category "Found at time of patient treatment" (Table 5) highlights the importance of working with awareness. Working with awareness is a less tangible "safety layer", but it is a major contributor to patient safety, resulting in as much detection as the sum of chart checking, in-vivo dosimetry and portal imaging. A distinction has been made between incidents discovered during the first patient treatment and those discovered at a later patient treatment. To date, the numbers collected under the sub-category of "First patient treatment" are consistent with the rest of our data where many reported incidents occur during pre-treatment, and could therefore be detected at the critical first treatment. This reinforces the fact that the first patient treatment is a step where careful consideration of all the components of the treatment by the treatment team is constructive to patient safety.

The importance of working with awareness has been documented in the literature [4,6] and is a core component of a safety culture. A safety culture should create a situation where "all duties important to safety should be carried out correctly, with due thought and full knowledge, sound judgment and a proper sense of accountability" [45]. The ability of staff to be ever-vigilant will depend on their education and training, including training on new equipment and techniques. Reinforcement for working with awareness should come from management, and be facilitated by appropriate training and working arrangements (e.g. quiet areas for concentration, suitable workload) [45–46].

Chart checks constitute another major method of detection. In general, chart checks provide an excellent opportunity to detect incidents during pre-treatment, however, the reported incidents detected by chart check are evenly distributed between being detected during pre-treatment and once the treatment has begun. It is likely that this is mainly a fact of more reports being made where the treatment has been delivered incorrectly, than a reflection of the true ratio of detection. Nonetheless, it does suggest that a modification of the checking process in these departments may enable more incidents to be detected during pre-treatment (Table 5). The importance of, and sometimes failure of, chart checking is a common feature in the literature [6,24,31–32,34,36, 39,47]. For future design of QA system one has to consider this finding especially when departments are going "paper-less" using electronic patient files.

Most reported incidents were detected by Radiation Therapists at the treatment unit (RTs/RTTs); however, it must be stressed that it does not follow that most incidents occur during the treatment. As reported previously [48], it seems that most reported incidents arise during pre-treatment, but are passing pre-treatment checks and are not detected until the patient is on treatment, or at follow-up. Opportunity to detect errors, and reporting bias could also explain the proportion detected by RTs/RTTs – differences between health care professionals have previously been identified [49,50].

A further hypothesis for the high proportion of errors that actually affect the patients may be a large number of un-reported near-incidents. In RO, a near-incident to incident ratio of 13.8 to 1 was detected for errors originating in the treatment preparation chain [31].

Finally, a reporting and learning system can yield interesting lessons; this is of value in itself, but may give further leads when combined with prospective methods. Data from prospective methods could be used to focus reporting on particular incidents, in order to obtain specific causative information. It can also be used as an estimate of how many such incidents/near-incidents could reasonably be expected to be reported, and as such could indicate the health of a reporting system. A reporting system may highlight particular incidents and/or procedures/processes, which are error-prone, and potential failures can then be hypothesised and investigated using prospective methods.

Conclusion

An international cross-organisational reporting system has been developed and implemented, yielding opportunities for learning from mistakes in Radiation Oncology. ROSIS covers a broad patient population, with reasonable averages of patients per MV unit, per oncologist, and per physicist. It is difficult to draw conclusions from the number of patients per RT/RTT. Some level of defence-in-depth is apparent in most departments.

The majority of ROSIS reports relate to external beam radiation treatment; half of the events reported resulted in some treatment delivered incorrectly. The results from reporting systems need to

be carefully interpreted and not over-analysed; however, areas for improvement can be identified since many incidents appear to arise during pre-treatment, but are not detected until later in the treatment process. The most commonly reported detection methods were "found at time of patient treatment" and "chart-check", with a higher proportion of near-incidents detected by chart-check. While the majority of the incidents that are reported are of minor dosimetric consequence, they affect on average more than 20% of the patient's treatment fractions.

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APPENDIX B

B. Examples of Scales on Severity

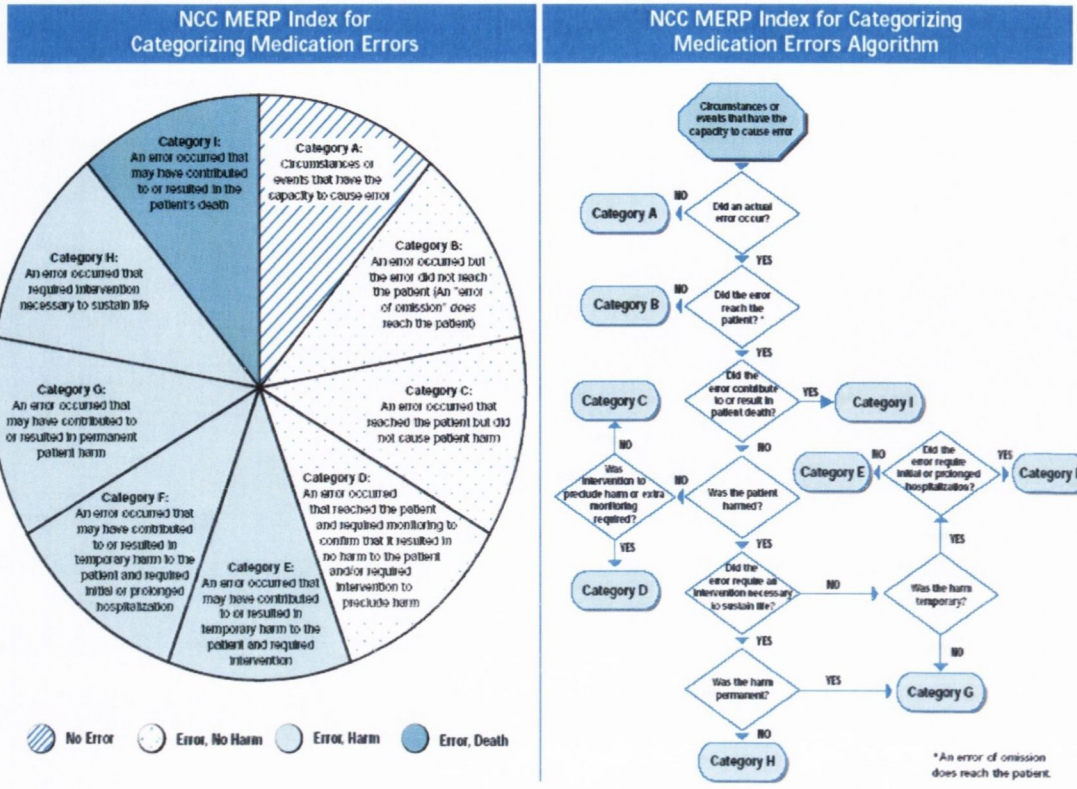
Table B-i: AIMS Severity Classification

Definitions of AIMS incident outcome levels 1 to 8	
LEVEL 1	An incident that involved a dangerous state or the possibility of harm occurring. For example: • Torn floor coverings.
LEVEL 2	An event occurred but was intercepted prior to causing harm to an individual. For example: • The wrong drug was drawn up but not given. • Medication was ordered for someone with an allergy to the drug but the error was discovered before the medication was given. • An elderly person using inappropriate equipment (eg. a wheelchair) for stability when mobilising.
LEVEL 3 (NO OUTCOME)	An event occurred and ran to completion but no harm came to the individual. For example: • The doctor was notified of an incident but did not review the patient. • The omitted dose was given when there has been no doctor review.
LEVEL 4 (MINOR OUTCOME)	An event occurred but there was only minor harm not requiring treatment. For example: • The subject was upset following an incident but required no interventions. • Extra observations or monitoring was required as a result of the incident. • Patient was moved closer to the nurses station for increased observation purposes. • Safety mechanisms were implemented (eg. cot sides, restraints).
LEVEL 5 (MODERATE OUTCOME)	The incident resulted in: • Minor diagnostic investigations (eg. x-rays, ECGs, blood tests, urinalysis, blood sugar level monitoring). • Minor treatments (eg. oral analgesia, minor dressings including band-aids and cold packs). • PRN, stat or nurse initiated medications including oxygen.

	• Medication dose increased, decreased or withheld. • Medication held awaiting review (no medical decision made at the time of report). • Patient's property replaced at hospital expense. • Counselling. • Police/fire services attendance. • Diversional therapy. • Restraint code called.
LEVEL 6 (MODERATE OUTCOME)	An incident that resulted in any of the following: • More complex diagnostic investigations (eg. procedures such as CT scans, telemetry and lumbar punctures). • The need for treatment with a new drug that would not have otherwise been required (eg. antibiotics, analgesia, commencement of IV therapy). • Surgical intervention (eg. theatre or sutures). • Cancellation or postponement of treatment. • Transfer to another service or area not requiring an increased length of stay. • 1:1 nurse to patient specialling. • Staff member going home early as a result of incident. • Staff member on work cover leave. • Minor fractures. • Self discharge. • Absconded patient is discharged whilst away from the ward without permission.
LEVEL 7 (SIGNIFICANT OUTCOME)	An incident that resulted in any of the following: • Seclusion. • Transfer to a High Dependency Unit or Intensive Care Unit. • Evacuation procedures. • CPR. • Morbidity which continued on discharge.
LEVEL 8 (SEVERE OUTCOME)	An incident that resulted in any of the following: • Permanent disability. • Death.

Table B-ii: ICPS Descriptors for Degree of Harm, and their comparison to French and ROSIS Scales

ICPS Descriptor of Degree of Harm:	Equivalent in French Scale:	Equivalent in original ROSIS Scale:
None – patient outcome is not symptomatic or no symptoms detected and no treatment is required.	0	None / Capture what it would have been
Mild – patient outcome is symptomatic, symptoms are mild, loss of function or harm is minimal or intermediate but short term, and no or minimal intervention (e.g., extra observation, investigation, review or minor treatment) is required.	1 or 2	Light (e.g. corrective action possible) **OR** Moderate (some clinical adverse effect cannot be ruled out)
Moderate – patient outcome is symptomatic, requiring intervention (e.g., additional operative procedure; additional therapeutic treatment), an increased length of stay, or causing permanent or long term harm or loss of function.	2	Moderate (some clinical adverse effect cannot be ruled out) **OR** High (clinical adverse effect is likely)
Severe – patient outcome is symptomatic, requiring life-saving intervention or major surgical/medical intervention, shortening life expectancy or causing major permanent or long term harm or loss of function	3	Severe (high probability for severe adverse effects or demonstrated effect)
Death – on balance of probabilities, death was caused or brought forward in the short term by the incident.	4-7	Severe (high probability for severe adverse effects or demonstrated effect)



Full-size copies are available: INDEX—www.nccmerp.org/010612_color_index.pdf; ALGORITHM—www.nccmerp.org/010612_color_algo.pdf

National Coordinating Council for Medication Error Reporting and Prevention Definitions

Harm
Impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.

Monitoring
To observe or record relevant physiological or psychological signs.

Intervention
May include change in therapy or active medical/surgical treatment.

Intervention Necessary to Sustain Life
Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.).

Figure B-i: NCC MERP Index for Categorizing Medication Errors [130]

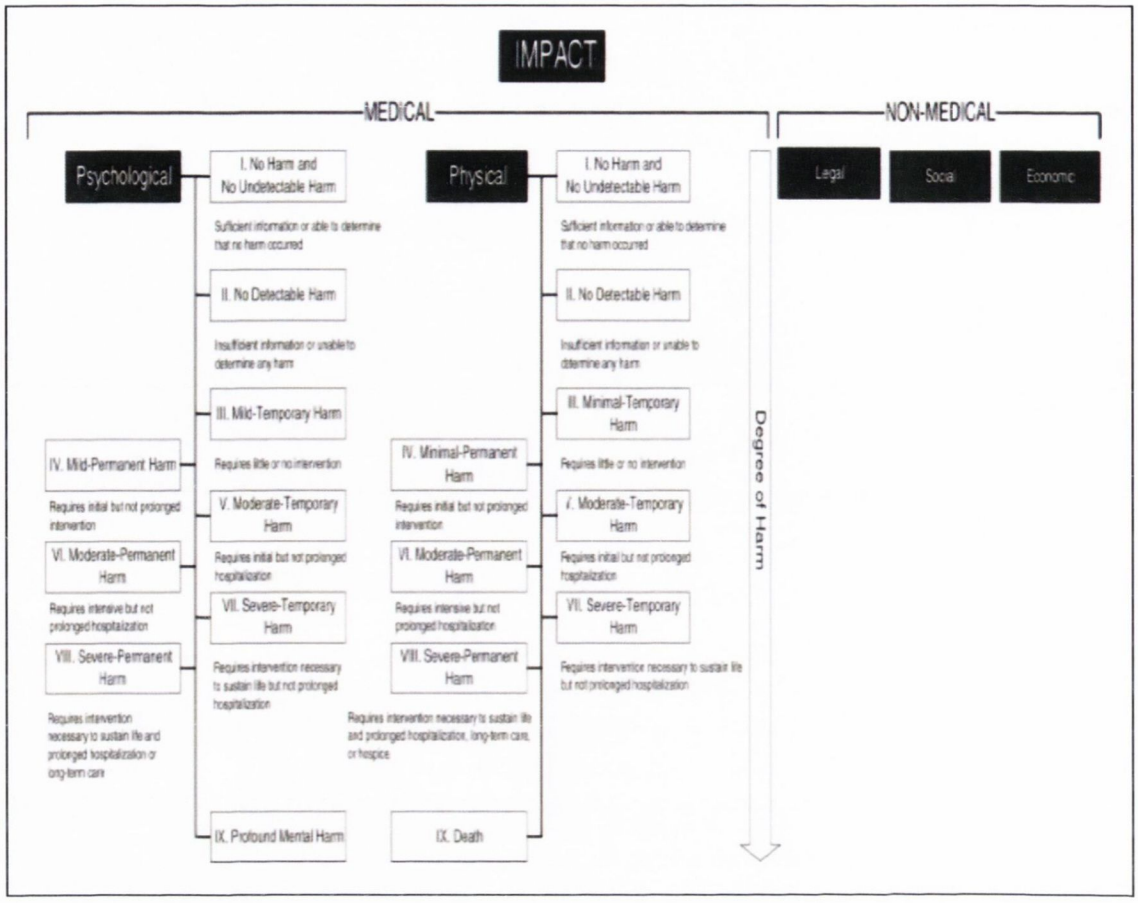


Figure B-ii: JCAHO Classification of Impact of Clinical Incidents [129]

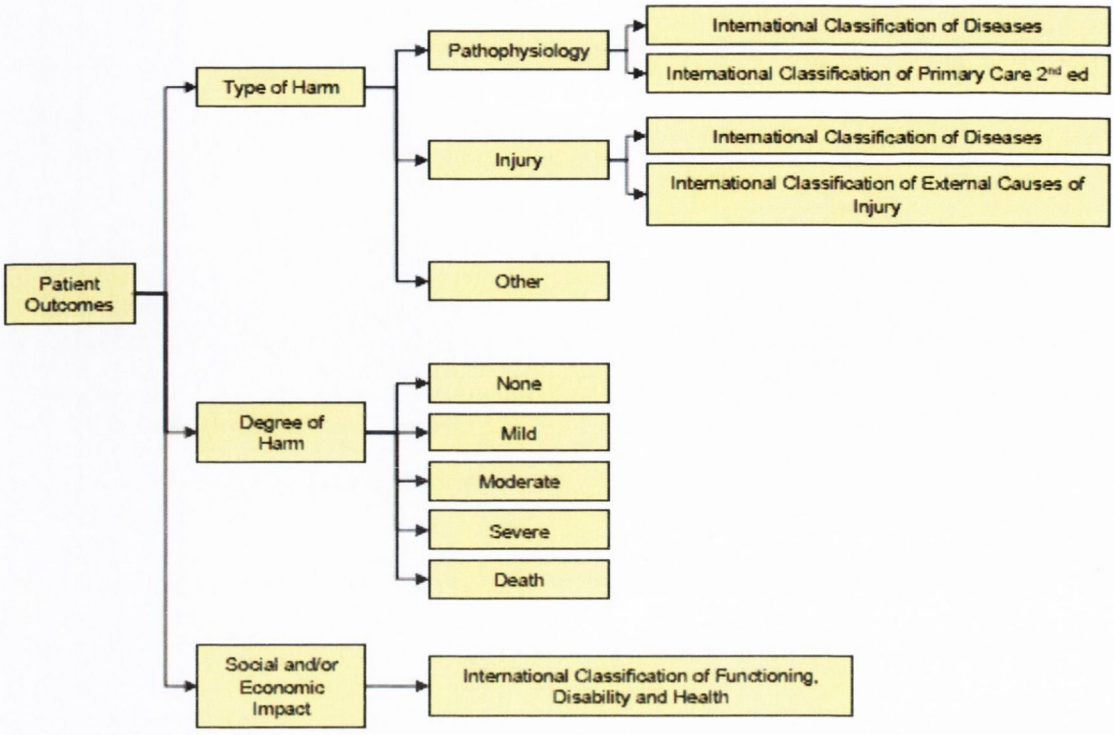


Figure B-iii: ICPS Patient Outcomes [47]

Table B-iii: ICRP Modifications of AAPM classification [24]

Table 2. Summary of the AAPM TG-35 sub-classification of Class I hazards in radiotherapy (AAPM, 1993)[a]. Remarks added here.

Type	Criteria	Remarks
Type A	25% overdose or more of the total prescribed dose	'The rationale for this choice is related to the observation that a 25% to 50% increase in total dose will often place the patient in the range of the LD50/5 (the probability of 50% lethal complications within five years)...'. For a typical treatment of 40-60 Gy, an overdose of 25% of the prescribed total dose corresponds to 10-15 Gy. This excess in dose can be reached either with an error on each fraction for several fractions during the week or with a large error in a single fraction.
Type B	5% [(i)] to 25% dose excess over the total dose[(ii)]	(i) The value 5% is derived from the TG 35 criteria where an overdosage of 20% during one week corresponds approximately to an overdosage of about 5% over the whole treatment.
	and most underdose situations	(ii) If the underdosage is not discovered within a time in which correction to the treatment can be successfully applied, the hazard should be considered as type A with similar percentage as for an overdose as indicated in the text

[a] Class I hazards are defined by the USA FDA as a condition that could cause death or serious injury. TG-35 considers type A hazards as those that can likely be responsible for life-threatening complications. Type B hazards increase the probability of an unacceptable treatment outcome (complications or lack of tumour control). The criteria refer to a typical treatment prescription of 40–60 Gy total dose with 2 Gy per fraction, and is based on the assumption that weekly quality controls are performed that will discover errors or equipment malfunctions within one week.

Table B-iv: ASN-SFRO Scale of Incidents in Radiation Oncology [49]

Events	Level	Example
Event without consequence	0	Error of dose, of identification of a patient compensable
Event with dosimetric consequences but no expected clinical consequence (grade 1) *No expected symptom*	1	Error of dose or volume non compensable on all of the treatment
Event leading to or liable to lead to a moderate impairment of an organ or function (grade 2) *Dose higher than recommended doses liable to lead to unexpected but moderate complications*	2[2]	
Event leading to a severe impairment of one or more organs or functions (grade 3) *Dose or irradiated volume higher than tolerable doses or volume*	3[2]	
Serious life-threatening event, disabling complication or sequelae (grade 4) *Dose or irradiated volume far higher than tolerable doses or volumes*	4[2]	Toulouse 4+
Death (grade 5) *Dose or irradiated volume far higher than normal leading to fatal complications or sequelae*	5 to 7[1]	Épinal 6

[1] In the event of death of several patients: the minimum level 5 is raised to 6 if the number of patients is higher than 1 but no more than 10; the minimum level 5 is raised to 7 if the number of patients is higher than 10.

[2] If the number of patients is higher than 1, a + sign is added to the chosen level

Table B-v: Canadian Scale of Patient Outcomes following RO Clinical Incident [51]

Incident Severity	Examples: Clinical Incident	Individuals to be notified
Critical Incident	Radiation dose or medication error causing death or disability. Dose variation from prescribed total dose of > 20%. Completely incorrect volume	*Immediately notify*: Senior Management, Manager, Supervisor, Physician
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 effects (e.g. Heart, lung, eyes, kidney etc.).	*Immediately notify*: Senior Management, Manager, Supervisor, Physician
Potential Major Incident	A near miss that could have been a major incident.	Manager, Supervisor
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.	*Within 24hrs notify*: Manager, Supervisor, Physician
Potential Serious Incident	A near miss that could have been a serious incident.	Supervisor
Minor Incident	Dose variation from prescribed total dose of < 5%. Near miss or unsafe condition which could potentially cause a treatment error.* Patient complaint.*	Supervisor, Physician*

* Physician should only be notified if there is ***actual*** patient impact

APPENDIX C

C. Examples of Classifications of Causes &/or Contributing Factors

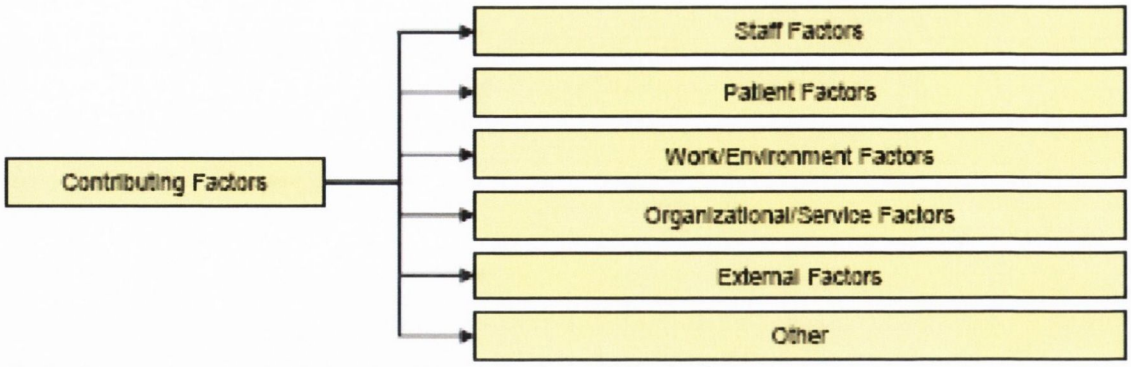


Figure C-i: ICPS Basic Categories of Contributing Factors [47]

Table C-i: ICPS Table of Contributing Factors [47]

Staff Factors:		
Cognitive Factors	Perception / Understanding	
	Knowledge Based / Problem Solving	Failure to synthesize / act on available information
		Problems with Causality
		Problems with Complexity
	Illusory Correlation	
	Halo Effects	
Performance Factors	Technical error in execution (Physical-Skill Based)	Slip/Lapse/Error
	Rule Based	Misapplication of good rules
		Application of bad rules
	Selectivity	
	Bias	Biased reviewing
		Confirmation bias
Behaviour	Attention issues	Distraction / Inattention
		Absentmindedness / Forgetfulness
		Overattention
		Out of sight, Out of mind
	Fatigue / Exhaustion	
	Overconfidence	
	Non-compliance	
	Routine violation	
	Risky behaviour	
	Reckless behaviour	
	Sabotage/Criminal Act	
Communication Factors	Communication Method	Paper Based
		Electronic
		Verbal
	Language difficulties	
	Health literacy	
	With Whom	With Staff
		With Patient
Patho-physiologic / Disease related factors	International Classification of Diseases	
	International Classification of Primary care, 2nd edition	
	Problems with Substance Abuse / Use	
Emotional factors		
Social factors		
Patient Factors:		
This consists of the same categories as staff factors.		
Work/ Environment Factors:		**External Factors:**
Physical Environment / Infrastructure		Natural environment

Remote / Long distance from Service
Environmental Risk Assessment / Safety Evaluation
Current Code / specifications / Regulation

Products, Technology &Infrastructure
Services, Systems and Policies

Organisational/ Service Factors:

Protocols / Policies / Procedures / Processes
Organisational Decisions / Culture
Organisation of Teams
Resources / Workload

Other

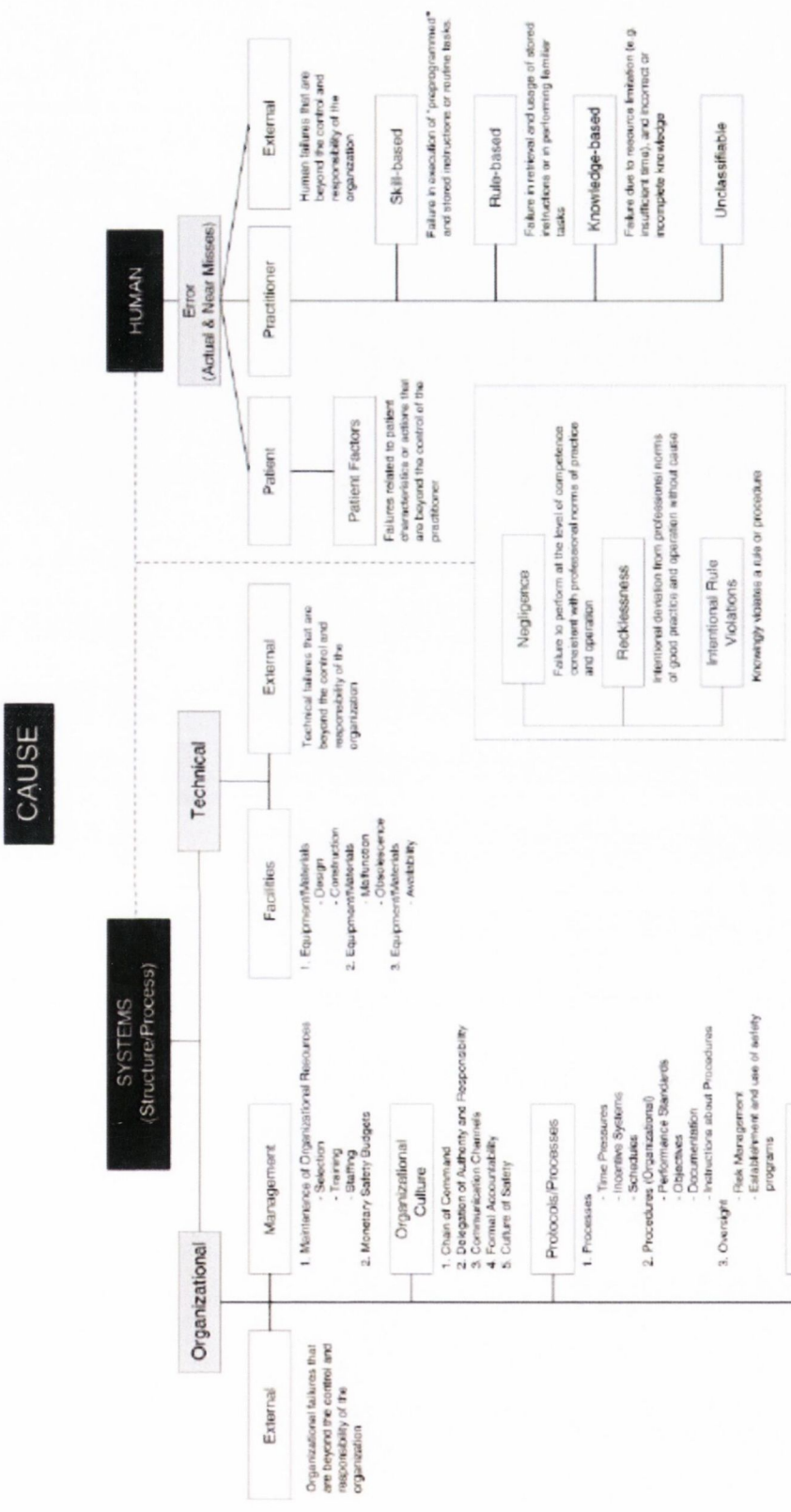


Figure C-ii: JCAHO Classification of Cause [129]

Table C-ii: Framework of factors influencing clinical practice [59, 162]

Factor types	Influencing contributory factors	Examples
Institutional context	Economic and regulatory context; national health service executive; clinical negligence scheme for trusts	Inconsistent policies, funding problems
Organisational and management factors	Financial resources and constraints; organisational structure; policy standards and goals; safety culture and priorities	Lacking senior management procedure for risk reduction
Work environment factors	Staffing levels and skills mix; workload and shift patterns; design, availability, and maintenance of equipment; administrative and managerial support	High workload, inadequate staffing, or limited access to essential equipment
Team factors	Verbal communication; written communication; supervision and seeking help; team structure (consistency, leadership, etc)	Poor communication between staff
Individual (staff) factors	Knowledge and skills; competence; physical and mental health	Lack of knowledge or experience of specific st
Task factors	Task design and clarity of structure; availability and use of protocols; availability and accuracy of test results	Non-availability of test results or protocols
Patient factors	Condition (complexity and seriousness); language and communication; personality and social factors	Distressed patient or language problem

Table C-iii: Overview of IAEA Safety Series 17 Causes / Contributing Factors

1. Resources: Personnel and Equipment
2. Human Factors
3. Training
4. Communication
   a. Failure to transmit information.
   b. Transmitting incorrect communication.
   c. Communication to the wrong person.
   d. Correction of a problem by an unqualified person without help or review.
   e. Oral communication, either in person or by telephone, without written confirmation, resulting in misunderstanding.
   f. Mistakes in reading or transferring information.
   g. Unreadable or confusing handwritten communication, informal expressions or use of jargon that is not understood by everyone in the same way.
   h. Misunderstanding of communication in a foreign language: This may include
      (1) manufacturers' instructions for the use of equipment, as well as communication
      (2) between staff and between staff and patients
   i. Incomplete or poorly written instruction manuals for complex equipment such as treatment machines and treatment planning computers. Of particular concern are instructions that do not cover unusual or special applications.
5. Equipment
   a. Insufficient redundancy in the design of equipment (single fault criterion, interlock failure);
   b. Software problems;
   c. Hardware incompatibilities in equipment and accessories (wedge or shielding block incompatible with coding system, or ionization chamber that does not fit an electrometer);
   d. Possibility of operating the equipment in a 'non-clinical mode' with the key in the usual 'beam-on' position.

6. Human-machine problems
   a. Problems of human-machine interface
   b. Bypassing of interlocks and operation in a 'non-clinical mode'
   c. Maintenance problems
7. Improper decommissioning of equipment and unsafe storage of radioactive sources
8. Documentation
9. Integration of Safety and QA
10. Safety Assessment
11. Regulatory Control

Table C-iv: Basic Cause Table [51] from [143]

Job Factors

1. Standards/Procedures/Practices
   - 1.1 Not developed
   - 1.2 Inadequate standard/ procedure/practice
   - 1.3 Standard/procedure/ practice not followed
   - 1.4 Inadequate communication of procedure
   - 1.5 Inadequate assessment of risk
   - 1.6 Not implemented

2. Materials/Tools/Equipment
   - 2.1 Availability
   - 2.2 Defective
   - 2.3 Inadequate maintenance
   - 2.4 Inspection
   - 2.5 Used incorrectly
   - 2.6 Inadequate assessment of material/tools/ equipment for task

3. Design
   - 3.1 Inadequate hazard assessment
   - 3.2 Inadequate design specification
   - 3.3 Design process not followed
   - 3.4 Inadequate assessment of ergonomic impact
   - 3.5 Inadequate assessment of operational capabilities
   - 3.6 Inadequate programming

Systemic/Management Factors

4. Planning
   - 4.1 Inadequate work planning
   - 4.2 Inadequate management of change
   - 4.3 Conflicting priorities/ planning/ programming
   - 4.4 Inadequate assessment of needs & risks
   - 4.5 Inadequate documentation
   - 4.6 Personnel availability

5. Communication
   - 5.1 Unclear roles, responsibilities, and accountabilities
   - 5.2 Lack of communications
   - 5.3 Inadequate direction/ information
   - 5.4 Misunderstood communications

6. Knowledge/Skill
   - 6.1 Inadequate training/orientation
   - 6.2 Training needs not identified
   - 6.3 Lack of coaching
   - 6.4 Failure to recognize hazard
   - 6.5 Inadequate assessment of needs and risks

Personal Factors

7. Capabilities
   - 7.1 Physical capabilities (height, strength, weight, etc.)
   - 7.2 Sensory deficiencies (sight, sound, sense of smell, balance, etc.)
   - 7.3 Substance sensitivities/ allergies

8. Judgment
   - 8.1 Failure to address recognized hazard
   - 8.2 Conflicting demands/ priorities
   - 8.3 Emotional stress
   - 8.4 Fatigue
   - 8.5 Criminal intent
   - 8.6 Extreme judgment demands
   - 8.7 Substance abuse

Natural Factors

9. Natural Factors
   - 9.1 Fires
   - 9.2 Flood
   - 9.3 Earthquake
   - 9.4 Extreme weather
   - 9.5 Other

APPENDIX D

D. EURATOM Survey and Results

SECTION 1 - TRANSPOSITION OF 97/43/EURATOM INTO LEGISLATION

1. Has the directive 97/43/EURATOM been transposed into your national legislation?
Yes No

If yes, please answer questions 2 Š 6
If no, please proceed to question 7

2. If Yes, on what date was it implemented?
Day _____ Month_____ Year_____

3. Which government department had responsibility for drafting this legislation?

4. Is radiotherapy identified separately within your national legislation?
Yes No

5. a) Does the legislation include mandatory incident reporting to a higher authority?
Yes No

b) If Yes, to whom?

c) If Yes, does this include potential incidents?
Yes No

6. a) Does this legislation include mandatory recording of incidents at a local/internal level?
Yes No

b) If Yes, does this include potential incidents?
Yes No

Additional Comments/Information ***(e.g. criterion for reportable incident-level)*** _____

_____

If this directive has not yet been transposed

7. When is the anticipated date of transposition?
Date_____

8. a) Is your current radiation protection legislation based on the preceding EU Directive 84/466/EURATOM?
Yes No

b) Is there independent legislation governing radiation protection of patients undergoing medical procedures in your country?
Yes No

If yes to either question 8a or 8b, please answer questions 9 - 13
If no, please proceed to Section 2

9. On what date was it implemented?
Day _____ Month_____ Year_____

1. Which government department had responsibility for drafting this legislation?

2. Is radiotherapy identified separately within your national legislation?
   Yes No

3. a) Does the legislation include mand atory incident reporting to a higher authority?
   Yes No

   b) If Yes, to whom?

   c) If Yes, does this include potential incidents?
   Yes No

4. a) Does this legislation include mandatory recording of incidents at a local/internal level?
   Yes No

   b) If Yes, does this include potential incidents?
   Yes No

Additional Comments/Information ***(e.g. criterion for reportable incident-level)***

_____

_____

_____

SECTION 2 - OTHER (NON RADIATION PROTECTION) NATIONAL LEGISLATION GOVERNING INCIDENT REPORTING IN HEALTHCARE

5. Is there a legal requirement for incident reporting in healthcare in your country?
   Yes No

6. When was this implemented?
   Day_____ Month___ _____
   Year_____

7. Which government department or professional organisation is responsible for enforcing this requirement?

17. a) Does this legislation include mandatory recording of incidents at a local/internal level?
   Yes No

   b) If Yes, does this include potential incidents?
   Yes No

Additional Comments/Information ***(e.g. criterion for reportable incident-level)***

_____

COUNTRY *Question(s)*	97/43/EUR. transp. *1,2*	Govn Dept responsible for draft *3*	R/Tseparate *4*	Mandat. inc. reporting *5*	Report inc. to *5*	Mandat. local recording *6*
Austria						
Bavaria (Govn)	Yes (26/07/2001)	Proably State rather than National Federal Environmental Ministry Bundesumweltministerium (BMU)	Yes	Yes (only to a higher authority) (no potential)	Bavarian Innenministerium (Internal Affairs) & Bavarian Ministry for Environmental Health	No
Belgium						
Denmark (Govn)	Yes (01/05/2000)	National Institute of Radiation Hygiene (NIRH)	Yes	Yes (no potential)	National Institute of Radiation Hygiene (NIRH)	No
Denmark (Phys)	Yes (1999-2001)	National Institute of Radiation Hygiene (NIRH)	Yes	Yes (no potential)	National Institute of Radiation Hygiene (NIRH)	Yes (no potential)
Finland (Phys)	Yes (12/05/2000)	Social and Health Ministry	Yes in some parts	Yes (incl. potential)	Radiation and Nuclear Safety Authority (RNSA)	Yes in direction given by RNSA (Pot. according to local QA-practice)
France						
Germany						
Greece (Phy)	Yes (06/03/2001)	Ministry of Development	Yes	Yes (no potential)	Greek Atomic Energy Commission	Yes (no potential)
Ireland (Govn)	No	Department of the Environment Department of Health and Children				
Italy	Yes (01/06/1998)	Ministero della Salute	No	Yes	ANPA (Techn. Dept of Ministry of Trade)	No
The Netherlands (Physics)	No - to be: 1/3/2002 (using legislation from 1987)	Housing and Environment Social affairs and labour Health Care and Culture No independent legislation	Will be included	Won't be included at national or local level		
Norway						
Portugal						
Spain (Govn)	Yes (14/07/2001)	Health Ministry	Yes	Yes (no potential)	Health Authority	Yes (no potential)
Sweden (Govn)	Yes (01/07/2001)	Swedish Radiation Protection Authority (SSI)	Yes	Yes (incl. potential)	Swedish Radiation Protection Authority	Yes (incl. potential)
Sweden (Physics)	Yes (1/7/2000)	Swedish Radiation Protection Authority (SSI)	Yes	No		Yes (no potential)
Switzerland						
United Kingdom	Yes (13/5/2000)	Department of Health	Yes	Yes (no potential)	Department of Health	No

APPENDIX E

E. Original Department Form

Register your clinic

When the data on this form has been processed we will send a CLINIC-ID number to you for use during future incident reporting.

Contact details

All contact information will be kept anonymous and will not be stored in the on-line database.

Name and address of hospital/clinic

Name of local contact person

Email address of the local contact person

Equipment and staff

Number of treatment units (linear accelerators and cobalt units)

Linacs Cobalt units Brachytherapy units:

Approximate number of patients per year: (New patients receiving radiotherapy)

Estimate proportion of CT based treatment plans: %

Record and verify system (R&V):

Select the most appropriate alternative.

○ No treatment unit has R&V ○ Some treatment units have R&V ○ All treatment units have R&V

Network:

Tick one or several boxes that best descibes your department.

☐ None (no network between units or TPS or R&V)

☐ Treatment planning system sends RT parameters to treatment unit

☐ Simulator sends RT parameters to treatment unit

☐ Full networking of RT parameters (i.e. field size settings, MU etc.)

☐ Full networking of RT images (i.e. electronic portal images, DRR etc.)

Number of staff :

Give the number of full time equivalent (FTE) staff, defined as your normal working day, for each category.

Radiation oncologists (physicians)

Medical physicists

Radiation therapists / Staff at treatment units treating patients

Radiation therapists / Staff at simulator and/or in-house CT

Staff doing dosimetry i.e. treatment planning etc

Staff doing technical maintenance on the radiotherapy equipment

How is the majority of your maintenance of the equipment performed:

○ In-house service ○ Service contract

Other staff not included above, please specify category and number of FTE:

QA procedures in the clinic

Select one or several alternatives that best describes the QA system at your department.

☐ Treatment charts are independently checked

☐ In-vivo dosimetry is used for most new patients

☐ Peer-review (planning conference) is done for most new patient prescriptions (dose and location)

☐ Portal films (or electronic images) are taken for most new patients

☐ Regular clinical review (of side effects etc.) of most patients

☐ Written quality control procedures and records for most treatment unit checks

☐ Written procedures for most of the clinical processes

☐ Formal quality management system (ISO etc.)

☐ Regular QA of treatment units

☐ External dosimetry audit by EQUAL or by other, please specify

☐ Other QA, please specify

Comments

Here you can enter comments about this form, the information collected (is something of importance missing) or ROSIS.

Submit Reset

These pages are maintained by T Knöös - Updated 2007-07-02

APPENDIX F

F. Original Incident Form

Submit an incident report to ROSIS

Incident Report Form

Clinic Id Number

Treatment modality where the incident occured or was discovered or about to occur

- External beam therapy
- Brachytherapy
- Other

Date of Discovery

(Enter the date as YYYY-MM-DD e.g. 2006-10-24

Who discovered the incident?

Check the appropriate box(es)

- 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
- Other (please specify)

How was the incident discovered

Check the appropriate box(es)

- Chart check
- In vivo dosimetry
- Portal imaging (radiographic film or EPID)
- Clinical review of patient

- [ ] Quality control of equipment
- [ ] Found at time of 1st patient treatment during regular checks
- [ ] Found at later stage during patient treatment
- [ ] External audit
- [ ] Other (please specify)

Where in the process was the incident found

Select the most appropriate.

- ○ Pretreatment (e.g. CT, simulator, planning)
- ○ Treatment
- ○ Follow-up
- ○ Non patient specific process

Was anyone affected by the incident?

Check appropriate box(es)

- [ ] Yes, several patients, number of patients affected: _____
- [ ] Yes, one patient
- [ ] Yes, staff or other non-patient
- [ ] None (but they could have been - potential incident)

Was any treatment delivered incorrectly?

○ Yes ○ No

If Yes how many fractions were delivered incorrectly? _____

Total number of fractions prescribed _____

Outcome for the patient(s)/person(s) affected

- ○ None
- ○ Light (e.g. corrective action possible)
- ○ Moderate (some clinical adverse affect cannot be ruled out)
- ○ High (clinical adverse effect is likely)
- ○ Severe (high probability for severe adverse effects or demonstrated effect)

Comments regarding severity:

Potential outcome for the patient(s)/person(s) if the incident was not detected/corrected

- ○ None

- Light (e.g. corrective action possible)
- Moderate (some clinical adverse effect cannot be ruled out)
- High (clinical adverse effect is likely)
- Severe (high probability for severe adverse effects or demonstrated effect)

Comments regarding potential outcome

Summarise the incident in one single sentence headline

If the incident-cause is related to equipment (hardware or software), please specify the make model including version number.

Description of the incident

Cause of the incident

Suggestions for preventive action(s)

Suggestions or comments regarding ROSIS and or this form

Submit Reset Form

APPENDIX G

G. Hazard Identification – List of hazards

HAZARD IDENTIFICATION - (WORK IN PROGRESS . . .)

(THE "WHAT")

ACCESSORIES

Bolus – incorrect/inappropriate use of, omission of, incorrectly made (size, thickness, material etc), inappropriately prescribed, applied to wrong area/scar, used bolus belonging to wrong patient

Pb – incorrectly made (mag factor, height, divergence etc)/mounted/prescribed, use of incorrect for field/patient, omission of, (? If coded/not), *use of incorrect tray*, template wrong (incorrectly made, oriented, for different pt/field), dr omitted to indicate pb required, pb used where not required, comp bug

Cutouts - incorrectly made/prescribed, same codes different sizes, use of wrong size

MLC – wrong field, wrong shape, wrong patient, computer transfer bug, omission of, (? if r&v/not), dr omitted to draw MLC on sim films, *wrong collimator angle*

Wedge/filter – wrong wedge/filter, wrong orientation, incorrect use of wedge/filter, omission of wedge/filter, comp bug

Immobilisation devices – inadequate immobilisation, incorrect use of/setting up device (e.g. bellyboard, breastboard, orfit/BDS esp neckrests and wedges), omission of device, use of/omission of mattress, insufficient set-up info

Mouthbite *– (?immob device)*

Compensator – omission of, use of incorrect for field/patient, incorrectly made, comp bug

PATIENT/ PATIENT POSITIONING

Patient acquisition – pt id, pt selection in r&v, patient notes/films

Patient position – "incorrect" - supine/prone, full/empty bladder, dentures removed, hf/ff, if standing: side of bed

Markings – lost, misinterpretated, difficulty setting up to marks, marks put on incorrectly,

TARGET VOLUME

Target Volume Definition

Image acquisition – insufficient area/volume, bad quality, incorrectly labelled, *patient unable to stay still*,

Target volume delineation – wrong area (esp rt/lt) wrong dimensions, insufficient/too large margin, drr not produced/incorrect, wrong image used

Field Specifications

Asymmetrics – omission of, wrong orientation, wrong direction, wrong size/extent

Field – incorrect orientation, wrong size (e.g. written down/transferred incorrectly, improper use of inverse sq law), wrong field

Geographical Miss

Reference moves – not made, incorrectly made, defined incorrectly, not updated after change, input incorrectly
Field placement – wrong gantry angle, wrong collimator angle, wrong iso, coll twist reversed, floor tilt, table top height
HDR Dwell positions, wire, standard, programming

SSD

FSD

- wrong technique used –iso/fixed FSD
- wrong SSD / not extended FSD

DOSE

Mus/Time(Co^{60}) wrong due to

- **Arithmetic** – error in adding/subtracting/multiplying/dividing mu, esp after alteration/change to planned mu
- **Calculation** – error in use of or omission of: factors (energy, fsd, tray, compensator, etc), EqSq, %dd/TMR; wrong field size, fsd, wrong daily dose/fractionation used etc
- **Calculation Data** – where error is in the given numerical values for factors, tables etc (e.g. due to incorrect commissioning/beam output data)
- **Calculation Method** – where policy/WI for calculation is wrong (e.g. Where factor is included but has already been accounted for by planning system), or using wrong method to calculate – e.g. Iso vs MPD
- **Data Transfer** – of mu onto treatment sheet, into R&V,
- **Wrong MU**– using the mu from another field or phase for current field/phase
- **Out-dated/old MU**– mus not updated following change/correction
- **Failure to verify** MU entered through computer bug/operator error (key in override position)

Radio-opaque structure – unintentionally treating through (e.g. metal bar on bed)
Energy – use of wrong energy to treat or using wrong energy data for calculations
Separation – incorrectly measured, incorrectly written, MPD calculated incorrectly
Plan – bad planning technique (e.g. position of ref/normalization point), inhomogeneity, mu values wrong, incorrect field weightings
Field Matching – hotspot/coldspot – incorrect gap distance, field arrangements etc
Prescription –

- Paper
  - not signed,
  - not enough info,
  - fractionation schedule incorrectly written,
  - field not prescribed,
  - unwanted field prescribed,

- wrong dose prescribed,
- prescribed for wrong patient.
- change to pres not communicated/noticed/updated,

o Execution

- **Treatment terminated** before field completed
- **Field omitted** from treatment (prescription not fulfilled)
- **Field treated more than once** in one session

TECHNICAL/ SOFTWARE FAULTS

LA/Sim - Mechanical/electrical fault, leakage, weakness
Laser beam Alignment
Light-beam congruence
Machine specifications/tolerances/Interlocks
HDR/LDR – after-loading/iridium wires
Co-60 – Source error
Other

OTHERS

Beam Naming
Missed treatment
Documentation
Portal Imaging
Organisation/ resource issue
Pharmacy
Quality Assurance

APPENDIX H

H. Spotlight Cases

ROSIS – Spotlight on In-vivo Dosimetry
March 2006

Radiation Oncology Safety Information System
http://www.rosis.info

Feedback letter March 2006
SPOTLIGHT ON IN-VIVO DOSIMETRY

- *This Newsletter* - Spotlight on In-vivo dosimetry.
- *Reminder:* Last places remaining on the **short course - "Working towards safer healthcare delivery: minimising the impact of incidents in radiotherapy"**. To avoid disappointment, and avail of discounted early registration, **book now!** See http://www.rosis.info for further details.
- *Reminder:* The new website will be online in the next month!

Dear ROSIS Contact,

The ROSIS group would like to draw your attention to some interesting incident reports in the database. **The theme of this month is in-vivo dosimetry.**
Reports are described below, together with some reflections. If you would like to read the full reports or make a comment, click on the links provided.

Best regards from Ola, Mary, Tommy, & Joanne (The ROSIS Group)

Report 1. Incident ID: 385 http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=385

For simple treatments, the monitor units (mu) in a clinic were calculated by a simple in-house computer programme. In this case, the physicist could not find the program (shortcut to the program removed by someone from the desk top) and did the calculations manually instead. The calculation gave 394 mu instead of the correct number of 453 mu. This was a new type of treatment where the physicist (or the treatment staff) did not have a feeling for what the correct mu would be. The physicist who checked the calculation did not discover the mistake. The in-vivo dosimetry measurement showed -15 % in dose and was repeated with the same result. An investigation discovered the mistake.

This report highlights the **importance of investigating deviations** found by in-vivo dose measurements.

Report 2. Incident ID: 303 http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=303

At treatment of a posterior field (gantry angle 180 degrees) the distance to the couch was set to 92.5 cm instead of the intended 97.5 cm. When measuring with diodes, the treatment was interrupted when the dose passed the expected value. When investigated, it was discovered that the wrong table height was used. It was difficult to see the distance scale against the black table top.

The centre suggested that a light table top could have prevented this mistake (or any other white surface), and that isocentric set-ups are preferable in this respect. It is noteworthy that the centre had a procedure for early detection (in-vivo dosimetry cut-off value), which **prevented further incorrect exposure**.

ROSIS – Spotlight on In-vivo Dosimetry
March 2006

Report 3. Incident ID: 722 http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=722

At the time of simulation, the wrong energy was entered into the Record and Verify system for two fields. This was found when the diode measurement for the first field was too low. The energy was changed for the second field before treatment.

It is difficult to see how this mistake would have been discovered if in-vivo dosimetry had not been used.

Please give **your comments** on these reports [snichuin@tcd.ie]. We will add selected comments to next month's feedback letter.

All these incidents show the importance of using in-vivo dosimetry as another layer of defence, but the value of in-vivo dosimetry can differ depending on how the system is calibrated and the type and magnitude of errors you aim to detect. A good discussion on diodes can be found in AAPM Report 87 (TG62) *"Diode in vivo dosimetry for patients receiving external beam radiation therapy"*; and in ESTRO Booklet 5 *"Practical guidelines for the implementation of in vivo dosimetry with diodes in external radiotherapy with photon beams (entrance dose)"* http://www.estroweb.org/ESTRO/upload/pdfs/booklet5.pdf

Remember that you can always do searches on the full ROSIS database at http://www.rosis.info
Keep the database alive and report your incidents! Reporting is confidential in relation to clinic. If you have forgotten your password, please contact ola@eircom.net

Best regards from the ROSIS group:
Ola Holmberg - ola@eircom.net
Mary Coffey - mcoffey@tcd.ie
Tommy Knöös - tommy.knoos@med.lu.se
Joanne Cunningham - snichuin@tcd.ie

If you do not wish to receive further emails from ROSIS, please state so in a reply to this message, and you will be removed from this mailing list.
If you have not received this message directly from ROSIS but would like to be added to our mailing list, please contact us at snichuin@tcd.ie .

ROSIS – Patient Identification
August 2006

An indication of the importance given to this problem can be seen in the fact that the first of the Joint Commission on Accreditation of Healthcare Organisations in the USA (JCAHO) National Patient Safety Goals for 2003 is to 'improve the accuracy of patient identification".

Radiotherapy involves correctly identifying the patient for each fraction to be delivered; this may be complicated by the fact that many patients attend as outpatients and do not have the same identification procedures as inpatients.

Accurate identification relies on obtaining separate items of personal information for each patient treated. Identity wristbands have been introduced in hospitals for many procedures but are prone to problems and published data details numerous errors recorded where wristbands are involved. Other high tech preventative measures include barcoding, radiofrequency identification, fingerprinting etc and are being introduced or considered for use in hospital settings.

There is some international variation on the number of items necessary to ensure correct identification. The UK and the New York State Department of Health recommend three independent items whereas the JCAHO in the USA recommends only two.

The items most commonly used are patient first and last name, date of birth and address. The hospital number should not be used. In verifying the information it should be carried out discretely and the patient should be asked to state his/her details that are then confirmed by the staff member who will check either the wristband, patient identify card, treatment chart etc. As can be clearly seen from cases in the ROSIS database detailed below patient details can be very similar and a fourth safety feature could be the inclusion of a patient photograph in the notes and record and verify system.

Chassin et al describe a case of misidentification and an analysis of the contributing factors. In addition to standardized protocols on verification of identification they recommend a comprehensive patient information system covering the full activities of the hospital and a medical record that contains legible, clear information about the reason for hospitalization and the planning investigations and treatments, and familiarization with your patients. (Mark R. Chassin et al, The Wrong Patient. Annals of Internal Medicine June 2002). This is very readily applicable in our radiotherapy departments.

The ROSIS data

Chassin et al believe that open and vigorous discussion is a prerequisite for robust solutions. This type of discussion can be facilitated by a system such as ROSIS allowing for sharing of information and learning from experience of others. Several examples of misidentification have been reviewed as part of this discussion paper. They occurred mainly on an external beam unit with one related to a brachytherapy procedure. These errors have different root causes including poor communication and incorrect data information entry. In some instances the error was detected before treatment was delivered but in some cases the patient received incorrect treatment. However no incident resulted in injury to the patient.

Incident ID 351: Lack of communication was cited when a student brought the wrong patient into the treatment room. This was discovered when the staff in the treatment room spoke to the patient. This incident is similar to many outlined in the literature and could have been prevented by the student following clearly defined protocols on patient identification. No details were available as to the stage in training of the student and it may also have been an inappropriate task for the student.
http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=351

Incident ID 437: An incorrect patient was also brought into the treatment room. In this instance the error was not discovered until the patient was setup and the reference marks did not fit. The cause cited was a change of bed numbers in the ward between two patients with similar first and last names. Available guidelines all clearly recommend not using hospital or bed numbers as a means of patient identification and this incident is a clear example of what can happen in those circumstances. In addition the staff on the treatment unit were clearly not

ROSIS – Patient Identification
August 2006

familiar with the patient and would appear not to have gone through any verification of identification process with the patient.
http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=437

Incident ID 479: the label in the header of the treatment chart did not correspond to the patient barcode. The barcode was correct and the cause was identified as inclusion of patient labels at different points in the patient pathway. This incident illustrates how the use of more sophisticated identification methods can reduce the potential for error and also the role of a seamless hospital wide information system as recommended by Chassin.
http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=479

Incident ID 473: A patient was discharged from a referring hospital where he was an inpatient. Following discharge another patient, with an identical name, was admitted to his bed. Transport to the radiotherapy was booked and the wrong patient subsequently presented for treatment. The error was noticed by the administration clerk when she checked the date of birth. Again this incident highlights the importance of identification verification procedures being in place and checked at all stages of the patient pathway. All staff should be aware of the procedures and follow the agreed protocol.
http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=473

For the majority of routine treatments in our department similar, evidence based protocols, are in place. This is consistent with best practice. It can however lead to the types of incidents described below where patients with the same disease are treated using the same prescription / technique adding a further layer of similarity and potential for incidents. If careful verification of identity which included checking the patient, notes, record and verificy data and checking all against the same parameters is not always adhered.

Incident ID 441: Two patients with the same pathology were to start treatment. The first patient treatment was started but when the second patient was called he said that that was not his correct name. The treatment was interrupted and the data checked. The first patient was slightly deaf and was treated in error. Setup references were ignored also in this incident.
http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=441

Incident ID 427: The patient name and ID included in the treatment plan did not correspond to the patient for simulation. The documentation was incorrect and related to a patient with a similar name. Lack of care and attention by the treatment planning staff was cited.
http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=427

Incident ID 49: Occurred during clinical review of a patient who had been simulated and marked for radiotherapy. At the marking up session that followed the CT scans presented were for a different patient who had the same name but a different date of birth. By this time both patients had had a CT scan of the brain. The incident occurred when incorrect CT scans were sent tot he simulator and the staff failed to check details other than name, again highlighting the need to check all three parameters on all information received.
http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=49

Incident ID 266: In this incident a patient was treated with an incorrect plan. Similarly to Incident 5 all parameters fitted with minimal differences. The cause again was failure to correctly identify the patient prior to treatment.
http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=266

Incident ID 312: Similar incident relating to a patient receiving treatment for breast cancer. A slightly larger volume than intended was treated. The centre suggest photographic identification in addition to verbal. This would also have been applicable in Incident 35.
http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=312

Incident ID 387: Again related to the treatment of a patient with another patient's prescription. In this incident there was an additional risk introduced when the patient was

ROSIS – Patient Identification
August 2006

moved to a second Linear Accelerator following breakdown and the staff forgot to check the correct identity.
http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=387

Incident ID 5: This incident related to a brachytherapy procedure. An incorrect patient database was used but with identical parameters. The incorrect patient was treated but fortunately received correct treatment. The suggestion given by the reporting centre was to include a photograph of the patient in the record and verify system. Verification of identification protocols and adherence by all staff would also have prevented this incident.
http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=5

The following incidents relate to patients with the same first name and surname. This type of incident can occur very readily and highlights the need for an even higher level of vigilance within the departments. It also raises the need for photographic identification to be incorporated into the data where possible as a further safety check.

Incident ID 35: This was discovered at time of treatment. A patient marked for treatment to her humerus remarked that she had never been treated previously but that her next door neighbour who had the same name and birthday but who was a year older had been treated by the same consultant 3 years previously. The booking form for the new patent had been completed correctly but an incorrect set of notes was sent to the clinic. The similarities between the 2 patients were very strong and it is possible that even with verification protocols in place and adhered to the incident could still have occurred. It perhaps highlights the importance of engaging in conversation with the patients.
http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=35

Incident ID 412: Two patients with the same first name and surname but with different middle initials were being treated for prostate cancer. One of the patients had already started the second phase of treatment with a reduced boost field. He was called in to the treatment room and setup using the incorrect parameters resulting in the irradiation in an unwanted region. The technologist team had just changed and were not informed of the two patients with the same name.
http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=412

Incident ID 568: A patient was simulated and the field areas marked onto the Beam Direction Shell. When the patient was treated the BDS from another patient who had the same name and treatment area was incorrectly used. In addition the BDS fitted well. This again highlighted poor patient and equipment identification.
http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=568

Incident ID 408: Again involved two patients with the same first and surname but a different middle initial. In this instance in the image acquisition sheet the setup parameters were different from the skin marks on the patient. The physician was called and recognized that the incorrect patient had been setup. This also shows the importance of continuity and knowing the patients in your care.
http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=408

Incident ID 578: A BDS for one patient was fitted to another patient with the same name at simulation. The patient was then simulated and the marks put on to an incorrect BDS. The BDS did not fit well but this was not noticed until the treatment stage when the treating radiographers realized that the area to be treated did not match the marks on the shell. A BDS that doesn't fit correctly should always be investigated further.
http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=578

The incidents described above are similar in cause to the numerous misidentification errors reported in other hospital settings and could all have been prevented by the

ROSIS – Patient Identification
August 2006

introduction and adherence to a robust patient identification verification system and by staff being constantly alert to the possibility of patient misidentification.

The IAEA, in the Basic Safety Standards (for Protection against Ionizing Radiation and for the Safety of Radiation Sources), considers that therapeutic treatment delivered to the wrong patient shall be promptly investigated (by registrants and licensees) and corrective measures shall be indicated and implemented to prevent recurrence following this investigation.

Please give your comments on these reports [snichuin@tcd.ie]. We will add selected comments to next month's feedback letter.

Comments on In-VIVO Dosimetry (ROSIS Newsletter, March 2006):

QUESTION on Incident ID 385 http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=385:
If the original calculation was wrong and it wasn't picked up at checking, how did the in-vivo dosimetry system know what the correct dose was?

ROSIS ANSWER:
This ROSIS answer is a potential scenario, and not based on any further investigation of the facts.

Two separate calculations were done here

1. MU calculation
2. Expected diode reading

It is possible that the physicist correctly calculated the dose in Gy per field (using the correct patient dimensions and depth doses), but when transferring this to MU with the field size dependent output factors, inverse square law etc, he/she made an error.
This error showed up using diodes as the dose delivered was 15% lower than expected.
It showed up because at least some part of the expected diode reading was done independently of the MU Calculation, and the same mistake that was made in the MU Calculation was not repeated in the diode calculation.

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Radiation Oncology Safety Information System

http://www.rosis.info

Feedback letter January 2007

SPOTLIGHT ON DATA TRANSFER

- *This Newsletter* – Spotlight on Data Transfer
- *Reminder:* The third ROSIS short course **"Working towards safer healthcare delivery:**
  minimising the impact of incidents in radiotherapy" will be held from 14th-17th May 2007. Further details and registration form are available on the ROSIS website. Early registration closes 15th March 2007, and offers excellent value at EUR395, with a EUR50 discount for two or more people from the same department. Places are strictly limited, so book now.
- *Reminder:* Have you seen our new website? See it now, at http://www.rosis.info

Dear ROSIS Contact,

The ROSIS group would like to draw your attention to some interesting incident reports in the database. **The theme of this newsletter is Data Transfer.**

This topic and related reports are described below, together with some reflections. If you would like to read the full reports or make a comment, click on the links provided.

The next newsletter will focus on record and verify systems, in a continuation of this current theme.

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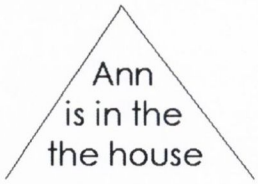
DATA TRANSFER



Did you read:

"Ann is in the house"?

If yes,

look again!

Data transfer is a common problem across many activities, and is well recognised as a challenge in radiotherapy. "Data transfer errors are mostly due to human mistakes or inattention. The reasons for these errors are transcription errors, rounding off errors, forgotten data or interchange of data . . ."(1)

As the complexity of radiotherapy increases, so too does the amount of data that must be transferred between the various stages of treatment preparation and delivery. The ICRP(2) estimated that for a treatment of 4 fields and 30 fractions, a total of 1,000 parameters will be set for the entire treatment. This of course is much greater for more conformal treatments.

The transfer of data is often made more complicated by the fact that some data must also be transformed from one type to another (e.g. from text to an image), and from one format to another (e.g. from paper to computer monitor). Failure to correctly transfer all data for a patient treatment has the potential to result in major under-/over-doses and/or geographic misses.

Independent verification of all the treatment parameters prior to or during the first patient treatment, using chart checks, beam checks, portal imaging, and in-vivo dosimetry is crucial to detecting data transfer errors in treatment preparation.

Both the literature and the ROSIS database testify to the existence of mistakes in radiotherapy due to incorrect data transfer. Readers are referred to the work of the The IAEA(32), Leunens et al(1), Holmberg et al(4), Valli et al(5), Macklis et al(6), Keung Yeung et al(7), Fiorino et al(8) for more research on data transfer errors in RT. *(References given at end of email message)*

ROSIS

Of the first 600 ROSIS reports, nearly half (49%; 294/600) were considered to have an element of data transfer which either directly caused or contributed to the occurrence of the incident. 130 of these 294 (44%) resulted in incorrect treatment being delivered (for at least one fraction). A substantial number of these data transfer errors had originated pre-treatment, but were not detected until treatment.

Of the 294 data transfer incidents,

- 156 (53%) were detected by chart check
- 100 (34%) were detected at the time of patient treatment
- 21 (7%) were detected by portal imaging

- 22 (7%) were detected by other means
- 8 (3%) were detected by quality assurance of equipment
- 7 (2%) were detected by clinical review
- 1 (0%) was detected by in-vivo dosimetry

(More than 1 detection method may be listed per report)

Of course, although percentages have been quoted here for comparison, care must be taken in interpreting data from reporting systems. According to Chappell(9):

"Incident data are ideally suited for

- proving the existence of a safety issue,
- understanding its possible causes,
- defining potential intervention strategies, and
- tracking the safety consequences once intervention has begun"

However, because reporting systems are dependent on people to report (and in many cases, identify) incidents, they may not reflect the true scenario. According to Chappell, "caution should always be used when employing incident data to determine the prevalence of a safety problem . . . [as] the relationship between incidents that are reported and those that occur is not known". From the ROSIS reports we know that data transfer is a problem – but we don't have information about its magnitude. We know some of the forms it can take, but we can't say we know them all. Nonetheless, we can prove that data transfer errors still exist in RT – meaning that at a local level, preventative strategies may be implemented or reviewed, and that further research may be needed.

Particular ROSIS reports which may be of interest include:

Incident Report 393, Incident Report 471, Incident Report 527, Incident Report 507, Incident Report 624, Incident Report 36, Incident Report 452
These reports highlight simple, straightforward, data transfer errors, that we are sure occur in all departments!

Incident Report 393: Interchange of Data: fields transposed
http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=393
"Treatment card prescribed incorrectly by clinician. Ant and Post fields annotated on treatment card and also at the simulation stage on setting up instructions the wrong way round. Therefore DICOM transferred incorrectly. Fortunately, monitor units for each field identical."

Incident Report 471: Wrong reference image sent
http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=471
"Planning department transferred incorrect DRRs to the patient database. When the first day images were taken on set, the radiographers noticed large discrepancies between the two sets of

images. Further investigation revealed that images from a different plan (same patient) had been sent."

Incident Report 507: Forgotten Data: Changed MU Values
http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=507
"Daily dose was altered by clinician. The updated treatment plan therefore registered new MU values. The new plan was not DICOM transferred to the linac and radiographers initially failed to notice the new mu's."

Incident Report 624: Forgotten Data: Changed relative moves to isocentre
http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=624
"Moves made from reference tattoos to isocentre based on review of EPIs taken at first 3 fractions of ph1. Additional moves of 4mm inf and 3mm left needed. These moves were not transferred to ph2 script/relative move section of Visir. Original moves used for 1st fraction of ph2. Realised at 2nd fraction that relative moves in Visir and on script did not tally with those in the messages that had been automatically carried over from ph1."

Incident Report 36: Transcription error: isocentre from film to treatment plan
http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=36
"Treatment planning staff incorrectly transferred the isocentre position onto the treatment plan from the simulator films. This resulted in an isocentre position 1.0cm too posterior"

Incident Report 452: Transcription error: field size
http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=452
"Incorrect electron field size indicated on polaroid, input into verification system and used for treatment. (1cm wider than intended). Field size indicated correctly on diagram on script but transferred incorrectly to polaroid. Picked up at chart check with 1 fraction remaining."

Incident Report 782.

Here, procedures were not followed for checking transferred data, resulting in incorrect treatment delivery.

http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=782
"Patient receiving parallel pair treatment to pelvis with 10 MV x-rays. Referred back to simulator to have ant field reconfigured (decided to use wedge in treatment field so needed to rotate collimator thro' 90 deg and re-conform MLC to shape field). New settings transferred electronically from simulator back to treatment unit, but photon energy was set to 6 MV (default). All treatment details for patients without a computer plan are exported for the default machine which only has 6 MV. The correct machine and energy is entered once the treatment has been imported into the R&V system. Because the patient was already on treatment, the full

process was not followed. In-vivo dosimetry measured entrance dose which was in tolerance because the 10 MV monitor unit setting was used. Error was found by chart check after 6 fractions of 6 MV."

Incident Report 52, Incident Report 727, Incident Report 388:

These reports illustrate the communication element of data transfer – where important information was omitted from the transfer of data. These mistakes could have been detected by appropriate portal imaging systems, but none were.

Incident Report 52 http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=52

"We used ct for the simulation and the dosimetry but this patient is treated for a tumour of the leg. The simulation was done with the foot first instead of the head and when the images were transferred to the TPS this information was not evident for the physicist and the position was inverted but the patient was treated as for the CT so the lateral beams were inverted. 10 fractions were done in this condition. After correction a dosimetry was done and the differences were not very important . . .

It is because when the images are transmitted from the CT not orientation is written on the films but due to the position of the treated volume the physicist normally should know this problem."

Incident Report 727 http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=727

"The patient needed mediastinal radiotherapy for non-Hodgkin lymphoma. He was planned for 3DCRT on mediastinal mass. In simulator tattooing two tattoos were done on the skin: one central and one for aligning in lower position. In CT acquisition the physician put metal marker on both. The physicist centred the beam on the lower tattoo (the alignment one) but didn't specify the shift in the setup note in R&V. The beam was cantered in the upper tattoo with a difference of 10 cm. The day of starting treatment DRR was not available in the image network and EPID image could not be matched to DRR. Another Epid image was not checked. The doctor who discovered the error visited the patient for dysphasia.

The correction consisted in making a new plan for giving dose to the missed lower volume."

Incident Report 388 http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=388

"A liver metastasis is to be treated with relatively small fields. There is one set-up isocentre and another treatment isocentre. The planned off set from the set up position to the treatment position is not performed. Portal images are taken and approved in a position more then 5 cm from the correct one. Bad routines for the transfer of information of the displacement. The reference images were too small, i.e. not enough anatomical information. The set up was 2 vertebras wrong."

Overall, it is clear that basic mistakes in data transfer are a frequent cause of misadministration of radiotherapy. These mistakes are most often a consequence of our fallibility as humans. Nonetheless, while it may be difficult to prevent the initial mistake, with good quality assurance procedures it is possible to catch most of these mistakes before or at the beginning of the patient's treatment.

Please give your comments on these reports [snichuin@tcd.ie]. We will add selected comments to next month's feedback letter.

Comments on Patient Identification (ROSIS Newsletter, August March 2006): http://www.clin.radfys.lu.se/reports/ROSIS_Newsletter_3_Patient_identification.pdf

ROSIS CONTACT COMMENT: "On the issue of patient identification, I wonder if the departments who filed these reports have photo ID? I know ROSIS is confidential, but perhaps the analysis of these incidents could suggest this as a useful tool. Whilst not infallible, it adds yet another layer of protection. We use patient ID photos on the record and verify system, along with date of birth etc to assist in the correct identification. We also use appointment cards. In combination, these measures are particularly useful where staff are coming in on a temporary basis, maybe haven't worked on a particular unit for some time, students are bringing patients in, etc."

ROSIS: It is of course extremely valuable to use a variety of identification methods. Obviously, as with any checking procedure, they must be used properly to be worthwhile. We actually don't ask departments at present what patient identification procedures they use - it would be a valuable question to ask, and thank you for pointing it out! We are revising our forms at the moment, so it will be included in the future.
However, in at least one of the patient identification incidents, we do know that the incident occurred despite having a patient photo - e.g. in Incident ID 312 the reporter lamented the fact that the incident occurred despite having a photo of the patient.
Being aware of the types of mistakes that occur and how they might occur should assist staff in noticing a mistake or an opportunity for a mistake, and in appreciating the value of the checking procedures, and so disseminating this information is one of the main aims of ROSIS. Hopefully, with a growing database of departments and reports, we will have sufficient information to fulfil this aim.

Comments on In-VIVO Dosimetry (ROSIS Newsletter, March 2006): http://www.clin.radfys.lu.se/reports/ROSIS_Newsletter_2_In_vivo_dosimetry.pdf

QUESTION on Incident ID 385 http://www.clin.radfys.lu.se/queries/q_search_ID.asp?number=385:
If the original calculation was wrong and it wasn't picked up at checking, how did the in-vivo dosimetry system know what the correct dose was?

ROSIS CONTACT COMMENT: At a guess, I would say that the reason the diode system picked up the 15% discrepancy was because of the fact that the treatment technique was probably a single field prescribed
at Dmax. When performing in vivo dosimetry on a d-max treatment, the expected diode dose will be very close to that of the prescription dose. Accordingly, the physicist may have used the prescription dose as the expected dose, which will certainly catch a dose difference of 15% and be independent of the calculated MU value.

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(1) Human errors in data transfer during the preparation and delivery of radiation treatment affecting the final result: "garbage in, garbage out". G Leunens, J Verstraete, W van den Bogaert, J Van Dam, A Dutreix, E van de Schueren. Radiotherapy and Oncology 1992;23:217-222

(2) Prevention of Accidental Exposures to patients undergoing radiation therapy. ICRP Publication 86 2000

(3) Lessons learned from accidental exposures in radiotherapy. Safety Reports Series No 17. IAEA, Vienna, 2000

(4) Preventing treatment errors in radiotherapy by identifying and evaluating near misses and actual incidents. O Holmberg, B McClean. Journal of Radiotherapy in Practice 2002;3(1):13-25

(5) Evaluation of most frequent errors in daily compilation and use of a radiation treatment chart. MC Valli, M Prina, A Bossi, LF Cazzaniga, D Cosentino, L Scandolaro, A Ostinelli, A Monti, P Cappelletti. Radiotherapy and Oncology 1994;32:87-89

(6) Error rates in clinical radiotherapy. Roger M Macklis, Tim Meier, Martin S Weinhous. J Clin Oncol 1998;16:551-556

(7) Quality Assurance in radiotherapy: evaluation of errors and incidents recorded over a 10 year period. Tai Keung Yeung, Karen Bortolotto, Scott Cosby, Margaret Hoar, Ernst Lederer. Radiotherapy and Oncology 2005;74(3) 283-291

(8) Quality assurance by systematic in vivo dosimetry: results on a large cohort of patients. Claudio Fiorino, Daniela Corletto, Paola Mangili, Sara Broggi, Antonio Bonini, Giovanni Mauro Cattaneo, Rossella Parisi, Alberto Rosso, Patrizia Signorotto, Eugenio Villa, Riccardo Calandrino. Radiotherapy and Oncology 2000;56:85-95

(9) Chappell. Using voluntary incident reports for human factors evaluations. In: N Johnston, N. McDonald, R Fuller. Aviation Psychology in Practice. Avebury Technical; 1994.

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ROSIS

Feedback letter July 2007
SPOTLIGHT ON RECORD AND VERIFY

- *This Newsletter* – Spotlight on Record and Verify
- *Reminder:* The fourth ROSIS short course **"Working towards safer healthcare delivery: minimising the impact of incidents in radiotherapy"** will be held from 12th-15th May 2008. Watch the ROSIS website for further details and the registration form.
- *Reminder:* Have you seen our new website? See it now, at http://www.rosis.info

Dear ROSIS Contact,

The ROSIS group would like to draw your attention to some interesting incident reports in the database. **The theme of this newsletter is Record and Verify.**

This topic and related reports are described below, together with some reflections. If you would like to read the full reports or make a comment, click on the links provided.

Remember that you can search the full ROSIS database at http://www.rosis.info

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RECORD AND VERIFY

Record and verify systems (R&V systems), or check and confirm systems, have been a crucial part of the technological advancement in Radiation Oncology – enabling the delivery of more sophisticated and complex treatments. However, although the implementation of R&V systems has reduced some types of "random" mistakes, new risks were also introduced.(1,2,3)

Many R&V-related mistakes arise during manual input of data. Reliance on computers often leads to operators trusting the information they contain – forgetting that the information could either be electronically corrupted, or that often the information has been manually input into the computer by a fallible human in the first place! Instances where much of the data is electronically transferred, but some is manually input can also give rise to a false sense of security.

As this data forms the basis of the patient's treatment, it is imperative that it is always correct. Approximately one-fifth of the reports in the ROSIS database related to incorrect data input into R&V systems, of which nearly half resulted in incorrect treatment delivery for at least one fraction. Other mistakes related to R&V systems were due to software / network problems, violations of approved procedure, or failure to update the R&V data with treatment changes.

The reports below highlight some of these issues.

Incident Report 453: Transcription Error: Wrong value input
http://www.clin.radfys.lu.se/queries/q_search_ID_new.asp?number=453

Some treatment parameters are to be introduced manually in the R&V system, even if others are transferred automatically from the TPS. One of the formers is the dose per field. Despite the fact that the dose calculation was correct a wrong dose per field has been introduced. The error has been detected by the physicist who checks all treatment parameters at the R&V system before treatment.

Incident Report 271: Transcription Error: Wrong value input
http://www.clin.radfys.lu.se/queries/q_search_ID_new.asp?number=271

Field input incorrectly onto Varis
Pt transfered from 1 unit to another to help reduce pts waiting times
Field treated as 7 x 8 instead of 8 x 7 for 1 field only - corrected on 2nd field

Incident Report 201: Transcription Error: Wrong value input
http://www.clin.radfys.lu.se/queries/q_search_ID_new.asp?number=201

Linac 3 broke down - pt moved to different Linac for 1#. On ant s'clav field size treated incorrectly, length should have been 9.9cm treated at 8.9cm - input incorrectly - check process did not pick up as done at short notice and did not go through normal pre-treatment system.

Incident Report 162: Incorrect data - ? due to error in electronic transfer
http://www.clin.radfys.lu.se/queries/q_search_ID_new.asp?number=162

A lung patient was treated with a 3-field technique. The prescribed gantry angles were 0, 167 and 209 degrees. At fraction no. 11 it is discovered that field 3 has been given in 249 degrees for all the previous 10 fractions. The gantry angle in the dose plan and treatment chart is correct, but wrong in the verification system. We use electronic transfer of data and we cannot rule out a transfer error although we have not been able to repeat it in tests. Another possibility (although unlikely) is that an authorised person manually have changed the angle, but for what purpose? At the first fraction a portal image was taken. Field 1 & 2 was approved, but not number 3 because it did not look

correct. It was decided to take another image the next day, which was done, but that second film was neither checked, nor approved.

Mistakes made in the transfer of the data are often missed where adequate checking procedures are not in place, or where they are in place but have not been used properly / were rushed etc. In these instances, it is common for some of the patient's treatment to be delivered incorrectly before the mistake is found.

Comprehensive checking procedures prior to the use of any data in the R&V system, and appropriate independent checks during the first treatments (or when using any new data) should ensure that most mistakes are detected at an early stage.(4)

As with any other area, it is important that the checking procedures are appropriate. For example – checking data on a R&V system computer screen against original data on paper can itself be very error prone. The data is in different formats (on-screen vs paper), and is probably also in a different layout (sequence of data may be different). The checker must be careful to avoid an "expectation bias" – i.e. where he/she sees a gantry angle of "0" on the paper, and looks to find a "0" on the screen, without also consciously checking that it corresponds to the gantry angle given on the screen.

In 1995, De Graaff and van Kleffens (5) described a system they developed to minimize manual data entry errors. This system was based on a programme, which automatically checked two independent manual data inputs, and highlighted any inconsistencies to the second inputter. They found that the "introduction of this system has shown a remarkable decrease in data entry errors on our machines."(5)

To date, ROSIS has not had the capability to explore issues associated with the use of particular R&V systems, but this will change with future revisions of ROSIS. We would be very interested to hear from anyone who has researched / is looking at this topic.

Please give your comments on these reports [snichuin@tcd.ie]. We will add selected comments to next month's feedback letter.

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REFERENCES

1 Leunens G, Verstraete J, van den Bogaert W, Van Dam J, Dutreix A, van de Schueren E. Human errors in data transfer during the preparation and delivery of radiation treatment affecting the final result: "garbage in, garbage out". Radiother Oncol 1992;23:217-22

2 Patton GA, Gaffney DK, Moeller JH. Facilitation of radiotherapeutic error by computerized record and verify systems. Int J Radiat Oncol Biol Phys. 2003 May 1;56(1):50-7

3 Barthelemy-Brichant N, Sabatier J, Dewé W, Albert A, Deneufbourg JM. Evaluation of frequency and type of errors detected by a computerized record and verify system during radiation treatment. Radiother Oncol 1999;53(2):149-154

4 Macklis RM, Meier T, Weinhous MS. Error rates in clinical radiotherapy. J Clin Oncol 1998;16:551-556

5 de Graaff C. H. W., van Kleffens H. J. Control of inputparameters in Philips SL25 Linear Accellerators. Radiother Oncol 1995;37:S56

APPENDIX I

I. Examples of existing ROSIS Incident Reports applied to full revised ROSIS Dataset

Sample Reports

Incident ID 7

Incident Form

Severity Classification

Incident ID 57

Incident Form

Severity Classification

Incident ID 19

Incident Form

Severity Classification

REPORTED TEXT IS HIGHLIGHTED IN GREEN

From Incident no 7

Dept ID	***freetext - Code***				
Incident	Description / Keyword	**Radiographers treated the patient incorrectly**			
	Who did it affect?	*Select option(s)*	**One patient**		
			Several patients	How many?	*Number*
			Staff	How many?	*Number*
			Visitor(s)	How many?	*Number*
		If patient(s), what was the treament intent?	*Select option*	**Radical**	*one option possible*
				Palliative	
				Prophyllactic	
				Benign disease	
Occurrence	Treatment Technique	*select option (one only)*	LA - Photons	**2-D RT**	
				2.5D RT	
				3-D CRT	
				4-D / Gating	*freetext for details of method*
				IMRT	Dynamic / Static — *one selection possible*
				Stereotactic	Radiosurgery / Radiotherapy / Intra-cranial / Extra-cranial — *multiple selections possible*
				TBI	
				HBI	
			LA- Electrons	TSEI	
				Skin Apposition	
			Orthovoltage		
			Co-60		

			Brachytherapy	HDR LDR 2-D 3-D 4-D	*multiple selections possible*			
			Intraoperative RT					
			Radio-isotopes					
			Protons					
			Neutrons					
			Light ions					
			Gammaknife					
			Cyberknife					
			Other (give details --- *freetext*----)					
	Treatment Site	*select option*	Brain Head and Neck Thorax **Breast** Abdomen Pelvis Extremity TBI HBI		*one selection possible*			
	Where/when in process	*select from lists*	*Pick activity from sheet* ***"process"***	*one "tree" possible*	**Treatment Delivery**	**RT Set-up**	**Couch Angle**	
	Description *(the details)*	*freetext*	**"3-field brast technique. Treatment couch was angled incorrectly during the treatment of the tangential fields"**					
	Cause	*freetext*	**"radiographer error"**					
	How / why	*select option(s)*	*Pick from sheet "Causes_Contributing factors"*	*multiple selections possible*	**(from that sheet - 2c, 4b, 4c, 5a, 5c, 6bii)**			

	Hardware (if involved)	*freetext*		
	Who - what discipline	*select option(s)*	Radiation Oncologist (physician)	*multiple selections possible*
			medical physicist	
			radiation therapist at treatment unit	
			radiation therapist at simulator and/or in-house Ct	
			staff doing dosimetry	
			staff doing technical maintenance	
			other *(please specify -------freetext-----)*	
Detection	Where/when in process	*select from list*	Imaging	*one selection possible*
			Simulation	
			Planning	
			Prescription	
			Dose calculation	
			Treatment Preparation	
			Treament Delivery	
	How / why	*Select option(s)*	Chart-check - pre-treatment	*multiple selections possible*
			Chart-check - during treatment	
			in-vivo dosimetry	
			portal imaging	
			volumetric imaging	
			clinical review of patient	
			quality control of equipment	
			found at time of 1st patient treatment during regular checks	
			found at later stage during patient treatment	
			external audit	
			other (please specify ------freetext-----)	

	Who - what discipline	*select option(s)*	Radiation Oncologist (physician) medical physicist **radiation therapist at treatment unit** radiation therapist at simulator and/or in-house Ct staff doing dosimetry staff doing technical maintenance other *(please specify -------freetext----)*	*multiple selections possible*
Severity	See sheet "severity"	potentially 5 questions	**See separate sheet Sample 1 Severity**	
Suggestions for future prevention	**This particular technique has just recently been changed. The previous technique required the floor to be rotated, but not the new technique. A written protocol has been produced, and training sessions have been implemented. The error could be mainly due to the department introducing this technique.**			

SAMPLE SEVERITY / OUTCOME QUESTIONS - Incident number 7

1. Was any part of treatment delivered incorrectly?	a. YES	i. How many fractions were delivered incorrectly?	**1**
		ii. How many fractions were prescribed in total?	**25**
		iii. What was the prescribed Dose/Fraction (Gy)?	**2**
		iv. ?AND/OR What was the prescribed total dose (Gy)?	**50**
		v. How was the treatment scheduled? – *select as applicable*	**1. 1 fraction per day**
			2. 2 fractions per day
			3. 3 fractions per day
			4. 2 fractions per week
			5. 1 fraction per week
			6. Treatment on weekdays
			7. Treatment on Saturday

			8. Treatment on Saturday
			9. Other _____ *(details)*
	b. NO		
2. *If from*			
a. *Q 1b* **"If the error did reach the patient, what would have been the <u>effect per fraction</u> in terms of dose and/or treated volume?**	**Select the most appropriate category:**	i. Less than 5% per fraction	
		ii. Between 5% and 9% per fraction	
		iii. Between 10% and 24% per fraction	
b. *Q 1a* **"What was the <u>effect per fraction</u> in terms of dose and/or treated volume?**		iv. Between 25% and 49% per fraction	
		v. between 50 and 99% per fraction	
		vi. Greater than 100% per fraction	
3. *(If from Q2b)* **Was this error corrected?**	a. YES		*Q 3 – include free-text box for Details*
	b. NO		
	i. Not correctable		
	ii. Not required		
4. Was the tolerance dose of any organ at risk exceeded?	a. YES	i. Name the organ and the dose received.	Q4 – free-text box
	b. NO		
5. Could this error have been detected by ***(tick all that apply)***	a. Portal imaging?		
	b. Volumetric imaging?		
	c. Central axis in-vivo dosimetry?		
	d. Off-axis in-vivo dosimetry?		
	e. Thorough chart check?		

REPORTED TEXT IS HIGHLIGHTED IN GREEN

From Incident no 57

Dept ID	*freetext - Code*				
Incident	Description / Keyword	**Confusing routines when introducing Virtual Simulation**			
	Who did it affect?	*Select option(s)*	**One patient**		
			Several patients	How many?	*Number*
			Staff	How many?	*Number*
			Visitor(s)	How many?	*Number*
		If patient(s), what was the treament intent?	*Select option*	**Radical**	*one option possible*
				Palliative	
				Prophyllactic	
				Benign disease	
Occurrence	Treatment Technique	*select option (one only)*	LA - Photons	2-D RT	
				2.5D RT	
				3-D CRT	
				4-D / Gating	*freetext for details of method*
				IMRT	Dynamic / Static — *one selection possible*
				Stereotactic	Radiosurgery / Radiotherapy / Intra-cranial / Extra-cranial — *multiple selections possible*
				TBI	
				HBI	
			LA- Electrons	TSEI	
				Skin Apposition	
			Orthovoltage		
			Co-60		
			Brachytherapy	HDR	*multiple*

				LDR	*selections possible*		
				2-D			
				3-D			
				4-D			
			Intraoperative RT				
			Radio-isotopes				
			Protons				
			Neutrons				
			Light ions				
			Gammaknife				
			Cyberknife				
			Other (give details --- *freetext*----)				
	Treatment Site	*select option*	Brain	*one selection possible*			
			Head and Neck				
			Thorax				
			Breast				
			Abdomen				
			Pelvis				
			Extremity				
			TBI				
			HBI				
	Where/when in process	*select from lists*	*Pick activity from sheet* ***"process"***	*one "tree" possible*	**Treatment Delivery**	**RT Set-up**	**Treatment Isocentre**
	Description *(the details)*	*freetext*	**"A tangential 2-field ca mam patient was virtually simulated. At time of scanning the location of the isocentre is not known (contrary to the situation with conventional simulation). Tattoos for lining up the patients (set-up tattoos) were entered and, after doseplanning, a chart describing the offset from set-up to isocentre were added to the treatment chart. The staff misunderstood the meaning of the tattoos and the first treatment and treated the patient in a couch position 3cm below the correct one. Portal images were taken and approved (!) by the doctor. The error was discovered the day after."**				

	Cause	*freetext*	**"The staff was not confident with the new simulation technique. According to the instruction the FSD should have been checked; this was not the case. The portal images should not have been approved, but the doctor was not used to DRRs as reference images and did not discover this rather big geographical error. If in doubt, he should have called a colleague. In the chart check (before treatment) the physicist shall check the couch height from the doseplan with the parameter at the treatment room; this was overseen."**		
	How / why	*select option(s)*	*Pick from sheet "Causes_Contributing factors"*	*multiple selections possible*	**(from that sheet - 4c, 5a, 5b, 5c, 6bii, 6bii)**
	Hardware (if involved)	*freetext*			
	Who - what discipline	*select option(s)*	**Radiation Oncologist (physician)**	*multiple selections possible*	
			medical physicist		
			radiation therapist at treatment unit		
			radiation therapist at simulator and/or in-house Ct		
			staff doing dosimetry		
			staff doing technical maintenance		
			other *(please specify -------freetext-----)*		
Detection	Where/when in process	*select from list*	Imaging	*one selection possible*	
			Simulation		
			Planning		
			Prescription		
			Dose calculation		
			Treatment Preparation		
			Treament Delivery		
	How / why	*Select option(s)*	Chart-check - pre-treatment	*multiple selections possible*	
			Chart-check - during treatment		
			in-vivo dosimetry		

			portal imaging	
			volumetric imaging	
			clinical review of patient	
			quality control of equipment	
			found at time of 1st patient treatment during regular checks	
			found at later stage during patient treatment	
			external audit	
			other (please specify ------freetext-----)	
	Who - what discipline	*select option(s)*	Radiation Oncologist (physician)	*multiple selections possible*
			medical physicist	
			radiation therapist at treatment unit	
			radiation therapist at simulator and/or in-house Ct	
			staff doing dosimetry	
			staff doing technical maintenance	
			other *(please specify -------freetext-----)*	
Severity	See sheet "severity"	potentially 5 questions	**See separate sheet Sample 2 - Severity 57**	
Suggestions for future prevention	**"New techniques, such as virtual simulation, should be introduced with more training, information and teaching than was the case. All staff groups must be familiar with all the aspects of the new technique before clinical introduction."**			

SAMPLE SEVERITY / OUTCOME QUESTIONS
Incident number 57

1. Was any part of treatment delivered incorrectly?	a. YES	i. How many fractions were delivered incorrectly?	**1**
		ii. How many fractions were prescribed in total?	**20**
		iii. What was the prescribed Dose/Fraction (Gy)?	**2.25**

		iv. ?AND/OR What was the prescribed total dose (Gy)?	45
		v. How was the treatment scheduled? – *select as applicable*	**1. 1 fraction per day** 2. 2 fractions per day 3. 3 fractions per day 4. 2 fractions per week 5. 1 fraction per week **6. Treatment on weekdays** 7. Treatment on Saturday 8. Treatment on Saturday 9. Other _____*(details)*
	b. NO		
2. *If from*			
a. *Q 1b* **"If the error did reach the patient, what would have been the <u>effect per fraction</u> in terms of dose and/or treated volume?**	**Select the most appropriate category:**	i. Less than 5% per fraction	
		ii. Between 5% and 9% per fraction	
		iii. Between 10% and 24% per fraction	
b. *Q 1a* **"What was the <u>effect per fraction</u> in terms of dose and/or treated volume?**		iv. Between 25% and 49% per fraction	
		v. between 50 and 99% per fraction	
		vi. Greater than 100% per fraction	
3. *(If from Q2b)* **Was this error corrected?**	a. YES		*Q 3 – include free-text box for Details*
	b. NO		
	i. Not correctable		
	ii. Not required		
4. Was the tolerance dose	a. YES	i. Name the organ and the dose received.	Q4 – free-text box

of any organ at risk exceeded?	b. NO
5. Could this error have been detected by (*tick all that apply)*	a. Portal imaging?
	b. Volumetric imaging?
	c. Central axis in-vivo dosimetry?
	d. Off-axis in-vivo dosimetry?
	e. Thorough chart check?

REPORTED TEXT IS HIGHLIGHTED IN GREEN

From Incident no 19

freetext - Code					
Description / Keyword	**"Modifying treatment beam sizes on treatment unit"**				
Who did it affect?	*Select option(s)*	**One patient**			
		Several patients	How many?	*Number*	
		Staff	How many?	*Number*	
		Visitor(s)	How many?	*Number*	
	If patient(s), what was the treament intent?	*Select option*	Radical	*one option possible*	
			Palliative		
			Prophyllactic		
			Benign disease		
	select option (one only)	LA - Photons	**2-D RT**		
			2.5D RT		
			3-D CRT		
			4-D / Gating	*freetext for details of method*	
			IMRT	Dynamic	*one selection possible*
				Static	
			Stereotactic	Radiosurgery	*multiple selections possible*
				Radiotherapy	
				Intra-cranial	
				Extra-cranial	
			TBI		
			HBI		
		LA- Electrons	TSEI		
			Skin Apposition		
		Orthovoltage			
		Co-60			
		Brachytherapy	HDR	*multiple*	

			LDR	*selections possible*		
			2-D			
			3-D			
			4-D			
		Intraoperative RT				
		Radio-isotopes				
		Protons				
		Neutrons				
		Light ions				
		Gammaknife				
		Cyberknife				
		Other (give details --- *freetext*----)				
Treatment Site	*select option*	**Brain**	*one selection possible*			
		Head and Neck				
		Thorax				
		Breast				
		Abdomen				
		Pelvis				
		Extremity				
		TBI				
		HBI				
Where/when in process	*select from lists*	*Pick activity from sheet* ***"process"***	*one "tree" possible*	**Treatment Delivery**	**Beam modification**	**Wedge**
Description *(the details)*	*freetext*	**"Treatment field was downloaded from "Lantis" to treatment unit. Field size was modified by hand control. Modified treatment field was "captured" by "Lantis" which did not record the VW wedge information for the field. Two subsequent treatments given without the VW wedge before error was detected."**				
Cause	*freetext*	**"Software problem"**				
How / why	*select option(s)*	*Pick from sheet "Causes_Contributing factors"*	*multiple selections possible*	**from sheet - 3eiii, 4ei, 5a**		
Hardware (if involved)	*freetext*	**Lantis v5.22c2**				
Who - what discipline	*select option(s)*	**Radiation Oncologist (physician)**	*multiple selections possible*			
		medical physicist				

		radiation therapist at treatment unit	
		radiation therapist at simulator and/or in-house Ct	
		staff doing dosimetry	
		staff doing technical maintenance	
		other *(please specify -------freetext-----)*	
Where/when in process	*select from list*	Imaging	*one selection possible*
		Simulation	
		Planning	
		Prescription	
		Dose calculation	
		Treatment Preparation	
		Treament Delivery	
How / why	*Select option(s)*	Chart-check - pre-treatment	*multiple selections possible*
		Chart-check - during treatment	
		in-vivo dosimetry	
		portal imaging	
		volumetric imaging	
		clinical review of patient	
		quality control of equipment	
		found at time of 1st patient treatment during regular checks	
		found at later stage during patient treatment	
		external audit	
		other (please specify -------freetext-----)	
Who - what discipline	*select option(s)*	Radiation Oncologist (physician)	*multiple selections possible*
		medical physicist	
		radiation therapist at treatment unit	
		radiation therapist at simulator and/or in-house Ct	

		staff doing dosimetry	
		staff doing technical maintenance	
		other *(please specify -------freetext-----)*	
See sheet "severity"	potentially 5 questions	**See separate sheet Sample 3 - Severity 19**	

"No longer using "capture" function on Lantis until further information from manufacturer received. UPDATE RECEIVED 11th March 2003 (The above report is amended): "We have since learned that the two tangential breast treatment fields were both edited in Lantis v5.22c2, not Primeview as reported previously. The wedge disappeared from one tangential field and we still do not know how this occurred as it is difficult to delete a wedge from the field in Lantis.""

SAMPLE SEVERITY / OUTCOME QUESTIONS - Incident number 19

1. Was any part of treatment delivered incorrectly?	a. YES	i. How many fractions were delivered incorrectly?	**3**
		ii. How many fractions were prescribed in total?	**10**
		iii. What was the prescribed Dose/Fraction (Gy)?	**3**
		iv. ?AND/OR What was the prescribed total dose (Gy)?	**30**
		v. How was the treatment scheduled? – *select as applicable*	**1. 1 fraction per day**
			2. 2 fractions per day
			3. 3 fractions per day
			4. 2 fractions per week
			5. 1 fraction per week
			6. Treatment on weekdays
			7. Treatment on Saturday
			8. Treatment on Saturday
			9. Other _____*(details)*
	b. NO		

2. *If from*			
a. *Q 1b* **"If the error did reach the patient, what would have been the <u>effect per fraction</u> in terms of dose and/or treated volume?**	**Select the most appropriate category:**	i. Less than 5% per fraction	
		ii. Between 5% and 9% per fraction	
		iii. Between 10% and 24% per fraction	
b. *Q 1a* **"What was the <u>effect per fraction</u> in terms of dose and/or treated volume?**		**iv. Between 25% and 49% per fraction**	
		v. between 50 and 99% per fraction	
		vi. Greater than 100% per fraction	
3. *(If from Q2b)* **Was this error corrected?**	a. YES		***Dose distribution re-constructed and attempt made to correct over remaining fractions***
	b. NO		
	i. Not correctable		
	ii. Not required		
4. Was the tolerance dose of any organ at risk exceeded?	a. YES	i. Name the organ and the dose received.	Q4 – free-text box
	b. NO		
5. Could this error have been detected by ***(tick all that apply)***	a. Portal imaging?		
	b. Volumetric imaging?		
	c. Central axis in-vivo dosimetry?		
	d. Off-axis in-vivo dosimetry?		
	e. Thorough chart check?		

APPENDIX J

J. ROSIS and AAPM consensus on Classification

4th February 2008

Radiation Treatment Program Information

1. Contact Details

Department	
Institution/Hospital	
Name of Primary Contact Person	
Position of Contact Person	
Email	
Phone	
Address	
Alternate Contact Person	
Email	

2. Program Clinical Workload (per year)

New patients		
External photon beam courses. 2D : 3D		
External photon beam fractions. 2D :3D		
External electron beam courses. 2D : 3D		
External electron beam fractions. 2D :3D		
HDR brachy procedures. 2D : 3D		
HDR brachy fractions. 2D : 3D		
PDR brachy procedures. 2D : 3D		
PDR brachy fractions. 2D : 3D		
LDR brachy procedures. 2D : 3D		
LDR brachy fractions. 2D : 3D		
IMRT courses. Step and Shoot: Dynamic		
IGRT courses		
4 D/Gating courses		
SRS/SRT courses		
TBI/HBI courses		
Intraoperative procedures		
Sealed source procedures		
Unsealed source procedures		
Other (please specify)		
Other (please specify)		

3. Educational Workload (number of students)

Radiation Oncology Residents	
Medical Physics Residents	
Fellows	
Graduate Students	
Therapists in training	

4. Program Infrastructure (number of units)

Preparation	Computed Tomography	
	Magnetic Resonance	
	Positron Emission Tomography	
	Ultrasound	
	CT Simulator	
	Conventional Simulator	
	Simulator with Cone Beam CT	
	2 D planning workstations	
	3 D planning workstations	
	Other (please specify)	
	Other (please specify)	
Delivery	Orthovoltage	
	Co-60	
	Linac – single photon energy; no electrons	
	Linac – multiple photon energies; no electrons	
	Linac with electrons	
	Linac with multileaf collimator	
	Linac with portal imaging	
	Linac with kV imaging : CBCT	
	HDR brachy	
	PDR brachy	
	LDR brachy	
	Sealed sources	
	Tomotherapy	
	Gammaknife	
	Cyberknife	
	Novalis	
	Other (please specify)	
	Other (please specify)	
	Full networking of RT parameters	Yes/No
	Full networking of RT images	Yes/No

Data management	TPS networked to treatment units	Yes/No
	Simulator/CT networked to TPS	Yes/No
	Linacs with Record and Verify	
	Other (please specify)	
	Other (please specify)	

5. Program Staff (full time equivalents)

Radiation Oncologists	
Medical Physicists	
Treatment Planners	
Simulator/CT/MR/PET Technologists	
Treatment Delivery Therapists	
Electronics/Machine shop Technologists	
Other (please specify)	

6. Quality Assurance – program

Formal quality management system	Yes/No
External dosimetry audit (please specify)	*free text*
Documented QC procedures and records	Yes/No
Documented clinical processes	Yes/No
Nuclear/X ray regulator (please specify)	*free text*
Other activities (please specify)	
Other activities (please specify)	

7. Quality Assurance – patient specific (% of patients)

Independent chart checks before treatment	%
Chart checks during treatment	%
Independent check of R and V entry	%
In vivo dosimetry	%
Peer review of new patient prescription	%
Verification images at treatment	%
On treatment physician consultation	%
Other activities (please specify)	%
Other activities (please specify)	%

8. Risk Management – Treatment Program

Structure	Risk management committee or equivalent	Yes/No
	Committee composition	*free text*
	Committee formed (year)	
	Committee meeting frequency (per year)	
Operation	Incident reporting	Mandatory/Voluntary
	Incident reporting	Confidential/Anonymous
	Method of analysis	*free text*
	Learning/feedback	*free text*
	Responsibility for corrective actions	*free text*

Incident Information

direct hyperlinks to the glossary

introductory paragraph asking people to fill in as many boxes as possible

(not known box on some)

(drop downs)

1. General Information

Who (was affected)?

Individuals	Actually affected	Potentially affected
Patients		
Staff		
Visitors		

1.1.2 as any part of a patient treatment delivered incorrectly? Yes/No

Link to yes in 1.1.2	
How many fractions were delivered incorrectly?	
How many fractions were prescribed in total?	
What was the prescribed dose per fraction?	
What was the prescribed total dose (Gy)?	

1.2 What (was the Site(s) and Treatment Intent for Patient Incidents)

Check boxes – not obligatory

Site
Brain
Head and Neck
Thorax
Breast
Abdomen
Pelvis
Extremity
TBI

Treatment Intent
Radical

Palliative
Prophylactic
Adjuvant
Benign
Not known

1.3 To whom (was it reported)

Immediate supervisor	
Head of Department	
Appropriate Committee	
Regulatory authority	
Other	
Please provide details	*Free text*

2. Incident Details

2.1 What type (of incident - Process or Infrastructure)
hyperlink with please proceed to section 4a Process or section 4b Infrastructure

2A Process

2A.1 Which (Clinical ~~Program~~ Modality)

Photons 2D: 3D		
Electrons 2D: 3D		
HDR brachy 2D : 3D		
PDR brachy 2D : 3D		
LDR brachy 2D : 3D		
IMRT.Step and Shoot: Dynamic		
IGRT		
4 D/Gating		
SRS/SRT		
TBI/HBI		
Intraoperative		
Sealed source		
Unsealed source		
Other (please specify)		
Other (please specify)		

2A.2 Where (did the incident originate)

Level 1	Level 2
Assessment	
Prescription	To be developed
Preparation	
Delivery	
Follow-up	To be developed

Preparation: Level 2 immobilization, localization, treatment planning, simulation, pre-treatment verification, data transfer.

Delivery: Level 2 first day set up patient positioning, beam modifiers, machine parameters, treatment chart interpretation

2A. 3 What (was wrong)

Check boxes of Joanne's detailed Level 3 list

2A. 4 What (happened)

free text

2B Infrastructure Incidents

2B. 1 Which (system was involved in the incident)

Preparation	Computed Tomography	
	Magnetic Resonance	
	Positron Emission Tomography	
	Ultrasound	
	CT Simulator	
	Conventional Simulator	
	Simulator with Cone Beam CT	
	2 D planning workstation	
	3 D planning workstation	
	Other (please specify)	
	Other (please specify)	
Delivery	Orthovoltage	
	Co-60	
	Linac – single photon energy; no electrons	
	Linac – multiple photon energies; no electrons	
	Linac with electrons	
	Linac with multileaf collimator	
	Linac with portal imaging	
	Linac with kV imaging : CBCT	
	HDR brachy	
	PDR brachy	
	LDR brachy	
	Sealed sources	
	Tomotherapy	
	Gammaknife	
	Cyberknife	
	Novalis	
	Other (please specify)	
	Other (please specify)	
Data Management	Network transfer of RT parameters	
	Network transfer of RT images	
	TPS network transfer to treatment units	
	Simulator/CT network transfer to TPS	
	Record and Verify	
	Other (please specify)	
	Other (please specify)	

2B. 2 What (happened)

free text

3. Detection

3.1 Where (was the incident detected)

Level 1	Level 2	Level 3
Where in process		

3.2 How (was the incident detected)

Independent chart check before treatment	
Chart check during treatment	
Independent check of R and V entry	
In vivo dosimetry	
Peer review of new patient prescription	
Verification images at treatment	
On treatment physician consultation	

Formal quality management system	
External dosimetry audit	
Daily QC	
Monthly QC	
Annual QC	
Maintenance	
Other activities (please specify)	

3.3 Who (discovered the incident)

Radiation Oncologist	

Medical Physicist	
Treatment Planner	
Simulator/CT/MR/PET Technologist	
Treatment Delivery Therapist	
Electronics/Machine shop Technologist	
Other (please specify)	

3.4 What (was detected)

4. Analysis of the Incident

4.1 Severity estimate

4.1.1 Estimate the maximum actual dose deviation from the prescription anywhere in the Planning Target Volume over a course of treatment.

< 5%
5-9%
10-24%
25-49%
50-99%
Greater than 100%
Not applicable

4.1.2 Estimate the maximum potential dose deviation from the prescription anywhere in the Planning Target Volume over a course of treatment had the incident not been identified and corrected?

< 5%
5-9%
10-24%
25-49%
50-99%
Greater than 100%
Not applicable

4.1.3 Was the tolerance dose of any organ at risk exceeded? Yes/no

If yes please state organ and dose.

4.1.4 What was the **actual** outcome for the patient(s)/person(s) affected?

None
Light (e.g. corrective action possible)
Moderate (some clinical adverse affect cannot be ruled out)
High (clinical adverse effect is likely)
Severe (high probability for severe adverse effects or demonstrated effect)

4.1.4 What would be the **potential** outcome for the patient(s)/person(s) over a course of treatment had the incident not been identified and corrected?

None
Light (e.g. corrective action possible)
Moderate (some clinical adverse affect cannot be ruled out)
High (clinical adverse effect is likely)
Severe (high probability for severe adverse effects or demonstrated effect)

5. Causal Analysis

See below

6. Corrective Actions

6.1 What actions were taken to correct the incident described in this report?

Free text

6.2 What preventive measures could be taken to minimize the probability and/or severity of the incident described in this report from re-occurring?

Free text

Causal analysis

1. Standards/Procedures/Practices
1.1 Not developed
1.2 Inadequate standards/Procedures/practice
1.3 Standard procedure/practice not followed
1.4 Inadequate documentation
1.5 Inadequate communication
1.6 Not implemented

2. Equipment/hardware/software
2.1 Availability
2.2 Defective equipment/hardware/software
2.3 Inadequate maintenance
2.4 Inadequate quality control
2.5 Used incorrectly
2.6 Inadequate hardware and software communication.
2.7 Inadequate equipment/hardware/software

3. Organisational Factors
3.1 Inadequate structure for risk assessment
3.2 Inadequate quality assurance program
3.2 Inadequate clinical process design
3.3 Inadequate ergonomic assessment
3.4 Inadequate total number of funded staff.
3.5 Inappropriate staff distribution/allocation
3.6 Inadequate equipment allocation
3.7 Inadequate work planning
3.8 Inadequate management of changing practices /equipment/hardware/software
3.9 Inadequate priorisation of conflicting tasks by management
3.10 Availability of appropriate staff
3.11 Inadequate identification of training requirements

4. Communication
4.1 Unclear roles, responsibilities and accountabilities
4.2 Lack of communication
4.3 Inadequate instructions/information
4.4 Misunderstood communications

5. Knowledge/skill
5.1 Inadequate training
5.2 Training needs not identified

5.3 Lack of skill development opportunities

6. Personal capabilities

6.1 Physical capabilities/health

6.2 Sensory deficiencies

7. Personal judgment

7.1 Failure to address recognized hazards

7.2 Inappropriate priorisation of conflicting tasks

7.3 Emotional stress

7.4 Fatigue

7.5 Criminal intent

7.6 Substance abuse.

B. Detection

C. Detector

Radiation Oncologist	
Medical Physicist	
Treatment Planner	
Simulator/CT/MR/PET Technologist	
Treatment Delivery Therapist	
Electronics/Machine shop Technologist	
Other (please specify)	

D. Description

free text

1 **Severity**
2 **Cause**
3 **Corrective actions**
4 **Learning**

APPENDIX K

K. ROSIS Trademark

OIFIG NA bPAITINNÍ
PATENTS OFFICE

Oifigí an Rialtais
Bóthar Hebron
Cill Chainnigh
Éire

Government Buildings
Hebron Road
Kilkenny
Ireland

Tel: (00-353-56) 7720111
Lo-Call: 1890-220223
Fax: (00-353-56) 7720100
Lo-Call Fax: 1890-220120
E-mail: patlib@entemp.ie
Website: www.patentsoffice.ie

03 September 2009

JOANNE CUNNINGHAM
Division of Radiation Therapy
Trinity Centre for Health Sciences
St James Hospital, Dublin 8

Dear Sir/Madam,

Re: Trade Mark No. 2009/00404

Your application of 02/07/2009 for amendment of the specification of goods in respect of the above numbered trade mark has been allowed .

The specification of goods now reads:

Class 9 : Software for reporting and learning system, including software for analysis. Training materials (i.e. video, web-based or electronic training materials)

Class 35 : Compilation of information into database. Systemisation of information into computer databases. Compilation of classification system for others.

Class 41 : Provision of training courses, workshops, congress in Risk Management in Radiation Oncology. Publication of books, scientific papers, circulars, on Risk management in Radiation Oncology. Production of videotape on Risk Management in Radiation Oncology.

Class 42 : Hosting of website. Design of software for reporting and learning system and for analysis.

Class 44 : Analysis of Risk and Safety in Radiation Oncology. Information on Safety in radiation Oncology. Consultancy on Safety in Radiation Oncology. Provision of classification system for Safety in Radiation Oncology.

Yours faithfully,

P Coffey

Patricia Coffey
Trade Marks Examinations
Direct Line: (056) 7720161
Ext: 4161

APPENDIX L

L. ROSIS Promotional Leaflet

Patient Safety in Radiation Oncology

Radiation oncology (RO) is the accurate delivery of high doses radiation to a prescribed area within the patient, in order to treat and cure cancer or to relieve a cancer patient's symptoms.

One in three people will develop cancer, and approximately 60% of cancer patients will require radiation at some time during the course of their disease. Radiation therapy works by destroying the cancer cells' ability to reproduce.

RO uses a multi-step process, high technology and the interaction of various disciplines in order to plan and deliver the prescribed treatment.

Although mistakes in RO are relatively uncommon, they can and do occur. Lessons learned from mistakes are not often shared, meaning opportunities to improve patient safety are lost. ROSIS provides a platform where RO clinics can share information on incidents and near-incidents in a confidential manner, making this information visible to the entire community in order to raise awareness, and collating and analyzing information collected to maximize learning and improve patient safety.

Radiotherapy Treatment

ROSIS: References

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ROSIS

Lund University

Trinity College Dublin

Radiation Oncology Safety Information System

For further information, please contact:
Mrs Mary Coffey / Ms Joanne Cunningham
Division of Radiation Therapy
Trinity Centre for Health Sciences
St James Hospital
Dublin 8, Ireland

Phone: +353 1 896 3249 / 3254
Fax: +353 1 896 3246
E mail: rosis@rosis.info

Radiation Oncology Safety Information System

ROSIS

Radiation Oncology Safety Information System

The International Online Safety Information System for Radiation Oncology

www.rosis.info

ROSIS

Radiation Oncology Safety Information System

What is ROSIS?

ROSIS Website

ROSIS is an acronym for "Radiation Oncology Safety Information System". It is a voluntary web-based reporting and learning system, based on incident reports from professional front-line staff. To date, more than 1200 incident reports have been received by ROSIS. ROSIS aims:

- To establish an international reporting system in RO , and
- To use this system to reduce the occurrence of incidents in RO
  - ⇒By enabling RO clinics to share and view reports on incidents
  - ⇒By collecting and analysing information on the occurrence, detection, severity and correction of RO incidents
  - ⇒By disseminating these results and generally promoting awareness of incidents and safety culture in RO.

Who are ROSIS?

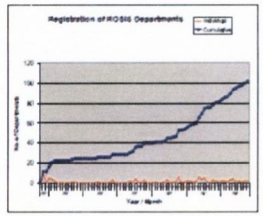
ROSIS was established in 2001 by key professionals in RO, and is sustained by the participation of a growing number of individual RO clinics worldwide (currently more than 100 clinics; 70 within Europe, 30 rest of world)

ROSIS: Improving Patient Safety

Information reported to ROSIS can be used to investigate incident occurrence and detection. ROSIS reports are available online in their original text, illustrating the occurrence of incidents.

These reports are also used as a source of information by major international organisations (e.g. WHO, ICRP, IAEA, UNSCEAR)

The information gained from the project can in future be used for more process-oriented risk management approaches to increase the accuracy in delivery of radiation therapy as well as increased safety for patients



Recruitment since the launch of ROSIS in 2003

ROSIS has established an annual short course in Risk management in RO; the fifth course will be delivered in 2009.

ROSIS Classification

A taxonomy for incidents specific to radiation oncology has been developed, and is incorporated into online dynamic report forms—ensuring ease of use and that classification will be undertaken at source by those familiar with the events.

This taxonomy will be compatible with the WHO International Classification for Patient Safety, and will be instrumental in analysing and learning from incidents.

Future Development

ROSIS is developing a stand-alone system for use by individual RO clinics, optionally communicating with the international ROSIS

The international system and the stand-alone system will be translated for non-English speakers.

The system and experience is transferable to other disciplines.

ROSIS Group

Mrs Mary Coffey, Dublin, Ireland
Dr Ola Holmberg, Vienna, Austria
Assoc Prof Tommy Knöös, Lund, Sweden
Ms Joanne Cunningham, Dublin, Ireland

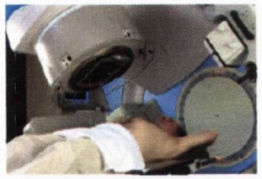
Email: rosis@rosis.info

APPENDIX M

M. ROSIS Course Flyer

Radiation Oncology Safety Course

A four day theoretical and practical course facilitating participants to identify factors involved in incident occurrence and analysis and preventative processes that can be implemented



Radiotherapy Treatment

Participants:

Health Professionals with an interest or involvement in risk management

Course Dates:

24th-27th May, 2010

Course Venue:

Division of Radiation Therapy, Trinity Centre for Health Science, St. James' Hospital, Dublin 8, Ireland.

Who are ROSIS?

ROSIS was established in 2001 by key professionals in RO, and is sustained by the participation of a growing number of individual RO clinics worldwide (currently more than 100 clinics; 70 within Europe, 30 throughout the rest of the world)

ROSIS: Improving Patient Safety

Information reported to ROSIS can be used to investigate incident occurrence and detection. ROSIS reports are available online in their original text, illustrating the occurrence of incidents.

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The information gained from the project can in future be used for more process-oriented risk management approaches to increase the accuracy in delivery of radiation therapy as well as an increased safety for patients.

ROSIS has established an annual short course in Risk management in RO; the sixth course will be delivered in Dublin, in May 2010.

ROSIS

Lund University

Trinity College Dublin

ROSIS

Radiation Oncology Safety Information System

Radiation Oncology Safety Course

ROSC 2010

24-27th May

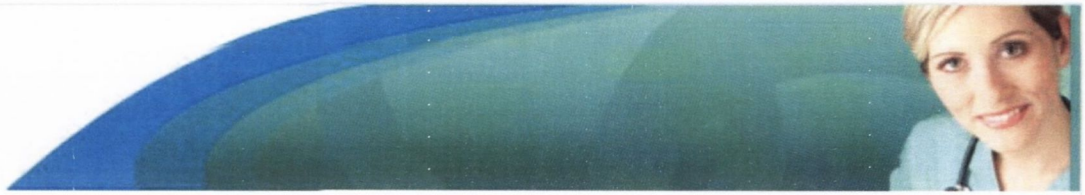
Division of Radiation Therapy, University of Dublin, Trinity College

In conjunction with ROSIS

www.rosis.info

ROSIS

Radiation Oncology Safety Information System



Course Aims:

⇒ To explore the occurrence of incidents in health care, in particular in radiation oncology (RO), to assess their impact, methods of prevention, detection, and correction

⇒ To heighten awareness of the occurrence of incidents and near incidents in radiotherapy

⇒ To achieve greater accuracy in radiotherapy through incident prevention

⇒ To encourage a culture of openness in relation to incidents

Course Objectives:

⇒ To give participants the tools and understanding of how to minimise the risk of incidents occurring - and having an impact - in radiotherapy, as applied in other health services systems

⇒ To ensure best practices in risk management in other sectors are considered when aiming to enhance safety in radiotherapy

⇒ To enable international collaboration in incident reporting and encourage a culture of reporting incidents

Course Participants 2009

Course Faculty:

Mary Coffey, Director of Division of Radiation Therapy, Trinity College, Dublin, and Senior Lecturer in Radiation Therapy.

Tommy Knöös, Head of Radiation Physics, Lund University Hospital and Medical Radiation Physics, Lund University, Sweden

Pierre Scalliet, Professor at the Catholic University of Louvain, Brussels, Belgium and Chairman of the Radiation Oncology Department at the UCL St-Luc University Hospital, Brussels.

Petra Reijnders-Thijssen, Manager patient safety and administration at MAASTRO clinic, and secretary of the association PRISMA-RT

Course Fee:

Includes course notes, lunches, tea and coffee and course dinner:

Early registration € 550**

(before 15th April, 2010)

Late registration € 650**

***Two or more participants from the same centre discount €50 for second or subsequent participants*

Further Information:

Please contact:

Mrs Mary Coffey,
Division of Radiation Therapy,
Trinity Centre for Health Science,
St. James' Hospital,
Dublin 8, Ireland.

Tel: + 353 1 8963248
Fax: + 353 1 8963249
Email: mcoffey@tcd.ie

ROSIS
Radiation Oncology Safety Information System

Registration Form:

Radiation Oncology Safety Course

24th - 27th May, 2010

Name: _____

Address: _____

_____

_____

_____

Tel: _____

Email: _____

Institution/Company:

_____

_____

Number of Course Participants from your Institution:

(EUR 50 discount per second and subsequent participants)

_____

Profession/Discipline: _____

Dietary Requirements: _____

Method of Payment: _____

Amount of Payment: _____

Payment can be made by either bank transfer or cheque. Make cheques payable to: TCD Division of Radiation Therapy. Please contact directly for bank transfer details.

Mrs Mary Coffey Email: mcoffey@tcd.ie
Phone: + 353 1 896 3246

Mrs Dalene Dougall Email: dougallm@tcd.ie
Phone: + 353 1 896 3246

Return Form:

By post to:

Mrs Mary Coffey,
Division of Radiation Therapy,
Trinity Centre for Health Science,
St. James' Hospital,
Dublin 8,
Ireland

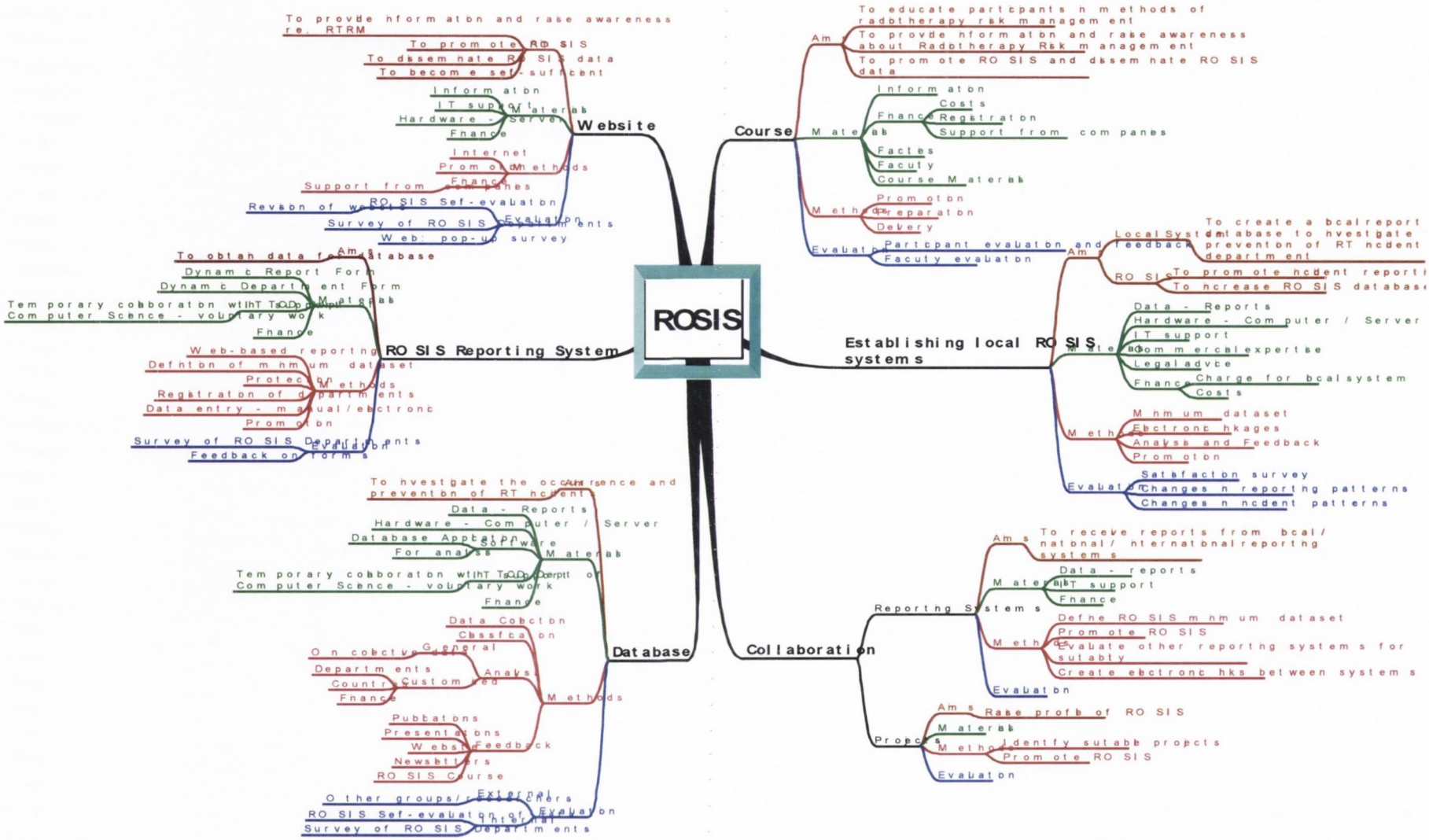
By fax to: + 353 1 8963249

By email to: mcoffey@tcd.ie

We look forward to seeing you in Dublin!

APPENDIX N

N. ROSIS Activities Mindmap


ROSIS
Website
To provide information and raise awareness re. RTRM
To promote RO SIS
To disseminate RO SIS data
To become self-sufficient
Information
IT support
Materials
Hardware - Server
Finance
Internet
Promotion
Methods
Finance
Support from companies
RO SIS Self-evaluation
Revision of website
Evaluation
Survey of RO SIS Departments
Web: pop-up survey
RO SIS Reporting System
Aims
To obtain data for database
Dynamic Report Form
Dynamic Department Form
Materials
Temporary collaboration with TSOD Department
Computer Science - voluntary work
Finance
Web-based reporting
Definition of minimum dataset
Protection
Methods
Registration of departments
Data entry - manual/electronic
Promotion
Survey of RO SIS Departments
Evaluation
Feedback on forms
Database
To investigate the occurrence and prevention of RT incidents
Aims
Data - Reports
Hardware - Computer / Server
Database Application Software
For analysis
Materials
Temporary collaboration with TSOD Department of Computer Science - voluntary work
Finance
Data Collection
Classification
General
Analysis
Customised
Methods
Publications
Presentations
Website
Feedback
Newsletters
RO SIS Course
External
Other groups/registries
Evaluation
RO SIS Self-evaluation of this part
Survey of RO SIS Departments
Course
Aims
To educate participants in methods of radiotherapy risk management
To provide information and raise awareness about Radiotherapy Risk Management
To promote RO SIS and disseminate RO SIS data
Materials
Information
Costs
Finance
Registration
Support from companies
Facilities
Faculty
Course Materials
Methods
Promotion
Preparation
Delivery
Evaluation
Participant evaluation and feedback
Faculty evaluation
Establishing local RO SIS systems
Aims
Local System
To create a local register database to investigate prevention of RT incident department
RO SIS
To promote incident reporting
To increase RO SIS database
Materials
Data - Reports
Hardware - Computer / Server
IT support
Commercial expertise
Legal advice
Finance
Charge for local system
Costs
Methods
Minimum dataset
Electronic linkages
Analysis and Feedback
Promotion
Evaluation
Satisfaction survey
Changes in reporting patterns
Changes in incident patterns
Collaboration
Reporting Systems
Aims
To receive reports from local/ national/ international reporting systems
Materials
Data - reports
IT support
Finance
Methods
Define RO SIS minimum dataset
Promote RO SIS
Evaluate other reporting systems for suitablity
Create electronic links between systems
Evaluation
Projects
Aims
Raise profile of RO SIS
Materials
Methods
Identify suitable projects
Promote RO SIS
Evaluation

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