ICRP REF: 32/147/07

INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION

PREVENTING ACCIDENTAL EXPOSURES FROM NEW EXTERNAL BEAM RADIATION THERAPY TECHNOLOGIES

DRAFT 8 (FEBRUARY, 2009)

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TEN MAIN POINTS

1. **The following conclusion for conventional radiation therapy from ICRP 86 is even more relevant and important for new technologies: *"purchasing new equipment without a concomitant effort on education and training and on a programme of quality assurance is dangerous"*. The lessons from reported accidental exposure have confirmed that embarking on new technologies makes revisiting staff qualifications essential. Chapter 3 and 4 of this report identify critical issues that may require additional training..**
2. **Increased complexity requires a strategy of combining:**
    - **Manufacturer design of safety interlocks, proper alerts and warnings, self-test capabilities for equipment, easy-to-understand user interfaces in a language understandable to the user and adherence to international standards to ensure compatibility between equipment from different manufacturers. All these safety measures are equally important for software.**
    - **Education and equipment specific training with formal involvement of manufacturers. Such training should address the understanding of warnings and interlocks provided by manufacturers, in particular those related to beam monitoring, and consider such warnings and interlocks in developing acceptance tests as well as in quality control procedures.**
    - **Risk-informed and cost-effective approaches for prioritizing tests and checks by means of prospective methods of risk assessment, to be performed in cooperation with manufacturers.**
3. **Hospital administrators and heads of radiation treatment programs should provide for an environment in which to "work with awareness", inviting concentration and avoiding distraction, and ensuring supervision of compliance with QA procedures. Reported experience has shown that skipping quality control checks has occurred even in well structured departments. An attitude of learning from experience should be cultivated, together with systematic reporting of near misses and unexpected events, which may help to reveal weak points in the system before an accident occurs. Excessive confidence in computers and**

automatic processes may result in relaxing attention to potential pitfalls that may still occur, even with these systems in place, as identified in sections 3 and 4 of this report.

4. **Hospital staff should stay aware of the fact that the overall responsibility for the correct absorbed dose determination and the correct treatment of patients remain with the user in hospital. These responsibilities include investigating discrepancies in dose measurements, before applying the beam to patient treatments. Manufacturers and suppliers, however, have subsidiary responsibility for delivering correctly functioning equipment with correct computer files and accompanying documents, and for providing correct information and advice, upon request from hospital staff.** Independent checks of measurements and calculations continue to be a vital safety layer
5. **Target dose escalation without a concomitant increase in normal tissue complication probability generally implies a reduction of geometrical margins, which is only possible with conformal therapy accompanied by precise, image-guided patient positioning and effective immobilization and a clear understanding of the accuracy achieved in clinical practice. Without these features, target dose escalation could lead to severe patient complications.**
6. **A programme for purchasing, acceptance testing and commissioning should not only** address **the treatment machine but also, increasingly, complex treatment planning systems, "record and verify" systems, imaging equipment used** for **radiation therapy, software, procedures and entire processes. There is a need for re-commissioning the relevant devices after equipment modifications or software updates and also to monitor impact on the related processes.**
7. **Timely and effective sharing of operational experience is critical in the phase of introducing new techniques and technologies and especially necessary for problems that appear infrequently, when certain conditions happen to coincide, because such problems may to escape conventional tests.**
8. **A computer crash may cause loss of data integrity. If it occurs during data processing or data transfer it may be very critical, because regular backup may**

not help in these situations as shown in this report. Procedures should include a systematic verification of data integrity routinely and particularly after a computer crash.

9. **When introducing new imaging technologies into radiation therapy practice, assessment of radiation doses from imaging becomes necessary. Such doses should be integrated and accounted for in the treatment planning and delivery processes. Consistent coordinate systems are required throughout the whole radiation therapy process. In addition specific procedures are required for recording image orientation with respect to the patient, for the choosing the correct images and CT numbers for tissue density estimation, and for giving specific consideration to possible image artefacts and possible geometric distortion.**
10. **When conventional tests and verification methods are not directly applicable or not effective for new technologies, measures to maintain the required level of safety are needed, even if they entail the design of new tests or the modification and re-validation of the old ones. In some cases the 'validation plan' on a phantom for new sophisticated treatment modalities may be the only major safety layer. Such verifications should not be relinquished until alternative checks are in place. Supervision to ensure the maintenance of the required level of safety is crucial.**

CONTENTS

1. INTRODUCTION

1.1. Background

(1) New technologies have been introduced in radiation therapy, principally aimed at improving the treatment outcome, by means of a dose distribution which more strictly conforms to the tumor (clinical target) volume. A highly conformal dose distribution allows for a dose escalation to the target volume without increase of the radiation dose to normal tissues. Conversely, a highly conformal dose distribution allows for a reduction of radiation dose to normal tissues without decreasing the dose to the target, or a combination of both. These new technologies include increased use of multileaf collimators, intensity modulated radiation therapy (IMRT) and arc therapy (IMAT), tomotherapy, image guided radiation therapy (IGRT), gated radiation therapy, radiosurgery, newer and more complex treatment planning systems, virtual simulation and “all inclusive” electronic information systems.

1.2. Trends in radiation therapy

(2) The development of these new technologies has been impressively fast during the last few years. As an example, 10 years after a new concept for the delivery of dynamic conformal radiotherapy was described (Mackie et al. 1993), called tomotherapy, a machine was put into clinical operation, and five years after the first clinical prototype, more than 200 tomotherapy machines are operating throughout the world. Although most machines are located in North America and Western Europe, a significant number of such machines are installed in Asia and the technology is also reaching the Middle East.

(3) Similar trends are observed for other rotational approaches using computer driven intensity modulation. These are being implemented on more “traditional” accelerators and are classified as “Volumetric Arc Therapy” techniques (VMAT) with the trade name depending on the manufacturer. Other recent developments include on-line volumetric imaging (Cone Beam Computed Tomography with kV or MV beams), robotic solutions (for example the Accuray© machine), particle therapy with proton or ion beams or additional devices based on “Information Technology” (Treatment Planning Systems, “Record and verify” systems).

(4) There is therefore a continuous evolution of what is considered a “standard” machine for radiotherapy, towards more sophisticated equipment which, in turn, requires more automation to remain efficient. This “standard” varies widely throughout different parts

of the world. For the high income countries (of North America and Western Europe), the "standard" has become, in the last five years, an accelerator equipped with a multileaf collimator and a flat panel portal imaging device, integrated with a "record and verify" device. More recently, an accelerator with intensity modulated radiation therapy (IMRT) has become the "standard" for many countries.

(5) While a manual cobalt machine combined with a 2D treatment planning system was still considered until recently as a good option in the developing countries, there is also a trend in such countries towards more sophisticated solutions with the acquisition of the necessary equipment. It is difficult to predict at which rate the new technologies will be taken up over the countries worldwide. However, there is a danger of not ensuring the availability of appropriate technical, scientific and medical resources for the safe introduction of these new approaches. The risk of accidental exposure as a consequence of this evolution in technology should be reduced by appropriate efforts on education as underlined in the present report.

1.3. **Trends in risk assessment**

(6) Minimizing the risk of accidental exposure to radiation therapy patients has largely been based so far on compliance with regulatory requirements, codes of practice and international standards, which can be considered a "prescriptive approach". Compilations of lessons learned from the review and analysis of accidental exposures in radiation therapy have been published (IAEA 2000, ICRP, 2000). These lessons can be used in safety assessments, for example by checking whether a given radiation therapy department has sufficient provisions in place to avoid accidental exposures similar to those reported. As an example, major accidents caused by errors in calibration and commissioning of radiation therapy equipment have led some departments to put in place preventive measures such as an independent determination of the absorbed dose to detect possible beam calibration errors. However, most existing reports relate to conventional radiation therapy as practiced prior to the widespread implementation of computerized patient data management systems, intensity modulated radiation therapy and other newer techniques.

(7) There is a need to assess to what degree lessons learned from conventional techniques can be also applied to newer more advanced and complex radiation therapy. Further, there is also a need to find out if there are new lessons to learn through a review of

recently available information on accidental exposures and near misses resulting from the use of new technologies.

(8) Approaches to the avoidance of accidental exposures have, to date, largely been “reactive” or “retrospective”. The limitation of such approaches is that of being confined to reported experience, i.e., they do not address the question of “what else could go wrong?” or “what are other potential hazards?” Thus latent risks from other possible events, which have not yet occurred or have not been published, will remain unaddressed, unless more “proactive approaches” are applied. In addition, the increasing complexity of new technologies and techniques means that “common sense” and intuition may no longer be as effective as a guard against accidental exposures. The ability to perceive “when something may be wrong” is diminished compared with the situation in conventional radiation therapy. For example, in a conventional two-to-four field technique, it was feasible for someone with experience to discover an error in dose calculation, by looking at the treatment time or monitor units (MU) and making relatively simple calculations to verify the monitor unit calculation to within a few percent.. This is no longer possible in intensity modulation radiation therapy (IMRT). Increased complexity requires a different strategy to deal with risk and new, selective, risk-informed, and cost-effective approaches to safety and the maintenance of quality are required.

(9) Prospective approaches to the identification and analysis of failure modes, assessment of their frequency and consequences and their evaluation in terms of risks, are available and are being used by some health care institutions to provide risk-informed strategies. Such approaches have started to be adopted by the radiation therapy community (Vilaragut, 2008, Duménigo, 2008, Ortiz, 2008, Huq 2007, 2008).

(10) In summary, both “retrospective” and “prospective” approaches are needed if the introduction of new technologies and techniques is to enhance the quality of patient treatment without compromising safety.

1.4. **Objectives of this report**

(11) The objectives of this report are both to summarize lessons from experience to date and to provide guidance on proactive approaches to the reduction of risk of accidental exposure in radiation therapy, with emphasis on the use of advanced and complex planning and delivery technologies and techniques.

1.5. **Scope**

(12) The current report focuses on external beam radiation therapy. As there are recent ICRP publications devoted to high dose rate brachytherapy and to permanent implants, this report does not deal with these techniques specifically. However, the approaches discussed here will also find application in reducing the risk of accidental exposure in brachytherapy.

1.6. **Structure**

(13) In Chapter 2, lessons learnt from conventional radiation therapy are summarized and discussed in the context of their applicability to the new technologies being introduced into the clinic. In Chapter 3, a review of new technologies and their implications for safety are presented. Reported case histories of accidental exposures and near misses when using new technologies and the lessons learnt from them are provided in Chapter 4. Three proactive approaches to enhancing safety are described in Chapter 5. These approaches enable the prioritisation of activities aimed at reducing the frequency of occurrence of errors and their severity and optimizing the quality assurance program so that errors may be detected before impacting clinical treatment. A recapitulation of lessons learnt and recommendations are given in Chapter 6. A larger sample of case histories are provided in the appendix.

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2. SUMMARY OF LESSONS FROM ACCIDENTAL EXPOSURES WITH CONVENTIONAL TECHNOLOGY

2.1. Organization and quality assurance programme

(14) Publication ICRP 86 (ICRP 2000) points out that most severe accidental exposures occurred in radiation therapy departments where a Quality Assurance (QA) programme was not in place, or if it existed, it was not fully implemented and/or verifications were omitted. Weaknesses identified from accidental exposures with conventional technology are: insufficient education and training, including poor understanding of the physics of the treatment equipment and treatment planning systems, absence of appropriate acceptance and commissioning procedures, misunderstanding instructions for users, verbally communicated instructions, omission of some of the checks of the quality control programmes, changing a procedure without validation, resuming treatments after a major repair without notifying the responsible person for beam verification, poor notification of unusual tissue reactions and poor patient follow up.

(15) As stated in publication ICRP 86, a systematic programme of quality assurance can detect systematic errors and decrease the frequency and size of random errors. Minimizing the probability of occurrence and severity of accidental exposures can be achieved with reasonable effort and expense in a radiation therapy department when *"two conditions are fulfilled: i) a comprehensive and coherent quality assurance programme is in place and ii) some in-vivo dose measurements are performed"*.

Recommendation

(16) Hospital managers need to put in place a quality assurance programme that addresses education, training and continuous professional development, assessment of the required number and qualification of staff, proper assignment of duties and responsibilities of qualified staff, organizational structure, written procedures and supervision of compliance. Procedures should include equipment purchasing, acceptance and commissioning, QA and periodic QC, use and maintenance and communications over the whole treatment process, patient observation and follow up of abnormal tissue reactions. Particularly important is the regular re-assessment of the number and qualification of staff as workload increases, new

equipment is purchased and new techniques are taken up into the radiation therapy programme.

2.2. **Special problem of the availability of qualified staff**

(17) In many parts of the world, especially in developing countries, the lack of qualified staff, which is crucial to safety, remains an unresolved issue. This problem affects radiation oncologists, medical physicists, technologists, dosimetrists and maintenance engineers. In particular, medical physicists, responsible for calibration of radiation beam and sources, dosimetric treatment planning and radiation physics aspects of quality assurance, are unavailable in many countries. The reasons for this shortage are twofold: firstly, there may be no programme of education and hands-on training established in the country and it may not even be feasible to maintain such an educational programme at a national level, because only a small number of professionals is required. Moreover, in many countries the profession of medical physics is not formally recognized and, as a consequence, appropriate candidates can not be attracted. Secondly, sending professionals abroad for education and hands-on training often results in losing them permanently because they then prefer to stay in the country where they have been trained. This is particularly true if the profession is not even formally recognized in their own countries, as a professional working in the health sector (among paramedical staff).

Recommendations

(18) Governments need to be aware of these difficulties when embarking on or maintaining a radiation therapy programme and to make provisions for a system of education, training (in the country or abroad), have in place a process of certification to formally recognize medical physics staff as health professionals and to put in place a programme to retain the staff that are essential in maintaining safety.

(19) The general recommendations from conventional radiation therapy summarized above are also valid for new technologies, although some of them, such as in-vivo dose measurements, may not be suitable for IMRT or may need further development in order for them to become suitable.

2.3. **Safety culture**

(20) A number of reported accidental exposures have been linked to inattention and lack of unawareness of signs that indicated that “something was going wrong”, e.g. conflicting signals, displays or messages, omission of follow-up of equipment malfunctions or false alarms. General unawareness was a common feature of most of major accidental exposures. As an example of lack of awareness, it is common to provide proper shielding for workplaces to comply with regulations, but it is less common to design the working environment in such a way that the control panel and patient monitoring devices during irradiation are located at a place that is free of distraction of the staff. The existence of a quality assurance programme is essential, but even many double checks may be rendered inefficient if the staff function “mechanically” without due thought.

Recommendation

(21) The basic principles of safety culture are of paramount importance to prevent accidental exposure in radiation therapy. Good practice is necessary but not sufficient. Avoidance and detection of errors require going beyond good practice, since even a well designed system of controls and verification can suffer degradation with time if not well implemented or parts are omitted or jeopardized. Radiation therapy should be performed with full knowledge, due thought, mindfulness, alertness and a proper sense of accountability. Hospital administrators and the heads of radiation therapy departments are responsible for cultivating these qualities and attitudes, and for encouraging excellence, particularly in matters related to safety. In particular, they need to provide for a working environment that invites concentration, avoids distraction, and promotes a questioning and learning attitude by the staff.

2.4. **Lessons from acceptance, commissioning and calibration**

(22) The absorbed dose calibration is determined at the commissioning stage or after a repair that may affect the beam. There are a number of opportunities for errors in the determination of absorbed dose or dose rate calibration, which can lead to under- or over-dose of all treatments as a consequence of the incorrect absorbed dose value. Thus, when the deviation is large enough to cause death or severe complications, such accidental exposure may be of a catastrophic nature. Potential errors may be related to misplacing the ionization

chamber, misunderstanding or misreading the ion chamber calibration certificate, misreporting the irradiation parameters used in the calibration, temperature and atmospheric pressure corrections, errors with any of the series of correction coefficients, or simply an error in the calculation. Case histories of this type of accidental exposure are given in the appendix. In addition, it is also possible that the absorbed dose is correctly determined, but incorrectly introduced in the treatment planning system; this type of accidental exposure is described separately under 3.3.1.

Recommendations

(23) The number of potential errors in dose calculations can be significantly reduced by using well proven spreadsheets based on widely accepted protocols (IAEA, 1997, 2000), but misuse cannot be entirely prevented.

(24) Errors can be detected by an independent absorbed dose determination. If two different persons come to nearly the same result (i.e., <5%), the probability of a major undetected error is extremely low, because it would require both persons to commit an error of the same magnitude and in the same direction. Both absorbed dose determinations should be really independent, i.e., they should not influence each other to avoid repeating the same error. One example of independence is the use of a postal TLD audit, provided that commencing patient treatment can wait until the TLD results are available. These safety measures are applicable to new technologies as well.

2.5. **Commissioning of treatment planning systems**

(25) Poor understanding of treatment planning systems (TPS) has led to severe reported accidental exposures involving large numbers of patients. Mistakes included entering the wrong basic data on which treatment doses will rely, such as absorbed dose at the reference point, depth doses, dose profiles, and wedge factors. Other types of mistakes included duplicating a correction for distance and for wedge factors, not being aware that the TPS already had included these corrections in the calculation of the treatment dose or monitor units. A simple type of error consisted of using the wrong decay rate (half life) or the wrong date associated with the initial source activity or initial absorbed dose rate.

Recommendations

(26) Formal purchasing agreements should include provisions to ensure that manufacturers provide training for the staff to become fully acquainted with the new system before the acceptance is completed. Systematic commissioning of a TPS is as important as the commissioning of the treatment machine. There are well recognized international protocols that can be used as guidance (IAEA, 2007, 2008) for the tests to be performed during both acceptance testing and commissioning of a TPS. The proper use should never rely upon verbal transmission of procedures or prescriptions. Instructions for use should be in a language understandable to the users. All of these lessons are also applicable to new technologies.

2.6. **Treatment related lessons**

2.6.1. Treatment preparation

(27) One of the major reported accidental exposures was related to a change in the use of the TPS, deviating from the normal procedures without validating the new procedures, and without independent calculation of the dose to a point for each patient.

(28) Nowadays, independent calculation of dose to a point or monitor units (MU) is done using a home-made spreadsheet or with the commercial MU calculators. There have been accidental exposures due to transfer of home-made sheets to others without proper understanding by the recipient. Mistakes were also made at treatment simulation due to incorrect labeling of the images resulting in treating the wrong side of the patient.

Recommendations

(29) Deviations from manufacturer instructions for use should be avoided, and when this is not possible, they should be thoroughly discussed with the manufacturer and subject to specific tests and validation before use for clinical treatments. Calculation of the dose to a point or monitor units (MU) for each patient independent from the TPS would have avoided most of the major accidental exposures. Quality assurance needs to be applied to home-made spreadsheets for MU calculations and to any commercial MU calculators. This is even more important with transferring the home-made spreadsheets to others.

(30) These recommendations are also applicable to new technologies, although the independent calculation of MU may no longer be as simple as with conventional techniques and may not even be feasible in the case of IMRT.

(31) “In vivo” dosimetry can also detect deviations in dose from that prescribed at the entrance or exit of the beam. These deviations may arise not only from the determination of absorbed dose at a reference point but also from errors in the calculation of treatment doses and in treatment set-up. Unfortunately, “in-vivo” dosimetry is neither suitable nor straightforward for some new technologies such as IMRT.

2.6.2. Treatment delivery

(32) Reported errors during treatment set up and delivery were related to treating the wrong patient, the wrong anatomical site, or using the wrong dose. There was a variety of reasons including using the wrong patient’s chart without proper identification (i.e. by a photograph or similar method), confusing fiducial marks and tattoos, different patient positioning for simulation and treatment, wrong selection of parameters, for example, machine set for rotation therapy rather than stationary treatment, failure to realize that the treatment of one of the sites was already completed and failure to introduce intended wedges.

Recommendations

(33) Identification of the patient, the treatment site and plan is essential. Provision for identifying the patient by a photograph is indispensable as is a provision for identifying fiducial markers and tattoos. Modern digital techniques make this approach simpler, as every radiation therapy department can have digital cameras and the means to incorporate the picture into the treatment chart. Modern techniques can also be useful to further ensure identification in future, such as individual identity card with bar code or fingerprint identification. Some of the positioning errors are automatically excluded by “record and verify” systems, although these systems can bring other type of problems such as relying too much on an automatic system as opposed to a manual system where the user is forced to maintain a higher degree of vigilance.

(34) Patient set-up mistakes can be avoided or detected by independent checks by two technologists. To make this task efficient it may be necessary to do a prior identification of critical safety steps to be double-checked and the appropriate instructions to be given to the technologists.

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3. SAFETY ISSUES WITH NEW TECHNOLOGIES

3.1. Issues of equipment design, acceptance testing and commissioning

- **Recent advances in radiation therapy have only been achievable by increasing complexity. As a result of complexity, "human common sense" may no longer be as effective a mechanism to perceive "when something may be wrong" as it is with conventional radiation therapy. The challenge is, therefore, to implement complex technologies in conjunction with the appropriate means to ensure that they can and will be used safely.**
- **The most important feature related to the complexity and sophistication of "new technologies" is the omnipresence of computers. There is a need for software design with proper warnings, self-test capabilities, self-explanatory user interfaces and internal safety interlocks to prevent improper use that may lead to an accidental exposure. Specific training becomes a major issue for users as well as for manufacturers and installation and maintenance engineers.**
- **A number or reports on accidental exposures with new technologies and near misses is given in chapter 4 and in the appendix, but there is a need for anticipating critical issues from the safety point of view. This chapter is an attempt to such anticipation, although more detailed proactive analysis is required, as explained in chapter 5.**

(35) The introduction of new technologies in radiation therapy is principally aimed at improving the treatment outcome, by means of a dose distribution which more strictly conforms to the tumor (clinical target) volume. A highly conformal dose distribution allows for a dose escalation to the target volume without an increase in the radiation dose to normal tissues, or for a decrease in normal tissue dose without reducing tumor dose, or a combination of both. Such refinement of the dose distribution actually delivered to the patient may be obtained through the following :

- providing technical solutions on the irradiation equipment to improve the dose distribution conformity to the target (beam intensity modulation combined or not with gantry rotation, multibeam approaches and hadrontherapy for example)
- providing treatment planning tools to optimize the dose distribution for each of these new technical solutions (inverse planning approach)
- providing the means to apply them accurately to individual patients (image guided

radiation therapy and breathing management techniques for example)

(36) Since most recent advances and improvements in radiation therapy are only achievable by increasing complexity in both equipment and treatment techniques they may also increase the number of opportunities and scenarios in which an accidental exposure may be triggered. In order to achieve the desired clinical outcome improvements without an increase in risk, safety provisions and strategies are necessary. The challenge is, therefore, to implement new technologies in conjunction with the appropriate means to ensure that they can and will be used safely.

(37) The most important feature related to the complexity and sophistication of “new technologies” is the omnipresence of computer based solutions. Computers are used at each stage of the process, from prescription to completion of the treatment. As a result of this complexity, “human common sense” may no longer be as effective a mechanism to perceive “when something may be wrong” as it is with conventional radiation therapy (Rosenwald 2002). In a conventional two-to-four field technique, it is feasible for someone with experience to identify an error, by looking at the treatment time or MU and making some simple calculations to confirm that these machine settings will result in the delivery of the correct dose to within a few percent. This is no longer feasible in IMRT for example in which, instead of a collimator with four jaws and a relatively simple control mechanism, multileaf collimators are generally required and these have 80 or more computer-controlled leafs, used to generate many irregular fields applied either as a descrete sequence (step and shoot mode) or dynamically (sliding window or rotational modulation).

(38) A strategy for the user to systematically deal with risks from complex procedures will be discussed in Chapter 5. In addition, the role of the manufacturers is of increasing importance. As far as software is concerned, there is a need for the design of proper warnings, self-test capabilities, self-explanatory user interfaces and internal safety interlocks to prevent improper use that may lead to an accidental exposure. Specific training becomes a major issue for users as well as for manufacturers and installation and maintenance engineers.

~~(39)~~ The normal process when introducing a new or upgraded piece of equipment or software component in a radiation therapy department starts with planning, followed by the purchase, installation and **acceptance.** Acceptance is the process in which the new item is tested with respect to predefined specifications agreed upon with the vendor and reflected in the purchase contract. Upon acceptance, the new item is declared compliant with the purchase

order which means that the vendor may be paid and that the warranty period may start. However, before the equipment or software is used clinically, it is essential to complete a **commissioning** phase that requires significant time and effort. The commissioning phase includes the calibration and customization of the system for clinical implementation at the user's site.

(40) Specific training on the particular equipment to be used is initiated as part of the purchase and acceptance process but it needs to be completed during the commissioning phase in order to ensure that all staff that will use the equipment or software has become familiar with it and its associated safety features and has developed the required expertise for its safe and effective use. If a calibration or basic data input error occurs during the commissioning phase it will be potentially propagated to all patients either planned or treated with this hardware or software component. New technologies are not different in this respect from conventional technologies but the increase in complexity entails new challenges when designing comprehensive commissioning programmes intended to detect any potential pitfalls. Risk-informed strategies to rationally deal with this problem are given in chapters 4 and 5.

(41) The steps of the treatment process are related to individual patients and each step presents associated risks. The major broad steps are:

- treatment prescription
- treatment preparation
- treatment delivery

(42) These steps are integrated into a workflow that makes extensive use of computer resources and requires **patient data management**. Patient data management is also identified as one cause of additional risk and has a separate section in this chapter. The main additional risks derived from the introduction of new technologies are grouped under these items.

3.2. **Treatment Prescription**

- **The dose distribution from intensity modulation radiation therapy (IMRT) may exhibit a less uniform dose distribution in the target than conventional approaches. This makes conventional dose reporting at a single specific point (the so called "ICRU reference point") somewhat hazardous and, therefore, no longer acceptable.**

- **IMRT and inverse planning require significant changes in the approach to dose prescription which now needs to be expressed in terms of dose-volume objectives (e.g. minimum and maximum doses within the target volume) and dose-volume constraints (i.e. maximum doses to specified volumes of the organs at risks).**
- **Dose escalation with associated geometrical margin reduction is only acceptable in conjunction with an improvement in the dose conformality, accompanied by accurate and sophisticated imaging methods to check and monitor patient positioning. If this requirement is not fully appreciated, there is a risk that prescribing dose escalation could lead to severe patient complications.**

(43) Treatment prescription is the responsibility of the radiation oncologist. It consists of choosing a therapeutic dose to be delivered to a given target volume according to a given time pattern or fractionation. The acceptable dose to organs at risk is also part of the prescription. The nomenclature and definitions of the various components of the prescription need to be standardized, in order to avoid misinterpretation of the prescription within a single institution or when sharing experience among several institutions. This standardization has been facilitated by the International Commission on Radiation Units and Measurements (ICRU) which has given recommendations about volume definition and dose reporting for "conventional" treatments (ICRU 1993, 1999).

(44) The development of intensity modulated radiation therapy (IMRT) and inverse planning has necessitated significant changes in the approach to dose prescribing which now needs to be expressed in terms of dose-volume objectives (e.g. minimum and maximum doses within the target volume) and dose-volume constraints (i.e. maximum doses to specified volumes of the organs at risks).

(45) The dose distribution in the target for an IMRT plan can be considerably less uniform than that achieved with conventional approaches. This makes conventional reporting at a single specific point (the so called "ICRU reference point") somewhat hazardous and, therefore, no longer acceptable.

(46) Clear recommendations at the national or international level and strict application of local protocols, are indispensable to avoid inconsistency between treatments given within a single institution or in different institutions. As an example, Das et al. (Das 2008) have reported large deviations between prescription and calculated doses for 803 patients treated with IMRT at five medical institutions (see Fig. 2.1, below). Part of this deviation may be

attributed to a lack of consistency in the prescription and/or reporting practice. Depending on the treatment planning system (TPS), the user may be tempted to prescribe in different forms and would not necessarily realize that the same intended prescription, if expressed in different forms, would yield different outcomes. Although such a deviation is not per se an accidental exposure, the associated risk should be recognized.

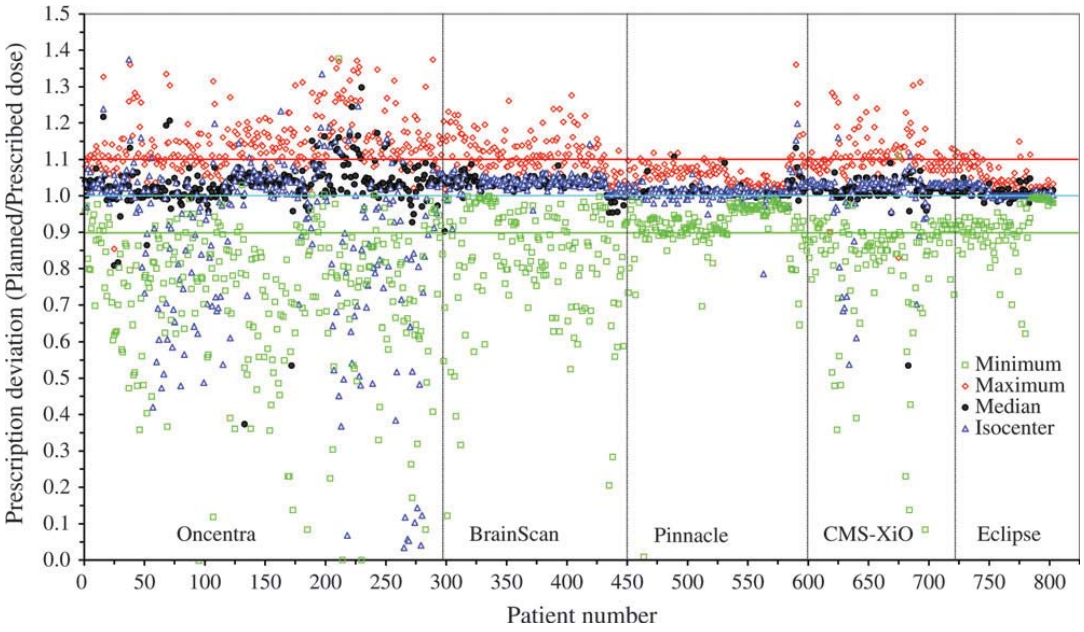

Fig. 2.1 taken from Das et al. JNCI, March 2008

Figure 2.1 illustrates the deviation between the prescribed dose and the dose calculated retrospectively for 803 patients treated with IMRT at five medical institutions, where different treatment planning systems were used. The calculated dose is indicated either at the isocenter (the ICRU reference point for most treatments) as represented by the blue triangular symbols, or as median, minimum or maximum dose within the target volume. For most patients the median dose is close to the prescribed dose (96% lie within ± 10%) but the dose at the isocenter shows much greater deviation since the isocenter might be in a high gradient region for some of the modulated beams This suggests that applying the ICRU reference point concept for IMRT prescription could lead to significant spread of the delivered dose amongst the patient population (Das et al. INCI, March 2008).

(47) An additional risk, which can accompany more advanced techniques, is related to dose escalation to the target volume, in order to achieve a better tumour control probability (TCP), while keeping an acceptable normal tissue complication probability (NTCP). This

requires an improvement in the dose conformality, as achieved by a reduction of geometrical margins, accompanied by accurate and sophisticated imaging methods to check and monitor patient positioning. If this requirement is not fully appreciated, there is a risk that prescribing dose escalation could lead to severe patient complications.

3.3. **Treatment preparation**

- **With the increased use of different imaging modalities in radiotherapy, consistency becomes a major safety issue: there is a need for consistency in the coordinate system from treatment preparation to delivery, in patient identification and in image orientation with respect to the patient. CT image artifacts become a potential source of error when CT numbers are converted into tissue densities. The need for integration of radiation exposure from imaging into the treatment plan also needs to be considered.**
- **Increased TPS complexity poses a challenge and requires understanding of its multiple functionalities, understanding of its limitations in anatomical modeling, adherence to the instructions for use of the system (avoiding changes in the way the TPS is used without proper testing and validation). The design and testing for software warnings and interlocks is becoming increasingly important.**

(48) Treatment preparation consists of all the tasks to be performed before the actual radiation delivery is initiated. Treatment preparation is also sometimes called “treatment planning” in a broad sense – see e.g. Fraass et al. 1998 and IAEA 2004 and includes the following steps :

1. patient immobilization
2. patient data acquisition, combined or not with virtual simulation[1]

[1] The conventional “simulation” done on a simulator, used to be a radiological verification of beam set-up. This task would normally fit between step 4 and 5. Conventional simulation tends to be replaced with the “virtual simulation”, in which the beams are defined on a computer console (possibly in real time) on the basis of the 3D reconstruction of the patient anatomy. This is sometimes combined with step 2 although covering partly steps 3 to 4,.

3. image segmentation and structure delineation
4. beam definition and optimization of dose distribution (sometimes called “dose planning”)

(49) The associated workflow through these steps requires networking and data exchange between, devices which may be from different manufacturers and which require full interconnectivity and interoperability. The risks related to the process itself will be dealt with in Chapter 5. In what follows, issues related to the equipment used at each individual step of the treatment preparation process and the accompanying procedures are addressed.

3.3.1. Patient immobilization

(50) Properly immobilizing the patient to help in interfraction reproducibility and in reducing intrafraction motion is the first step of the treatment planning process. Immobilization has always been difficult in radiation therapy. Modern immobilization techniques do not present major risks in terms of excessive temperature or chemical toxicity. The most severe risk to consider might be the restriction of vital patient movements (e.g. breathing normally, vomiting in the case of nausea and avoiding a collision). It should be possible for the patient to immediately warn the operator if anything abnormal occurs, either during treatment preparation or beam delivery. A possibility is to give to the patient access to a push button alarm. This is done for patients treated with automatic breathing control (ABC), where a valve inhibits patient respiration when the beam is on.

(51) The need for more accurate patient positioning may encourage people to use more constraining patient immobilization devices and may therefore require more attention to the associated risk. On the other hand, the development of image guided radiation therapy (IGRT) may provide more flexibility due to the possibility of correcting, in real time, any patient misalignment with respect to the treatment beams.

3.3.2. Patient data acquisition and virtual simulation

(52) Most modern treatment plans are based on CT data. More and more, other imaging modalities are added to provide more accurate delineation of the target volumes and organs at risk. Virtual simulation, which follows patient data acquisition, is becoming increasingly popular. It can be performed when the patient is still present (which allows skin marking of the simulation beam projections) or after the patient has left **(**using a coordinate

system referenced to radio-opaque markers present during image acquisition and referring the repositioning for simulation with respect to this system).

3.3.2.1. Patient orientation for imaging

(53) The CT data acquisition procedure as such does not bring significant additional risks. However, with the increased use of CT images, identification of the patient and, more importantly, of patient orientation becomes crucial. Although the most common patient orientation is “head first–supine” (HFS), it could be necessary to use other orientations, for instance having the patient prone to treat the spinal cord (medulloblastoma) or “feet first” to treat a leg. In any case, a clear distinction is needed between the orientation used 1) for CT data acquisition 2) for treatment planning and 3) for treatment delivery. It is expected that the orientation would remain the same for all steps and that the consistency would be guaranteed by the use of DICOM standardization. However, there are many possible combinations and special circumstances where it might be necessary to setup the patient with a given orientation but to “declare” another orientation for any of these 3 steps. There is then a potential for error that could lead to severe accidental exposures.

3.3.2.2. Tissue density values from CT data

(54) The direct connection of CT numbers with tissue density required for subsequent dose calculation is an important and very useful feature but also brings new risks. If artifacts are present or if a contrast medium is being used, it might be incorrectly interpreted as a patient organ density. Magnetic resonance imaging (MRI) can produce image distortion. Combining several imaging modalities brings an additional risk of misregistration[2], resulting in a significant error in the location of either the target or a critical structure.

3.3.2.3. Consistency of coordinates and beam characteristics

(55) Virtual simulation requires that the coordinate origin and conventions are correct and consistent between image data acquisition, virtual simulation, dose planning, and

[2] Registration is the process of linking image data from different studies to a single coordinate system, typically that of the treatment planning CT.

treatment delivery. There is another potential error arising from using the beam characteristics defined at the time of simulation (sometimes called “set-up fields”) directly for treatment planning or delivery, without checking that all properties that could influence monitor units (MU) or dose calculation are correct. For example, accessories which are not required for the simulation process (e.g. trays, wedge filters) should be added as necessary when using these beams for treatment. It could also happen that simulated beams are not used for treatment or are modified, but that they are mistakenly kept by the system and then used.

3.3.2.4. Significant exposure from imaging

(56) The growing importance of imaging in the treatment planning process and the reduction of CT image acquisition times are likely to increase the number of pre-treatment or post-treatment x-ray examinations and therefore the patient exposure to diagnostic quality x-rays. One example is the use of 4D CT acquisition where each single slice is replaced potentially by 10 slices acquired at different phases of the respiratory cycle. This additional exposure for imaging which, until recently was considered negligible as compared to the therapeutic exposure, is becoming significant and needs to be taken into account and assessed prior to undertaking a CT based preparation (Murphy et al. 2007).

3.3.3. Image segmentation and structure delineation

(57) Image segmentation is an image processing method to enhance and distinguish an object or its boundaries (lines, curves) from the rest of the image. In radiation therapy, this is typically used to more clearly locate and delineate organs or structures in images. This phase of treatment preparation is performed using either the tools of the treatment planning system (TPS) or with software provided specifically for virtual simulation. There are a number of potential errors, which depend on the software tools that are available and on the requirements for the subsequent phase of planning, for example, the system capabilities for automatic external or internal structure extraction or for 3D expansions. In most cases, improper tools or improper use of them will result in a loss of geometric accuracy with a possible underdosage at the periphery of the target volume and overdosage of normal tissue without a change of the dose at the reference point**.** However, dose planning algorithms may inherently have some constraints on how the anatomical model should be prepared (number or spacing of slices, contour regularity, absence of intersections or overlapping regions, CT number allocations, etc.) that may not be explicitly identified by embedded warnings or interlocks. If such

warning and interlocks are not present and if the user does not understand the limitations of the anatomical modeling, severe errors may appear in the subsequent handling of this data for beam set-up or dose calculation. For example, some algorithms will not reconstruct a continuous patient surface from a limited number of CT slices. The calculated dose distribution and number of monitor units would be then affected by some error, especially if the beam axis lies between distant slices or if a non-coplanar beam is used across a top section that is considered as “empty”. Another example is if the user forgets to assign a density to a slice defined from a contour.

3.3.4. Beam definition and optimization of the dose distribution

(58) This step consists essentially of calculating the dose distribution resulting from the beam set-up proposed for treatment. This step is carried out using a computerized treatment planning system (TPS). However it is clear that TPSs are no longer restricted to the computation of dose distributions. Instead, they can be considered essential pieces of the process of transforming the radiation oncologist’s prescription (dose, volume, time pattern) into an optimized plan, ready to be transferred to the treatment machine. Although some past accidental exposures have been caused directly or indirectly by the use of TPSs (IAEA, 2001), it is generally recognized that the main source of error comes from a poor understanding of some of the TPS functionalities combined with a lack of redundancy in the determination of the number of monitor units (double check with independent calculation and/or in vivo dosimetry). Before using any TPS for real treatments, a time consuming commissioning phase is indispensable and the incorrect input of basic parameters may lead to systematic errors. In addition, errors may also occur in the TPS daily use.

(59) A typical list of the main tasks performed when using a TPS is given in Table 3.1. With each task, a risk index has been associated. The risk index combines an estimation of the probability of occurrence and severity (adapted from the French Society of Medical Physics (SFPM)) of an error. The purpose of this table is to help build a safety system with emphasis on the most hazardous steps such as the beam configuration, the use of wedge filters (or other beam modifiers), the management of beam weights and the computation of monitor units (MU). The risk indices are defined as follows :

1 : geometrical or dosimetric deviation from the « correct » plan without expected significant clinical consequences (low severity)

2 : low probability, high severity

3 : high probability, high severity

Table 3.1. List of tasks performed when using a treatment planning system (adapted from SFPM, 2006).

Task	**Risk index**	**Comment**
Preparation of the beam data library (parameterization)	3	Critical step, particularly regarding reference dose rate and output factor
Patient anatomical data acquisition and data transfer to TPS	2	Main risk is related to patient orientation management (see section 4)
Delineating the external contour and building the patient anatomical model	1	It has direct influence on the tissue thickness used for monitor unit (MU) calculations; there is a specific risk from top and bottom slice characteristics, especially for non coplanar beams
Definition of shapes and densities for inhomogeneous regions	1	It has direct influence on MU calculations
Target and critical organs delineation	1	It has direct influence on beam set-up and dose volume histograms
Target volume expansion	1	It has direct influence on beam set-up and dose volume histograms
Choosing treatment machine, modality and energy	2	In this step there is a risk if using obsolete data and of consistency with actual equipment characteristics
Beam set-up definition	2	In this step, critical issues are: the distinction between SSD and isocentric techniques: the meaning of the displayed coordinates (e.g. if SSD is different from SAD) and the consistency of collimator and table rotations scales
Defining field shape	1	No serious risk if there are embedded safety features preventing wrong input (cf. Panama accident, IAEA 2001)

Task	Risk index	Comment
Adding beam modifying devices (shielding blocks tray, wedge filters, compensators…)	3	Critical here is the awareness of the presence and nature of the modifiers since they have a strong influence on MUs
Choosing beam weighting points	3	Critical in this step is the avoidance that the beam waiting points are not lying in a region where dose is low (e.g. under a block) or where the dose gradient is high (e.g. field edge)
Defining (total or fractional) beam weighting (contribution)	2	It has direct influence on MU calculations; sometimes difficult to understand the exact meaning
Dose distribution calculation and display	1	Critical issue is awareness of calculation options
Dose volume histograms calculation and display	1	Critical issue is awareness of calculation options and volume definitions (are structures completely enclosed into sampling region?)
Decision on final approved treatment plan	2	Critical issue when several studies have been performed, is assurance that the approved plan will be actually used for treatment
Monitor unit calculation	3	Could have been achieved prior to the final plan approval or could be performed on a separate system; critical step is verification of all relevant data
Data transfer from TPS to treatment machine	3	Another critical step where the verification of all relevant data

(60) Modern TPSs are very complex and offer a full range of functionalities with many possible pathways. It is, therefore important to follow formal acceptance testing procedures to check all possibilities. On the other hand, all systems are inherently likely to fail when used under special circumstances. Most of the failures would result in a system crash with no other consequences than a loss of data and time. Only in very peculiar circumstances would some failures influence the treatment outcome. Trying to control these circumstances by instituting preventive actions (e.g. through redundancy) is precisely the aim of a systematic safety

assessment approach as described in Chapter 5. Such risk can be reduced by providing the system with a fluent user interface and sufficient warnings and interlocks. However the most important risk is associated with human error, related to inappropriate use of some functionalities because of insufficient training or poor understanding of some aspects of the TPS. Such errors have direct implications for treatment quality and safety. Very severe accidental exposures of this type have already occurred in conventional radiation therapy.

3.4. **Treatment delivery**

- **A consistent coordinate system is to be used in all steps from virtual simulation through treatment planning to treatment delivery, in order to avoid errors. Treatment delivery may require a manual shift of the patient couch to correctly place the patient with respect to the treatment beams. With manual shifting, there is a risk for error if there is no systematic image verification, and if coordinate systems are inconsistent. This risk is even higher if the delivery system does not allow the visualization of the actual irradiation field, for instance in tomotherapy.**
- **Working with geometrical coordinates may lead to a tendency to focus too much on coordinates and to lose awareness of what is actually being treated (for example treating the correct side in the case of a lateral tumor)**
- **Systems for automatic matching of image structures against a reference image are a substantial improvement in patient positioning and for inter and intrafraction motion correction. On the other hand, errors and mistakes when taking or using the reference image may be difficult to detect and may affect the whole treatment course.**
- **The radiation dose from portal imaging may be significant and can lead to a deviation from the prescribed dose, if not taken into account and integrated into treatment planning and delivery.**
- **Small fields pose additional challenges in their measurement and calibration and may, therefore, require a review of training and the manufacturer's system explanatory notes and warnings.**
- **With dynamic wedges the output varies with the moving jaw position and this variation depends very much on the manufacturer's design. Without proper**

information and alerts from the manufacturer there is a significant risk of error during the calibration (or commissioning) procedure.

(61) The actual delivery of the treatment can start as soon as the plan has been transferred from the TPS to the treatment machine. The transfer process is part of patient data management and is dealt with in Section 3.5. In order to guarantee that the treatment is given accurately at the proper anatomical location, the patient and beam set up has to be kept consistent according to the plan prepared during virtual simulation and/or during dose planning.

3.4.1. Verification of patient and beam setup

(62) Verification of the patient position relative to the beams requires that the patient is properly immobilized. The risks related to fixation or immobilizing devices have been already addressed in section 3.3.1 and will not be further discussed here.

3.4.1.1. Coordinates and external marks and references

(63) Historically, patient setup relied on skin marks, drawn during simulation at the center and/or at the edges of the treatment fields. In modern systems, adjustment of the patient position with respect to the linear accelerator coordinate system quite often requires a translation (shift) of the table coordinates with respect to a patient reference coordinate system.

(64) The patient reference coordinate system is determined by the alignment of radio-opaque and/or tattooed skin markers to the light projection from the wall mounted lasers, while the required shift is determined during virtual simulation or from dose planning. The shifting method is necessary unless the patient is firmly fixed to the table with an indexing system allowing the use of absolute coordinates.

(65) Relative shifting is carried out preferably with table scales, or by measuring with a ruler. Although some systems allow the table coordinate origin to be reset to the origin of the patient reference coordinate system, in most systems the shift needs to be accounted for by an addition or subtraction from the actual absolute table position. It is then possible to commit an error and use the wrong value or wrong direction for patient positioning. This risk is even higher if the system does not allow the visualization of the actual irradiation field, for instance in tomotherapy.

(66) As a consequence of this ‘new’ approach of working with geometrical coordinates, technologists may tend to focus on the coordinates and to lose very basic awareness of what they are treating (for example treating the correct side in the case of a lateral tumor). There is also a tendency for them to rely quite heavily on the record and verify system which would not necessarily catch such errors (i.e. table coordinates without human supervision or too loose tolerances).

3.4.1.2. Position verification against patient internal structures

(67) X-ray imaging is required for the verification of patient position by visualizing internal structures. This was traditionally achieved with radiographic portal films, which have been replaced more recently by electronic portal imaging devices (EPID). Typically, the verification takes place on the first treatment day or one day before. It may be repeated several times at the very beginning of the treatment course and once every week thereafter. With higher demand on the conformality of the dose distribution and with margin reduction, an accurate patient setup is required and this can only be guaranteed if image based verification is repeated more often. Ideally a daily check could be recommended but then the additional radiation dose given to the patient may be no longer negligible. This is particularly the case when low sensitivity systems are being used (typically liquid ionization chamber-based EPID) but, even with the development of relatively high sensitivity amorphous silicon detectors, if this dose contribution is ignored, it could easily result in an over dosage equivalent to one fraction for a full treatment course. Several solutions may be applied to deal with this problem: compensation at each fraction for the additional verification monitor units, overall compensation at the end of the treatment or adjustment of the prescription and integration of the image dose contribution into the patients’ treatment plans.

(68) A further difficulty arises because the region which has to be imaged for verification purposes is not strictly limited to the target volume and could possibly include sensitive structures. This is well known from the double exposure techniques which were used in conjunction with radiographic portal films. It also happens when standard beam orientations (typically AP and lateral) are used to verify the position of a patient treated with oblique incidence (coplanar or non coplanar beams) and for the more advanced techniques of image guided radiation therapy (IGRT), where the recommended protocol could be a daily acquisition of cone beam computerized tomography (CBCT), serial tomography

(tomotherapy) or standard in-room x-ray image pairs (proton therapy, cyberknife…). In all cases the resulting dose should be assessed and taken into account.

3.4.1.3. Position correction

(69) Correction of patient position is applied according to a strategy and procedure under the overall responsibility of the radiation oncologist, even if the task is delegated to technologists or it is done under the supervision of medical physicists. Formerly, the adjustment of the patient position was performed by technologists essentially from oral or written instructions given by radiation oncologists from what they saw on portal images (e.g. “move the patient 0.5 cm in the cranio-caudal direction and 1 cm to the left”). This approach is being replaced by image or structure matching approaches where the patient shift aims at superimposing the current on-treatment image on a reference image (e.g. DRR) obtained from virtual simulation or from the TPS. The correctness of the shift is validated (or not) by comparing with the image in the corrected position with the reference (implying additional radiation dose). Apart from the additional exposure as discussed above, there is a risk of relying too much on the reference image which may be wrong due to errors made during virtual simulation or at the TPS. Such errors, if they occur, would be difficult to detect and would likely be there from the beginning up to the end of the treatment course.

3.4.2. Intensity Modulated Radiation Therapy and other advanced dynamic techniques

(70) In the last decade there has been an impressive development of intensity modulated radiation therapy (IMRT) made possible by the advent of computer assisted inverse planning and technical solutions to accurately control the field shape of multileaf collimated (MLC) fields as a function of delivered monitor units. More recently tomotherapy and the cyberknife offered additional degrees of freedom, the former allowing 360° rotation of the x-ray source around the patient and continuous table motion, the latter providing optimized directions of hundreds of minibeams emerging from an accelerator mounted on a robotic arm. Other new techniques include intensity modulated arc therapy (IMAT) and hadrontherapy employing photons and heavy charged particles respectively.

(71) In spite of the inevitable pressure to achieve improvements by using new technology and of the wish of the radiation oncology community to make the benefits available to patients as soon as possible, the clinical application of these advanced techniques has been, in general, kept reasonably well under control. Specific quality control procedures have either been developed and published by advanced groups in charge of clinical tests

before commercialization or provided by the manufacturers as part of the purchased "package". An example of such a procedure is the quite common practice of pre-treatment plan validation on a phantom (sometimes called "hybrid plan") before any IMRT treatment[3]. Spreading these new techniques over a larger number of centers or involving a larger number of patients needs to be achieved progressively, accompanied by adequate quality control procedures (IAEA, 2008). Several factors may increase the risk of accidental exposure, if appropriate safety barriers are not implemented:

- The multiplication of the number of parameters to be monitored during treatment makes them more difficult to keep under control.
- The mechanical aspects of the robotic approach, which is being used to control the spatial position of the accelerator or of the patient, is a potential source of danger (collision or failure of the control systems).
- The development of "segmented" irradiation techniques, in which coverage of large irradiation volumes is achieved by the superposition of many elementary dose distributions puts stricter requirements on instantaneous dose rates. Such techniques could be static (step and shoot mode) or dynamic (sliding window, tomotherapy, multiconvergent robot driven beams…). One important safety issue is the ability to stop the beam fast enough to avoid significant overdosage in the case of failure of one component. This is particularly relevant for dynamic techniques (including scanning beam approaches) where severe overdosage can occur in case of failure of the mechanical or electronic system used to scan the beam over the entire treatment volume.

(72) However, as in other branches of complex activities with potential for major accidents (aeronautical and nuclear industries) the technology is mature. Provided that the equipment is developed with proper consideration of safety issues according to industrial standards (IEC, 1997, 1998, 2000, 2005) and with reinforcement of safety interlocks

[3] Such a practice is representative of what should be done when starting with a new complex procedure where there is concern for some unexpected event with possible consequences for safety or accuracy. However, after some time and experience, these procedures could be revised and simplified as staff become more confident with equipment stability and safety. This is slowly being introduced in centers with the larger experience in IMRT which tend to abandon systematic pre-treatment verification and replace it either by reinforced specific quality control of the equipment or by systematic in vivo exit dose measurements with EPID.

compared to more traditional treatments (e.g. redundancy), there should not be significant additional risk directly related to the implementation of such advanced technology. The following issues deserve separate discussion:

3.4.2.1. Exposure outside the target

(73) The segmental nature of most IMRT techniques implies not only an increase of the instantaneous dose rate but also an increase of the total number of MU required for a given dose to the target. Therefore, the dose at distance from the irradiated volume due to collimator leakage or head scatter, although generally negligible in conventional radiation therapy, might become significant for IMRT techniques. The neutron dose at a distance from the target volumes treated with hadron beams and passive techniques (scattering foils and mechanical modulator) is also relevant to protection and safety. The quantification of these contributions and their impact on the risk of second cancers is still debated and is the subject of a separate ICRP/ICRU report (in preparation).

3.4.2.2. Complex dose measurements in combined small beams

(74) Dose measurements are more difficult to perform when small static or dynamic beams are combined to create the required dose distribution (IMRT, multibeam radiosurgery tomotherapy…). The choice of the appropriate detector (size, energy response, calibration…) and the experimental setup for beam calibration are of utmost importance. Although the users are clearly responsible for properly commissioning such systems, which should be preferably done with the help of experienced colleagues and/or in the framework of structured networks or user groups, manufacturers should alert users to the configuration and complexity of such devices and their implication on dose measurements.

3.4.2.3. Software control of accelerator output

(75) The output of computer-controlled accelerators are much harder to predict using physics rules since the response of the controlling or measuring devices can be corrected electronically or by software look-up tables more or less easily accessible to users. For example, most often the monitor response is the result of a computation which can include, or not, corrections related to the collimator opening or presence of wedges. As an illustration, the output of the one particular accelerator brand in the presence of “enhanced wedges” varies

rapidly as a function of the position of the fixed jaw (and not as a function of the equivalent field size) whereas, for another type of accelerator, virtual wedges (which are based on the same general principle) the output is practically independent of the jaw position. The reasons for these differences are rather complex and may be explained by the detailed difference in controlling electronically the dose rate or cumulative dose as a function of the moving jaw position (Leavitt et al. 1997, Liu et al. 1998, van Santvoort 1998, Faddegon and Garde 2006). Without proper information and alerts from the manufacturer there is a significant risk of error during the calibration (or commissioning) procedure.

3.5. **Patient data management**

- **Communication among different components, including those from different manufacturers, requires standardized transmission control protocols and the DICOM format. However, there may be still a number of pitfalls. Examples are potential misinterpretation of certain data by a device, such as of data entered in an optional DICOM field, or errors in data conversion to match data used by different devices from different manufacturers.**
- **Record and verify systems substantially increase protection against human errors in daily treatments, but they leave scope for other risks. Reliance on a system which is assumed to be error free may lead to overconfidence and to relaxing attention; errors may arise in special treatments, or modification of treatments, requiring manual entry of additional data or when transferring a patient from one machine to another. The manual data selection for conventional daily treatments, which was subject largely to random errors, is now replaced by single data entry to the system, which, if done incorrectly, may turn a random error into a systematic one affecting the whole treatment course.**
- **Electronic chart functionalities facilitate moving towards a "paperless" department, but without careful backup planning, data availability may be compromised. The reference dose, meant to give a warning when that dose, or number of fractions, is reached, has the potential for failure under certain conditions, for example, in the case of a machine fault, when the treatment session is moved to another machine or to a non-working day.**

- **Image handling systems with automatic image numbering and automatic image transfer add reliability, but when image related information needs to be entered manually, errors can be electronically propagated through the whole chain.**

3.5.1. Description of existing patient data management systems

(76) The use of computerized data management systems as the backbone of the organization of a radiation therapy department makes it necessary to have a clear perception of the general workflow and to interface the different components in such a way that data exchanges are safe and reliable. There were several steps in the historical development of patient data management systems :

3.5.1.1. Record and verify systems

(77) Earlier systems were the so called “Record and Verify Systems” (R&V) which were interfaced with treatment machines. They used a database containing, for each patient, the prescribed machine parameters (i.e. gantry angle, field size, number of MU/beam, etc.) obtained either from the TPS or from the simulator. For each fraction and each beam these values were automatically checked against the actual machine parameters that were set manually. In the case of a deviation larger that some predefined tolerance, a warning was displayed and an interlock prevented the treatment from starting. Additionally, for each fraction, the main machine parameters actually used for the treatment were recorded and could then be reviewed.

(78) The functionalities of record and verify systems are still of major importance for the radiation therapy process. One of them is the verification of the machine setup (the “V” of R&V) which improves safety but also introduces some risks as discussed in Section 3.5.2. The second of these is the possibility to automatically fill-in a document which traces the details of the patient treatment in the form of an “electronic patient chart” (the “R” of R&V), as discussed in Section 3.5.3.

3.5.1.2. Radiation therapy information systems

(79) Modern systems are no longer strictly R&V systems but they have expanded into “radiation therapy information systems” (RTIS) that integrate more or less effectively many different components of the patient workflow, such as management of administrative data

such as billing, management of internal or external resources (people, equipment, rooms), scheduling and creation and updating of the patient treatment charts, etc. These software systems might also include image management with picture archiving and communications system (PACS) functionalities. They might be huge and difficult to understand properly (Fraass 2008). They are meant to interface with other in-house existing databases and require assistance from computer specialists.

3.5.1.3. Direct control of machine parameters

(80) In addition to RTIS, with the development of IMRT, there are new requirements for direct software control of the machine parameters in order to automatically sequence the beams and drive the components used for beam modulation (MLC, cumulative MU, gantry rotation, etc.). Then the system is no longer limited to "verifying" that the machine parameters are correct but it directly assumes control. Therefore other means should be found to guarantee the consistency between prescription and delivery.

3.5.1.4. Communication among different components

(81) The communication between the different components of an integrated RTIS is generally achieved by a standardized approach such as "transmission control protocol / internet protocol" (TCP/IP) network, digital imaging and communication in medicine (DICOM) format and DICOM RT based exchanges. This provides flexibility and allows integration of equipment from different companies. However the variety and the complexity of the available solutions can lead to many potential pitfalls, essentially due to the introduction of data in the optional fields of the DICOM format or to a particular use of some planning or treatment data by one manufacturer's device that can be misinterpreted by the others.

3.5.2. Machine setup verification functionalities of "record and verify" systems

(82) The verification functions of "record and verify" (R&V) systems were designed to increase the reliability and safety of the radiation therapy process, against human error in daily treatment delivery. These features cannot be circumvented when complex techniques are used because it entails dealing with a very large number of parameters (e.g. for IMRT) which could not be set manually. It has been demonstrated that R&V systems are effective in detecting random errors which are operator dependent (e.g. checking the presence of wedge

filters or the number of monitor units) (ref.). However they are also responsible for new types of errors (Fraass et al. 1998a, Patton et al. 2003), for the following reasons:

- The daily use of an R&V system has an impact on the state of mind of technologists who know that there is an automatic safety system working in the background, and with this state of mind, they inevitably tend to relax their attention as compared to a manual system which would be under their control. A typical example is the application of the treatment parameters of a wrong patient (ref.) by simply clicking on the wrong line as part of a process which is becoming highly repetitive.
- The data of an R&V system are normally exported from the TPS through a network that should provide an error free solution provided that the whole system is properly commissioned. However, the transfer can be incomplete for some treatments which then requires additional manual data input. Such manual input is prone to error, but with the false confidence of working with an “error-free” system.
- As for TPS, the number of possible pathways of so many functionalities is very large and occasional errors may occur in special circumstances such as purposely modifying a plan for a treatment that has already started or transferring a patient from one machine to another.
- R&V systems are strongly interdependent on the other components of the radiation therapy network. Some manufacturers are even integrating the TPS functionalities as one module of the full radiation therapy information system. Thus, although a number of safety interlocks are normally included, it has become very difficult to clearly understand the possible consequences of any action performed on the patient electronic chart leading to an increased risk of misinterpretation and error.
- The presence of an R&V system is likely to change into systematic (and therefore much more severe) many of the errors that would have been random for a manually based treatment setup (Fraass et al. 1998a, Huang et al. 2005). As an example, an incorrect field size setting or the unintended omission of a wedge that could occur on one day in manually based treatment setup, as the result of a human error, would occur systematically every day with an R&V system, if the that error is made when introducing the data into the R&V system. This consideration should not be interpreted as a discouragement to use R&V systems (which have also the

advantage of giving access to statistics on error rate) but as a warning about the potential shift from one type of error to another one (Goldwein et al. 2003)

3.5.3. Electronic chart functionalities of “record and verify” systems

(83) Automatic recording of treatment parameters for each fraction offers the possibility to dispense with the traditional paper sheet where technologists manually record the basic information related to each fraction (e.g. the number of monitor units), for each patient and each beam. This step leads to evolving into a “paperless” department.

(84) Such a change is difficult and requires careful analysis for the following reasons :

- The availability and reliability of computer systems and data have to be guaranteed. Backup solutions require careful thought in advance to cover any failure situation.
- The patient chart is the traditional location where one can find handwritten information related to the treatment prescription, the treatment execution and instructions for any change occurring during the treatment course. In principle, the replacement by a computerized system has the advantage of forcing all categories of staff to fill-in the needed information. It is then well adapted to the standard processes as defined in existing protocols. However, for any special situations (e.g. a modification after the treatment has actually started) it could be difficult to find a proper replacement solution for smooth and safe communication between professionals, depending on the tools available in the computerized system and of the local rules for describing unexpected events that could happen during a treatment course.
- Special attention has to be paid to the follow-up from the delivery of each fraction. Most R&V systems offer the possibility of accumulating the dose at one (or several) reference point(s) as the treatment proceeds and of giving a warning if the dose (or number of fractions) exceeds the prescribed value. There are several possibilities for misreporting in the electronic chart that should be carefully investigated (e.g. machine failure, treating the patient on another machine or a non-working day) and hence there is the risk of either repeating a session that has not been recorded or stopping before the end of the course, if technologists rely too heavily on being alerted automatically by the system.

(85) It is difficult to review the numerous possible pitfalls related to the introduction of an electronic chart recording system in a radiation therapy department. It is, therefore, important to develop thorough procedures and to plan a commissioning phase and a “probing period” before such a system may be used safely. Proactive systematic approaches to find out what can go wrong, are described in Chapter 5, and they can be used as tools to develop such procedures and commissioning plans.

3.5.4. Image handling

(86) Images are becoming an essential component of the patient record and some systems incorporate them directly into the radiation therapy information system. These images may be :

- pictures taken to confirm the patient identity or to help in patient set-up
- diagnostic images
- images used in for patient anatomical reconstruction
- reference images, either acquired directly at a simulator or digitally reconstructed (the so called “digitally reconstructed radiographs” or DRR)
- portal images used to confirm the field shape and its position with respect to anatomical structures
- verification images (kV or MV images of orthogonal verification beams, CT or cone beam CT images) acquired in the treatment room to confirm patient position with respect to the machine isocenter

(87) In all cases careful image identification is required and there is a need to know without ambiguity not only to which patient the images belong but also to have access to information such as the date and time, the device used for imaging, the geometrical imaging characteristics, the doctor or technologist who performed the image acquisition, the related beam and session number whenever relevant. Image orientation with respect to the patient and to the beam should also be known precisely. DICOM standardization helps to ensure that such information is attached to digital images and automatic image transfer reduces the risk of error. However, in many cases, it might be necessary to manually complete image related information and this could cause the propagation of an erroneous identification throughout the whole chain.

(88) The most frequent and most severe cause of error may be related to the reference images used to check or adjust the beam position with respect to the patient. If, in the database, they are manually attached to the relevant beam there is a possibility of using as reference either another beam of the same patient or a similar beam from another patient or from another plan than the approved one. The consequence could be a systematic geometric mismatch that would remain undetected during the whole treatment course. In all cases, images play an important role in the safety and precision of treatment delivery but errors could occur leading to significant consequences for treatment outcome.

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4. REPORTED ACCIDENTAL EXPOSURES WITH NEW TECHNOLOGIES

- **A number of reports of accidental exposures involving new technologies has become available in recent years and these provide valuable lessons for prevention. Analyses of lessons learnt confirm and substantiate most of the safety issues and potential for errors identified Chapter 3.**

(89) This chapter contains descriptions of representative cases reported in the literature, to the Radiation Oncology Safety Information System (ROSIS) or to the Event Notification Reports of the United States Nuclear Regulatory Commission. Each case relates to some specific new radiation therapy technology or procedure. For each case, a summary of the case history is presented, followed by a discussion on the lessons to learn from the event. Short descriptions of more events are included in the appendix.

4.1. Events related to beam output and calibration

4.1.1. Calibration problems of small-fields

Case 1: Inappropriate detector size used when commissioning micro-multileaf collimators (ASN, 2007, Derreumaux, 2008).

(90) A characteristic of micro-multileaf collimators is the ability to form very small irradiation fields with high precision. These fields can be used when irradiating small targets in, for example, the brain, such as in radiosurgery applications. When commissioning a treatment unit equipped with a micro-multileaf collimator, beam data should be collected by using dosimeters with an appropriate detector size considering the potentially small size of the irradiation fields.

(91) In April of 2006, a hospital physicist commissioned a new stereotactic unit capable of operating with micro-multileaf collimators (3 mm leaf-width at isocenter) or conical standard collimators. With this unit it is possible to shape clinically usable fields down to the very small field size of 6 mm x 6 mm. When collecting beam data for the treatment planning system, it is necessary to measure the beam dose characteristics down to this field size. The beam data is subsequently used for treatment planning purposes. Data collected for the micro-multileaf collimator is handled separately from data collected for standard collimators.

(92) When measuring absorbed doses and collecting beam data (scatter factors) for very small beams formed by micro-multileaf collimators, the physicist at the hospital used a Farmer 0.6 cm^3 ionisation chamber, which is too large for this type of measurements. Consequently, the dose measurements were incorrect for all small micro-multileaf collimated fields, whereby the calibration files for all micro-multileaf collimated fields were wrong. This caused the wrong absorbed dose to be administered when these fields were used with a maximum overdose of ~200%. Patients treated with conical standard collimators were not affected.

(93) The anomaly in the calibration files from the hospital were discovered by the vendor some time later, when they were reviewing the calibration files collected from European centers. They informed the hospital in April of 2007. At this stage, 172 patients had been treated stereotactically on the unit. 145 of them had been treated using micro-multileaf collimators and had thus been affected by the erroneous measurement. In most cases, the dosimetric impact was evaluated to have been small. However, patients were identified for whom tolerance doses in normal tissues and organs were exceeded.

Discussion and lessons:

(94) The use of micro-multileaf collimators poses new challenges to physics knowledge and expertise. It, therefore, requires revisiting staff qualifications, i.e., verification that physicists in the department have a thorough understanding of the new technology, its features and the measurements to be performed. In particular, full knowledge is required of the small fields involved with micro-multileaf collimators, of the conditions they impose on detector size, and of the physical effects of a partial irradiation of a detector that is larger than the beam cross-section.

(95) After revisiting the training issues a thorough preparation for commissioning would have been necessary. This includes the preparation of procedures for the specific measurements with micro-multileaf collimators, or a conscious decision on the adoption of relevant procedures from recognized protocols

(96) Finally, independent checks of the measurements and calculations, and clarification of any discrepancy would have been necessary before the radiation therapy equipment is clinically used. An independent check would have been further enhanced, for example by inviting physicists from another hospital to check measurements and calculations

using their own equipment and calculation methods. With these measures in place, such an accidental exposure would be very unlike to occur.

4.1.2. Intra-operative radiation therapy beam calibration issues

Case 2: Intra-operative calibration error from a wrong calibration file (ROSIS, 2008)

(97) New intra-operative radiation therapy (IORT) equipment was delivered to a clinic. The clinic received no information on how the absorbed dose at specific distances from the intra-operative applicators was measured by the manufacturer, including measurement geometry, and thus how the pre-installed calibration files containing the information required for the calculation of treatment times were devised.

(98) A phantom was created locally to measure the absorbed dose on-site in the clinic at the commissioning of the IORT equipment. Each single applicator had a specific calibration file provided by the manufacturer. During commissioning, it was noted that the two applicators with a diameter of 4 cm were equal in all geometrical aspects but differed by 20% in measured output in relation to each other when the respective calibration files were used to calculate the treatment times for a certain dose. This was mentioned to the company engineer who had installed the system. The engineer was of the view that the local physicists did not measure the absorbed dose correctly for verification of the calibration files using a locally created phantom.

(99) Some time later, in connection with a meeting on other technical issues, the matter was brought up again with the company. The company realized that they had provided an incorrect calibration file for one of the 4 cm applicators, causing the dose to differ by +20% from the intended dose. Due to the low energy of radiation (50 kV), only 1.5 to 2 mm extra tissue got irradiated with an excessive dose.

Discussion and lessons:

(100) The most important point from this event is that, when discrepancies in dose measurements are found, it is the ultimate responsibility of the hospital to thoroughly investigate why these deviations are occurring, before applying the beam to real patient treatments. However, it is also the responsibility of manufacturers, suppliers and installers to deliver the correct equipment with the right calibration files and accompanying documents, for which an effective internal quality control is needed to discover errors before the

equipment is handed over, and to provide correct information and advice, upon questions formulated by the hospital staff.

(101) Furthermore, the supplier bears responsibility for delivering equipment-specific information for its safe use (including measurement geometry used when creating calibration files). A lesson that suppliers could learn from this event is the need to ensure training for their engineers on the tests to be performed and documented, before and during acceptance, including the issue of calibration files and the advice given to the hospital staff.

(102) The reliance of the physicist on an informal opinion of the engineer suggests additional lessons for the hospital, i.e., the need for including in the purchase contract, the list of acceptance tests to be performed, and a procedure to follow up on discrepancies during acceptance, as well as during commissioning and afterwards.

4.1.3. Beam output drift in tomotherapy

Case 3: Incorrect tolerance for the interlocks of a tomotherapy machine (SLH 2008)

(103) On a tomotherapy machine, on which daily morning checks were systematically performed to assess the beam output stability, a sudden drift was observed one morning, with an underdosage larger than 10%. The internal safety interlocks of the machine were not « seeing » this drift. Further treatments of patients were cancelled, although there was a doubt on the validity of the response of the local dosimeters used for these measurements that seemed to differ from the response of a dosimeter supplied by the manufacturer.

(104) After further investigation, it appeared that the deviation between the local and the manufacturer’s dosimeter was only 1.3% but that the safety threshold used for the interlock of the output of the tomotherapy machine had been set previously with a tolerance larger than ±10%. The examination of the log-book of treated patients revealed that three patients treated in the afternoon of the day preceding the faulty morning check were underdosed by 12 %. It was later discovered that the incorrect setting of the interlock was there from the original installation of the machine. Apparently, the installation technician enlarged the tolerance to facilitate the adjustment of the beam output and forgot to set it back to the correct values. It is still unclear why the interlock was set with such a wide tolerance and why there had been a sudden drift of the machine output (but the magnetron and the target were replaced after the problem was discovered, before the machine was restarted for new treatments).

Discussion and lessons

(105) The output verification of a radiation therapy machine is performed according to a predefined schedule (typically daily). The dose delivery for all patients treated between two consecutive checks relies on the stability of the machine and its dose monitoring system. In principle, internal safety interlocks should prevent incorrect output but they are set according to a certain tolerance which is not usually accessible to the user or checked as part of the local internal QA procedures. If the tolerance is too large and if a problem occurs with the machine output between two consecutive checks, it could remain undetected until the next check. For a tomotherapy machine the dose rate is critical because it is used in combination with the table translation to control the delivered dose. However, similar problems can be found on a conventional linear accelerator e.g. with respect to the beam uniformity or monitor response control.

(106) The lesson of this incident is that the users need to understand how the beam is monitored and which interlocks are provided by the manufacturer. This need may have to be linked to the acceptance tests. With the assistance of the manufacturers, the users should include in their internal QA procedure a method to check that the safety interlocks are set properly, especially after maintenance or repair. In addition, manufacturers should develop more advanced solutions, preferably automated, to avoid machine parameters being set outside of the allowed range.

4.2. **Issues related to treatment preparation**

4.2.1. Problems with dynamic wedges

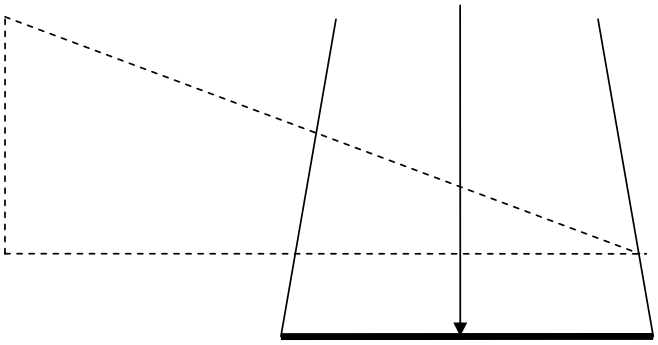
Case 4: Monitor unit calculation for the wrong type of wedge (ASN, 2007a, SFPM, 2006, Ash, 2007, Derreumaux, 2008)

(107) A new treatment technique was being introduced in 2004 at a hospital, when it was decided to change from static mechanical (hard) wedges to dynamic (soft) wedges for the treatment of prostate cancer patients. When treating with open fields or using hard wedges in this center, the standard practice was to independently verify monitor units through calculation checks, as well as using diodes for an independent check of the dose delivered. The physicist involved in the change of technique at the time was the only physicist working at the facility, and was also on-call in another facility.

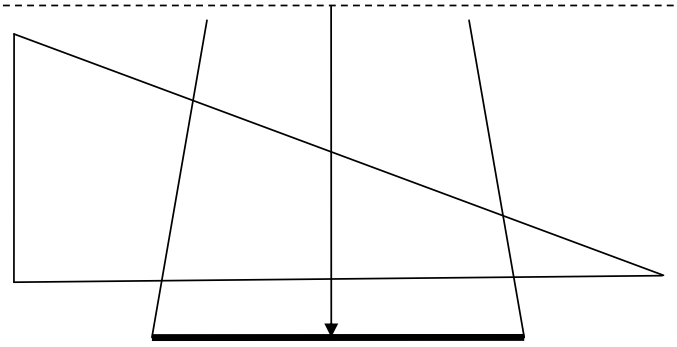
(108) As part of the introduction of the new treatment technique, two of the dosimetrists (TPS operators) were given two brief demonstrations on how to use the software. When changing treatment technique, the previous safety barriers of independent calculation of monitor units and verification with diodes were removed. The reasons for this were that the independent calculation software was not adapted to dynamic wedges and the interpretation of diodes results would have been much more difficult when using soft wedges compared to when using hard wedges.

(109) The terminology of the treatment planning software, including displays, was in English, as were the operator manuals. Not all the French operators correctly understood the abbreviated English display on the interface to the treatment planning system and they mistakenly selected hard wedges identified with their angle when intending to select the plan with soft wedges. The correct box to tick in the treatment planning system software for soft wedges was indicated “EW” (enhanced dynamic wedge) without any angle indication, which was not easily understandable and did not correspond to the terminology in French. When the treatment planning of a patient had been finalized, and the dose distribution had been optimized with hard wedges, the parameters, including the monitor units (MU) were manually transferred to the treatment accelerator where the dynamic wedge option was manually selected. The calculated number of monitor units for hard wedges that were used was much greater than the number of monitor units that were needed to deliver the same absorbed dose with soft wedges. Consequently, the patients affected by this error received a higher absorbed dose than intended. The reason for the higher number of MU is illustrated in Figure 4.1 and Table 4.1 below.

Fig 4.1 In this particular accelerator, when the dynamic wedge function is used, at the beginning of the irradiation the collimator is almost closed and the jaws are aligned on the field edge where the higher dose is to be delivered (right side of the figure).. As the irradiation begins, the moving jaw starts moving towards the opposed edge of the field (left on the figure). This is analogue to a hard wedge with its thin edge aligned to the right field edge. A physical wedge in a symmetric field, however, is centred with the beam (see lower part of the figure) and is designed to cover the largest field size. Thus, the thin edge of the physical wedge does not coincide with the field edge, except when the largest field size is selected. Therefore, for this particular accelerator design, it is only for the largest field size that the attenuation of the physical wedge would be equivalent to the dynamic wedge and the ratio of MU between hard and soft wedge would be close to unity. For all smaller field sizes the attenuation of the phyisical wedge is higher than the dynamic wedge and the ratio of MU is > 1. The smaller the field size the higher the MU ratio, as shown in table 4.1 below.



Enhanced dynamic (soft) wedge in this particular accelerator is equivalent to a shifted physical wedge (variable attenuation at beam axis depending on the field size)



Physical wedge centred with field. The attenuation at beam axis is always the same, and the value is dictated by the maximum design field size

Table 4.1 Ratio of the numbers of monitor units (MU) for physical / dynamic wedge, for the same dose delivered at 15 cm depth, isocentric technique, physical wedge 45º

	6 MV	**20 MV**
Field size	**Ratio of MU for physical / dynamic wedge**	**Ratio of MU for physical / dynamic wedge**
5 cm x 5 cm	1.83	1.83
10 cm x 10 cm	1.55	1.61
15 cm x 15 cm	1.32	1.43
20 cm x 20 cm	1.12	1.27

Adapted from Rosenwald, Institute Curie, France

(110) Between May 2004 and August 2005, at least 23 patients received an overdose of 20-35% more than the intended dose. Between September 2005 and September 2006, four patients died as a result of this accident. At least ten patients showed severe radiation complications, with symptoms such as intense pain, discharges and fistulas. Regional authorities were informed the month following the accident, but national authorities only received information a full year after the accident had taken place.

Discussion and lessons

(111) Two “brief demonstrations” to two dosimetrists are not sufficient to move from static wedges to the newer technology of dynamic wedges, an important increase in complexity, and a critical safety issue. Rather, more thorough and effective training, is required. The difference in the number of MU between static and dynamic wedges, in this particular accelerator design, was not fully appreciated. This insufficient understanding was aggravated by the removal of some check provisions such as independent calculations of monitor units and dose checks with diodes. In summary, insufficient understanding of a new, more complex technique, inadequate user interface, instructions and displays in a language not understood by operators, and removal of checks made the accident more likely.

(112) One important lesson is that there may be a temptation to remove checks, when they can not be applied to a new technology in a straightforward manner. This is a challenge

inherent in more complex technology. The safety philosophy is to increase supervision at the implementation of a new technique and to maintain the required level of safety, even if it entails the design of appropriate verifications or adapting the old ones, but the decision should never be to compromise safety.

4.2.2. Computer problems with intensity modulated radiation therapy

Case 5: Computer crash and loss of data in IMRT planning (CP, 2005, NYC-DHMH, 2005)

(113) A patient with head and neck cancer (oropharynx) was going to be treated with intensity modulation radiation therapy (IMRT) at a radiation therapy facility in March 2005. An IMRT plan was prepared, as per standard protocol. A verification plan was also prepared and tested prior to treatment (as required in by the QA programme of the hospital) in order to verify that the calculated dose distribution would be achieved at irradiation. This verification plan confirmed the dosimetric correctness of the plan through use of portal dosimetry. Subsequently the treatment of the patient was delivered correctly for the first four fractions.

(114) After these fractions, a physician reviewed the case and came to the conclusion that the dose distribution needed modification in order to reduce the dose to specific organs at risk. This task was given to a dosimetrist who started by copying the treatment plan in order to work with modifications on the copy. Re-optimization started, where existing fluences were deleted and new fluences were optimized to follow the new instructions for an optimal dose distribution. When completed, these new fluences were saved to the database. As the next step in the generation of the new plan, final calculations were started. In this step the multileaf collimator (MLC) motion control points were generated in order to guide the MLC motion for achieving the desired dose distribution through the IMRT treatment. This was performed correctly, and a new digitally reconstructed radiograph (DRR) was also obtained.

(115) The new treatment plan was now complete, and the final step was to save the plan to the database. A “Save all” process started. The items to be saved were (1) the newly generated actual photon fluence data; (2) the new DRR; and (3) the new MLC control points. When saving the items to the database, the data is first sent sequentially to a holding area on the server. It is not until all items have been received at this holding area that they will be saved permanently in the database.

(116) The actual fluence data was saved to the holding area, but when the DRR was being saved a problem occurred. An error message appeared on the treatment planning system, indicating that the data could not be saved. This “transaction error message” read:

“Please note the following messages and inform your Systems Administrator: Failed to access volume cache file <C:\Program Files\...\504MImageDRR>. Possible reasons are ... disk full. Do you want to save your changes before application aborts? Yes. No”. The operator pressed “Yes”, which began a second, separate, save transaction. The DRR was, however, still locked in to the faulty first save transaction, causing the second save transaction to be unable to complete the process whereby the software appeared to be frozen.

(117) In reconstruction of the event, it appears that the operator then tried to terminate the software application manually, either by pressing ctrl-alt-del or through the Windows task manager. This manual termination would have caused the database to perform a roll-back to the last valid state, which in this case contained the newly created actual fluence data, which had been saved in the first save transaction, and an incomplete part of the newly created DRR from the same save transaction. However, since the saving of items is sequential, there was no file containing the MLC control points which should have been saved after the DRR.

(118) A few seconds later, the operator calls up the patient’s treatment plan on another TPS workstation. Since the new fluence had been saved, the operator was able to calculate the new dose distribution and save this. This could be done regardless of the fact that there was no MLC control point data saved.

(119) According to the QA procedure in the clinic, the next step should have been to produce a new “verification plan” (sometimes called “hybrid plan”) and perform in-phantom measurements to verify the consistency of the dose distribution achieved at irradiation. Also according to the QA procedure of the facility, a physicist should have reviewed the new treatment plan prior to irradiation of the patient. The “verification plan” was not calculated at this time, and it is unclear if a physicist reviewed the plan independently. Had these steps been taken it would have been noticeable that the irradiated area outline lacked an MLC shape, both in the TPS and at the treatment console, thus using an open field.

(120) The patient was treated with the incorrect plan, i.e., an open field, for three fractions. Due to the higher number of monitor units that the MLC collimator shaped field would have required, the overdose to the patient treated with an open field became substantial. The patient received 39 Gy in 3 fractions to the head and neck area.

(121) Only after the third fraction, was a “verification plan” created. When this plan was tested on the treatment unit, the absence of the MLC became apparent and the accident was revealed.

Discussion and lessons

(122) There are four levels at which this type of problem can be detected: 1) when planning the new treatment configuration there is an opportunity to detect that the dynamic MLC option was not set as intended; 2) an independent review of the plan by a second dosimetrist or a physicist could also detect this type of error; 3) when doing the treatment preparation for the initial set up it could be seen on the treatment console that the unit was not doing what was expected (i.e. no MLC-leaf movement for an IMRT-patient) and 4) a "verification plan", as prescribed by the quality control programme of the hospital would definitely discover the wrong dose and dose distribution. A computer "crash" is not an uncommon event, but in radiation therapy treatment planning and delivery it can be very dangerous. Analysis of the potential effect of a computer crash needs to be integrated in the safety assessment and a procedure needs to be in place for the radiation therapy staff to systematically verify data integrity after a computer "crash".

(123) In summary, even when a QA programme exists, it can be rendered inefficient if work is performed somewhat "mechanically", and QA procedures are ignored in some situations. It is also possible that the staff applies the procedures correctly for new treatment plans, but fails to do so for a change of the treatment plan. To reduce this type of problem, heads of radiation therapy departments and hospital administrators need to provide continuous encouragement to "work with awareness" and supervise compliance with QA procedures, not only for the initial treatment plan but also for treatment modifications.

4.2.3. Errors in imaging for radiation therapy treatment planning

Case 6: Reversal of MRI images (NRC, 2007)

(124) When preparing the treatment of a patient's brain tumour at a clinic, an MRI study of the brain was undertaken. Standard practice was to position and scan the patient "head first", i.e. entering the scanner with the head first, and then import the scans into the Gammaknife treatment planning system for optimization of absorbed dose, dose distribution and treatment geometry. However, for this patient, due to the "feet first" scan technique being selected in the software of the imaging unit, the right and left sides of the brain were transposed in the MRI images. When importing the images into the TPS, this was not noticed. The treatment planning that was subsequently performed thus targeted an incorrect location in the brain. As a result, the patient received a high radiation dose to the wrong side of the brain.

Discussion and lessons

(125) It seems that the imaging staff performing the MRI scan was not aware of the need for an accurate scanning and recording protocol, including image orientation when imaging for the radiation therapy department, in this case, "scanned head first". There are two measures to avoid this type of error: 1) to have clear instructions visibly posted with written protocols known to and followed by the imaging staff, when imaging for radiation therapy treatment planning and 2) to include in the quality assurance program, procedures for verifying 'left from right' in safety critical images, e.g. by using fiducial markers, where appropriate.

4.2.4. Treatment set up errors from virtual simulation markers

Case 7: Confusing set-up markers and tattoos when introducing virtual simulation [ROSIS, 2008a]

(126) During the early stages of introducing virtual simulation into a clinic, a breast cancer patient was undergoing this new simulation technique. The intention was to simulate a standard two-field tangential isocentric treatment set-up. The personnel were used to conventional simulation, where this isocentre is determined at the time of simulation. In virtual simulation, the treatment isocentre location is not known at the time of scanning.

(127) At the time of the virtual simulation scanning of this patient, tattoos for lining up the patient (set-up tattoos) were marked on the patient's skin. The intention was to use these tattoos to indicate the origin of the CT coordinate system (reference point). In the subsequent

treatment planning, the offset from the CT origin reference point to the isocentre of the treatment was determined and noted in the patient's treatment chart.

(128) When the patient came for the first treatment, the staff at the treatment unit misunderstood what the tattoos indicated, and thought that they were indicating the location of the treatment isocentre. As a result, the patient was treated in a couch position 3 cm below the intended couch position.

The treatment procedure indicated that a check of the source-to-skin distance should be performed. The different distance to the breast with the patient shifted 3 cm in the axial direction should have been noticed, but this verification was not done. Electronic portal images of the field placements were taken at this first fraction. These were compared with digitally reconstructed radiographs (DRR) and seen and approved by the physician, who was not used to seeing digitally reconstructed radiographs as reference images. The treatment procedure also indicated that the physicist should have compared the couch axial position from the treatment plan with the actual couch position in the treatment room at the patient set-up, but this was overseen.

Discussion and lessons:

(129) The radiation therapy technologists did not seem familiar with the different meaning of the tattoos used for virtual simulation and misunderstood them. A lesson from this event is that new procedures for using virtual simulation should be introduced only with sufficient training, including exercises for all relevant staff groups, until it can be ensured that they understand them and are aware of critical aspects. As with any new technique, when introducing virtual simulation, it is important to follow the QA programme, in particular quality control procedures. In this case, skipping the check of SSD at treatment and the verification of axial couch position made the accidental exposure more likely.

4.2.5. Digitally reconstructed radiograph errors

Case 8: Geometrical distortion of digitally reconstructed radiographs (CIB, 2007)

(130) Digitally reconstructed radiographs (DRR) are often created in the treatment planning process to be used as reference images for the intended set-up of the patient in relation to the treatment unit isocentre and beam placement. The geometric integrity of reference images is of great importance. At the same time, the underlying algorithms for DRR

reconstructions in a treatment planning system are difficult to verify for the clinical end-user of the system.

(131) A specific treatment planning system used several methods in parallel for the creation of DRR. For one of these methods, which was introduced with an updated version of the treatment planning software, an error was detected which resulted in incorrect formation and display of the DRR when certain conditions were fulfilled. The problem originated in an error in how the information from the CT slices was loaded into the graphics memory of the TPS computer, causing the volume to be stretched out in the z-axis in comparison with the scale of the actual CT series. As a result, there could be a positioning error equal to the minimum distance between slices in the CT series, or in some cases up to twice this distance.

(132) Since the DRR exported by the system could have the same problem if created using the faulty method, the error would then propagate to the incorrect geometric set-up of the patient if this incorrect DRR was used as reference image.

Discussion and lessons

(133) A software update (in this case, involving DRR images) is as important as new software or new equipment and should be tested in the factory and also properly commissioned at the hospital. The manufacturer can lower the probability of delivering faulty software by performing stringent software tests in the factory, challenging the system in a systematic way in these tests. The hospital needs to select, plan and carry out a subset of the relevant commissioning tests on the TPS and data transfer. However, a problem that appears only occasionally, when certain conditions are fulfilled, tends to escape tests and verifications. This type of problem is suitable for sharing among users and manufacturers and lessons and commissioning approaches should be disseminated in a timely manner.

4.3. **Events related to patient data management**

4.3.1. Errors when using “record and verify” systems

Case 9: Incorrect manual transfer of treatment parameters (SMIR, 2006, Mayles, 2007, Williams, 2007)

(134) In May 2005, the record and verify system at a hospital was upgraded to a more comprehensive electronic patient data management system. Previously, the transfer of treatment parameters had been performed manually, while after the upgrade the system could

perform these transfers electronically. This was implemented for most, but not all, treatment procedures in the clinic.

(135) Towards the end of 2005, a young patient came to the hospital with a relatively rare brain tumour (pineoblastoma) and it was decided to give this patient a radiation treatment to the whole central nervous system. The absorbed dose prescribed was 35 Gy in 20 fractions to the whole CNS, followed by 19.8 Gy in 11 fractions to the site of the tumour. The craniospinal radiation therapy was prescribed to be performed using two lateral fields covering the brain, matched with an upper and a lower spine field. This type of treatment was considered to be of a complex type, and it was only performed about six times per year in the clinic.

(136) As part of the quality assurance procedures in the clinic, dosimetrists[4] were categorized as belonging to one of five categories ranging from the most junior category to the most senior. At the same time, treatment plans were categorized as belonging to one of five categories ranging from the simplest to the most advanced plans. Contrary to approved procedures, a junior dosimetrist was given the task of developing this advanced treatment plan, with the opportunity to be supervised by a more senior dosimetrist when creating the plan. There are indications that this supervision was not an active supervision, but had a more reactive nature to queries from the person being supervised. The junior dosimetrist did not have queries to the supervisor and seems to have been unaware of some of the complexities in the plan.

(137) With the new procedure for automatic electronic transfer, monitor units to give the prescribed dose to the dose prescription point are calculated directly in the treatment planning system. With the old procedure, monitor unit calculations were done by the planning system, firstly by giving the absorbed dose 1 Gy to the normalization point, and subsequently scaling it up to the prescribed dose by manual multiplication with the dose per fraction. The craniospinal treatment technique was one of the few techniques that had not yet been included in the new procedure of automatic electronic transfer. Instead, the treatment planning was performed according to the old procedure.

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[4] The meaning of the word “dosimetrists” is not uniform throughout the world; it is used in this report to mean the person who performs the treatment planning and clinical dosimetry.

(138) When planning the left and right lateral fields covering the brain in the treatment of this particular patient, the junior dosimetrist let the TPS calculate the MUs for the prescribed dose, as in the new procedure, instead of calculating the MUs to deliver 1 Gy as in the intended old procedure. The junior dosimetrist then transferred this MU setting to the manual planning form which was passed to a radiation therapy technologist for manual calculations of the MU. This manual planning form contained the MUs corresponding to the prescribed dose instead of 1Gy. The technologist performed the subsequent up scaling of the monitor units according to the old procedure, which meant that the number of MU was now 67% too high for each of the lateral head fields. It should also be noted that the dosimetrist had made a second error when filling out the MU settings in the manual planning form, in that the figure for the total number of fractions had been wrong in the calculations, leading to the 67% overdose, instead of 75%, according to the ratio of 1.75 Gy to 1 Gy. This error was not found by the more senior planner who checked the calculations.

(139) In the resulting treatment, the patient received 2.92 Gy per fraction to the head instead of the intended 1.75 Gy. This went on for 19 fractions, when the same junior dosimetrist committed the same error with another plan. This was spotted by the checker of this new treatment plan and the original error was found. The patient died nine months after the accident.

(140) It should be noted that radiation therapy physics staffing levels in Scotland were less than 60% of the recommended levels at the time of the accident, and that staffing levels in treatment planning in the clinic also were well below the level recommended by the professional body in that country.

Discussion and lessons

(141) The initial comment to make is that using two different methods to transfer data, with the associated opportunity for errors, should be avoided as much as possible. If there are strong reasons to keep the manual transfer of treatment parameters for some treatment procedures, and if a type of treatment is used only a few times a year, it may be sensible to always assign the treatment to the same person (or two persons). The next reflection points to a real challenge for hospital administrators: the challenge of ensuring a working environment that facilitates alertness, due thought and compliance with procedures. Relaxation seems to have occurred at two different levels at this hospital; 1) assignment of the advanced task to a junior planner, contrary to hospital procedures, and 2) failure of a calculation check by the

senior dosimetrist. An important lesson is that this occurred in spite of the quality assurance programme in place, with a sophisticated staff structure, grouped in five different categories of treatment planners.

4.4. Events related to treatment delivery and treatment verification

4.4.1. Significant radiation exposure from electronic portal imaging

Case 10: Excessive exposure by the daily use of electronic portal imaging (Derreumaux, 2008)

(142) Since the introduction of electronic portal imaging devices (EPID), clinics have the opportunity to monitor the set-up of individual patients more readily than with portal films. While a modern EPID can display a portal image with a short and, therefore, low exposure of the patient, typically a few monitor units, some of the earlier models of EPID required a much longer exposure to form an image.

(143) A clinic, the same one as in Case 4 above, had installed the type of EPID that was based on a matrix of liquid ionization chambers and had decided that the set-up position of patients treated for prostate cancer should be verified daily. In order to do this, they took two daily single exposure images for each patient (i.e. one anterio-posterior and one lateral image). In addition to these daily positional images, once a week portal images were taken for each patient and for all fields to confirm the correct placement of the irradiation fields. The weekly portal images were performed using a double-exposure technique where the same anatomical parts were exposed twice.

(144) As part of the clinic’s practice, when performing the weekly double exposure verification of the treatment beams, the MUs used for the irradiation field were deducted from the MUs to be used for the treatment in order to give the intended absorbed dose. However, the increased exposure arising from the daily positional images was not considered in the recording of the dose given to the patient, nor the part of the weekly double exposure of the patient outside the irradiation fields.

(145) The EPID in the clinic required a relatively high exposure for an electronic portal image. As a result, it has been estimated that each patient received a daily absorbed dose of between 0.15 and 0.20 Gy in excess to the prescribed dose due to the electronic portal imaging routines. In total, 397 patients were affected between 2001 and 2006 in that they

received an absorbed dose between 8 and 10% higher than intended. All patients affected by the overdose in Case 4 were also affected by this case, thus adding to the already substantial overdose of those patients.

Discussion and lessons

(146) There seems to have been unawareness of the magnitude of the absorbed dose resulting from frequent use of the imaging system used for setup, and that this dose could be significant with respect to the total treatment dose. This unawareness seems to be the reason for not taking the radiation dose from daily imaging into account. Before introducing new imaging technologies and verification procedures into clinical practice, procedures for assessing the exposure from imaging should be required.

4.4.2. Errors with stereotactic radiosurgery field size

Case 11: Incorrect field size used for stereotactic treatment (Derreumaux, 2008)

(147) A clinic was using a linear accelerator for stereotactic treatment of intracranial targets using a set of additional cylindrical collimators with opening diameters ranging from 10 to 30 mm mounted on an opaque supporting tray to be attached to the accelerator's accessory holder. For the correct use of these cylindrical collimators, it was necessary to set the collimator aperture to a size of 4 cm x 4 cm.

(148) When treating a patient with arterio-venous malformation (AVM) with a single fraction, the additional cylindrical collimator for stereotactic treatment was attached to the linear accelerator. The operator was verbally instructed by the physicist to narrow the collimator aperture to "40 40", but instead of using the field size 40 mm by 40 mm, the operator used the field size 40 cm by 40 cm.

(149) As a consequence of this, the fully opened field was applied to the patient through the brass tray supporting the additional cylindrical collimator, which would only cause a very limited attenuation of the beam, thereby giving nearly a full absorbed dose to large areas outside the target volume.

(150) When evaluating the magnitude of overexposure locally, the impact was underestimated, leading to an incorrect assessment of the severity of the clinical consequences, which were not fully appreciated or provided for.

(151) The clinical consequences attributed to this were fibrosis and osteo-tracheal (??? oesophago-tracheal) fistula which led to a surgical intervention and subsequently death of the

patient from hemorrhage. The very severe clinical consequences do not seem to match the dose calculated for this volume suggesting the potential presence of an additional problem.

Discussion and lessons

(152) The following reflection can be made from this event: when the operator heard “40 40”, he/she associated it to a conventional radiation therapy field of 40 cm x 40 cm, instead of thinking of radiosurgery. Furthermore, a cylindrical collimator of a few mm diameter, inside the “40 cm x 40 cm beam” did not appear strange to him/her or it did not trigger a question. Thus the operator seems to have been performing a new technique - stereotactic radiation therapy, without full awareness of this technique. The next question is whether there was a well documented prescription and treatment procedure, given the fact that the instruction on the field size was verbal, and its misunderstanding caused the accidental exposure. In summary, there seems to be a combination of insufficient training in the new technique, and work based on a verbal instruction instead of a written prescription or treatment plan. Furthermore, the local evaluation of the impact of the accident seems to have been inadequate, and point to the usefulness of calling for external expert guidance when unusual irradiation conditions in an accidental exposure are being evaluated.

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5. PROSPECTIVE APPROACHES TO AVOIDING ACCIDENTAL EXPOSURES

(153) While valuable lessons can be learnt from the detailed analysis of incidents and accidental exposures which have occurred, these lessons are limited to reported experience. There may be non-reported incidents or potential incidents which have not yet happened but are possible. Such accidental exposures can only be avoided if they are anticipated. In addition, increased complexity places new demands on quality assurance programmes, and the approach of following all-inclusive test lists and all possible controls may become impractical within the context of limited resources. Therefore, with technological and process changes, retrospective approaches are not sufficient and all-inclusive quality control checks may not be feasible. There is, thus, a need for proactive, structured, and systematic approaches to the identification of system weaknesses and the anticipation of failure modes, evaluating and comparing potential risks from each identified failure mode. Such approaches should allow a rational selection of the checks to be performed and facilitate the distribution of resources in a manner, likely to be most beneficial to the patient.

5.1. **Treatment process flow diagrams.**

(154) The identification of weaknesses in the system requires an understanding of the system itself. A helpful approach to the understanding of the system is through visualization by means of a process flow diagram. The generic process through which a patient passes in any encounter with a health care system includes the following five steps: assessment, prescription, preparation for treatment, treatment delivery and follow up (Ekaette, 2006). Patient data flows from one step to the next with return loops as necessary. A feature which characterizes modern radiation therapy is an electronic patient data management system (PDMS) which may form part of the electronic medical record and links together electronically all or most of the processes involved in the five steps above. It is the availability of such systems capable of transferring large amounts of data that has enabled new treatment strategies such as IMRT and IGRT to be introduced into the clinic.

(155) The intermediate three steps of prescription, preparation and delivery are those of most interest in this document. Each of the major steps can be divided into substeps. For example, preparation for treatment includes patient immobilization, image segmentation and structure delineation, calculation of three dimensional dose distributions and machine settings

(such as monitor units) and the transfer of data to the patient data management system. Should it be useful for the analysis, these substeps may be further subdivided. For example, the dose calculation substep includes the specification of objectives and constraints used in the optimization of the plan. An example of a process flow chart for the three intermediate steps in radiation therapy has been presented by Rath (2008).

(156) An alternative representation of the activities taking place prior to and during a course of radiation therapy is known as a process tree. The trunk of the tree conducts the patient from entry into the system to successful completion of the treatment. The boughs connected to the trunk represent the tasks, such as immobilization, image segmentation and structure delineation and treatment planning, which are necessary for completion of the treatment. Along each bough the substeps, such as choice of fusion and segmentation algorithms and margin selection, are identified. An example of a process tree for HDR brachytherapy has been presented by Thomadsen (2003).

The clinical processes, visualized by means of the clinical process flow diagram or clinical process tree, are carried out using the clinical infrastructure of the institution (hardware, software, documentation, etc.). Establishing and maintaining the clinical infrastructure of an institution also involves processes which are principally acceptance testing, calibration, commissioning and ongoing quality control. Process flow diagrams describing activities related to the maintenance of the clinical infrastructure are also useful in the identification of failure modes. Past experience indicates that it is infrastructure failures that generally have the most significant consequences as their effects are systematic and they can affect large numbers of patients.

(157) The importance of acknowledging the possibility of failures of both infrastructure and processes can be seen from the examples in Chapter 4. For example, although each step in the patient process may be carried out correctly it is possible that the infrastructure is faulty, due for example to an error in calibration (Case 1 in Chapter 4). Failures of processes involved in the commissioning of clinical infrastructure can lead to very high severity incidents in which many patients will be potentially affected. Similarly, it is possible that although each relevant component of the clinical infrastructure is performing as expected, the clinical process is flawed with severe consequences for a large number of patients (Case 4).

(158) Clinical process flow diagrams and trees are graphical representations, broadly in chronological order, of the activities required to be performed for the successful completion

of treatment of a patient. They may also be inferred from the several classification schemes used for clinical incident reporting and analysis (for example: “Towards Safer Radiation therapy”, https://www.rcr.ac.uk/membersarea/shop/layout6.asp?PID=261&Child=Child). As mentioned above it may be helpful to separately construct an infrastructure process tree which describes the calibration, commissioning and on-going quality control of equipment, maintenance and release of clinical data and procedures together with any other components required for the treatment of all or a cohort of patients.

(159) The process flow diagram or tree developed for use in an individual clinical program should reflect the structure of that program and the sequence of activities taking place in a manner that is logical and clear to the multidisciplinary team responsible for the care of the patient. A balance needs to be struck between simplicity, to maintain comprehensibility, and complexity, to capture all possible failures of the system. An approach to the validation of local process diagrams and trees is the assessment of their ability to capture all the historical incidents described in this and other relevant documents as far as they are applicable to local circumstances. This is a necessary but not sufficient condition for the adequacy of the representation. In the case of new technologies and treatment strategies, additional processes over and above those identified from historical events will need to be incorporated.

5.2. **Process flow diagram and the design of Quality Assurance programmes**

(160) Process flow illustrations can facilitate the design of quality assurance programmes. Each process or group of processes should be recognized within the quality assurance programme. Key components of quality assurance in radiation therapy are the commissioning and re-commissioning of infrastructure and clinical processes and regular quality control. The quality control program needs to encompass infrastructure (for example monthly checks of a linear accelerator), clinical processes (for example, checks of calculated monitor units for individual treatments) and, increasingly, patient specific activities (for example, experimental verification of the fluence distribution for IMRT beams). An agreed upon process flow illustration is helpful in the design of a comprehensive, effective and efficient quality assurance programme.

5.3. **Failure modes**

(161) Process flow diagrams and trees facilitate the next step in a prospective approach to risk management which is the identification of possible failure modes at each step in the process. As this is a prospective approach, prior statistically valid experience is likely to be limited. The approach normally adopted for the identification of failure modes is to convene an expert panel which reviews the process flow illustrations and, within a structured context, uses their judgment to prepare a list of possible failure modes. There are two major challenges in completing this step. The first is to be confident that all possible significant failure modes have been identified. In meeting this challenge the range of experience of the expert panel will be important. As a minimum, possible failure modes should include those reported in the literature and on public databases. The second challenge is describing the failure modes unambiguously. Not only must the description of the failure mode be completely clear but the same failure originating from different sources need to be differentiated. A failure in some step that led to a particular clinical consequence that could arise from equipment malfunction or human error needs to be identified as two failure modes. The clinical outcome might be the same but the likelihood of occurrence and, importantly, remedial measures could be quite different.

(162) The amount of detail and the degree of specificity in the description of a failure mode is the analyst’s decision. However, to be useful the description should be sufficient to guide any process or quality assurance changes that result from the analysis. Examples of failure modes attributed to the historical accidental exposures described in Chapter 4 are given in the Appendix.

(163) Having identified, on the basis of global experience and the opinion of local experts, ideally with input from equipment manufacturers, potential failure modes, the next step is to assess the risk associated with each failure mode.

5.4. **Risk**

(164) For the purposes of this document, risk can be regarded as some function of the probability of an event’s occurring and the severity of the consequences for the patient should the event occur. Severity indices may also reflect the numbers of patients involved.

(165) The diagram below illustrates how risk might be assessed. The graph represents an idealized frequency distribution of delivered doses, when there are no systematic errors present, with the central peak indicating the radiation oncologist's prescribed dose. Some variability in the relationship between the prescribed and delivered doses is inevitable due to uncertainties in calibration of the treatment machine, algorithm limitations in the treatment planning system and patient positioning reproducibility over a course of treatment requiring 30 or more fractions. It is possible using clinical data and observation to determine a range of acceptability for the delivered dose (Mijnheer et al. 1987). At some deviation from the prescription, the treatment becomes unacceptable in terms of the negative consequences for the patient. Although overdosing often attracts more attention, inadvertent underdosing can clearly also have major consequences for the patient. The thresholds at which catastrophic clinical events occur will depend on the clinical situation. However, in order to track significant accidental exposures some regulators have defined the threshold to be at a specific value over a course of treatment (for example, the Nuclear Regulatory Commission in the United States (USNRC), http://edocket.access.gpo.gov/cfr_2003/10cfr35.3045.htm). The region between acceptable and unacceptable treatments could be described as sub-optimal. There may not be clear clinical evidence that treatments falling in that region result in deleterious effects on the patient. However, significant departures from (evidence based) prescription are clearly not desirable.

(166) It is important to note that the diagram describes the situation in which there are no systematic errors causing dose deviations from prescription, such as an error in either the calibration (Case 1) or use of the technology (Case 4). When systematic deviations are present the curve will no longer be centered on the oncologist's prescription and hence the frequency of either under or overdosing will be increased. . If there is a systematic error affecting all patients, the whole curve would shift to the right (overdose) or left (underdose), by the amount of the deviation (see Figure 3). There may also be systematic deviations affecting only certain types of treatments, and therefore affecting only part of the patients, which is also represented in fig xx. The end result will be that systematic deviations will result in larger numbers of patients exceeding the threshold of acceptability and by a larger amount thus enhancing the severity associated with systematic errors (ICRP 2000).

(167) In the diagram, the abscissa could be four dimensional dose, i.e. including fractionation in time. A distribution could also be constructed to reflect inadequacy in following the oncologist's prescription for the volumes to be irradiated and, equally

important, the volumes not to be irradiated. It is noted that volume in this context is also four dimensional as its location within the patient may change with time due to, for example, respiration. One of the newer technologies under active investigation is gated therapy for lung cancer. Loss of synchrony between the target motion and time of irradiation can have severe deleterious effects. Enhancing safety is interpreted as reducing the mass density of the distribution in the regions of unacceptability. If the distribution is not centered on the oncologist's prescription, systematic effects are present and must be rectified. If the distribution is Gaussian or close to it, shrinking the tails will also narrow the peak, corresponding to reduced variability and hence an improvement in quality for a centered distribution.

5.5. **Three prospective approaches**

(168) Once the failure modes have been identified, the task becomes that of assessing the probability of an unacceptable event's occurring (the first contribution to the ordinate in the diagram), assessing the severity or consequence of the event should it occur (the abscissa), and in some of the approaches, assessing the likelihood that the event, should it occur, will not be caught during quality control procedures (the second contribution to the ordinate) and hence have a negative impact on the patient's treatment. The prospective approaches of risk assessment described below employ methods of analyzing the problem in this way.

(169) The three prospective approaches which are most commonly used are failure modes and effects analysis (FMEA) (Stamatis, 1995), probabilistic safety assessment (IAEA 2006) and risk matrix (RM) (Ortiz et al., 2008). They are not totally independent, as FMEA is often used as the first step to probabilistic safety assessments, as described later in this document.

5.5.1. Failure mode and effect analysis

(170) An example of the application of a Failure Modes and Effects Analysis to radiation therapy is that performed by Task Group 100 of the American Association of Physicists in Medicine (Huq, 2008). Three numerical values were used to describe each failure mode. **O (for occurrence)** describes to the probability that a particular untoward event occurs. **S (for severity)** is a measure of the severity of the consequences resulting from the failure mode if it is not detected and corrected. **D** (for detectability) describes the probability that the failure will be detected before the treatment commences or the failure is effective. In

the TG100 implementation, O ranges from 1 (failure unlikely, < 1 in 10^4) to 10 (highly likely, more than 5% of the time). S ranges from 1 (no danger, minimal disturbance of clinical routine) to 10 (catastrophic if persists through treatment). D ranges from 1 (very detectable - 0.01% or less of the events go undetected throughout treatment) to 10 (very hard to detect, >20% of the failures persist through the treatment course). An important point to note in the evaluation of detectability, D, is that the failure mode is assumed not to have been detected through routine quality control within the sub-process of occurrence. Thus, in TG 100's implementation of FMEA, the likelihood of (lack of) detection at any point further downstream from the sub-process in which the failure occurred is estimated.

(171) Multiplying these three numbers together yields a Risk Probability Number (RPN) which can be used for prioritizing quality control tests and activities.

(172) The presentation of a complex and comprehensive FMEA is challenging. An instructive approach is to incorporate the findings of the FMEA within the process flow diagram or process tree which was developed at the initiation of the analysis. For example, failure modes with risk probability numbers (RPN) greater than a certain threshold might be highlighted in a process tree. This diagram then contains the essential elements of a fault tree. Fault trees can be constructed using either or both retrospective and prospective analyses and thus are a flexible and useful tool in safety analysis.

(173) The calculation of risk probability numbers implies knowledge of the functional relationship between probabilities of occurrence and detectability and the severity of the consequences in quantifying risk. Institutional judgment may dictate that higher severity events, even with a relatively low probability of occurrence, deserve increased attention. Such a policy can also be incorporated into the fault tree by displaying failure modes the severity of which exceeds some threshold irrespective of the probability of occurrence/detectability.

5.5.2. Probabilistic safety assessment

(174) Probabilistic Safety Assessment (PSA) is a prospective tool that has been successfully used in the aeronautics, nuclear and petrochemical industries, but it has also been proposed for use with radiation sources in industry and in medicine (ICRP, 1997). PSA provides safety assessments in an exhaustive and structured way by combining the effects of equipment faults, procedural and human errors and hence provides insights into the strengths and vulnerabilities of the process being studied, the dominant contributors to the overall risk and options to reduce it.

5.5.2.1. Example of an application of PSA to radiation therapy treatment with a linear accelerator.

(175) An example of the application of a PSA to treatments with linear accelerators (ESTRO Congress 2008, IRPA 12, 2008) is that performed by a task group of the Ibero American FORO of Nuclear and Radiation Safety Regulatory Agencies. The task group was multidisciplinary (radiation oncologists, medical physicists, technologists, regulators, maintenance engineers and specialists in probabilistic safety assessments). The study was devoted to conventional treatments with accelerators, as a first step to progression to newer technologies.

(176) In this study, equipment failure modes and human error analysis was used to obtain an exhaustive list of deviations with a reasonable probability of occurrence and which might produce significant adverse outcomes. Accident sequences were graphically modeled by means of fault trees and event trees. After combining the appropriate models, a Boolean reduction was conducted by computer software to obtain sequence “cut sets”, i.e. the minimum combination of equipment faults and human errors which produce a given accidental sequence. This step was very important in finding common-cause event sequences.

(177) Given the scarcity of statistical data on reliability of equipment and human errors available from radiation therapy, generic data bases from several sources (AAPM 1993, NRC 1995 a and b) were used to estimate the reliability of equipment as it is typically recommended for topical PSAs that are applied for the first time. For human error probabilities, screening values were used, i.e. conservative values which allow filtering the most important human actions and focusing efforts on them in further detailed analysis. This approach allows for relative analysis from the absolute results obtained, since the whole quantification was done using the same type of self-consistent data.

5.5.2.2. Summary of results

(178) As many as 443 failure modes, which could potentially cause the postulated undesired events, were analyzed by the failure modes and effects analysis (FMEA A summary of these failure modes, and their relative impact is given in the following paragraphs.

5.5.2.3. Accidental exposures involving single and multiple patients

(179) Common-cause analysis of the probabilistic safety assessment has shown that as few as eight different event sequences are responsible for 90% of the potentially catastrophic

accidental exposures involving multiple patients. These events are summarized in the following table

Table 5.1 . Individual and cumulated contribution of failure modes and human errors to the total frequency of accidental exposures involving multiple patients

Failure mode or human error	**Individual contribution**	**Cumulative contribution**
Using a TPS in a different manner from the instructions for use, modification of its procedures, without validating the modified procedure	45.5%	45.5%
Omitting external beam revalidation in the monthly quality control of the TPS or doing it incorrectly.	32%	77,5%
Neglecting medical control of patients during the course of treatments or overlooking abnormal signs	3.9%	81,4%
Missing out independent checks of the dosimetric plan or doing it inefficiently, i.e., overlooking errors.	2.7%	84%
Missing out patient observation by the radiotherapy technologists during daily treatment or overlooking abnormal signs.	2.4%	86.5%
Missing out portal imaging or obtaining a poor image, not suitable for the purpose.	1.9%	88.4%
Missing out in vivo dosimetry[5], where applicable	1.5%	89.9%
Skipping portal imaging at the initial treatment session or performing it incorrectly.	1,4%	91,3%

(180) The most vulnerable step of the treatment process is treatment planning, with a 93% contribution to the total probability of accidental exposures involving multiple patients. The high contribution stems from potential human error in the use of treatment planning

[5] For more complex technologies, such as IMRT or tomotherapy in vivo dosimetry is not used, but dosimetric checks by phantoms irradiation are done instead.

systems (TPS). If treatment planning systems are used in a different way from what is written in the instructions, it is possible to introduce errors in the calculation of doses and dose distributions, which may escape software interlocks and system warnings. If the error is made repeatedly, i.e., making a change in the instruction, in written or non written form, and the modified procedure is not validated it may cause an accidental exposure of multiple patients similar to that which occurred in Panamá, in 2000-2001 (IAEA, 2001).

(181) Single patient accidental exposures are much more likely than multiple patient accidental exposures. Single patient accidental exposures amount to 98 % of all patient accidental exposures. This quantification is a significant contribution from the probabilistic safety assessment. Although much more attention has been devoted so far to reports of catastrophic-type, low-probability accidental exposures involving multiple patients, other events, with less catastrophic, but still significant consequences, are much more likely to occur. They may be underreported but also deserve attention.

(182) The contribution of each step in the treatment process to the total risk of single patient accidental exposure shows that the most vulnerable steps in the treatment are misunderstanding the delineated treatment volumes (59%), followed by initial treatment session (21%), patient positioning for daily treatment (15%), daily treatment delivery (9%), and treatment planning (8%).

(183) The most important events involving single patient accidental exposures are human errors at the volume delineation step, which may consist of mistaking as gross tumor volume what is meant to be the clinical target volume or vice versa on the TPS, and omitting one or several secondary target volumes or one or several organs at risk. The higher risk associated with these actions is the fact that, for this particular type of errors by the radiation oncologist when delineating treatment volumes, there are hardly any redundant or independent safety measures after the error. It can perhaps be detected by the discussion between radiation oncologist and the medical physicists at the treatment planning phase and at the approval of the treatment plan. The efficiency of such opportunities is limited because it is mainly the same person who made the mistake who can detect it.

Analysis of importance: risk increase and risk reduction factors

(184) Probabilistic safety assessment includes tools to perform sensitivity analyses, in order to obtain knowledge on how important a given element is, i.e. how much would the risk increase if the element were to fail or not be present, and how much would be the risk

reduction if the element were never to fail. This information is crucial for risk-informed decision making and rational allocation of resources. In this short summary, only a few examples are given

1. Software is responsible for controlling multiple functions and is assumed to be reliable. Changing the assumption to postulate a software fault would mean an increase of the risk of multiple patient accidental exposures, by a **factor of 30 to 300,** depending on the system and the type of fault. For this reason, development of software safety standards and evidence of compliance with these standards are essential. Regulation and further standardization of software development and testing are needed.
2. The 'record and verify' system of medical accelerators drastically reduces the risk of nine initiating events related to daily treatment delivery. Absence of this system increases the risk by a **factor of 75**, according to the computations of probabilities made in this research. New equipment should, therefore, include 'record and verify' systems.
3. Mistakes related to irradiating 'the wrong patient' can be avoided by bar codes or by assigning a space for a photograph of the patient on treatment cards, on electronic treatment sheets and on CT forms. Absence of this provision can increase the risk of single patient accidental exposures by up to a **factor of 18**. Patient positioning mistakes can be reduced by assigning a specific place in the treatment sheet for a picture of the initial patient setup.
4. The presence of two technologists during treatment preparation and delivery permits one of them to be dedicated to double check patient preparation and positioning. Absence of this measure increases the risk of accidental exposure by a **factor of 10**. At least one of the two technologists should be the same during the whole course of treatment, from the initial setup until the end of the treatment.
5. . Independent review of the TPS calculation substantially reduces the risk of single patient accidental exposure. Absence of this safety measure increases the risk by a **factor of 10**.

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5.5.3. Risk matrix

(185) The risk matrix approach is kept much simpler, as compared with probabilistic safety assessments, in order to be usable in each individual radiation therapy department. The quantitative assessment of probabilities is replaced by a simpler, semi quantitative, four-level scale (for example, very low, low, high and very high) and the complex algebraic analysis of the event sequence done in probabilistic safety assessment is replaced by a logical combination of the four levels of the frequency of the initiating event, the likelihood of failure of the safety provisions and the severity of the consequences. This combination results in a global risk for each event. The result in term of risk is also four-level scaled. This part is used as a screening process to filter out negligible-risk events and focus on the higher risks.

(186) The next step is a deeper analysis of the event sequences, that have been “labeled” by the risk matrix as having unacceptable risk (high or very high). The deeper analysis addresses the effectiveness of the existing safety provisions and the need for additional measures. For example, in the screening process the likelihood of failure of the set of safety measures is estimated from the number of measures only, while in the deeper analysis, their strength is checked by asking, for each event sequence with unacceptable risk, the following questions: “can the safety provisions be considered robust enough for their estimated probability of failure to be reclassified as “low”?”; “can the frequency of occurrence of the event sequence or its consequences be reduced?”; “is there a need to add one or more safety provision to reduce the risk to an acceptable level (low or very low)?”. The answers to these questions provide corrections to the risk matrix and constitute the conclusions and recommendations from the study.

5.6. Closing the loop and applying prospective methods.

(187) The objective of the application of any of these prospective analyses is the minimization of the risk of accidental exposure to patients. The methods of prospective analysis discussed above, anchored as they are in process flow diagrams and process trees, suggest how improvements in safety might be implemented. A given failure mode will result in consequences of a given severity. Estimates of severities of failure modes provide an opportunity for prioritising safety improvement initiatives. The analysis also provide estimates of the likelihood of a failure occurring and the likelihood of its being detected. Over both of these probabilities the institution does have some control. If a prospective analysis has

identified a failure mode with a high probability of occurrence this suggests that the activities involved warrant re-examination. Linking the analysis to the clinical or infrastructure process flow illustrations identifies which process or processes are involved. Where a weakness is identified, either prospectively or retrospectively, that process requires revision with the intention of minimizing the probability of occurrence. Similarly, failure modes associated with low detectability suggest that quality control procedures need to be re-examined. With a quality assurance program built on the foundation of a process flow illustration, the activities which may require closer scrutiny will also be more readily identified.

(188) Whether a quantitative (FMEA and probabilistic safety assessment) or a more qualitative (RM) prospective analysis is undertaken the results will facilitate prioritisation of remedial measures based on overall estimated risk to the patient or severity or some other criteria selected by the institution.

(189) It appears from the foregoing that, full prospective analyses are complex and time consuming. National and international organizations and professional bodies can assist individual clinics in recommending easily interpretable scales for quantifying occurrence, severity and detectability and by illustrating the use of prospective techniques applied to generic process trees (Huq 2008). Developers of patient safety databases, while primarily facilitating retrospective analyses, can, through the thoughtful design of their databases, facilitate prospective analyses as historical information is useful for validating, in part, process illustrations.

(190) To summarize, prospective analyses are an essential component of a safety assessment, particularly for technological and process changes and are, in addition, a useful approach to managing risks with existing equipment and current work practices. A properly conducted prospective analysis helps identify potential failure modes and the severity of the ensuing clinical consequences. Where a particular failure mode is associated with a high risk of occurrence then the infrastructure component or clinical process needs to be revised, re-designed and conducted accordingly. When the prospective analysis indicates that a particular failure mode is unlikely to be detected then the quality control programme and safety measures require strengthening.

(191)

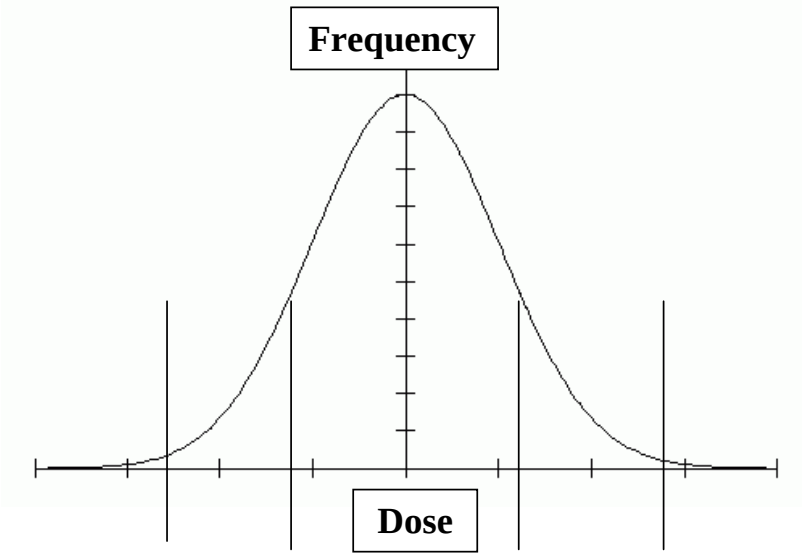

Figure 3a. Frequency distribution of the ratio of delivered to prescribed dose in the absence of systematic effects.

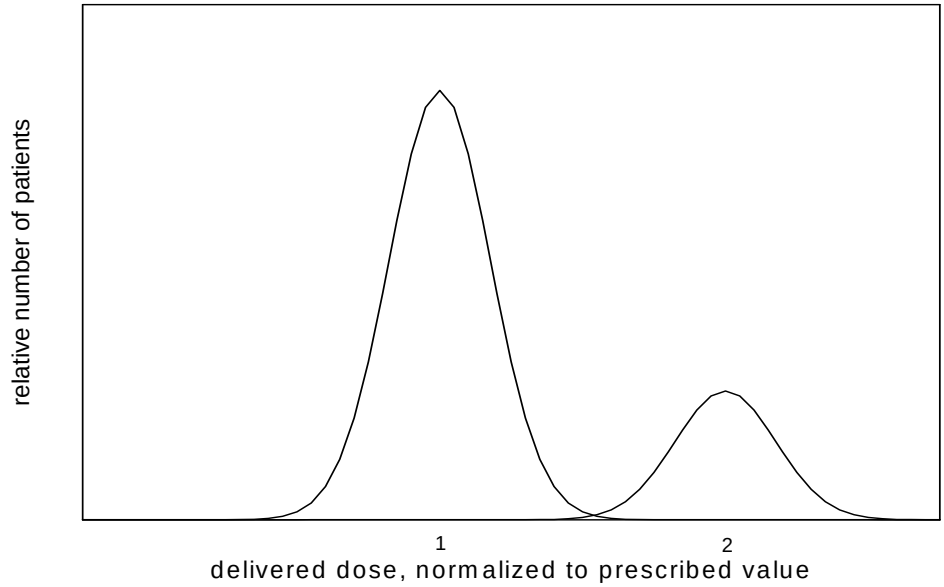

Figure 3b.. Frequency distribution of the ratio of delivered to prescribed dose, in presence of a systematic deviation affecting approximately one third of the patients. This case is similar to the event occurred because of a modified use of the TPS in which only some patients treated in the abdominal area were affected (reference Panama)

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6. CONCLUSIONS AND RECOMMENDATIONS

(192) This chapter is a summarized recapitulation of the main points made in Chapters 2 and 4 on lessons from accidental exposure and near misses, from the safety implications of new technologies as anticipated in Chapter 3 and from prospective approaches to safety assessments treated in Chapter 5.

6.1. **Complexity**

(193) Substantial improvement in radiation therapy has been achieved in association with increasing complexity and the omnipresence of computers. As a result of complexity, “human common sense” may no longer be as effective a mechanism to perceive “when something may be wrong” as it is with conventional radiation therapy. The number of possible quality control tests increases to the extent that it may become unaffordable. Increased complexity requires a different strategy to deal with risks.

(194) The primary responsibility remains with the user for the safe application of new and existing technologies and treatment strategies. However, other parties having subsidiary responsibility can, and should, assist the user in meeting this responsibility. The manufacturer should, through pre-release testing, identify both limitations in performance and pathways which may lead to the misuse of their equipment. Updated information, as experience is gained, needs to be rapidly disseminated to users.

- **Increased complexity requires a strategy of combining**
    - **Manufacturer design of safety interlocks, alerts and warnings, self-test capabilities for equipment and easy-to-understand user interfaces in a language understandable to the user and adherence to international standards to ensure compatibility between equipment from different manufacturers. All these safety measures are equally important for software.**
    - **Education and equipment-specific training for new technologies, with formal involvement of manufacturers. Such training should address the understanding of warnings and interlocks provided by manufacturers, in particular those related to beam monitoring. Such warnings and interlocks should be considered in developing acceptance tests and quality control**

procedures.

- **Risk-informed and cost-effective approaches for prioritizing tests and checks by means of prospective methods of risk assessment, to be performed in cooperation with manufacturers.**

6.2. **Dose escalation**

(195) Tumour dose escalation requires a reduction of geometrical margins, in order to avoid an increase of normal tissue complication probability. This is only feasible with **an improvement in the dose conformality, accurate and precise patient positioning and immobilization and by image guided irradiation. It also requires a clear understanding of the overall accuracy achieved for patients in clinical practice in order to safely reduce margins**. Without these features, tumour dose escalation could lead to severe patient complications.

6.3. **Increased role of imaging**

(196) Radiation exposure from imaging which, until recently was considered negligible as compared to the therapeutic radiation exposure, is becoming significant due to its increased use. In addition, the dose distribution from imaging may be different from that of the treatment, as a result of the different beam energies and field sizes used for imaging and treatment. The fact that different beam characteristics are used during treatment preparation and delivery involves a risk of confusing them and giving the wrong dose and dose distribution if the wrong beam characteristics are used in the calculation (Case 10, Chapter 4, and Derreumaux, 2008)

(197) The increasing number of different types of imaging modalities requires identification of patient orientation when passing through the gantry of the imaging equipment (CT, MRI, virtual simulation); “head first” or “feet first” stays consistent through all steps, i.e., from image acquisition, treatment planning to treatment delivery, as this becomes a critical issue (see Chapter 4, Case 6 and NRC, 2007). In addition, a risk from geometric distortion and wrong tissue density arises from the direct use of CT numbers for subsequent dose calculation, especially because of artifacts and the presence of contrast media (Chapter 4, Case 8 and **CIB, 2007**).

- **When introducing new imaging technologies into radiation therapy practice, assessment of imaging doses becomes necessary and they should be properly integrated and combined in treatment planning and delivery. Procedures are needed for recording image orientation with respect to the patient ensuring consistency through the whole process from prescription to delivery, and for choosing the correct images and CT numbers for tissue density estimation, giving specific attention to possible image artifacts and possible geometric distortion.**

6.4. Increased demands on purchasing, acceptance and commissioning

(198) New technologies are not different from conventional radiation therapy approaches with respect to the propagation of errors in commissioning to all patients, but the increase in complexity makes it more challenging to design comprehensive commissioning programmes that would catch all potential pitfalls.

- **A programme for purchasing, acceptance testing and commissioning should not only address the treatment machine but also increasingly complex treatment planning systems, "record and verify" systems, imaging equipment used for radiation therapy, software, procedures and entire processes.**

(199) Case 2 in Chapter 4 (ROSIS, 2008) shows that reliance on an informal opinion by the installation engineers has lead to an accidental exposure, related to the delivery of a wrong calibration file. When dose deviations are found, the hospital or clinic is responsible for investigating and understanding the cause of deviation, before applying the beam to clinical patient treatments.

- **Hospital staff should stay aware of the fact that the overall responsibility for the correct absorbed dose determination and the correct treatment of the patients remains with the user in hospital. This includes investigating discrepancies in dose measurements, before applying the beam to patient treatments.**

(200) On the other hand, subsidiary responsibility lies with manufacturers and suppliers. They should also have an internal quality assurance programme encompassing the training of service engineers and the tests to be performed and documented, including the issue of calibration files.

- **Manufacturers and suppliers, however, have subsidiary responsibility for delivering the correct equipment with the correct calibration files and accompanying**

documents, and for providing correct information and advice, upon request from the hospital staff. They should, therefore, have a policy and procedures to provide correct advice, upon questions formulated by relevant hospital staff, especially those questions related to deviations and discrepancies.

- **Independent checks of measurements and calculations continue to be a vital safety layer.**

6.4.1. Re-commissioning of modifications and updates

(201) A software update related to DRR images led to an incident (Case 8 in Chapter 4 and CIB, 2007). Modifications or software updates are as important as new software or new equipment and they need not only tests in the factory but also proper commissioning at the hospital.

- **There is a need for re-commissioning of the relevant devices after equipment modifications and software updates and also to monitor impact on related processes.**

(202) A problem that occurs only rarely, when certain conditions happen to coincide, tends to escape tests and verifications (Case 8 in Chapter 4 and CIB, 2007).

- **Timely and effective sharing of operational experience is critical in the phase of introducing new techniques and technologies and especially necessary for problems that appear only seldom, when certain conditions happen to coincide, because this type of problems tends to escape ordinary tests.**

6.4.2. Specific safety issues related to treatment planning systems

(203) Complex modern TPSs offer so many functionalities with so many possible pathways that it becomes extremely important to follow formal acceptance testing procedures (IAEA, 2004, 2007) and to check system functions, document different capabilities and verify the accuracy of dose calculation algorithms. Commissioning of a TPS is also very critical. The wrong input of basic parameters may lead to severe systematic errors involving many patients. A misunderstanding related to the use of a TPS can lead to severe consequences as shown by reported accidental exposures. Many failures would result in a system crash with no other consequences but in some peculiar circumstances some failures lead to a compromised outcome (Case 5 in Chapter 4, and CP, 2005, NYC-DHMH, 2005).

- **It is advisable to use proactive safety assessment approaches, as described in this document, to identify circumstances potentially leading to accidental exposure and to**

choose safety measures in a selective manner. Although users are responsible for commissioning such systems, proactive safety assessment should be preferably done with the help of experienced colleagues and/or in the framework of structured networks or user groups, and manufacturers should alert them about the characteristics of the measurements involved.

6.5. **Omnipresence of computers**

(204) One of the most important features of "new technologies" is the omnipresence of computer based solutions. Computers are used at each stage of the process, from prescription to completion of the treatment. Simple traditional displays on the console are now replaced by dialogue with the machine, which may be in a language not fully understandable to the operators. This becomes more important if there are abbreviations in another language. An example of this was the abbreviation EW, for enhanced dynamic wedges (Case 4 in Chapter 4, ASN, 2007a, SFPM, 2006, Ash, 2007, Derreumaux, 2008). In addition, computer crashes are not uncommon, but in radiation therapy they can be extremely dangerous if not managed properly (Chapter 4, Case 5, NYC-DHMH, 2005).

- **Equipment instructions and human-machine communication should be understandable to the users. Procedures should be in place to deal with situations created by computer crashes, which may cause loss of data integrity. These procedures should include a systematic verification of data integrity after a computer crash, occurring during data processing or data transfer.**

(205) The use of computers has an impact on the "state of mind" of the staff. As an example, technologists who know that there is an R&V verify system working in the background, inevitably tend to relax attention in comparison with a manual system which entirely depends on their actions. There are possibilities of misregistration in electronic patient charts, that should be carefully investigated, but it is difficult to review the numerous possible pitfalls related to their introduction.

- **It is necessary to develop procedures and to plan a commissioning and a "probing" period when introducing an electronic patient chart, until it is confirmed that such a system can be used safely.**

6.6. **Education and training**

(206) Errors in calibrating small radiation beams from micro collimators and the error of misunderstanding of field size in radiosurgery have shown that new technologies require deeper knowledge and understanding of the science and techniques involved (Case 1 in Chapter 4, ASN, 2007, Derreumaux, 2008**)**. When a new technology or technique is being introduced, education and training needs revisiting at three levels: 1) education on the proper understanding of the physics involved in the process, 2) "hands-on" training to obtain the necessary expertise before being allowed to use the new techniques "alone", and 3) specific training in the equipment and techniques to be used.

There is a danger of underestimating the required training associated with an increase in complexity, and there may be a temptation to oversimplify the issue by replacing proper training with a short briefing or demonstration, from which important safety implications of new techniques cannot be fully appreciated (Case 4 in Chapter 4 and ASN, 2007a, SFPM, 2006, Ash, 2007, Derreumaux, 2008).

- **The following conclusion for conventional radiation therapy from ICRP 86 (ICRP 2000) is equally applicable, and even more relevant and important, for new technologies: *"purchasing new* equipment *without a concomitant effort on education and training and on a programme of quality assurance is dangerous".* The lessons from reported accidental exposure have confirmed that embarking on new technologies makes revisiting staff qualifications necessary. In particular, a solid understanding is required, for example, the physical effects of a partial irradiation of a detector if it were larger than the beam cross-section (micromultileaf collimators); dynamic wedges and their impact on the delivered dose for different accelerator designs; the labeling, recording and interpretation of imaging parameters; the complex functionalities of treatment planning systems; the particular requirements of stereotactic radiosurgery, such as the field sizes and collimator settings involved.**

6.7. **Use of proactive safety assessment in designing a quality assurance programme**

(207) Due to increasing complexity, quality control as implemented with conventional technologies may become impractical because of the extensive checklists aimed at measuring everything possible. Quality assurance programmes, including lessons learned from reported

accidental exposures and near misses, are very important but are not sufficient to identify other possible accidental exposures, which occurred but were never reported or latent risks which never manifested themselves and hence remain unknown. This is especially true for new technologies, for which the time is too short to have enough operational experience in the form of reports. These problems can be overcome with a combination of the following tools:

- **The programme of checks should be rationalized and simplified with the help of manufacturers, by designing proper alerts and warnings, self-test routines, especially related to software, easy-to-understand user interfaces, internal safety interlocks as well as training in the proper and cautious use of the equipment.**
- **Increased complexity requires a strategy to choose control checks, based on selective, risk-informed, approaches to identify and prioritize tests. In cooperation with manufacturers, mechanisms should be found to perform proactive safety assessments when a new product, technology, or technique is being introduced.**
- **Timely and effective sharing of operational experience is crucial in the phase of introducing new techniques and technologies. This could be achieved by organized and structured sharing mechanisms, for example, creating moderated electronic FORUMs and by early establishment of panels of experts.**

(208) With these recommendations in mind, there are a number of more specific issues which are summarized below.

6.7.1. Change in processes and staff responsibilities

(209) As shown in Chapter 3, new technologies lead to the changing of processes, procedures and also the shifting of staff resources. An example is that of patient positioning and selection of parameters which may be simplified by a modern record and verify system and data transfer, but treatment planning becomes more sophisticated. The introduction of new technologies and techniques might also affect surrounding processes not directly part of the new technology.

- **Changes in processes, procedures and task allocation also need to be commissioned and regularly quality controlled. The full potential impact of such changes should be assessed.**

6.7.2. The problem of tests that are no longer effective

(210) Conventional checks may not be easily applicable to complex treatments such as IMRT, for example, the manual check of the number of monitor units. An important lesson from one of the accidental exposures described in Case 4, Chapter 5, is that there is a temptation to remove safety checks, which were carried out for conventional techniques, because they can not be easily applied to new technologies.

- **When conventional tests and checks are not applicable or not effective for new technologies, the safety philosophy is to find measures to maintain the required level of safety. This may need the design of new tests or the modification and validation of the old ones. A conscious decision is required to avoid compromising safety.**

6.7.3. Consistency in prescription

(211) Intensity modulated radiation therapy (IMRT) and inverse planning have introduced significant changes in the approach to prescribing radiation therapy. Without establishing protocols, lack of consistency between treatments may result in substantial deviations, when the same intended prescription is expressed in different forms (Chapter 3, Das, 2008).

- **Protocols for prescription, reporting and recording, such as ICRU reports, should be kept updated to reflect and accommodate new technologies and adopted at a national level. Professional bodies can be instrumental in achieving this need.**

6.7.4. Coordinates, reference marks and tattoos

(212) It is very important to maintain consistency of co-ordinate systems following through all the steps of the treatment chain. In case 7 the radiation therapy technologist did not seem familiar with the different meaning of the markers and tattoos used for virtual simulation and misunderstood them (Case 7 in Chapter 4, and ROSIS 2008a).

- **Procedures for virtual simulation, and their implications in the whole treatment chain, should be introduced with sufficient training to ensure confidence that the staff is familiar with them and aware of all the critical aspects. A consistent coordinates system is required for the whole process from virtual simulation through treatment planning to delivery.**

6.7.5. Handling of images

(213) Images play an important role for the accuracy of treatment delivery and safety and errors could lead to significant consequences for the treatment outcome, since the error may affect the whole course of treatment, from the beginning to the end. An example is the attachment of the reference image to an incorrect beam or vice versa. Another type of error is laterality in which the labeling of images, such as left-right sides, is incorrect (Chapter 4, Case 6 and NRC, 2007).

- **Written instructions should be visibly posted and followed by the imaging staff, which performs the imaging for radiation therapy treatment planning and delivery. These instructions should include procedures for verifying left and right in critical images, e.g. by using fiducial markers.**

6.7.6. Uniformity and clarity in data transfer approaches

(214) Keeping more than one method in the department for planning patient treatment and transferring data (e.g. automatic and manual) to the accelerator is often inevitable, but it is a potential source of error with the risk of applying a procedure to a case for which it is not intended (Case 9 and SMIR, 2006, Mayles, 2007, Williams, 2007).

- **When several methods and different protocols for data transfer are used for treating patients in a given department, the patient categories to which the protocols are applicable should be clearly defined and communicated, including details about which planning system and which data transfer method is applicable.**

6.7.7. Safe communication among interdisciplinary professionals

(215) Loose communication, combined with other human errors, triggered the accidental exposure described under Case 11, which ended with the death of the patient. The field size of “40 x 40” was taken to be in “cm” instead of “mm”. It was probably taken for granted that the technologist was familiar with typical field sizes used in stereotactic neurosurgery and assumed that he/she would correctly interpret the meaning. Although there was apparently an added problem of the technologist not being trained and familiar with radiosurgery, the role of correct communication should never be underestimated. Loose communication can also lead to ignoring, or to insufficient investigation of, unexpected radiation effects on patients, as has occurred in some accidental exposures in conventional

radiotherapy, thus minimizing the possibility of mitigating the consequences of accidental exposure.

- **Communication should follow a given pattern regarding content and format, as well as formal recording of safety critical issues. Unambiguous communication is essential, especially considering the complexity and the multidisciplinary nature of radiotherapy.**

6.7.8. Maintenance, repairs and notification of the physicist

(216) A severe accidental exposure with conventional techniques showed it is necessary that a report produced by a maintenance engineer after a repair is seen by the physicist, who can judge whether or not the work done may affect the beam characteristics or the beam output and can then perform the required checks (IAEA, 2000, CRP, 2000).

- **Procedures to notify a physicist of maintenance or repair activities were identified as crucial in conventional technology, but are even more necessary in new complex technologies, in which modifications, software updates, adjustments and calibration files can be introduced in computer dialogue among various devices and might go undetected, unless formally notified.**

6.8. Safety culture

(217) Lack of awareness of the differences implied by new techniques, and thinking in terms of conventional techniques, combined with an ambiguous verbal communication led to a fatal misunderstanding (IAEA, 1998, 2000, ICRP, 2000). Case 9 in Chapter 4 (SMIR, 2006, Mayles, 2007, Williams, 2007) shows that a programme of quality assurance can be rendered ineffective if the work is done “mechanically”, and QC procedures are ignored. It is also possible that the staff applies the procedures correctly for new treatment plans, but fails to do so for a modification of the treatment plan (Case 5 in Chapter 4, CP, 2005, NYC-DHMH, 2005).

- **Hospital administrators and heads of radiation therapy departments should provide a work environment that encourages “working with awareness”, invites concentration and avoids distraction. They should supervise compliance with QA procedures, not only for the initial treatment plan but also for treatment modifications.**

6.9. **References**

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APPENDIX A. SHORT REPORTS ON INCIDENTS FROM THE RADIATION ONCOLOGY SAFETY INFORMATION SYSTEM

A.1. Reports relating to Record and Verify (RV) Systems

ROSIS Incident Report #19: Capturing treatment parameters incorrectly on a treatment unit

Treatment field parameters were transferred from the RV system to the linear accelerator, including the monitor units (MU) for dynamically wedged (DW) fields. The field size was intentionally modified manually for a treatment field by using the linear accelerator hand control. When the new field size was captured by the RV system, the previous information on MU for the DW was lost. Two subsequent treatments were given without the DW before the error was detected.

ROSIS Incident Report #107: RV failure to register a given treatment

A network communication failure occurred between a linear accelerator and an RV system causing communications to break down. 30 MU (wedged field) had already been given to the patient when this failure occurred. To restart communication, the RV system was rebooted, after which the RV did not acknowledge that part of the treatment of the patient had already been given. When treatment resumed, the radiation therapists gave the full treatment, including the previously given 30 MU.

ROSIS Incident Report #116: Incorrect MU registration by RV system

A patient was treated with a field that was open for one part of the treatment and wedged for another part (using a motorized wedge). When the wedge automatically moved out of the field in order for the open field to be delivered, no information was received by the RV system, thus continuing to register MU for the wedged field. A faulty microswitch stopped the correct information from being sent to the RV, but the actual treatment had been performed correctly.

ROSIS Incident Report #141: Error in manual set up due to RV not being used because of "millennium bug" problems

An RV system was taken out of clinical use in a hospital because it was considered that there were problems with millennium bug or year 2000 (Y2K). The system was not replaced on the

linear accelerator from which this system had been removed, leading to manual treatment set up and selection of treatment parameters and accessories. A patient treated with two tangential beams for breast cancer noted that the number of wedges used was different from one day to the next, asking the radiation therapist if there was a reason for this and if it had any importance. A wedge had been forgotten at the manual set up of one of the tangential fields of the patient causing an incorrect absorbed dose to be delivered.

ROSIS Incident Report #690: Inadvertent rotational treatment of a patient

During the first treatment of a patient with an electron field, it was noted that the gantry started to rotate. The prescription was for static treatment, not for a rotational one. An error had been made when preparing the RV entry of the treatment, where a checkbox had been accidentally checked for rotational treatment. It was also noted in another report to ROSIS (Incident Report #689) that, for this particular type of RV system, the checkbox for rotational treatment on the screen was placed near the icon for closing the window after finalized RV entry, leading to inadvertent activation of rotational treatment.

ROSIS Incident Report #725: Problems in selecting the correct field in the RV system

A patient was treated with overlapping large and small fields, to be delivered every other day. This was programmed into the treatment schedule of the patient in the RV system. One day when the patient was treated, it was found that the system allowed the selection and treatment of both series (large and small fields) on the same day, and that after having irradiated the patient with the first field, the RV system automatically chose the next field with the lowest number, which should have been used for treatment the next day. This was noted after a few MUs had been given. The treatment was interrupted.

A.2. Reports relating to soft wedges on linear accelerators

ROSIS Incident Report #20: Treatment with soft wedges in the wrong direction

During the process of treatment planning, the field names of two tangential breast fields (e.g. left medial and left lateral tangential fields) were reversed, thus the treatment parameters were associated with the wrong field names and vice versa At treatment set up, the fields were called up on the RV system. The technologists set up the correct gantry angle, which did not match the angle recorded in the RV. Subsequently they overrode the gantry angle on the RV

record, leaving the remaining parameters from the other field. These parameters included dynamic wedge data, thus wedge direction were from the other field, i.e., the opposite direction to that intended.

ROSIS Incident Report #284: Inadvertent loss of wedge code information

Due to a breakdown of a linear accelerator, a patient was moved to another accelerator for a single fraction. As an inherent part of the design of the RV system, the wedge information in the RV system was not transferred automatically to the new treatment unit. The wedge code was manually input properly for the single fraction at the second unit, but when the patient was transferred back to the original unit, the wedge code was not put in again. As a result, the patient received treatment without wedges for three fractions before discovery, causing the accidental delivery of the incorrect absorbed dose and dose distribution.

ROSIS Incident Report #310: Wrong manual transfer into RV system of data on soft wedges

After a patient's treatment had been re-planned, the wedge code for the dynamic wedges was not manually entered into the RV system. This meant that both fields of the treatment set up were used without the intended wedges for three fractions, before discovery.

ROSIS Incident Report #314: Incorrect manual entry of soft wedge direction

The wedge code for a dynamic wedge was entered manually into the RV system. When performing this entry, the wrong wedge direction was chosen, i.e. "Out" instead of "In", leading to an incorrect dose distribution in the patient for one fraction before the error was discovered.

A.3. Reports relating to multileaf collimators on linear accelerators

ROSIS Incident Report #132: Connectivity problems between RV system and MLC unit

For a specific combination of RV system model and linear accelerator model, there was no verification of the MLC configuration of the treatment fields, i.e. the MLC files containing the information on the MLC settings for each field had to be opened separately on the linear accelerator control software in order to set the MLC configuration, without the possibility of having the correctness of the MLC setting verified. For one field, it was forgotten to open the

corresponding MLC file and to set the MLC configuration, thus starting to irradiate the patient without MLC shielding. At the reported instance, the error was detected after a few MU, and the treatment could be stopped, but the incident report indicates that this problem is a recurring issue.

ROSIS Incident Report #707: Loss of MLC shape after portal imaging

The imaging feature in an RV system was used to make a double exposed portal image, starting with an open large field in order to make anatomic landmarks more clearly visible in the portal image. The second exposure of the sequence was intended to be of the actual treatment field. The MLC settings did however not return to the intended treatment settings. This was noticed at the treatment unit, and treatment was interrupted.

A.4. Reports relating to Computerized Treatment Planning System (TPS) Tools

ROSIS Incident Report #326: Printout of beam's eye view (BEV) put together incorrectly

Printouts of beam's eye view (BEVs) were used to check the shape of the irradiation fields prior to patient treatment, by placing the scaled printouts on the treatment couch at a certain distance from the source and comparing with the light field of the corresponding treatment field. The use of large fields made it necessary to print out the BEV on two sheets of paper and to put them together in order to cover the whole field. When checking a particular field, it was noticed that there was no agreement between the BEV and the light field. When investigating this further, it was found that the two sheets of paper had been put together incorrectly. It was felt that a contributing factor to this mistake was the insufficient identification markings on the BEV paper sheets by the system

ROSIS Incident Report #471: Transfer of the wrong digitally reconstructed radiographs (DRR) of the patient.

At the first treatment of a patient, electronic portal images of the treatment fields were taken. The radiographers on the treatment unit noticed large discrepancies between these images and the DRR images that were used as reference images of the intended field placement. Further investigations revealed that DRR images from a different treatment plan of the same patient had been sent.

ROSIS Incident Report #623: Incorrect labelling of simulator film leading to incorrect BEV and to incorrect block positioning

A simulator film showing the intended field shape was labelled on the wrong side. This meant that, when digitized into the TPS, the BEV was mirrored in relation to the intended field shape, leading to the incorrect positioning of the lead shielding in the treatment field. Since the BEV was used to verify the correctness of the block positioning before treatment, the patient was treated with the block in the incorrect position before the error was discovered through portal imaging.

A.5. Reports relating to Imaging for Treatment Planning

ROSIS Incident Report #454: CT images associated with the wrong patient when entered into the TPS

When performing an electronic transfer of CT images, it was necessary to manually associate the data with a specific patient, since the information of patient identity in the CT data was not recognized electronically by the treatment planning system. When the CT images of one patient were transferred into the TPS, the CT data was introduced into the records of another patient. The error was detected at a later point in the treatment planning process.

A.6. Reports relating to Virtual Simulation

ROSIS Incident Report #161: Problems due to inadvertent energy selection originating in the virtual simulation process

When performing virtual simulation with a particular system, a field had to be entered electronically into the patient CT data in order to set an isocentre in the simulation process. Thus, a specific photon energy had to be selected for that field, even if the staff at that time in the process did not know which energy was the most appropriate. As a rule, 6 MV was always chosen in the clinic, when creating the field for setting the isocentre. When creating the treatment plan for a pelvic treatment, the planner should change this initial energy to a higher energy, but for a particular patient this was not done. The treatment was a three-field technique with two wedged lateral fields. Prior to starting treatment delivery it was noted that the energy was too low for a pelvic treatment and the planner made a new plan with a higher

photon energy. When the energy of the field was changed, the information on the wedges of the lateral fields was lost. This was not noticed by the treatment planner. Furthermore, the MUs were already calculated and checked before the change of energy and were not re-checked after the change. The mistake was discovered after the first field was given.

ROSIS Incident Report #573: Different length units in virtual simulation and linear accelerator

A very small field (6 mm) was virtually simulated. This treatment was not to be calculated by the computerized TPS, but manually calculated, and therefore it was not electronically transferred. When the radiographers on the treatment unit were recording the treatment parameters into the RV system, they interpreted the field size incorrectly. While the length unit used in the virtual simulation system was millimetres, the different length units on the linear accelerator led to the field size being interpreted as 0.6 mm. The mistake was discovered before the start of the treatment.

A.7. References

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