

‘THE DEVELOPMENT OF A RADIATION QUALITY
CONTROL MANUAL BY ANALYSING THE PREVALENCE
OF ADVERSE INCIDENTS DURING RADIATION
THERAPY AT UNIVERSITAS ANNEXE, BLOEMFONTEIN’

By

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In loving memory of my father, Billy Kinsella.

Dedicated to my wonderful mother, Arenda Kinsella.

Thank you.

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'Modern radiation therapy, if nothing else, is a triumph of precision engineering. The gantry of a linear accelerator weighs 3 tons, the couch 1.5 tons. The gantry can be rotated through 360° and positioned with an accuracy of one tenth of a degree. The 4.5 tons of couch and gantry, weighs as much as three family cars and can be moved so that the isocentre can be located within a sphere of 2 mm diameter. If we put that on a dartboard: we can place an object, weighing 750 kg, to lie within 0.05 mm of any desired position on the periphery of the dartboard' (Faithfull & Wells, 2004: 35).

SUMMARY

From January to June 2007 a clinical quality audit was performed at the Oncotherapy Department, Universitas Annexe, Bloemfontein to identify deviations from the planned arrangements of quality activities and to initiate corrective actions in the event of any deviations observed. The objective of the audit was to set up a quality control procedure manual, designed to minimise the occurrence and consequences of any events which could lead to an adverse incident in the radiation therapy schedule of a patient and thus potentially have an impact on the quality and safety of patient treatment.

A total of 7 838 patients were treated with 37 026 radiation treatment fields in 11 466 radiation treatments, during the period of the study at the Oncotherapy Department, Universitas Annexe, Bloemfontein. During this time a total of 15 minor adverse incidents were reported: 46% were due to errors in dose calculations; 13% respectively, due to incorrect patient positioning, error in field positioning and incorrect lead shielding and 7% respectively, due to treatment unit malfunction and incorrect radiation treatment energy.

The study contributed to the advancement of the quality control management system at the Oncotherapy Department, Universitas Annexe, Bloemfontein, with the focus on the radiation treatment delivery process. Information obtained from the study was used in conjunction with information obtained from the literature study to generate a quality control procedure manual to facilitate in the monitoring, evaluation and improvement of the quality of radiation therapy at the Oncotherapy Department at Universitas Annexe, Bloemfontein. Once implemented, procedures and/or protocols in this manual can now assist in more accurate, effective and higher quality radiation treatment delivery.

OPSOMMING

'n Kliniese oudit is uitgevoer, vanaf Januarie tot Junie 2007, by die Onkoterapie Departement, Universitas Annex, Bloemfontein, om enige deviasies in kwaliteitsaktiwiteite vanaf die beplande handeling te kontroleer en om die korrekte aksies te inisieer in die geval van enige geobserveerde deviasies. Die objektief van die oudit was die samestelling van 'n kwaliteitskontrole prosedure handleiding, wat ontwerp is om die voorkoms en gevolge van enige gebeure wat kan lei tot 'n adrese insident in die bestralingsterapie regime van die pasiënt en 'n potensiële impak op die kwaliteit en veiligheid van die pasiënt se behandeling kan hê, tot 'n minimum te beperk.

'n Totaal van 7 838 pasiënte is behandel met 37 026 bestralings velde in 11 466 bestralingsbehandelings tydens die periode van die studie by die Onkoterapie Departement, Universitas Annex, Bloemfontein. Gedurende hierdie tyd is 'n totaal van 15 minor adrese insidente gerapporteer: 46% was as gevolg van foutiewe dosisberekeninge; 13% as gevolg van foutiewe pasiënt posisionering, foutiewe veld posisionering en foutiewe afskerming, respektiewelik en 7% as gevolg van behandelingseenheid wanfunksionering en foutiewe behandelingsenergie, respektiewelik.

Die studie het bygedra tot die bevordering van die kwaliteitskontrole bestuursistiem by die Onkoterapie Departement, Universitas Annex, Bloemfontein, met die fokus op die bestralingsterapie leweringsproses. Inligting wat ingevorder is met die studie is in samewerking met literatuur inligting gebruik vir die ontwerp van die kwaliteitskontrole prosedure handleiding om te fasiliteer in die monitering, evaluasie en verbetering van die superioriteit van bestralingsterapie. Met die implementering van die handleiding kan die prosedures en/of protokolle bydra tot meer akkurate, effektiewe en hoër kwaliteit bestralingsterapie.

DECLARATION

I, hereby declare that the work hereby submitted, is the result of my own independent investigation. Where help was sought, it is acknowledged. I further declare that this work is submitted for the first time to the university / faculty towards a Masters Technologiae Degree in Radiography (Therapy) and, that it has never been submitted to any other university / faculty for the purpose of obtaining a degree.

Billyndé Kinsella

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LIST OF ACRONYMS

AAPM	-	American Association of Physicists in Medicine
ACR	-	American College of Radiology
COHSASA	-	Council of Health Service Accreditation of South Africa
CT	-	Computerised Tomography
CTV	-	clinical target volume
DCE	-	dose calculation error
DRR	-	digitally reconstructed radiographs
EPI	-	electronic portal images
FP	-	field positioning
GTV	-	gross tumour volume
IAEA	-	International Atomic Energy Agency
ICRU	-	International Commission of Radiation Units and Measurements
IVD	-	in vivo dosimetry
LS	-	lead shielding
MLC	-	multi-leaf collimators
MRI	-	Magnetic Resonance Imaging
MU	-	monitor units
NMI	-	Nuclear Medicine Imaging
PP	-	patient positioning
PTV	-	planning tumour volume
QA	-	quality assurance
QC	-	quality control
RE	-	radiation energy
RT number	-	radiation therapy number
RV	-	record-and-verify systems
TPS	-	treatment planning system
TUM	-	treatment unit malfunction

- VI - verification imaging
- 3DCRTP - three dimensional conformal radiation treatment plans

CHAPTER 1

ORIENTATION TO THE STUDY

1.1. INTRODUCTION

On 27 February 2001 a transitory loss of electrical power resulted in the automatic shutdown of a Polish built NEPTUN 10P® type linear accelerator during the radiation treatment of a patient at the Białystok Oncology Centre in Poland. After the electrical power was restored the linear accelerator was restarted, the controls checked and radiation treatment continued. The patient receiving radiation treatment at the time of the incident as well as four other patients received further radiation treatment. During the radiation treatment, two patients experienced itching and burning sensations. This led to the staff terminating the treatment. After numerous tests the discovery was made that the machine's output was significantly higher than expected, the dose monitoring system of the accelerator was not functioning properly, and that one of the electronic components of the safety interlock system was damaged. Thus, a radiation accident occurred where five patients developed local radiation injuries of varying severity. Medical examination revealed that the local injuries of all five patients were worsening significantly and required surgical treatment (International Atomic Energy Agency Vienna, 2004: 1). This is but one of many radiation therapy incidents that occur annually all over the world. What is radiation therapy and how can these incidents be avoided?

Radiation therapy, in its numerous forms, e.g. external beam radiotherapy, intracavity and intraluminal therapy, plays an essential role in the treatment of most primary malignant tumours and metastatic disease (Griffiths & Short, 1994: 1). One third of all cancers can be cured if the best available method of treatment is used (Chapman & Hall Medical, 1997: 21).

According to the American College of Radiology (ACR) (2006: 923) up to sixty percent of cancer patients are treated with radiation therapy either to cure the patient or for palliative relief.

Radiation therapy of cancer patients involves the selection of an intended target volume to provide sufficient coverage of the tumour volume and any relevant surrounding margins, which includes any microscopic spread and patient movement variations in the radiation treatment area. An adequately high dose of radiation has to be delivered to this intended target volume while taking into consideration the probability of complications in the normal tissues surrounding the target volume (Leer, McKenzie, Scalliet & Thwaites, 1998: 5). Early complications can appear during the radiation therapy course or immediately after completing the radiation therapy course. The late effects usually transpire between 12 and 24 months after the treatment and may develop gradually throughout the rest of the patient's life (Tubiana, Dutreix & Wambersie, 1990: 141).

Thus, taking into consideration the strong demands that tumour control and normal tissue complications make on the accuracy and precision of the radiation treatment delivered to the patient it is evident that radiation therapy of cancer patients is a multidisciplinary speciality, using complex equipment and procedures for the assessment, planning and delivery of treatment. Due to the intricate nature of the radiotherapy process, quality assurance (QA) and quality control (QC) should be greatly emphasised throughout the entirety of the delivery process of radiation treatment (Leer *et al.*, 1998: 5).

According to Leer *et al.*, (1998: 9), people and apparatus are fallible and in any activity performed is the possibility of it being inaccurate. It seems unlikely that any individual can carry out even a routine procedure repeatedly without eventually making a mistake. For example, a person cannot go to work everyday over a career of approximately 40 years and

handle computers, calculators and highly specialised equipment without ever making a mistake. If a mistake is made in radiation therapy it presents unique challenges in the regard that the radiation cannot be seen, heard, smelled, felt, or tasted (Leer *et al.*, 1998: 9).

This chapter provides a brief orientation of the study. The study will be outlined in the various categories of importance. This incorporates the introduction to the study, audits and inquisitions, adverse incidents, the problem statement, the research objectives, outcome of the study, significance of the study, research methodology, statistical analysis and data presentation, ethical aspects, manpower and infrastructure, the arrangement of the dissertation and the conclusion.

1.2. AUDITS AT THE ONCOTHERAPY DEPARTMENT OF UNIVERSITAS ANNEXE

Representatives from the International Atomic Energy Agency (IAEA) visited the Oncotherapy Department at Universitas Annexe (the department), Bloemfontein in 2004 as part of their investigation of radiation therapy departments in South Africa. In the report, they concluded that the centre is suitable to perform the functions that the IAEA requires from an oncology centre of competence (IAEA Report, 2004).

However, they did find the lack of portal imaging as a routine verification of field set-up, surprising. It was acknowledged that the lack of resources barely allowed for the use of X-ray films. At the time of the study , two of the four linear accelerators, the Elekta SL25 (Elekta Limited SL25, 2003) and the Elekta Precise (Elekta Limited, 2003), have been equipped with portal imaging and a third one, the SL75-5 (Philips Radiotherapy Systems SL75-5, 1988) is in the process of being fitted with a portal imaging device (IAEA Report, 2004).

The IAEA representatives also noted that International Commission of Radiation Units and Measurements (ICRU) reports are not followed for reporting adverse incidents, according to international standard. However, there is a high level of consistency within the department for dose specification and reporting of radiation treatment (IAEA Report, 2004).

The department was audited and accredited by the Council of Health Service Accreditation of South Africa (COHSASA) in March 2004. COHSASA assists health care facilities to meet quality standards and maintain those standards once they have been achieved. Through its quality improvement methods, the organisation empowers health care professionals to measure themselves against their quality standards and monitor the improvements. COHSASA inspected the treatment, the method of treatment and the quality of the treatment that the patients received. Their overall impression of the department was agreeable and they concluded that the treatment received by the patients was up to standard (COHSASA Report, 2004).

The findings from these audits and conclusions point to the fact that the quality of the radiation treatment at the department, adheres to the standards of COHSASA but, that quality aspects, such as the reporting procedures, can be revised and formalised in a QC procedure manual for the department.

1.3. ADVERSE INCIDENTS

The fact that radiation treatment preparation and delivery consists of various links like the localization, simulation, dosimetry and the treatment of the tumour, with each link comprising of approximately 50 parameters for every treatment field, makes it a complex treatment process that may generate errors in every step (Van Esh, Bogaerts, Kutcher & Huyskens, 2000: 110).

The transfer of data at the simulator, treatment planning system, 'record-and-verify' (RV) system and the radiation treatment unit is prone to errors that will vary between departments depending on the organisation, equipment, information generation and transfer as well as error handling and documentation of a department. The development of improved control and quality mechanisms is necessary due to the ever-increasing complexity of the radiation treatment process that leads to an increased probability of adverse incidents (Van Esh *et al.*, 2000: 110).

Adverse incidents leading to the inaccurate delivery of radiation treatment to a patient can occur at any of the numerous complex processes used to reach the planned end result of the treatment. This can include the diagnosis of the patient, the choice of treatment by the oncologist, the planning of the treatment, the manufacturing of the shielding and bolus used in the radiation treatment and the delivering of the treatment itself.

Over a period of six months an estimated 12 000 radiation treatment fields are used to treat an average of 130 patients every weekday from Monday to Friday at the Radiation Therapy Department of the Universitas Annexe. Although every step of the radiation treatment process is checked and double-checked by the radiation therapists, as well as the medical physicists, there is still ample opportunity for errors to be generated.

According to the American Association of Physicists in Medicine (AAPM) Radiation Therapy Committee Task Group 40 the International Commission of Radiation Units and Measurements (ICRU) recommends that the radiation dose delivered to the patient should be within 5% of the prescribed total radiation dose. Bearing in mind the many steps and parameters involved in delivering radiation dose to the intended target volume in a patient, each step must be performed with an accuracy much better than 5% to achieve the ICRU recommendation (Kutcher, Coia, Gillin, Hanson,

Leibel, Morton, Palta, Purdy, Reinstein, Svensson, Weller & Wingfield, 1994: 584).

A systematic approach, with formalised and comprehensive quality systems and programmes, is necessary for the carrying out of radiation therapy. This is due to the increasing complexity of radiation therapy techniques as well as some recommendations following reported adverse incidents. The implementation of a good quality system can be a tool for reducing the frequency and effects of adverse incidents and thus providing good quality radiation treatment (Leer *et al.*, 1998: 9).

1.4. PROBLEM STATEMENT

Although QC procedures relating to the set-up and execution of radiation treatment are followed on a daily basis, the lack of formal written QC protocols to use as a standard for the delivery of radiation treatment at the department is a concern. Procedures to record and report any adverse incidents leading to inaccurate delivery of radiation treatment do not currently exist at the department. This was also concluded by the IAEA and COHSASA during their audits and inquiries (IAEA Report, 2004) (COHSASA Report, 2004).

1.5. AIM OF THE STUDY

The aim of the study was to identify deviations from the planned daily quality activities and to have corrective actions in place, which can be immediately initiated in the event of any deviations being observed. The objective is to set up QC methods, which can be followed on a daily basis and are designed to minimise the occurrence and consequences of any actions, which could potentially affect the intended outcome of the radiation treatment of the patient (Leer *et al.*, 1998: 74).

1.6. RESEARCH OBJECTIVES

The objectives of this study:

1. Determine the origin and frequency of adverse incidents leading to inaccurate delivery of radiation therapy to patients at the Oncotherapy Department, Universitas Annexe, Bloemfontein and classify these adverse incidents as major or minor adverse incidents.
2. Compare the results of the study with other radiation therapy centres that have published information on the prevalence of adverse incidents in radiation therapy delivery.
3. Develop a QC procedure manual that will focus on the responsibility of radiation therapists in QC and assurance procedures. The QC procedure manual will contain guidelines to reduce and / or eliminate adverse incidents leading to inaccurate delivery of radiation during the course of radiation treatment of a patient. It will also outline the role of the radiation therapist in QA at the department.

1.7. OUTCOME OF THE STUDY

Information obtained from the study will be used as a basis to compile and design a QC procedure manual for the department. Through the assessment of the origin and frequency of adverse incidents during radiation therapy at the department an adverse incident report procedure and form was designed to assist in the monitoring of deviations and need for improvements in the daily QC methods. These results were then incorporated in the QC procedure manual, which will assist in the identification and documentation of adverse incidents. Implementing the QC procedure manual will ultimately reduce and/or eliminate adverse incidents to improve the quality of radiation treatment delivered.

Procedures and / or protocols in this manual have the aim to support a more accurate and effective radiation treatment delivery with an overall enhancement in the quality standards of the treatment. This QC procedure manual includes the responsibilities of radiation therapists regarding QC procedures during the course of radiation treatment of a patient. According to Roth, Roser, Brunner & Sander (1998: 84) QC is one of the biggest components of QA and thus with the improvement of QC procedures, the study will contribute to the advancement of the QA management system, with the focus on the treatment delivery process.

The results of the study will be used for the completion of a dissertation for a Masters Technologiae qualification. The data will also be published.

1.8. SIGNIFICANCE OF THE STUDY

The focus of this study is to address the incident prone areas in treatment delivery to patients and to identify the adverse incidents leading to the inaccurate delivery of radiation therapy. This means that a radiation treatment to a patient deviated from the prescribed treatment to the target volume. In addition, the information collected from the above-mentioned was used to compile a QC procedure manual.

This QC procedure manual will provide the department with an effective method of reporting adverse incidents and finding ways of improving radiation treatment delivery with the minimum number of adverse incidents. It will also facilitate superior radiation treatment delivery at the department.

1.9. RESEARCH METHODOLOGY

A clinical audit on adverse incidents was performed at the department from January 2007 to end of June 2007. For a period of six months, any adverse

incidents occurring during the radiation therapy of a patient at the department were monitored.

1.9.1. Adverse Incidents

As previously discussed, all the steps involved in the delivery of the radiation therapy to a patient should be carried out with accuracies much better than 5% to achieve the ICRU recommendation for the total radiation dose to be within 5% of the prescribed total radiation dose (Kutcher *et al.*, 1994: 584). If an incident occurs that causes a deviation from the prescribed radiation dose it can be referred to as an adverse incident. An adverse incident with a deviation of less than 5% from the prescribed radiation treatment protocol still falls within tolerance and acceptable limits, as recommended by the ICRU and are referred to as a minor adverse incident. A deviation of more than 5% from the prescribed radiation treatment is referred to as a major adverse incident (Kutcher *et al.*, 1994: 584).

These adverse incidents include any events that result in a deviation from the prescribed treatment and according to Swann-D’Emilia, Chu & Daywalt (1990: 186) can be categorised as the following:

- Errors in dose calculations;
- Incorrect use of shielding, wedges, field sizes, gantry angle collimation or bolus;
- Incorrect patient positioning;
- Treatment unit malfunctions during treatment that results in a deviation from the prescribed dose.

1.9.2. Adverse Incident Report Form

An adverse incident report form (See Appendix 2) was designed to capture the relevant information about any adverse incidents that came about. This document provides a description of the adverse incident, the origin of the adverse incident and steps taken to correct it. Upon identification of an

adverse incident, the radiation therapist in charge of the sub-section should immediately complete the adverse incident report. The adverse incident was then reported to the oncologist in charge of the treatment of the patient. The oncologist and the reporting radiation therapist both signed the report (See Appendix 2).

1.9.3. Data Collection

The adverse incident reports were filed at the treatment units and the researcher collected the forms weekly. The adverse incidents were recorded on data forms (See Appendix 3) on which the adverse incidents were divided into major (>5%) and minor (<5%) categories (See 1.9.1.). Discussions were held where the adverse incident, the origin and preventative steps were reviewed with all personnel involved. Minutes of the meetings were taken and kept for future reference and corroboration of the study. The information obtained from the adverse incident report forms and the meetings was incorporated in the QC procedure manual.

1.9.4. Data Processing

An analysis of the documented adverse incidents was done by examining the magnitude (quality) of the adverse incident and categorising it into major and minor adverse incidents. The expertise of a medical physicist was obtained in the categorising of adverse incidents. The importance of an individual adverse incident was determined by the deviation from the prescribed dose. Any deviations of less than 5% from the prescribed treatment was classified as minor adverse incidents while deviations of more than 5% was classified as major adverse incidents. This classification was done according to the ICRU recommendation (Kutcher *et al.*, 1994: 584).

A quantitative analysis was done by taking into consideration the number of adverse incidents reported. Data forms were completed where the

occurrence of the adverse incidents was noted and the adverse incidents were divided into major and minor categories (3.2). The results obtained from this study were then compared with other centres that have published articles in this field.

1.9.5. Preliminary Investigation

A preliminary investigation was done over a period of eight months in 2005 to determine whether an extensive investigation was feasible. The efficiency of the adverse incident report forms was also established. From February 2005, preliminary adverse incident report forms that have been completed with the occurrence of any actions leading to deviations from the prescribed radiation treatment were collected monthly and quantitative analyses of the documented adverse incidents were done.

The results obtained from the preliminary investigation illustrated that a more extensive investigation was justified and would be welcomed at the department. It was also evident from the preliminary investigation and feedback that the original adverse incident report forms needed some adjustments (See 3.2.5. for more detail).

1.9.6. Quality Control Procedure Manual

A written QC procedure manual was developed, for the radiation therapists, which detailed the quality procedures, the frequency at which these quality procedures needed to be performed, the action criteria that should be followed to apply the procedures, the records that should be kept and the responsibility to perform these procedures in the department.

A framework of all the QC protocols, applicable to radiation therapists, regarding the treatment units, the planning systems, dose calculations, treatment files, the actual radiation treatment and patient care were established through utilizing the guidelines given by the AAPM Radiation

Therapy Committee Task Group 40 in their report on Comprehensive Quality Assurance for Radiation Oncology (Kutcher *et al.*, 1994: 583-615). This framework together with the information acquired from the monitoring and investigation of the reported adverse incidents were used in conjunction with the knowledge obtained from the literature study on quality assurance and quality control in the development of the QC procedure manual.

1.10. STATISTICAL ANALYSIS AND DATA PRESENTATION

A quantitative analysis of the documented adverse incidents was done to determine the frequency of the adverse incidents in their different categories. A proportional test was done to determine the statistical differences in comparison with other centres that have published articles in this field.

Tables and graphs were used in the presentation of the results. Frequency distribution tables will demonstrate the number of observations falling in each class. Graphic presentations of the data will be done to demonstrate the data's general structure and to emphasize and reveal trends and relationships more distinctly (Lues, 2002: 20).

1.11. ETHICAL ASPECTS

The proposal was submitted to the Ethics Committee of the University of the Free State for approval and to determine if it falls within an appropriate code of practice. It received the necessary clearance and was provided with the following ethics code: ETOVS 33/06.

1.12. MANPOWER AND INFRASTRUCTURE

A complete functioning Oncotherapy Department with all the apparatus and personnel was needed for this study. Permission to conduct the study was obtained from the head of the department (See Appendix 1). This department was available and fully co-operative. This includes all the pre-treatment and treatment units as well as the personnel (radiation therapists) who were willing to take part in the QC study and documented any adverse incidents.

1.13. ARRANGEMENT OF DISSERTATION

Chapter One – This chapter includes a brief overview of the study that includes the problem statement, research objectives, outcome, significance, research methodology, ethical aspects, manpower and statistical analysis of the study.

Chapter Two – An in depth overview from the literature are given about QC in radiation therapy and all the aspects of importance to the study are addressed.

Chapter Three – In this chapter the research design and methodology are explained in detail. All aspects of how the study was performed are illustrated.

Chapter Four – This chapter includes the presentation of the results. A qualitative and quantitative analysis of the reported and documented adverse incidents is done. Frequency distribution tables and graphic presentations are used to demonstrate the results of the qualitative analysis and the proportional tests.

Chapter Five – A written QC procedure manual was developed which details the QC procedures, their frequency, the action criteria, the records and the personnel required to perform them. The study is concluded and future recommendations are made.

1.14. CONCLUSION

The delivery of treatment in an accurate and consistent manner is by no means easy to achieve. The radiation therapy process is a complex interweaving of a number of related tasks for designing and delivering radiation treatment to the patient. Chapter 1 offers a glimpse into this world of radiation therapy and a little insight into the study.

In Chapter 2, the literature review will be discussed. The areas touched on in the literature study in Chapter 1 will be explored and discussed in Chapter 2. An in depth overview will be given about QA in radiation therapy and all the aspects of importance to the study will be addressed. This includes radiation therapy, treatment volume, areas of radiation therapy, the role of the radiation therapist in QA procedures, categories of adverse incidents, QA, quality systems, the QC procedure manual and previous related studies.

CHAPTER 2

LITERATURE OVERVIEW

2.1. INTRODUCTION

Chapter 2 provides a literature overview about QA and QC in radiation therapy and the aspects of their relevance to the study. Included in this overview is radiation therapy, treatment volume, the radiation therapy process, the role of the radiation therapist in quality procedures, accuracy in radiation therapy, QA, QC system, adverse incidents and reporting, the QC procedure manual and related studies.

The literature study was done by utilising internet resources, the Central University of Technology of the Free State library resources, the Oncology Department Universitas Annexe resources, various medical and oncology journals, the University of the Free State library and intranet resources and by doing a NEXUS search. This included a computer-based search of 'Google' and 'Google Scholar' search engines and a 'PubMed' search of the e-journal collections on radiotherapy, medical physics and nuclear medicine were performed. Keywords used during the literature search were radiation therapy, radiation therapy incidents, QC in radiation therapy, QA in radiation therapy, accidents during radiation therapy, QC procedure manual and the role of radiation therapists in QA.

2.2. RADIATION THERAPY

Radiation is not a new man-made invention of the technological age. It has always been there and is as old as life itself and ever-present in the evolution of life on earth. What is man-made however is the *additional* radiation that humans are subjected to, but which is largely due to medical purposes (Moss & Cox, 1989: 1). X-rays were discovered by Roentgen in

1895, Becquerel discovered radioactivity in 1896 and radium was isolated by Curie in 1898 (Faithfull & Wells, 2004: 71). Although ineffective, radiation therapy was used on patients soon after these discoveries. Systemic research was done at the Institute Curie in Paris from 1919 until 1930 which improved the effectiveness of radiation therapy considerably (Tubiana *et al.*, 1990: 174). Today, radiation therapy plays an integral role in the curative and palliative treatment of cancer (Griffiths & Short, 1994: 1). Chapman & Hall (1997: ix) confirm this by saying that radiation therapy is the backbone of most cancer care. It has been estimated that one-third of all cancer patients will be cured if the best available (optimum) method of treatment were used.

So what exactly is radiation therapy? It is the treatment of disease, primarily malignant tumours, through the utilisation of electromagnetic and particle radiations in the form of external beam radiation and/or radioactive sources into the body cavities, which is known as intracavitary or intraluminal radiation therapy (Griffiths & Short, 1994: 1). When a malignant tumour is exposed to a specific radiobiological pre-determined amount of radiation the tumour will be destroyed due to the effects of the exponential cell kill. Frequently dividing normal tissue cells adjacent to the radiation area will also be killed. However, the tumour may be locally destroyed without serious damage to the normal tissue cells by planning the radiation treatment so that the tumour receives the highest possible amount of radiation with the lowest possible amount of radiation to the normal surrounding tissue. Normal tissue cells have a higher capacity for recovery and if the radiation therapy is fractionated or spread out the normal tissue can recover between treatments (Griffiths & Short, 1994: 2).

Thus, an intended target volume are meticulously selected to provide sufficient coverage of the tumour volume and any relevant surrounding margins, which includes any microscopic spread and patient movement

variations, in the radiation treatment area. An adequately high dose of radiation is delivered to this intended target volume while taking into consideration the probability of complications in the normal tissues surrounding the target volume. It is a multidisciplinary speciality that calls for the use of complex equipment and procedures for the assessment, planning and delivery of the radiation treatment (Leer *et al.*, 1998: 5). Each step in this process involves cooperation, liaison and mutual respect between the different staff groups if the patient's progress is to be as seamless as possible (Faithfull & Wells, 2004: 6).

The main areas related to radiation therapy practice are anatomy and physiology, oncology, radiobiology, radiation physics and equipment, radiation protection, radiation therapy planning and technique and patient care, and are all linked through the different phases of the radiation treatment process. The prescription of the radiation treatment dose, the treatment plan, and radiation treatment delivery must be done accurately and appropriately to achieve tumour cure with the minimum normal tissue damage. The patients have to be closely observed and monitored for any signs indicating intolerance to the radiation treatment regime (Griffiths & Short, 1994: 3). Radiation therapy complications may present themselves as early complications or late complications. Early complications can be observed during or directly after the radiation treatment course whilst the late effects of the radiation treatment usually emerge between 12 and 24 months after the radiation treatment (Thwaites *et al.*, 1995: 62).

According to Faithfull & Wells (2004: 6), a technically successful course of radiation therapy is dependent on a number of factors. The clinical target volume (CTV) has to be identified and evaluated correctly. Then the planning target volume (PTV) has to be carefully selected and defined before a radiation treatment plan is designed to deliver a uniformly high dose of radiation to the PTV while taking into consideration the critical structures

and the normal surrounding tissue. This radiation dose has to be given in the correct fractionation schedule until the optimal dose has been delivered. All of this has to be performed accurately with the patient in the correct radiation treatment position and with effective patient immobilization to ensure consistent patient set-up and exact radiation treatment delivery.

2.3. RADIATION TREATMENT VOLUME

The fundamental aim of radiation therapy is the delivery of a high dose to the target volume to control the initial malignant disease. The initial malignant disease has to be controlled whilst keeping the dose to the normal surrounding tissue to a minimum to reduce the risk of damage to the normal tissue, which makes the planning and delivery of radiation therapy a multistep process that is patient and tumour specific (De Vita, Hellman & Rosenberg, 2005: 534) (Mijnheer, Mills & Thwaites, 2007: 408).

The anatomical volume that needs to be treated with radiation therapy are determined by taking into consideration the clinical and surgical findings during the staging process, the extent of the tumour and the typical area of microscopic involvement (Peckham, Pinedo & Veronesi, 1995: 703). This area can be described as the volume occupied by the mass of tumour and is referred to as the gross tumour volume (GTV) (Griffiths & Short, 1994: 152). The GTV can include the demonstrable primary tumour, involved lymph nodes and/or metastatic disease (Kahn, 2007: 117).

Another biological border is then added to the GTV as an oncological safety margin to ensure that any clinically undetectable cancer cells are included in the treatment volume. This margin is referred to as the clinical target volume and is determined by the tumour characteristics (Peckham *et al.*, 1995: 703). There can be multiple variations during the course of radiation treatment. The patient may lose or gain weight and that can result in a

change of the patient's structure. Rectal or bladder filling can occur as well as changes in the size of the tumour. Breathing, swallowing, bowel movements and chest movements can also occur during the actual radiation treatment. To compensate for these movements internal margins are added to the CTV and are called the internal target volume (ITV) (Kahn, 2007: 117).

It is of utmost importance that the radiation dose applied to the CTV is sufficient to ensure adequate tumour control and to minimise the risk of recurrence (Tschirley, Beier & Wust, 1999: 1). Thus, yet another border, the planned target volume (PTV), is added to the ITV. This border compensates for technical uncertainties that are caused by potential localisation errors, incorrect simulation procedures and difficulties with the reproducibility of the treatment positions (Peckham *et al.*, 1995: 703). This makes the planning and delivery of radiation therapy patient and tumour specific (De Vita, Hellman & Rosenburg, 2005: 534).

Taking into consideration that a high dose of radiation needs to be delivered to the PTV while, the dose to the normal surrounding structures and tissues should be kept to a minimum, it is evident that strong demands are made on the accuracy and precision of every step involved in the process of radiation treatment delivery. This, in turn, leads to an emphasis on the QA and QC on all of the steps, processes and equipment involved in the delivery of radiation treatment (Leer *et al.*, 1998: 5).

2.4. THE RADIATION THERAPY PROCESS

The multifaceted interlinks between the numerous related tasks necessary for the design and delivery of the radiation treatments makes the accurate and consistent delivery of radiation therapy very challenging (Kutcher *et al.*, 1994: 583).

In order to determine the extent of the disease patient-specific information is acquired from numerous diagnostic imaging sources such as conventional radiography, computerised tomography (CT), sonography, magnetic resonance imaging (MRI) and nuclear medicine imaging (NMI) (Kutcher *et al.*, 1994: 583). Once the decision to treat the patient with radiation therapy has been made, the patient is simulated or localised. Diagnostic patient-specific information and parameters are fused to determine the size, extent and location of the target volume in relation to the surrounding normal tissue and the external anatomical landmarks. Radiation therapy simulators and CTs are used for this process as well as for the simulation of the treatment plan (Fraass, Doppke, Hunt, Kutcher, Starkschall, Stern & Van Dyke, 1998: 1776).

A treatment planning system (TPS) is used in conjunction with the CT to determine the delivery of the radiation dose to the patient. The TPS consists of three-dimensional imaging and software algorithms that require beam entry parameters for an exact match between calculated and measured data. This represents the radiation characteristics of the radiation treatment units that then give an accurate dose distribution of the planned radiation dose delivered to the patient (Kutcher *et al.*, 1994: 583). The increased demand and introduction of additional devices and new radiation treatment procedures and techniques increases the complexity of the radiation therapy process and subsequently the potential for error (Klein, Drzymala, Purdy & Michaelski, 2005: 82).

Accurately calibrated radiation treatment units, which match the TPS, together with treatment aids (e.g., bolus and shielding) and appropriate immobilisation devices are required to administer the planned radiation treatment in the planned radiation treatment position to the patient. A record-and-verify (RV) system, electronic portal imaging (EPI) and

verification imaging (VI), and in vivo dosimetry (IVD) are then used to verify the correct delivery of the radiation treatment (Kutcher *et al.*, 1994: 584). Adequate quality control and assurance must be in place and committed to, to produce radiation treatment plans of the highest quality and to delivering them accurately and precisely. Only then will all the advances in the technology of radiation therapy translate into improvement in clinical results (Cox & Ang, 2003: 546).

Maintaining complication rates within acceptable limits while delivering the highest possible tumour control rates, requires a very high accuracy of radiation therapy (Mijnheer *et al.*, 2007: 408).

2.5. ROLE OF THE RADIATION THERAPIST IN QUALITY PROCEDURES

Radiation therapists are highly skilled professionals, qualified by education, with specific planning capabilities learnt on-the-job, to provide radiation therapy-related services under supervision of a radiation oncologist. They are responsible for radiation treatment planning and the accurate administration of the radiation treatment, prescribed by the radiation oncologist, through the utilisation of specialised radiation treatment apparatus. They have a major role to play in ensuring that accurate and appropriate planning and treatment techniques are used, and in developing and improving the practice of radiation therapy (Duggan, Kron, Howlett, Skov & O'Brien, 1997: 297) (Kutcher *et al.*, 1994: 614). The role of the radiation therapist in the various radiation treatment sections is described.

2.5.1. Pre-treatment Preparation

Kutcher *et al.*, (1994: 614) state, that the radiation therapist must understand treatment methods and protocols. S/he must coordinate the necessary procedures to initiate the radiation treatment planning process. The radiation therapist must utilize the data required from the CT and the

simulator to generate two-dimensional and three-dimensional isodose plans. Manual or computer generated dose calculations are also performed by the radiation therapist. S/he has to document and communicate all facets of the radiation treatment plan to the radiation therapy team at the radiation treatment unit and make sure the team has a copy of the plan (Fraass *et al.*, 1998: 1796).

2.5.1.1. The Simulator

The simulator is a specialised diagnostic X-ray unit where the patients are marked for their radiation treatment. The simulator 'simulates' the movements and geometry of the radiation treatment units. Patients are set-up in the correct reproducible radiation treatment position, the radiation treatment is simulated and X-ray films are taken to visualise the anatomy included in the proposed radiation treatment area (Griffiths & Short, 1994: 114). These films are then examined and if approved, prescribed by the oncologist. When the oncologist is satisfied with the treatment position and radiation treatment field of the patient the exact location of the field is anatomically marked on the patient with tattoos. Where the radiation field falls within sensitive noticeable areas like the patient's face, the location of the field centre is given through X, Y and Z axial coordinates. Offcord-treatments, smaller fields and boosters are also marked and controlled with X-ray check films in the same manner as described above.

If a patient receives a three-dimensional co-planar radiation treatment plan the isocentric treatment marks, used for referencing, are transferred onto the patient as stipulated by the radiation treatment planning unit. The exact radiation field arrangements are then set-up according to the radiation treatment plan and control X-ray films are taken to verify the accuracy of the radiation fields and as such the radiation treatment. During this process the patient's separation and tattoo locations are also controlled.

2.5.1.2. Radiation Treatment Planning

The three-dimensional co-planar radiation treatment plans are formulated on three-dimensional computer generated reconstructions of the patient at the radiation treatment planning unit. The radiation beams are positioned around the target volume and 3D beam's-eye view volume dose displays are generated. The radiation beams are then repositioned and/or adjusted accordingly to deliver the required dose to the target volume while sparing the normal surrounding tissue and critical structures. The planning radiation therapist is responsible for the contouring of the patient and the critical structures, the design of the 3D treatment plan and all the technical data and documentation needed to execute the 3D treatment plan at the radiation treatment units (ACR 2006: 970). Radiation treatment dose distributions are also performed at the planning unit when a radiation treatment unit is out of order and the patient has to receive treatment on another radiation treatment unit. For patients with breast cancer dose distributions are done according to the information received from the simulator.

2.5.2. Delivery of Radiation Therapy

The radiation therapist must be able to deliver a planned course of radiation therapy utilising the necessary radiation treatment units, field sizes, gantry and collimator angles, monitor units, shielding, wedges and patient positioning. S/he must verify prescriptions, maintain daily treatment records of the patients and document technical details of the delivered treatment (Kutcher *et al.*, 1994: 614).

S/he must ensure the quality and uniformity of clinical patient data collected and verifies the consistency between the radiation treatment protocol and the radiation treatment delivery (Maciá, Rubio, De Blas, Monfa & Bonet, 1993: 150). Faithfull & Wells (2004: 108) recommend that the clinical progress of the patient must be observed for any signs of complications and the radiation therapist must decide whether it is necessary to consult the

radiation oncologist responsible for the patient. This includes any adverse reactions to the radiation treatment or a progressive deterioration of the patients' physical well-being.

According to Kutcher *et al.*, (1994: 614) as well as Duggan *et al.*, (1997: 297) the radiation therapist must be attentive to radiation treatment unit malfunctions and know the safety limits of the equipment operation. S/he must have a good understanding of the function and utilization of the equipment and all the radiation treatment accessories.

2.5.2.1. Radiation Treatment Units

The actual radiation treatment is delivered to the patient at the radiation treatment unit. After the patient has passed through the simulator and a radiation treatment plan has been configured the end-result is the radiation treatment itself. One radiation treatment consists of a pre-determined amount of fields as established during the treatment planning process. It can range from one to four or even twelve radiation fields per radiation treatment. The radiation therapists at the radiation treatment unit are the front-line operators responsible for the correct and accurate execution of the radiation treatment plan. The patient has to be positioned, the isocentric movements are to be done, any treatment accessories put into place and the numerous machine parameters set and controlled. All this has to be done with an exceptional degree of accuracy (Nuclear Regulatory Commission (NRC) 1995: x).

2.5.2.2. Brachytherapy

The radiation therapist is responsible for obtaining the appropriate verification films at the correct angles to control the position of the sources in order to calculate the dose. S/he must assist in the preparation of the brachytherapy unit where the patient will be receiving the brachytherapy

treatment. S/he is responsible for the verification of the source dwell times and positions for each used treatment channel from the output planning data prior to the treatment as well as the administration of the treatment (Kutcher *et al.*, 1994: 614).

At the Oncotherapy Department at Universitas Annexe, Bloemfontein the brachytherapy procedures are performed at the simulator. This procedure requires a multi-disciplinary team consisting of an oncologist, an oncology nurse, two radiation therapists and a medical physicist. The procedure starts with the insertion of the brachytherapy applicators, the assessment of the applicator position through fluoroscopy, the required adjustments and stabilisation of the applicator position and the control X-ray films. The patient is then carefully moved to the afterloading suite. There the computation of the dose distribution is done to determine the source configurations. These configurations are then programmed into the afterloading system and controlled before treatment is commenced. The treatment details e.g. the source configurations, the total radiation dose received and the applicator types used are then documented in the patients' treatment file (Griffiths & Short, 1994: 223).

2.6. ACCURACY IN RADIATION THERAPY

Radiation therapy should be administered accurately, meticulously and sensibly, as there is little chance to rectify a poorly planned or administered radiation treatment course. Once the radiation treatment has been delivered, it cannot be removed or erased. The planned radiation treatment should include all tumour-bearing tissues and prevent the unnecessary irradiation of normal tissues. This makes accuracy the primary quality and expected outcome of radiation therapy (Khan & Potish 1998: 37).

Treatment preparation and delivery consist of localization, simulation,

dosimetry and treatment with a large number of parameters in each step. Every step and data transfer in the radiation treatment process is error prone and may produce erroneous data. This makes it a very complex and intricate process (Van Esh *et al.*, 2000: 110). Errors will differ from department to department depending on the different equipment, methods and procedures used. Improved QC mechanisms need to be developed to maintain the superior quality of radiation therapy in the face of the growing complexity of the treatment processes (Valentin, 2000: 56).

Correct dose calculations, accurate positioning *and* repositioning are needed to guarantee that the radiation therapy is repeatedly delivered in an optimal and accurate manner (Levitt, Khan & Potish, 1992: 16). The accurate positioning and execution of the fields comprises of field size, gantry and collimator angles, monitor units and the prescribed time as well as the perfect repositioning of the patient with the correct immobilisation devices (Peckham *et al.*, 1995: 703). Numerous technical and physical factors can cause inaccurate definition of the target volume, inadequate treatment planning, unreliable and inconsistent patient positioning, incorrect administration of the dose and the incorrect use of the shielding, wedges, field sizes, gantry angle, collimation or bolus (Levitt *et al.*, 1992: 16).

It is easy to make mistakes in radiation therapy, and uniquely challenging. It is easy in the aspect that it is a routine procedure performed daily on computers, calculators and highly specialised equipment and no person can perform routine procedures daily for approximately 40 years without making one mistake. Radiation therapy mistakes are uniquely challenging because radiation therapy mistakes cannot be seen, heard, smelled, felt, tasted or erased (Leer *et al.*, 1998: 9).

Due to the many steps involved in delivering radiation dose to a target

volume the ICRU recommends that the radiation dose to the patient must be delivered with an accuracy much better than 5% to actually be within 5% of the prescribed dose (Kutcher *et al.*, 1994: 584). Thus, it seems unlikely that each and every patient can be treated without an incident resulting in a deviation from the prescribed radiation treatment.

2.7. QUALITY ASSURANCE

The aim of QA is to assure that the performance of a product or a process will be within the prescribed stipulations (Peckham *et al.*, 1995: 703) and that the desired goals are achieved and fall within the predefined standards (Thwaites *et al.*, 1995: 63). It is an industrial concept that has been tailored and developed to suit the needs of the medical profession (Peckham *et al.*, 1995: 703).

To ensure an accurate and effective treatment it is imperative that QA should be present and performed at all of the various steps, processes and levels of the radiation therapy course. To progress from the initial clinical decision to the actual radiation treatment delivery requires numerous interweaved stages and processes involving specialised equipment, procedures and staff groups. Radiation therapy is a multidisciplinary speciality with an intense need for applicable QA (Leer *et al.*, 1998: 9).

Mijnheer *et al.*, (2007: 4010) found that the absence of or the incorrect application of QA programmes are responsible for most of the radiation therapy incidents. QA has long been present in the physical, technical, dosimetric and treatment delivery aspects of the radiation therapy process. There has been a growing need that QA should broaden its scope and include *all* aspects of the radiation therapy process in an all-embracing integrated approach (Leer *et al.*, 1998: 9). This approach should be systematic where more formalised QC systems and QA programmes will be

necessary due to the ever-increasing complexity of techniques and the associated QA and QC procedures (Thwaites *et al.*, 1995: 63).

QA and risk management goes hand in hand. The probability of a planned objective not being obtained due to the failure of a specific action or system is referred to as risk. Risk can be detrimental to any activity with a precise planned outcome e.g. radiation therapy. The effort to minimize this risk is called risk management (Scalliet, 2006: 275). The incidence of low quality and high risk of errors are directly linked to the time and effort invested into QA. The results of a good quality program will improve immediately when more time and effort are invested into it. Risk management consists of four components: 'identifying the possible sources of risk of failure or malfunction, analysing the frequency of incidents of failure or malfunction, taking corrective action to minimise such failure and monitoring the outcome of such changes' (Khan & Potish, 1998: 140). Thus, by managing the risks effectively good quality is assured.

2.8. QUALITY CONTROL SYSTEM

A QC system describes the methods and procedures by which quality can be guaranteed and can be defined as the organisational structure and responsibilities necessary for implementing QA. A QC system provides a well-documented formal written scheme to ensure that all the key aspects of QA in the department are defined, documented, understood and put into practice (Leer *et al.*, 1998: 9). All the necessary quality procedures are interlinked to facilitate in the communication and co-operation between the various staff groups and treatment process levels and to minimise uncertainty in responsibilities and tasks. A QC system is actually a management system that enables the monitoring of the realization of the quality requirements in the radiation therapy practice in regards with the formal written system (Leer *et al.*, 1998: 9).

According to Roth *et al.*, (1998: 84) QC is a major component of QA and in the general quality improvement of radiation therapy. QC is an important tool in achieving the overall aim of QA, which is good quality radiation therapy and more importantly that good quality patient care are delivered. Patient treatment should be the main objective and incentive for a good quality system to function effectively (Leer *et al.*, 1998: 10).

Quality standards have to be in place and applied in the department before a quality control system can be implemented. If there are no quality standards in place, there is nothing to control and thus a quality control system would be futile. The goal of the quality control system is to ensure that the predefined standards are met. A good quality control system therefore requires good predefined standards regarding treatment methods, treatment protocols and treatment execution (Leer *et al.*, 1998: 10). If no errors, mishaps or incidents are reported through the QC system it confirms the good and correct work performed by the staff. By giving satisfactory feedback and involving the staff in the QC system their motivation can be increased by commending them. The increased motivation is to the ultimate benefit of the patient because the staff will be more focused on their responsibilities (Roth *et al.*, 1998: 87).

Through the correct implementation of specified QC procedures, random and systematic incidents can be detected and prevented in future radiation therapy procedures, thus reducing the probability or the consequences of adverse incidents (Thwaites *et al.*, 1995: 63). However, whilst the adoption of a QC system will indeed fulfil the role of reducing the frequency and effect of incidents, the more fundamental reason for following this approach of QC is to help to provide good quality radiation treatment to the patient (Leer *et al.*, 1998: 13). The ultimate goal of radiation therapy is to improve the outcome of the radiation therapy and the overall quality of life for patients

living with cancer (Chen, Trotti, Coleman, Machtay, Mirimanoff, Hay, Chir, O'Brien, El-Gueddari, Salvajoli & Jeremic, 2006: 1449).

2.9. ADVERSE INCIDENTS AND REPORTING

When a radiation treatment is delivered and it deviates from the prescribed radiation treatment prescription, due to either unit treatment malfunction or human error, it can be referred to as an adverse radiation incident (Swann-D'Emilia, Chu & Daywalt, 1990: 185).

As discussed in 2.6., the ICRU recommends that the radiation dose delivered to the patient should be within 5% of the prescribed total radiation dose (Kutcher *et al.*, 1994: 584). If an incident occurs that causes a deviation from the prescribed radiation dose it can be referred to as an adverse incident. An adverse incident with a deviation of less than 5% from the prescribed radiation treatment protocol still falls within tolerance and acceptable limits, as recommended by the ICRU and are referred to as a minor adverse incidents. A deviation of more than 5% from the prescribed radiation treatment is referred to as a major adverse incident (Kutcher *et al.*, 1994: 584). Duggan *et al.*, (1997: 300) also state that the probability of local tumour control can significantly decrease and the complication rate associated with radiation therapy can be significantly increased with variations greater than 5% from the prescribed radiation treatment.

Any stage of the radiation process and/or any staff group may be responsible for the occurrence of an adverse incident. Critical areas are crossing points between the various staff groups and different stages of the process where good communication and the correct transfer of data are imperative to the success of the radiation therapy process. General human causes of adverse incidents include 'complacency, inattention, lack of knowledge, over-confidence, pressure on time, lack of resources and failure

in communication (Mijnheer *et al.*, 2007: 413). Williams (2006: 1) adds that a lack in checking procedures, failure to update written working practices and a lack of training in the specific field can increase the incidence of adverse effects.

Different researchers used different categories for incident reporting. Swann-D'Emilia *et al.*, (1990: 186) categorise adverse incidents into categories to aid in the examination of the accumulated data. These categories of adverse incidents can be defined as treatment unit malfunctions; calculation errors and treatment delivery errors. Treatment unit malfunction is when a deviation from the prescribed radiation dose occurs due to a malfunction of the radiation treatment unit. Calculation error is a mistake made during the monitor unit calculations or any error on the isodose plan that leads to a deviation from the prescribed radiation dose. Treatment delivery errors are any incorrect action that occurs during the delivery of the radiation treatment and includes incorrect use of the shielding, multi-leaf collimators, wedges, field sizes, gantry angle, collimation, bolus or calculated monitor units. Block fabrication errors are any inappropriate use of shielding due to incorrect block mounting and/or labelling. Calandrino *et al.*, (1997: 272) uses geometrical parameters, energy, block fabrication, data entry, normalization, wedge and tray factor as incident categories. Patton *et al.*, (2003: 51) categorised the incidents according to incorrect patient identification, incorrect data field, incorrect site and incorrect beam modifications and Yeung *et al.*, (2005: 287) classified the source of error as: documentation, absolute dose calibration, treatment planning, patient set-up, patient data management system, machine/accessories fault and miscellaneous. The categories described by Swann-D'Emilia *et al.*, (1990: 186) were initially used in the current study, but as the study progressed, the need for additional categories arose (See Section 3.2.2.).

If a well-designed QC program, with adequate layers of safety is in place

and applied correctly, it will hamper the development of an adverse incident from the original erroneous event (Leer *et al.*, 1998: 74).

According to Patton, Gaffney & Moeller (2003: 51) any adverse incidents should be documented on a technical error reporting form. These forms can then be reviewed immediately or periodically. Immediate review is done for corrective action needed during the radiation therapy treatment course. Periodic reviews of the error report forms are done to assess the overall operations and procedures, to track trends, provide feedback, educate and advocate necessary modifications of policies and procedures to create an environment which allows for general system improvements. Dunn (2003: 52) also suggests that incident-reporting systems can be used to analyze the data collected, interpret it and convey it among the concerned staff groups to lead to an improved quality system that can identify methods to prevent future incidents from occurring. If the reports are not analysed and followed-up it can weaken support for constructive response in future.

Huang, Medlam, Lee, Billingsley, Bissonnette, Ringash, Kane & Hodgson (2005: 1591) used an incident report form in their study that included the patient's name, diagnosis, attending doctor, time in radiation treatment course, place of treatment and reporting therapist. Recommendations on corrective actions were done by a senior radiation therapist and a physicist, as well as methods to avoid such errors in the future. The clinical significance of the error was indicated by the attending radiation oncologist as none, minor, moderate, or severe, with no standard definition of these severity grades.

2.10. QUALITY CONTROL PROCEDURE MANUAL

The accurate completion of a radiation treatment prescription through the correct implementation of radiation therapy techniques, methods and apparatus is the ultimate goal of QA and QC. Through efficient QA and QC procedures, uncertainties in radiation therapy can be quantified to reduce the risk of incidents linked to radiation treatment equipment, acquisition of anatomical data, the design of the radiation treatment plan and the actual delivery of the radiation treatment (Aletti, Bey, Chauvel, Chavaudra, Costa, Donnareix, Gaboriaud, Lagrange, Manny, Ponvert, Rozan, Valinta & Van Dam, 1995: 9).

The study of incidents to determine the origin and cause is an effective tool to determine whether a QC system was in place. It is also useful in illustrating the role of QC systems in reducing the probability of incidents (Leer *et al.*, 1998: 12). Efficient checking procedures can detect adverse incidents before or during radiation therapy. An adverse incident reporting system that forms part of the QC procedure manual can assist in the evaluation of QC systems to determine whether it is up to standard (Yeung, Bortolotto, Cosby, Hoar & Lederer, 2005: 283). Huang *et al.*, (2005: 1591) state that random and systemic errors can be detected by the implementation of good QC protocols. Leer *et al.*, (1998: 13), states that the absence of a QC system, which expects mistakes to be made, contributes to the origin of incidents. Future incidents can thus be prevented or minimised by the investigation of past incidents.

A lack of adequate checking procedures during dose calculations and data transfers can lead to serious systematic errors eluding the system and cause initiating events to progress into actual adverse incidents (Fiorino, Corletto, Mangili, Broggi, Bonini, Cattaneo, Parisi, Rosso, Signorotto, Villa & Calandrino, 2000: 95). A systematic evaluation of the existing QC systems should be done to determine the areas that need improvement. This quality

audit can lead to modifications of the quality systems which results in top quality radiation therapy procedures (Leer *et al.*, 1998: 74).

Bradby (199-: 2) indicates that a QC procedure manual is intended to be used as a facilitation tool to monitor and evaluate the radiation therapy process. It can also be used as a tool to improve the quality and appropriateness of radiation oncology care. It sets mechanisms into place for identifying mistakes before they affect the patients' radiation treatment (Huang *et al.*, 2005: 1591). All employees of a radiation oncology department are responsible for the implementation of a QC plan (Bradby, 199-: 2). It is important to keep in mind that quality should be part of everyday management. Unfortunately, there can never be a single ideal solution because quality issues are not an exact science (Kehoe & Rugg, 1999: 282).

According to Bradby (199-: 2) the aim of a QC procedure manual is to identify ways of improving the effectiveness of radiation therapy by means of a methodical approach to the radiation therapy process through which problems regarding the radiation therapy can be identified, communicated and effectively resolved. Effective systems should be developed for the objective evaluation of the efficiency, safety and accuracy of the radiation therapy. Through this, the risk to benefit relationship for patients receiving radiation therapy can be optimised.

Taking into account particular quality issues, the QC procedure manual can provide a framework and pre-defined structure for QA procedures, tasks and required documentation regarding radiation therapists. It can aid in the safe, efficient and accurate implementation of changes in radiation treatment techniques and protocols (Leer *et al.*, 1998: 10). Mijnheer *et al.*, (2007: 414) state that human error will always occur in any organisation and in any activity but that the existence of a comprehensive, systematic and

consistently applied QA programme will minimize the number of incidents and identify them at the earliest possible opportunity.

The QC procedure manual can ensure that the responsibilities of the radiation therapist are clearly defined and that newly recruited personnel or students are directed towards relevant procedures and work instructions and will aid in their introduction to a new environment (Leer *et al.*, 1998: 10). Thus, a QC procedure manual can offer insurance that the patients receive the intended radiation therapy and that the likelihood of an incident is miniscule.

2.11. RELATED STUDIES

Several searches e.g. literature searches, internet searches and Nexus searches, were performed to locate related published studies. There is an abundance of literature information of general QA in radiation therapy and QA specially aimed at radiation physics and physicists. Very few related published studies specifically on the analysis of incidents during radiation therapy of cancer patients were found.

Patton *et al.*, (2003: 50) also state that there are many publications with extensive literature under the general label of radiation therapy errors but unfortunately it is usually on the subject of patient set-up and reproducibility. This includes patient positioning, organ motion, set-up error and radiation dose determination. Reports addressing radiation therapy treatment mistakes or incidents which include data transfer errors, incorrect patient, incorrect radiation energy, incorrect shielding and treatment unit malfunction are relatively few. These will be discussed next.

In a study about the detection of systematic errors in external radiation

therapy before treatment delivery, performed by Calandrino, Cattaneo, Fiorino, Longobardi, Mangili & Signorotto (1997: 272) over a period of 61 months, from September 1991 to November 1996, in Milan a total of 217 errors were detected. This gives an average of 3.6 errors detected per month.

Swann-D'Emilia *et al.*, (1990: 187) performed a study on the misadministrations of prescribed radiation dose over a period of 24 months from 1988 to 1989 at the Fox Chase Cancer Centre, Philadelphia. In the first 12 months a total of 54 misadministrations occurred, averaging four per month. In the last 12 months a total of 33 misadministrations occurred with an average of three per month.

Williams, Bradnam, McCurrah, Deehan & Johnston (1991: 200) performed a quality audit at Beatson Oncology Centre, Belvidere Hospital, Glasgow, from December 1987 to July 1989 but due to program revisions during the study the last nine months of the study were used for the actual results. They recorded a total of 28 genuine errors during this nine month period. They were presented with a total of 14 incidents with a deviation of 5% or more from the prescribed radiation treatment.

Huang *et al.*, (2005: 1593) performed a study at Princess Margaret Hospital in Canada from January 1, 1997 through December 31, 2002 where the errors in the delivery of radiation therapy were analysed retrospectively. During the study period, there were 28 136 patient treatments delivered to a total of 43,302 treatment regions. There were 555 treatments with detected treatment errors. From July 1, 2000, through December 31, 2002, there were 241 187 fractions delivered, 711 with errors.

Patton *et al.*, (2003: 51) performed a study at the Department of Radiation Oncology at the University of Utah between July 1, 1999 and June 30, 2000.

During this study period a total of 22 542 external beam radiation therapy treatments were performed and 67 339 fields were treated and 38 technical error reporting forms were submitted. These technical error reporting forms were reviewed for a crude radiation therapy error rate of 0.17% of patient treatments administered during this 12-month period. A treatment error was documented in 3.3% of the 1 163 radiation therapy courses administered during this period.

According to Yeung *et al.*, (2005: 287) 13 385 patients have undergone radiation treatment at the Northeastern Ontario Regional Cancer Centre between November 1992 and December 2002. Over this period of time, 624 incidents were reported. The majority of the incidents (42.1%) were related to errors in 'documentation' and most of these could be attributed to 'error in data transfer' or 'inadequate communication'. 'Patient set-up error' accounted for 40.4% of the incidents and about half of these errors were related to shielding. Errors in 'treatment planning' accounted for 13.0% of the incidents. A more in depth discussion will be given in Chapter 5.

2.12. CONCLUSION

When a patient is treated with curative intent, radiation therapy is a very effective method to destroy the tumour in the treatment volume. The maximum radiation dose to the target has to be delivered with minimum damage to the normal surrounding soft tissue in order for the radiation treatment to be successful and to achieve the highest possible local and / or distant tumour control with the minimum amount of side affects (Van Esh *et al.*, 2000: 109). Effective radiation therapy strives for a cure of the tumour and thus the lengthening of a patients' life together with an acceptable quality of life (Chen *et al.*, 2006: 1449).

Accurate radiation treatment delivery is an absolute necessity for effective radiation therapy. The assessment of the standard of the QC system and

the frequency and origin of incidents during radiation therapy as well as the design of a QC procedure manual can result in more effective and advanced quality treatment. The objective of this QC procedure manual is to facilitate in the monitoring, evaluating, and improvement of the quality of radiation oncology care.

In Chapter 3, the research methodology of the study will be discussed. Perspective will be gained in the implementation of the study and the acquisition of the results.

CHAPTER 3

RESEARCH METHODOLOGY

3.1. INTRODUCTION

Basic dosimetry, treatment unit parameters, delineation of the target volumes, planning and calculation methods, the daily set-up of the patients and all the other numerous steps involved in the preparation and execution of radiation therapy can play a role in the risk involved of delivering a absorbed radiation dose to the patient (Van der Schueren, Horiot, Leunens, Rubens, Steward, Van Dongen, Van Oosterom & Vanongelen, 1993: 177). Chapter Three presents an in depth look at the steps involved in the execution of the present study and in attaining the research objectives.

The research objectives of the study were: to determine the origin and frequency of adverse incidents leading to inaccurate delivery of radiation therapy to patients at the department; to classify these adverse incidents as major or minor adverse incidents; to compare these results with other radiation therapy centres that have published information on the prevalence of adverse incidents in radiation therapy delivery; and to develop a quality control procedure manual that will focus on the responsibility of radiation therapists in quality assurance procedures.

This chapter will be reviewing the procedures followed to establish the adverse incidents and to compile a quality control procedure manual designed for radiation therapists at the department. This will include the research design, adverse incidents report forms, adverse incidents, data collection and processing, statistical analysis, preliminary investigations and the design of the quality control procedure manual.

The study consisted of three main parts. The first part was the accumulation of raw data by means of the adverse incident report forms. This part of the

study was quantitative in nature as it was the objective part of the study where the facts were calculable, quantifiable and unprejudiced. Numbers and statistics are used as the collection method for the data and a cause-and-effect correlation could be made (Neill, 2007).

The second part of the study was the meetings that were held and the information gathered from the opinions of the radiation therapists. This part of the research was qualitative in nature. It uses very different processes of gathering information that is much more subjective and e.g. focus groups and the researcher was the 'data-gathering instrument'. It is probing, unrestricted and non-structured and it involves the investigation of data such as words and statements (Neill, 2007).

In the third part of the study the processed data from the first two parts of the study came together to ultimately give rise to the quality control procedure manual. The quantitative and qualitative research were combined with the information obtained from the literature study to produce this manual specifically designed for this department.

3.2. RESEARCH DESIGN

From January 2007 to the end of June 2007, a clinical audit was performed at the department to establish the prevalence of adverse incidents during radiation therapy. For this period of six months, any adverse incidents occurring during the radiation therapy of a patient at Universitas Annexe were strictly monitored.

A meeting was held in January 2007, where the reasons for the reporting of adverse incidents and the method of reporting the adverse incidents were explained to the radiation therapists. The personnel involved were informed that the data collected from the adverse incident reports could be used in an effort to identify and decrease the possibility of adverse incidents such as

those reported during the preliminary investigation (3.2.6). By doing so, the existing quality levels of the delivery of radiation treatment at the department can be addressed and where necessary, improved.

During the period of the study the department consisted of

- Two simulators (Philips Radiotherapy Systems Simulator, 1987) – these are used for the marking of the patients, where the treatment position and fields of the radiation therapy are simulated and recorded on X-ray film.
- One Cadplan planning unit (Varian Oncology Systems CadPlan, 1999) – used to do the three-dimensional conformal planning of the planned target volumes.
- Four linear accelerators: Elekta SL75-14 (Philips Radiotherapy Systems SL75-14, 1986); Elekta SL75-5 (Philips Radiotherapy Systems SL75-5, 1988); Elekta SL25 (Elekta Limited SL25, 2003) and Elekta Precise (Elekta Limited, 2003) – responsible for the actual radiation treatment delivery to the patients.
- One Philips orthovoltage unit – used for the treatment of superficial lesions (Philips Radiotherapy Systems RT 250 (III), 1982).
- One afterloading high dose rate brachytherapy system (Nucletron M/HDR afterloader Ir192).
- One afterloading low dose rate system (Nucletron LDR selectron Cs137) – used for brachytherapy.
- One workshop and plastic laboratory – this is where all additional apparatus, leadshielding and bolus are made that are used during the treatment of the patient.

Due to the malfunctioning of the Computerised Tomography (Somatom Hi-Q) unit – responsible for CT scan images, the patients were scanned at

Universitas Hospital X-ray Department and the data transferred to the planning units.

At the time of the study the above mentioned treatment units were operated by 23 qualified radiation therapists, seven student radiation therapists, three laboratory technicians, four permanent medical physicists, six medical physics students and one engineer in the department. According to the departmental report, an average of 130 patients receives radiation therapy in this department every workday from Monday to Friday. All of these units and personnel were either directly or indirectly involved in the study.

3.2.1. Adverse Incident Report Form

An adverse incident report form (See Appendix 2) was designed, by utilising literature references and departmental experience, to capture the information required for reporting the adverse incident and for corrective actions. From the discussion in 2.9., it is evident that there is a variety of different categories for incident reporting which are used by different researchers. Calandrino *et al.*, (1997: 272), Patton *et al.*, (2003: 51), Yeung *et al.*, (2005: 287) and Swann-D'Emilia *et al.*, (1990: 186) all use a different categories of adverse incidents for reporting.

Upon discovery of an adverse incident, the radiation therapist in charge of the unit completed the adverse incident report form. The radiation therapist in charge was allocated for this task to minimise the 'blame-effect'. It was felt that if the person at fault were forced to complete the adverse incident report forms the subject would become too sensitive and the reported adverse incidents would not be a true reflection of the actual adverse incidents. The date, treatment machine, details of the patients' treatment plan, and where in the treatment regime the patient was at the moment of the discovery of the adverse incident, were completed.

A detailed description of the adverse incident was given with a reason for the occurrence of the adverse incident. If there were any corrective steps to be taken, it was also explained on the form. Any preventative steps that were being taken to prevent a similar adverse incident from occurring were verbalised on the report. The adverse incident was reported to the oncologist in charge of the radiation treatment of the patient. The oncologist and the reporting radiation therapist both had to sign the report (See Appendix 2).

3.2.2. Adverse Incidents

Initially the adverse incident categories recommended by Swann-D'Emilia *et al.*, (1990: 187) were used for the current study and included any event that resulted in a deviation from the prescribed treatment and were categorised as:

- Errors in dose calculations;
- The use of shielding, wedges, field sizes, gantry angle collimation or bolus that is inconsistent with the prescribed radiation treatment;
- Incorrect patient positioning;
- Any treatment unit malfunctioning during treatment that results in a deviation from the prescribed dose.

However, during the course of the study it became apparent that the present study required additional categories for the classification of the reported adverse incidents. Thus, the categories suggested by Swann-D'Emilia *et al.*, (1990: 187) was used in combination with categories described by Patton *et al.*, (2003: 51) and customized according to the needs of the current study.

The reported adverse incidents were categorised as:

- data transfer error (DTE)

- dose calculation error (DCE);
- incorrect field positioning (FP);
- incorrect patient (IP);
- incorrect patient positioning (PP);
- incorrect radiation energy (RE);
- incorrect shielding (IS);
- treatment unit malfunction (TUM).

These classifications were determined by the type of adverse incidents that were reported during the current study.

3.2.3. Data Collection

The radiation therapist in charge of the unit filed the adverse incident reports at the treatment units where the researcher collected the forms weekly. The adverse incidents were recorded on data forms (See Appendix 3). In cooperation and consultation with a medical physicist, the magnitude of the adverse incident was determined and the adverse incidents were then divided into major and minor categories accordingly.

Because the frequency of the monthly meetings was determined by the available time permitted by the workload, the planned monthly meetings were held every second month (see numbering of minutes in Table 3.1). Thus, a discussion, with all personnel involved, was held every second month, where the adverse incident, the origin and preventative steps was discussed. At these discussions, all the radiation therapists present had the opportunity to air their opinions and make recommendations on any corrective actions that could be taken. Minutes of the meetings were kept by the researcher as well as an appointed minutes keeper. These minutes were kept as qualitative data for future referencing, the construction of the quality control procedure manual and to support the study.

Table 3.1 Summary of meetings

Meeting No	Date	Main Discussion Points
1/2007	7 March 2007	Reported adverse incidents Opinions Preventative steps
2/2007	9 May 2007	Reported adverse incidents Opinions Preventative steps
3/2007	4 July 2007	Reported adverse incidents Opinions Preventative steps

3.2.4. Data Processing and Statistical Analysis

After collection of the adverse incident report forms from the radiation treatment units, the details of the adverse incidents were thoroughly studied. The degree of deviation of the adverse incident was determined by calculating the difference between the planned prescribed radiation treatment and the radiation treatment actually given. The expertise of a medical physicist was obtained for these calculations.

After the calculations were made, the adverse incidents were categorised as major or minor according to the ICRU guidelines (Kutcher *et al.*, 1994: 584). The importance of an individual adverse incident was determined by the deviation from the prescribed dose. Any deviations of less than 5% from the prescribed radiation treatment dose was classified as minor adverse incidents while deviations of more than 5% from the prescribed radiation treatment dose was classified as major adverse incidents. The type of adverse incident and the extent of the adverse incident were then meticulously documented on the data forms (See Appendix 3). The adverse incident rate was calculated as one incident report form equal to one

incident with the totality of the incident used for the calculation of the deviation from the prescribed radiation treatment dose e.g. three fractions treatment with a 0.2Gy deviation equals 1 incident with a 0.6Gy deviation from the prescribed radiation treatment dose. All of the information above as well as a summarised version of the adverse incident report forms were used in the presentation and discussion of the results during the meetings that were held.

At the end of the period of the study (June 2007), the completed data forms were reviewed. A quantitative analysis was done by taking into consideration the number of adverse incidents reported, the number of adverse incidents reported in the various categories and the extent of the reported adverse incidents. This was done to determine the frequency of the reported adverse incidents and their manifestation in the different categories. The results obtained from this study were compared with other centres that have published results related to this field.

Following the analysis of the reported adverse incident forms and the data forms, tables and graphs were prepared for the presentation of the data. Frequency distribution tables were used to demonstrate the number of observed reported adverse incidents falling into each adverse incident category. The data's trends and relationships were revealed by utilising tables and graphic presentations. This demonstrated the data's general structure more clearly as well as their proportional relationship to other centres that have published articles in this field (Lues 2002: 20).

3.2.5. Preliminary Investigation

As discussed in Chapter 1, a preliminary investigation was done over a period of eight months in 2005 to determine whether an extensive investigation was feasible. The efficiency of the adverse incident report forms was also established. During these eight months 1 965 patients were

treated with 55 571 radiation fields in 17 868 treatments. A total of 24 adverse incidents were reported. The adverse incidents reported during the preliminary investigation are demonstrated in Table 3.2. according to the different categories. As demonstrated in Figure 3.1 it is evident that no correlation could be found between the number of treatments and the reported adverse incidents.

Table 3.2 Adverse incidents reported during preliminary investigation

2005	Dose	Energy	Field size	Shielding	Incorrect Field	Other	Total
February	1	0	0	0	2	0	3
March	0	0	0	0	0	0	0
April	1	1	1	0	1	1	5
May	2	0	1	0	0	2	5
June	0	0	0	0	1	0	1
July	0	2	2	1	0	0	5
August	0	0	0	0	1	0	1
September	0	0	1	1	1	1	4
TOTAL	4	3	5	2	6	4	24

The results obtained from the preliminary investigation illustrated that a more extensive investigation was justified and will be welcomed at the department. It was also evident from the preliminary investigation and feedback that the original adverse incident report forms needed some adjustments. These adjustments required the adverse incident report forms to be more user-friendly and to generate more effective reporting.

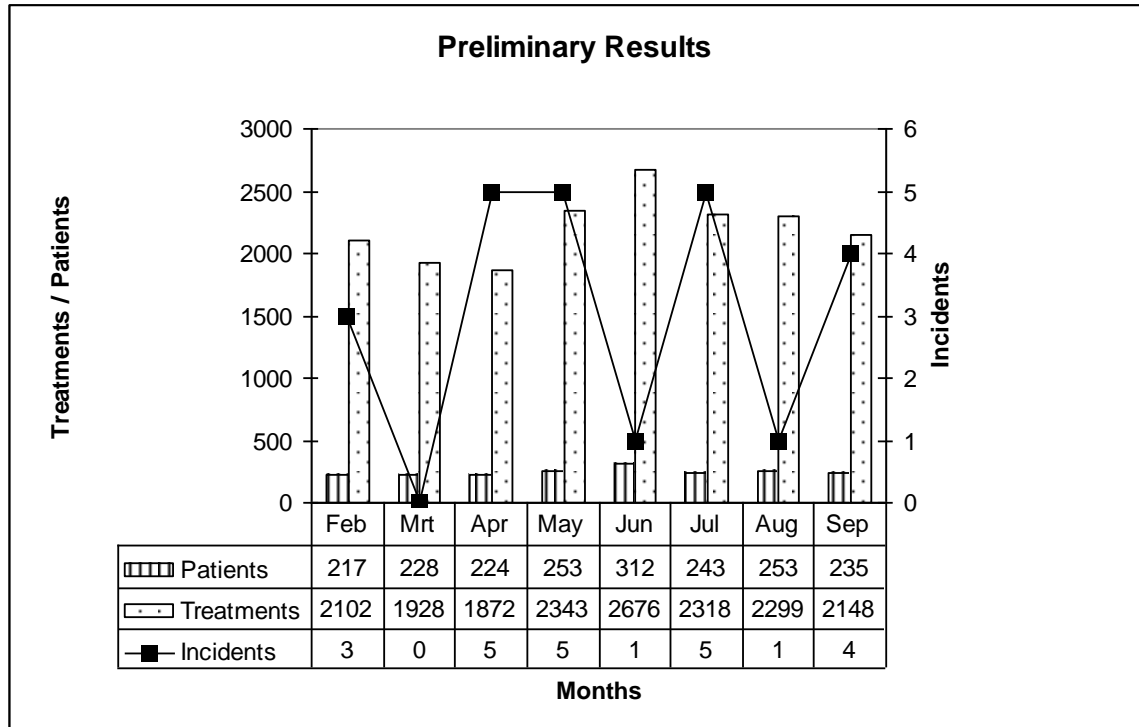


Figure 3.1 Preliminary study results

3.3. QUALITY CONTROL PROCEDURE MANUAL

A quality control system can be defined as the organisational structure, responsibilities, procedures, processes and resources for implementing quality assurance. The general aim of developing a quality control procedure manual is to provide a formal written scheme of the quality system to ensure that all-important aspects of quality control in the department are defined, documented, understood and put into practice (Leer *et al.*, 1998: 7).

3.3.1. Investigation

From January 2007 to end of June 2007 a quality audit of the existing quality control system and the responsibility of radiation therapists in quality assurance procedures, at the department, were done. The quality audit was

performed to identify deviations of quality activities from the planned arrangements and to initiate corrective actions in the event of deviations being observed (Leer *et al.*, 1998: 74).

Leer *et al.*, (1998: 74) state that the objective of a quality audit is to formulate QC procedures that are designed to minimise the occurrence and consequences of any events, which could potentially affect the quality of patients' radiation treatment. These QC procedures are then included in the quality control procedure manual designed for the radiation therapists.

An assessment of all the quality control protocols, applicable to radiation therapists, regarding the radiation treatment machines, the planning systems, dose calculations, radiation treatment files and the actual radiation treatment was done. This assessment was done by making use of the guidelines given by the AAPM Radiation Therapy Committee Task Group 40 in their report of Comprehensive Quality Assurance for Radiation Oncology (Kutcher *et al.*, 1994: 583-615).

These guidelines assisted in the evaluation of the identification of the patient, identification of the treatment target site ('localization'), radiation treatment planning process, simulation of the treatment and placement of body marks (tattoos), the positioning and immobilization during simulation and treatment, data acquisition, contouring, two-dimensional and three-dimensional radiation treatment planning, the radiation treatment prescription, data transfer, the use of correct field sizes, the plan evaluation and computation of monitor units. As well as the use of beam modifiers, plan implementation, QC for individual patients, the radiation treatment plan review, monitor unit calculation review, radiation treatment plan implementation of the first treatment session, the in vivo dosimetry, daily patient positioning and selection of parameters and treatment accessories,

accumulation of doses in the patient's chart and modifications during the course of treatment at the department.

3.3.2. Adverse Incidents

As described by Khan & Potish (1998: 140) in section 2.7 risk management is closely associated with quality assurance. Risk management is achieved by identifying the possible sources of risk for adverse incidents; analysing the frequency of adverse incidents; taking corrective action to minimise such adverse incidents and by monitoring the outcome of such actions.

Thus, the adverse incident report forms were examined and meticulously reviewed to establish the prevalence and nature of the adverse incidents occurring during the radiation treatment of patients. From this it could be established which adverse incidents were more common and the reasons for this occurrence.

During the meetings, the reported adverse incidents were discussed. The distribution of the adverse incidents, possible reasons as well as any corrective actions and preventative steps that were to be taken were deliberated. The information obtained from these meetings was employed in the creation of the quality control procedure manual. It enabled the researcher to gain insight in the problematic areas of the existing quality system of the department and incorporate it into the quality control procedure manual.

3.3.3. Contents

From the information obtained from literature, together with the data gathered during the quality audit and the clinical audit of the adverse incidents, a written quality control procedure manual was developed. This QC procedure manual details and formalises the quality procedures, their frequency, the action criteria and records, and the responsibility of the

radiation therapists to perform them in the radiation treatment department at Universitas Annexe, Bloemfontein.

Once implemented this quality control procedure manual should provide the department with an effective method of reporting adverse incidents and with ways of improving radiation treatment delivery with the minimum number of adverse incidents. It has the potential to facilitate superior radiation treatment delivery at the.

3.4. CONCLUSION

Chapter 3 presented a multifaceted look at the implementation of the study. All the steps involved in achieving the research objectives were reviewed and discussed. This included the clinical audit, the layout of the department, adverse incidents report forms, adverse incidents, data collection and processing, statistical analysis, preliminary investigations and the design of the quality control procedure manual.

In Chapter 4 the findings of the study will be presented. A qualitative and quantitative analysis of the reported and documented adverse incidents will be provided. Frequency distribution tables and graphic presentations were used to demonstrate the results of the quantitative and qualitative analysis of the study as well as a comparison with other published related studies.

CHAPTER 4

RESULTS

4.1. INTRODUCTION

From January 2007 until the end of June 2007 (here after referred to as duration of the current study) 1 093 patients received radiation treatment at the Radiation Department of Universitas Annexe, Bloemfontein. These radiation treatments ranged from straightforward opposing field treatments for palliation to complex multiple field radiation treatment plans with MCPs, multi-leaf collimators (MLC) and motorised wedges for radical treatment.

As discussed in Chapter 1 the objectives of this study were: to determine the origin and frequency of adverse incidents leading to the inaccurate delivery of radiation therapy to patients at the department; to classify these adverse incidents as major or minor adverse incidents; to compare the results of the study with other radiation therapy centres that have published information on the prevalence of adverse incidents in radiation therapy delivery and to develop a quality control procedure manual that will focus on the responsibility of radiation therapists in quality control procedures at the department.

Chapter 4 will include the presentation of the results as well as a short description of each of the units to demonstrate the type of tasks performed. Qualitative and quantitative analyses of the reported and documented adverse incidents were done. Frequency distribution tables and graphic presentations were used to demonstrate the results, the data's general structure and to reveal trends and relationships of the reported adverse incidents. The quality control procedure manual will be presented and discussed in Chapter 5.

4.2. THE SIMULATOR

During the current study a total of 1 918 patients traversed through the simulator. Brachytherapy treatments were given to 417 patients during this period and 1 920 X-ray check films were taken (Figure 4.1).

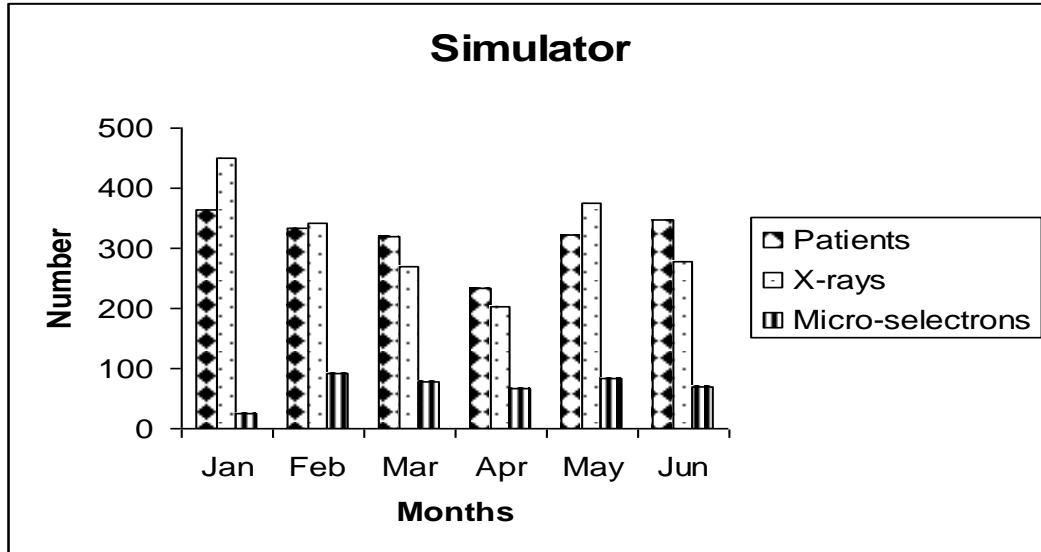


Figure 4.1. Simulator productivity from January – June 2007.

During January 2007 the largest number of patients (365) passed through the simulator and the highest number of X-ray films (451) was taken. February reported the highest number of brachytherapy treatments performed. The lowest number of patients (233) and X-ray films (203) were recorded in April 2007 and just 25 brachytherapy treatments were performed in January 2007 (figure 4.1).

4.3. THE RADIATION TREATMENT PLANNING UNIT

During the period of the study 160 contours were done, 137 distributions were calculated and 250 three-dimensional radiation treatment plans were drawn up. January had the highest total of distributions, contours and 3D

plans that added up to 124. May showed the least amount with 82. This low number is due to the fact that the CADPLAN was out of commission during the last week of May. Figure 4.2 illustrates the monthly distribution of the generated radiation treatment plans and distributions.

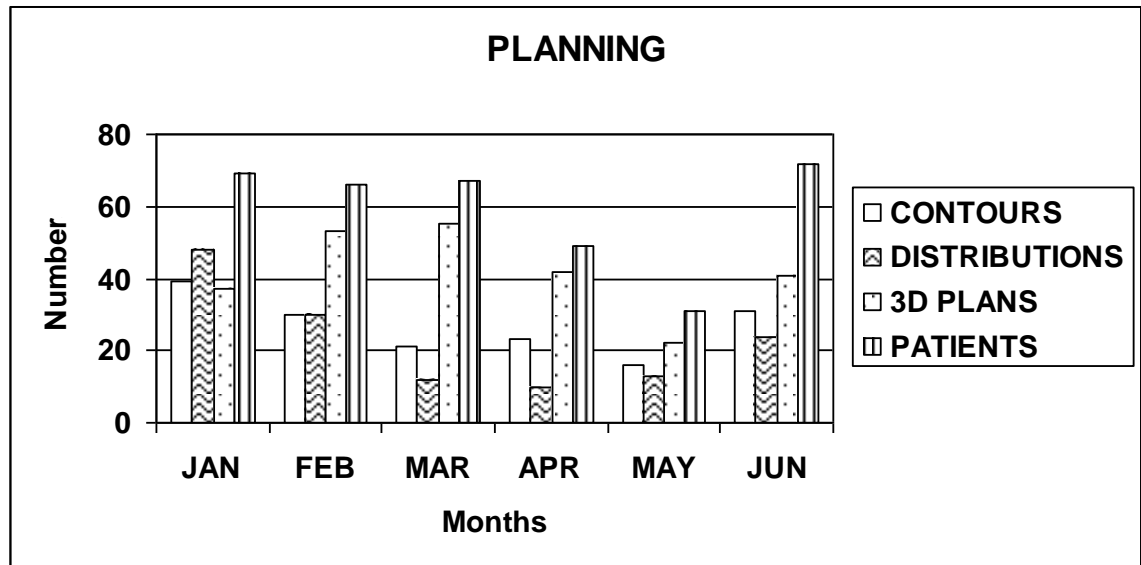


Figure 4.2. Planning unit productivity from January – June 2007.

4.4. RADIATION TREATMENT UNITS

For the duration of the current study a total of 1 093 patients received radiation treatment on the various radiation treatment units. The number of radiation treatments added up to 11 466, consisting of 37 036 radiation treatment fields. One individual radiation treatment can vary from one single orthovoltage radiation treatment field, for superficial skin lesions, to two opposing megavoltage radiation treatment fields, for the palliative patients, to anything up to nine radiation treatment fields, for the radical patients with more complex radiation treatment plans. Figure 4.3 illustrates the monthly distribution of the radiation treatment fields given during this period. It is clearly demonstrated that during February the number of

radiation fields were the highest and during January and April they were the lowest.

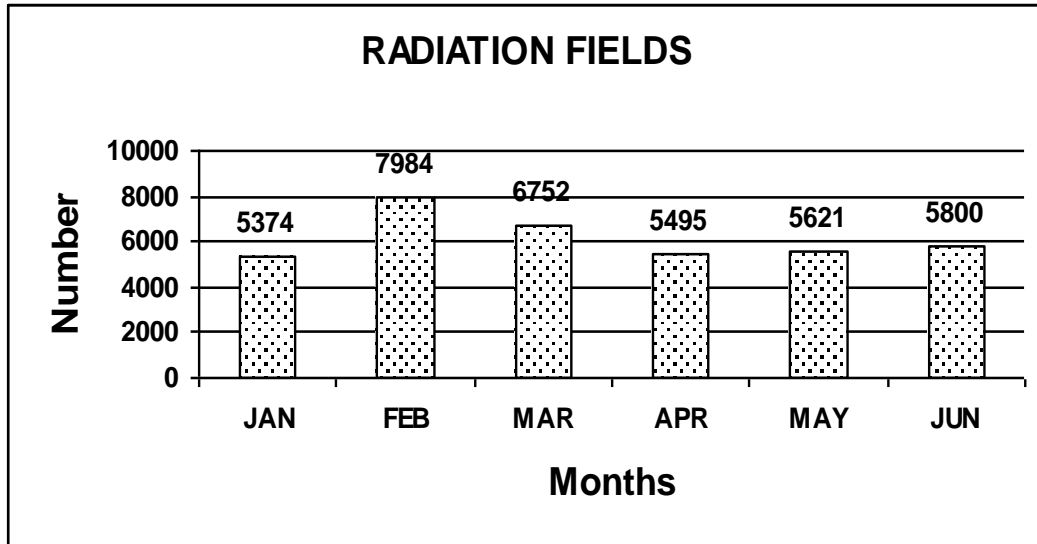


Figure 4.3 Radiation treatment fields delivered from January – June 2007.

With the examination of Figure 4.4 it can be seen that the radiation treatments delivered, exhibits the same trend as the radiation treatment fields delivered, during the period of the study.

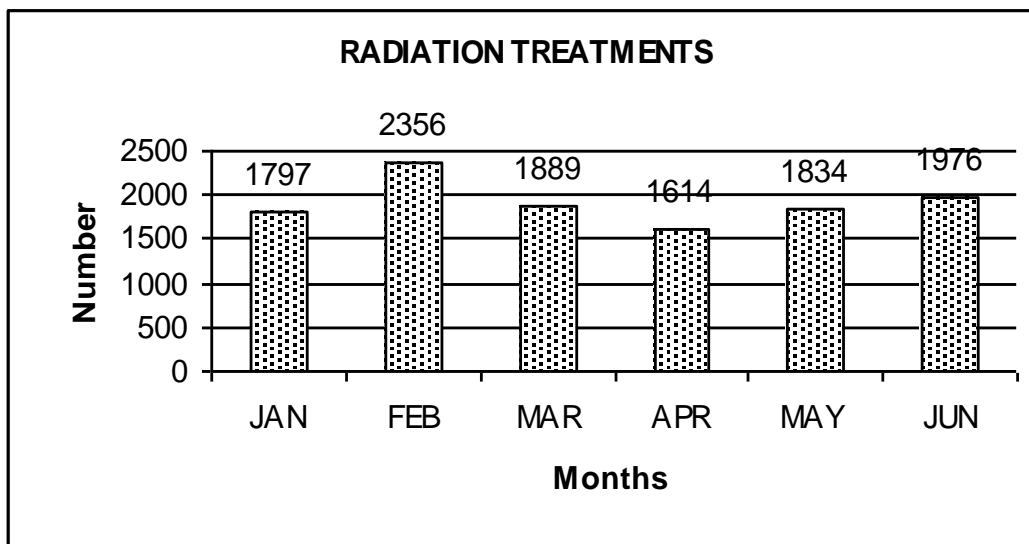


Figure 4.4 Radiation treatments delivered from January – June 2007.

The monthly distribution of the patients that received radiation treatment at Universitas Annexe, Bloemfontein during the study period corresponds with the trends observed in Figures 4.3 – 4.6 regarding the radiation treatment fields and the radiation treatments delivered (Figure 4.5), with February and June having the highest radiation treatment activities.

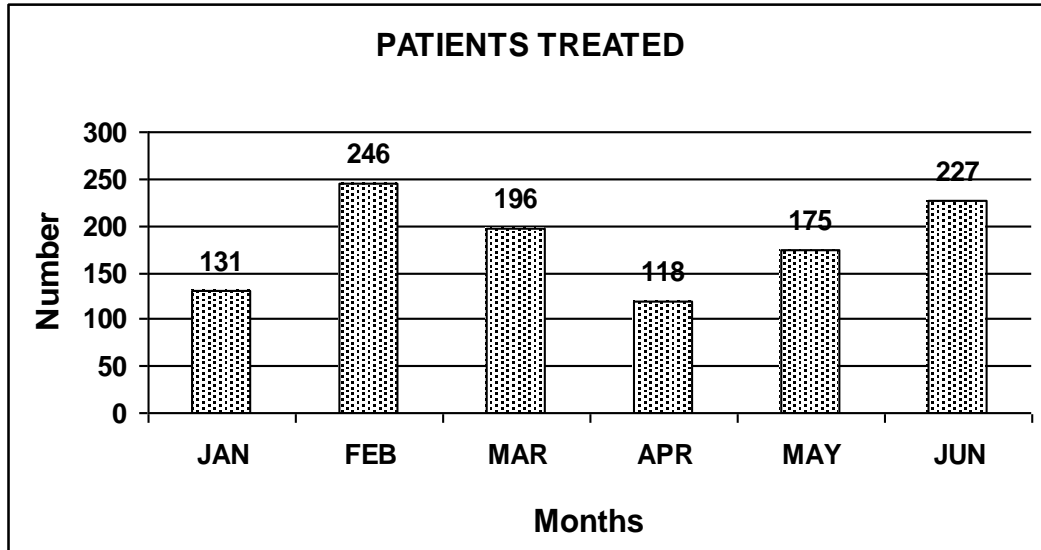


Figure 4.5 Number of patients that received radiation treatment from January – June 2007.

4.5. PERSONNEL

During the period of the study an average of 23 radiation therapists were operational in the department. These 23 radiation therapists had to operate the four linear accelerators, the two simulation units, the planning unit, the orthovoltage unit and the CT unit. Figure 4.6 illustrates the distribution of the personnel on the different sub-categories of the department from January 2007 to June 2007. February had the highest number with 27 staff members performing duties and June the least with 19 staff members. January and February had the least amount of personnel on leave or sick leave with only seven people taking leave during this month. From March to June, an average of 15 staff members was off-duty during each month.

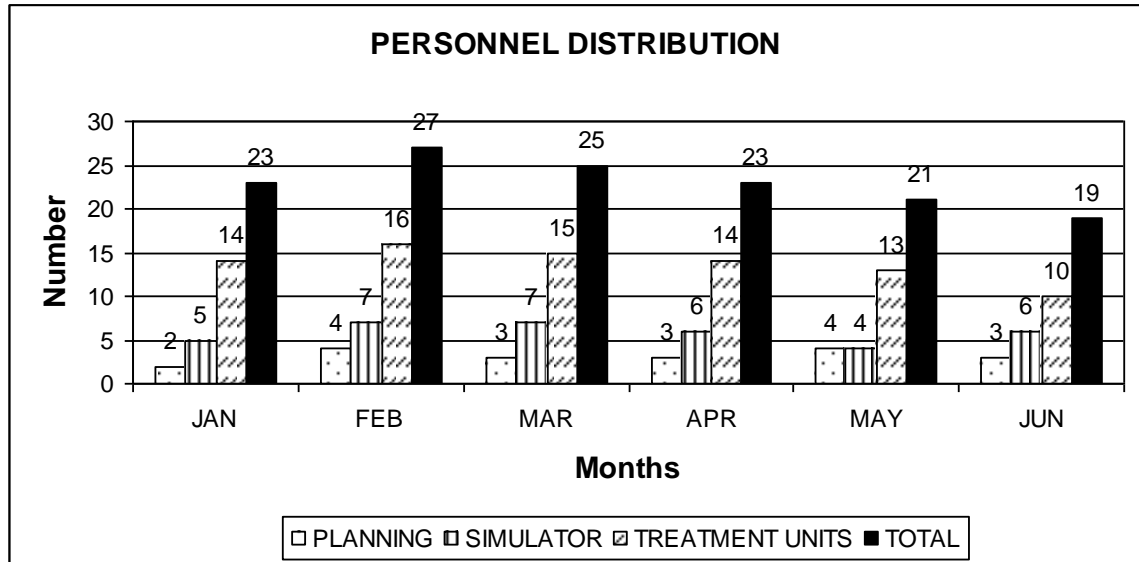


Figure 4.6 Radiation therapists performing duties from January – June 2007.

4.6. DISTRIBUTION OF REPORTED ADVERSE INCIDENTS

During the study and with the accumulation of the data it became apparent that the present study required additional categories to these suggested by Swann-D'Emilia *et al.*, (1990: 187) for the classification of the reported adverse incidents. The reported adverse incidents were categorised as:

- ▤ data transfer error (DTE)
- ▤ dose calculation error (DCE);
- ▤ incorrect field positioning (FP);
- ▤ incorrect patient (IP);
- ▤ incorrect patient positioning (PP);
- ▤ incorrect radiation energy (RE);
- ▤ incorrect shielding (IS);
- ▤ treatment unit malfunction (TUM).

A total of 15 minor adverse incidents were reported. The monthly distribution of the reported adverse incidents during the period of the study manifested itself as follows (Figure 4.7): January 2 minor adverse incidents were reported; February 1 minor adverse incident reported; 2 minor adverse incidents were reported in March; April presented 4 reported minor adverse incidents; in May 1 minor adverse incident were reported and June had the highest reported number with 5 minor adverse incidents.

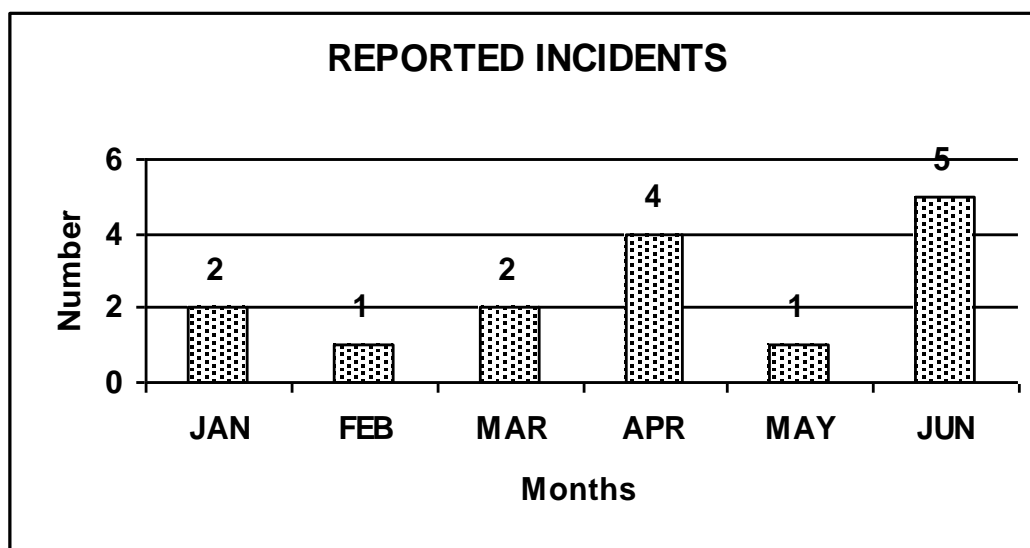


Figure 4.7 Reported adverse incidents during radiation therapy during January – June 2007.

Of the total of 15 reported adverse incidents, 5 were due to errors in dose calculations. Data transfer errors, error in field positioning and incorrect shielding contributed 2 of the total reported adverse incidents each. Treatment unit malfunction, incorrect radiation treatment energy, incorrect patient positioning and the incorrect patient each represented 1 of the reported adverse incidents (Figure 4.8).

Figure 4.8 provides a detailed illustration of the distribution of the reported adverse incidents in the various categories. From the total of 15 reported

adverse incidents it was possible to rectify 60% of them. It was not workable to do an intervention for the other 40%.

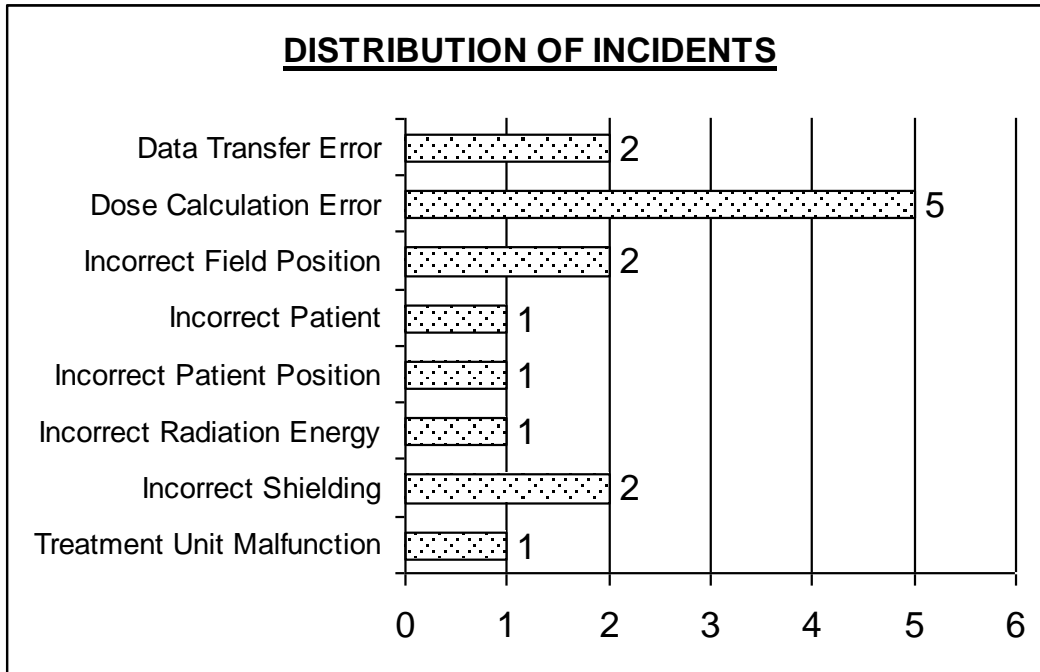


Figure 4.8 Distribution of reported adverse incidents in the various categories from January – June 2007.

4.7. REPORTED ADVERSE INCIDENTS

The adverse incidents will now be discussed individually according to their monthly appearance.

4.7.1. January 2007

In January 2007, two minor adverse incidents were reported. One incident occurred due to a dose calculation error and the other because of incorrect data transfer.

Adverse incident 1 (DCE) - Radiation prescription: 1.8Gy x 28 fractions (#).
Total radiation dose: 54Gy.

The dose calculation for the radiation treatment was done for 2Gy # while 1.8Gy # was prescribed. The patient received 5 # radiation treatment on this dose before the error was detected. Thus, the patient would have received a total dose of 51.4Gy instead of 54Gy. A correction was made for the adverse incident by compensating for the additional dose.

Adverse incident 2 (DTE) - Radiation prescription: 3Gy x 7 #, 3Gy x 3 # on offcord fields, rest two weeks, 3Gy x 7 # on offcord fields and 3Gy x 3 # on booster fields. Total radiation dose = 60Gy.

Due to a change in the patients' separation measurement the dose monitor units were altered after the patient returned for second course radiation. It went unnoticed at the treatment unit and the patient received seven fractions radiation treatment on the offcord fields with this radiation dose. The patient received a total radiation dose of 60.4Gy instead of the prescribed 60Gy. The patient completed this specific segment of his radiation treatment and no correction could be made.

4.7.2. February 2007

One adverse incident was reported in February 2007.

Adverse incident 1 (FP) – Radiation prescription: 2Gy x 25 #. Total radiation dose = 50Gy.

A patient received a radiation treatment plan with electron fields. With the set-up of the patient during treatment, the collimation degrees were altered and did not correspond with the instructions received from the treatment planning unit on the patients' treatment plan. The patient received two

fractions radiation treatment with the incorrect collimator angle. The electron field still covered the prescribed radiation treatment area but not according to the instructions of the treatment planning unit. It was not possible to correct this adverse incident.

4.7.3. March 2007

In March 2007, two minor adverse incidents were reported. An error in dose calculations was the cause of the one adverse incident and the use of the wrong radiation treatment energy resulted in the second adverse incident.

Adverse incident 1 (DCE) – Radiation prescription: 2Gy x 25 #. Total radiation dose = 50Gy.

A dose distribution was done for the isodose curve of 115% while the oncologist prescribed the radiation dose to the 110% isodose curve. The patient received one fraction radiation treatment with this radiation dose resulting in a 1.4Gy deviation from the prescribed total dose. No correction was made for this adverse incident because the deviation from the prescribed radiation treatment was miniscule.

Adverse incident 2 (RE) – Radiation prescription: 100KV x 13 # and boost x 2 #.

The patient received orthovoltage radiation treatment. The patient received two fractions radiation treatment with 250KV radiation energy instead of the prescribed 100KV radiation energy. Due to the effect of the higher energy given the total number of radiation fraction treatments given were decreased in an effort to achieve the same result.

4.7.4. April 2007

April 2007 had a higher occurrence of reported adverse incidents with a total of four reported adverse incidents. One adverse incident was due to treatment unit malfunction; one adverse incidents due to a dose calculation; one was a data transfer error and one incorrect patient.

Adverse incident 1 (TUM) – 2Gy x 25 #. Total radiation dose = 50Gy.

The treatment unit did not call up the last field in the patient's radiation treatment sequence and the controller did not notice that not all the radiation fields had been given. The patient received one fraction radiation treatment like this. A distribution was done at the planning unit to calculate the deviation from the prescribed radiation dose. The patient received an equivalent of a 1.4Gy fraction dose instead of the prescribed 2Gy # dose. The adverse incident was rectified by compensating for the 'lost' 0.6Gy through 6 x 2.1Gy # and then returning to the normal radiation prescription.

Adverse incident 2 (DCE) – Radiation prescription: 3Gy x 7 #, 3Gy x 3 # on offcord fields, rest two weeks, 3Gy x 7 # on offcord fields and 3Gy x 3 # on booster fields. Total radiation dose = 60Gy.

The dose calculation was done incorrectly at the simulator and it was not checked at the radiation treatment unit before the patient received his first radiation treatment. The patient received one fraction radiation treatment with this dose resulting in an overdose of 0.22Gy. The adverse incident was corrected the following day by compensating for the incorrect radiation dose.

Adverse incident 3 (DTE) – Radiation prescription: 2Gy x 25 #. Total radiation dose = 50Gy.

The monitor units were wrongly indicated on the radiation treatment plan and erroneously entered into the radiation treatment unit record-and-verify system and was not checked before the patient received radiation treatment. Patient received one fraction radiation treatment on this dose resulting in a 0.5Gy overdose. The adverse incident was corrected the following day by compensating for the imprecise radiation dose.

Adverse incident 4 (IP) - Radiation prescription: 3Gy x 7 # opposing, 3Gy x 3 # on conformal plan, rest two weeks, 3Gy x 7 # on conformal plan and 3Gy x 3 # on booster plan. Total radiation dose = 60Gy.

The wrong patient entered the radiation treatment room when another patient was called and the radiation therapist did not notice. The incorrect patient was receiving similar radiation treatment as the patient that was called so the tattoos on the patient correlated with the radiation plan given and contributed to the fact that the radiation therapists did not notice the error. Thus, the patient received one fraction radiation treatment on another patients' radiation treatment plan. A distribution was done at the planning unit where the wrongly received treatment was incorporated with the patient's prescribed radiation treatment plan. The fact that the patients were receiving similar treatment in the same anatomical region on the same radiation treatment unit limited this incident to a minor incident. No correction could be made for this adverse incident.

4.7.5. May 2007

One minor adverse incident regarding error in dose was reported.

Adverse incident 1 (DCE) – Radiation prescription: 2Gy x 25 #. Total radiation dose: 50Gy.

The monitor units were incorrectly calculated and erroneously entered into the radiation treatment unit's record-and-verify system and were not checked before the patient received radiation treatment. The patient received one fraction radiation treatment on this dose, which resulted in an under-dosage of 0.27Gy. The erroneous dose was compensated for in the next fraction radiation treatment.

4.7.6. June 2007

June 2007 had the highest occurrence of reported adverse incidents in the period under investigation, with a total of five adverse incidents reported. The adverse incidents were distributed evenly across the categories with one patient positioning error; one dose calculation error; one field positioning error and two shielding errors.

Adverse incident 1 (DCE) – Radiation prescription: 3.4Gy x 11 #. Total radiation dose = 37.4Gy.

The monitor units were incorrectly calculated and entered into the radiation treatment unit's RV system and were not checked before the patient received his first radiation treatment. The patient received one fraction radiation treatment on this dose that resulted in an overdose of 0.12Gy. The adverse incident was corrected by compensating for this radiation dose.

Adverse incident 2 (IS) - Radiation prescription: 2Gy x 20 #, 2Gy x 10 # on offcord fields and 2Gy x 5 # on booster fields. Total radiation dose = 70Gy.

The patient received treatment with extra shielding as if he was being treated with off-cord fields, while he was supposed to be treated with normal big fields with shielding of the cerebellum. The patient received one fraction radiation treatment like this. The adverse incident was corrected by deducting one fraction radiation dose from the original prescription of this specific segment of his radiation treatment course.

Adverse incident 3 (FP) - Radiation prescription: 3Gy x 10 #. Total radiation dose = 30Gy.

The isocentre coordinates were described incorrectly in the simulator instructions. The error was discovered with the electronic portal imaging. The patient received two fractions radiation treatment on this set-up. No correction could be made for this adverse incident.

Adverse incident 4 (PP) – Radiation prescription: 1.8Gy x 23 # on conformal 3D plan and 1.8Gy x 5 # on conformal 3D booster plan. Total radiation dose = 54Gy.

A child was marked for radiation treatment of the brain and spinal cord. With the marking of the booster fields, it was discovered that his radiation treatment set-up position differed slightly from the original position. This was due to the fact that the child was scared, stressed and crying during the marking and immobilisation process. As his radiation treatment course progressed, he started to trust the process and relaxed. This caused an alteration of 5 mm in the position of his neck, which in turn caused an important part of the target volume to be shielded. Two additional radiation fields were given together with his booster fields to compensate for the lost radiation dose over the target volume.

Adverse incident 5 (IS) - Radiation prescription: 1.8Gy x 22 #, 1.8Gy x 3 #

on smaller fields and 1.8Gy x 3 # on booster fields. Total radiation dose = 54Gy.

The shielding tray was made incorrectly. Too much of the target volume was shielded during the patient's first fraction of radiation treatment. No correction could be made for this adverse incident.

4.8. ORIGIN OF REPORTED ADVERSE INCIDENTS

All the members in the sub-categories of the multi-disciplinary team of the radiation process are equally responsible for the correct execution of every step in this process. This includes the localisation process at the simulator, the planning process at the planning unit and the carrying out of the actual radiation treatment at the treatment unit. As discussed in 4.4 the radiation therapists at the radiation treatment unit are the front-line operators responsible for the correct and accurate execution of the radiation treatment regimes and thus unfortunately they tend to be left with the mishaps of everyone who has played a role in the design of the radiation treatment procedure (NRC 1995: x). In essence, these radiation therapists have the greatest responsibility to stop any potential incidents from turning into actual incidents. If an incident originated at the simulator or the planning unit and the personnel at the radiation treatment unit did not detect it, a potential incident turns into an actual incident. Figure 4.9 illustrates the origins of the reported adverse incidents.

In January one incident had its origin at the planning unit where the incorrect dose fraction size was calculated. The second incident originated at the radiation treatment unit. February saw one incident due to the actions of the radiation treatment unit. March had two incidents with one originating at the planning unit and one at the radiation treatment unit. In April four adverse incidents were reported with its origins distributed between the

units – one at the planning unit, one at the simulator and two at the radiation treatment unit. In May there was one incident reported which originated at the simulator. June had the highest number of adverse incidents reported with three originating at the simulator and two at the treatment units.

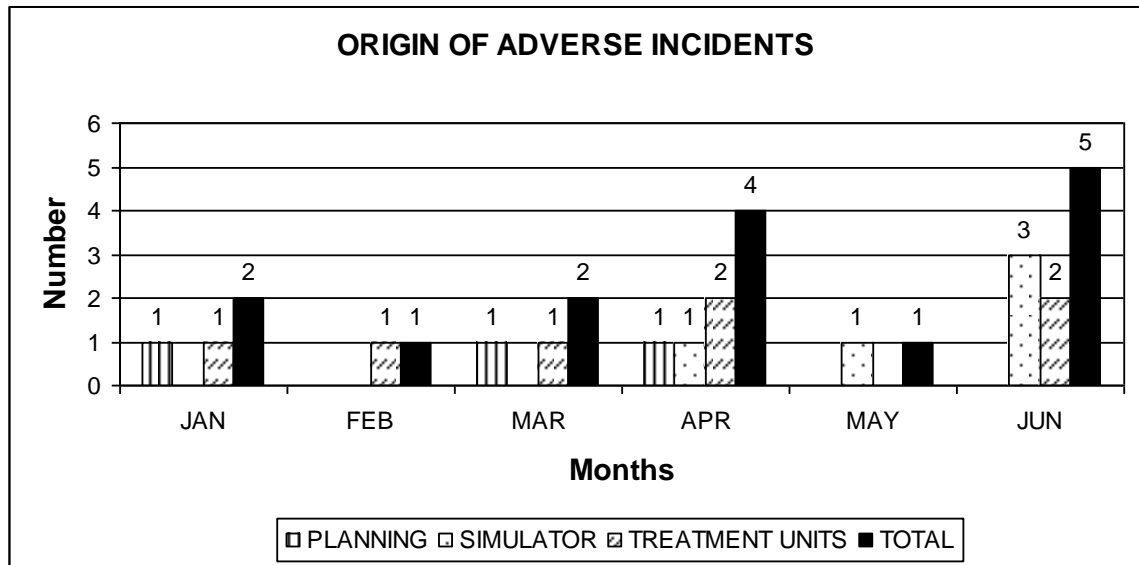


Figure 4.9 Origin of reported adverse incidents in the various categories from January – June 2007.

4.9. INFORMATION OBTAINED FROM MEETINGS

During these meetings (3.2.3) the reported adverse incidents, their distribution in the different categories, possible reasons for the occurrence of the adverse incidents and any corrective actions and preventative steps that were to be taken, were discussed. One of the items on the agenda of these meetings was the opportunity for the radiation therapists to air their views and comment on possible reasons for the reported adverse incidents as well as solutions and preventative steps to be taken to minimise or avert future incidents.

4.9.1. Factors contributing to the occurrence of adverse incidents: opinions of the radiation therapists.

There are numerous factors that can play a role in the occurrence of the reported adverse incidents, as deduced from the opinions of the radiation therapists during the meetings. The following views, regarding factors influencing the occurrence of reported adverse incidents, were expressed by the radiation therapists during the meetings (See Appendix 5).

April had the lowest recorded number of patients and radiation treatments but also the lowest number of working days due to the numerous public holidays that included Easter weekend and Freedom Day. This puts extra stress on the personnel because some patients have to receive two radiation treatments on one day to finish in time to return to their homes. The patients also get agitated and impatient and want to be treated as soon as possible which pressures the radiation therapists into increasing their work pace. The SL14 treatment unit were out of commission for one week during April and the patients receiving treatment on that unit had to be distributed amongst the remaining radiation treatment units. The distribution of the patients between the radiation treatment units necessitated the calculation of new applicable doses and the patients' radiation treatment information had to be entered into the newly allocated radiation treatment unit's computerised record-and-verify system (See Appendix 5 – Meeting 2/2007 - 2.2.2.). Thus, the second highest adverse incident rate was recorded in April.

June had the highest reported incident rate but the second highest recorded workload. In June the SL25 radiation treatment unit were out of order for one week and the patients receiving treatment at that unit had to be distributed between the other radiation treatment units in the same manner as described above. There was also one week in June when all the students were absent due to examinations. This together with numerous personnel

falling ill led to a shortage of personnel who had to cope with a very high workload (See Appendix 5 – Meeting 3/2007 - 3.2.2.).

Other factors that were discussed included the shortage of personnel, the rotation of personnel and the fact that the department is a training facility. They noted that radiation therapist rotation on the radiation treatment units could affect the occurrence of adverse incidents due to the fact that the newly rotated personnel were not familiar with the patients or their radiation treatment set-up (See Appendix 5 – Meeting 2/2007 - 2.2.2.). Universitas Annexe is an academic hospital and fulfils the role of a learning institute. New students, who are still in the early stages of their training, did not possess the required knowledge to perform duties accurately and needed constant monitoring, assistance and attention. This situation may influence the occurrence of adverse incidents negatively (See Appendix 5 – Meeting 1/2007 - 1.1.2.).

If the findings of the present study are then compared to findings in the literature, there are several similarities that can be pointed out. In a study performed by Huang *et al.*, (2005: 1592) a multidisciplinary site-specific working group met weekly throughout August 2001, to discuss the occurrence of adverse radiation therapy incidents. In concordance with the study performed at Universitas Annexe concerns were identified about the role of patients being moved between radiation treatment units due to machine service. Additionally, radiation therapists that were frequently relocated between radiation treatment units also raised concern.

According to Valentin's (2000: 43) findings a lack of appropriate personnel resources and insufficiently qualified or untrained personnel, together with an increase in the workload, contributed to the occurrence of adverse radiation incidents. This can be brought in line with the comments made by the radiation therapists that the new students do not possess the required

knowledge to perform duties accurately and effectively. Valentin (200: 43) also commented that need for effective systematic quality control procedures, the reassessment of personnel expertise and resources, as well as adequate training on newly purchased radiation treatment units also affected the occurrence of adverse radiation incidents.

Dunn (2003: 62) also states that special consideration should be given to personnel workload, which may become excessive in the case of installation of new equipment, set-up of a new technology or an increase in patient load. This will lead to an increased risk of adverse incidents because of the difficulty of fully applying the quality control procedures in these situations.

All of the contributing factors mentioned above also correspond with the findings of the Royal College of Radiologists (RCR) (2008: 9) regarding factors contributing to the occurrence of adverse incidents. The RCR lists lack of training, competence or experience as a contributing factor. This corresponds with views of the radiation therapists at Universitas regarding the students. The RCR (2008: 9) states that fatigue and stress also contributes to the incidence of incidents. As well as the poor design and documentation of procedures, poor communication and staffing and skills levels.

4.10. PREVENTATIVE STEPS

The meetings that were held with the radiation therapists gave the opportunity to discuss potential preventative steps that could be taken to minimize the occurrence of adverse incidents. These steps were additional to the quality procedures already implemented at the department. Some of the suggestions made during the meetings were steps that were already in place in the existing quality control system. However, attention to these quality steps was overlooked in the daily routines. Upon reflection on the

adverse incidents, the following opinions were conveyed during these meetings, in order to address the quality of a patient radiation therapy schedule.

4.10.1. The Simulator

- The radiation therapists working at the simulator should double-check each other on the simulator set-up instructions and the calculated monitor units before the radiation treatment files are passed on to the radiation treatment units (See Appendix 5 – Meeting 2/2007 - 2.2.3.).
- The complete process of starting a patient for radiation therapy at the radiation treatment unit can take up to an hour. Thus, the personnel at the radiation treatment units have to be informed before any unscheduled patients are marked for radiation treatment at the simulator, so that they can be prepared for the patients and arrange their already demanding work schedule accordingly (See Appendix 5 – Meeting 1/2007 - 1.1.2.).

4.10.2. Radiation Treatment Units

- Bearing in mind that extended working hours e.g. shifts, are improbable due to the shortage of personnel, a time limit should be determined in the afternoon at the radiation treatment units, where after patients are not allowed to start with radiation treatment. This would apply, unless it is for emergency radiation treatment, such as bleeding patients, patients with paralysis or those having difficulty with breathing. The time limit should be implemented, to decrease the pressure on the personnel and to minimise the probability of adverse incidents occurring (See Appendix – Meeting 1/2007 – 1.1.2.).
- No patients are to start with their radiation treatment before all the necessary verification checks have been performed. These verification checks include the dose calculation checks and the

secondary checks on the information that was entered into the computerised record-and-verify system at the radiation treatment unit (See Appendix 5 – Meeting 1/2007 – 1.1.3.).

- Patient identification is of utmost importance. Before a patient enters the radiation treatment room the patient name, birth date and photo should be controlled (See Appendix 5 – Meeting 2/2007 – 2.2.3.).
- Any shielding accessories e.g. shielding, MCPs and multi-leaf collimation has to be verified before the radiation therapy of the patient commences (See Appendix 5 – Meeting 3/2007 - 3.2.3.).
- The radiation therapists who do the initial radiation set-up on the first day of treatment, have to carry out the first radiation treatment completely to check for any irregularities during the radiation treatment session and between the individual radiation treatment fields (See Appendix 5 – Meeting 3/2007 - 3.2.3.).
- If there are any queries or doubts about a prescription or radiation treatment set-up, at the start of, or during the radiation treatment of a patient, the relevant personnel, be it the oncologist, the planning radiation therapist or the simulator radiation therapist, have to be contacted and consulted on the matter. This needs to be done to clarify any uncertainties regarding the radiation treatment of the patient (See Appendix 5 – Meeting 1/2007 - 1.2.3.).

Holmberg & McClean (2002: 14) suggest that different personnel groups should perform primary and secondary checks separately, on the initial radiation treatment calculations. Colleagues of equal stature should review prescriptions and simulations of the radiation treatment plans should be performed to verify the geometric settings. At the department, the radiation therapists perform the primary and secondary verifications before the radiation therapy commences and the medical physicist does the third verification before the patient receives his third fraction radiation therapy, for opposing fields. The medical physicist controls three-dimensional conformal

plans before a radiation treatment is given on that plan. Weekly overview inspections of major parameters in treatment charts and in the record-and-verify system are and should be performed according to Holmberg & McClean (2002: 14).

The ICRP (2001: 51) also reported the occurrence of adverse incidents due to the delivery of radiation treatment to the wrong patient. It is stated that provisions and procedures should be in place to eliminate incidents like this from occurring. These procedures include the identification of the patient through a patient photograph, patient name, patient identification number and/or address. Huang *et al.*, (2005: 1591) reports that personnel rotation on the radiation treatment units plays a role in the occurrence of adverse incidents and recommends that personnel allocations be extended on specific treatment units. At Universitas Annex, the shortage of personnel limits the personnel rotation but personnel from one treatment unit are relocated to another unit when for a short period of time when there is a shortage due to illness or annual leave. It is advised that these personnel work under strict supervision.

According to Patton *et al.*, (2003: 52) four elements must be present for an external radiation beam treatment to be administered correctly: the correct patient; the correct data; the correct radiation treatment site and correct radiation beam modifications. Deficiencies in these elements lead to mistakes. Patton *et al.*, (2003: 55) states, that continuous personnel alertness and critical verification of correct treatment parameters before administering radiation treatments, are a necessity. The risk of adverse radiation incidents due to incorrect radiation treatment parameters can be significantly reduced with the use of electronic, rather than manual transfer of treatment parameters between the treatment planning unit and / or simulator and the record-and-verify systems of the radiation treatment units.

Electronic data transfer is currently only available on two of the four radiation treatment units at the department.

Patton *et al.*, (2003: 55) advise that the departmental procedures for radiation therapy following simulation and radiation treatment planning, should include a double check of the radiation treatment parameters received from the simulator and / or treatment planning unit. These controlled parameters should then be entered into the record-and-verify system of the radiation treatment unit. These controls should be performed by a dosimetrist. The department does not employ a dosimetrist, thus the controls are all performed by the radiation therapists themselves, with additional verification by the medical physicist. Weekly radiation chart reviews, as well as a final chart check at the end of the patient's radiation treatment course, should also be included in the departmental procedures. Verification of the patient identification should be done by using a photograph and by name. In the department, photographs are attached to the patients' radiation treatment files. The electronic portal images are verified by the radiation therapist before the first radiation treatment, and then reviewed by the oncologist after radiation treatment.

4.11. COMPARISON WITH RELATED STUDIES

The study demonstrated the trends and frequency of adverse radiation incidents during radiation therapy at the Oncotherapy Department, Universitas Annexe, Bloemfontein, from January 2007 to June 2007.

When comparing the results with similar data reported in related studies (See 2.11), the above-mentioned department falls well within the reported error rate, with a total of 15 minor adverse incidents reported over a 6-month period. Calandrino *et al.*, (1997: 272) reported a total of 217 errors over a period of 61 months from September 1991 to November 1996 with

an average of 3.6 errors detected per month. Swann-D'Emilia *et al.*, (1990: 187) reported a total of 87 misadministrations over a period of 24 months with an average of 3.6 errors per month. Williams *et al.*, (1991: 200) recorded a total of 28 genuine errors over a period of 9 months which gives an error rate of 3.1 errors per month. Huang *et al.*, (2005: 1593) reported an average error rate of 7.7 errors per month with a total of 555 treatments delivered with errors from January 1, 1997 through December 31, 2002. Patton *et al.*, (2003: 52) reported 38 technical error reporting forms with an average of 3.2 per month which were submitted between July 1, 1999 and June 30, 2000. According to Yeung *et al.*, (2005: 283) a total of 634 incidents were reported between November 1992 and December 2002 with an average of 5.1 per month (2.11) (See Figure 5.2).

If we look at the work distribution within these departments, the study with the highest error rate of 7.7 errors per month, Huang *et al.*, (2005: 1593), had the most radiation treatment units. This study was performed at the Princess Margaret Hospital which is the largest radiation therapy center in Canada and over the study period operations were performed on 17 radiation therapy units. The study period was also the second longest with 72 months.

The second highest error rate of 5.1 errors per month was reported by Yeung *et al.*, (2005: 283), which also had the longest study period with 121 months and the highest number of patients treated per treatment unit per month. An average of 30 patients was treated per month per radiation treatment unit. The department with the lowest error rate reported was the Beatson Oncology Centre (Williams *et al.*, 1991: 200), which recorded an average of 3.1 errors per month. This study information was obtained over the shortest study period of nine months. This department also had the lowest amount of three radiation treatment units and reported the lowest amount of radiation treatments, 79 per month performed per treatment unit.

Thus, in correlation with these studies, the results obtained at the Oncotherapy Department, Universitas Annexe, Bloemfontein compared favourably. During the six-month study period an average of 2.5 adverse incidents per month were reported. Taking into consideration that an average of 45 patients were treated with an average of 478 radiation treatments per radiation treatment unit per month it concludes in an error rate of 0.52% of the radiation treatments.

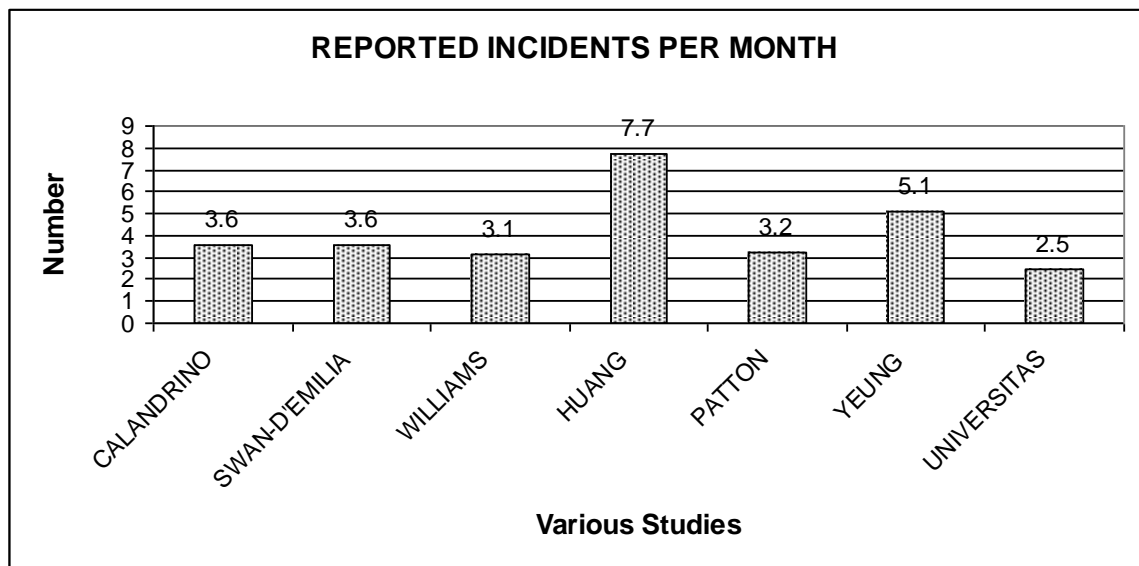


Figure 4.10 Reported incident distributions of various studies

4.12. CONCLUSION

The reported and documented adverse incidents were discussed and presented with the aid of frequency distribution tables and graphs. The radiation patients, radiation treatments, radiation fields and personnel figures, during the period of the study was also presented.

A detailed depiction of the reported adverse incidents is given in table 4.1 (See Appendix 4). The reported adverse incidents are depicted according to the month of occurrence, category of the reported adverse incident and the magnitude of the reported adverse incident.

Chapter 5 will include an assessment of the results where it will be discussed in greater detail. Chapter 5 will furthermore contain the quality control procedure manual as deduced from the results.

In a combined effort from the personnel at the department, the adverse incident monitoring, adverse incident discussions and literature reviews, the quality control procedure manual for Radiation Therapists at Universitas Annexe have been compiled to assist and guide in the delivery of radiotherapy of the highest standard at the above mentioned department.

CHAPTER 5

DISCUSSION

5.1. INTRODUCTION

In Chapter 4 the results of the study were presented, answering the first two objectives of the study namely to determine the origin, frequency and classification of adverse incidents leading to inaccurate delivery of radiation therapy to patients and to compare these results with similar published results. The impact of these findings on the quality assurance and control procedures concerning radiation therapy at the department will be discussed in more detail in Chapter 5.

This chapter will provide a summation and discussion of the study which will include an overview; the distribution of the adverse incidents; the factors influencing the occurrence of the adverse incidents; opinions of the radiation therapists; preventative steps; a comparison with related studies; an in depth look at the quality control procedure manual which was designed, based on the results of the study and the literature information gathered on the subject; the limitations of the study; recommendations and the final conclusion.

5.2. OVERVIEW

From January 2007 to June 2007 a clinical quality audit was performed at the department to identify deviations of quality activities from the planned arrangements and to initiate corrective actions in the event of deviations observed. The objective of the audit was to set up a QC procedure manual designed to minimise the occurrence and consequences of any events that could lead to an adverse incident in the radiation therapy schedule of a

patient and thus potentially have an impact on the quality and safety of patient treatment (Leer *et al.*, 1998: 74).

The data collection was executed by determining the origin and frequency of adverse incidents leading to inaccurate delivery of radiation therapy to patients and classifying them as major or minor adverse incidents by employing an adverse incident reporting system. The frequency and origin of the reported adverse incidents were studied, discussed and combined with all of the information from literature to produce a quality control procedure manual that will focus on tasks of the radiation therapists at the department and facilitate in the monitoring, evaluation and improvement of the superiority of radiation therapy which would result in a more effective and advanced quality radiation oncology care.

5.3. RESULTS

A total of 1 093 patients were treated with 37 036 radiation treatment fields in 11 466 radiation treatments during the period of the study at the department. The simulator handled 1 918 patients and the radiation planning unit did a combination of 547 contours, distributions and three-dimensional plans. An average of 23 radiation therapists was performing duties during the period of the study. During this time a total of 15 minor adverse incidents were reported.

During this study it was revealed that adverse incidents occurred in all of the various phases of the complex process of radiation therapy at the department. The phases include the simulation; radiation treatment planning; shielding accessories; dose calculation and the radiation treatment execution. Human errors as well as treatment unit errors contributed to the sum of all the adverse incidents that were reported during the period of the study.

As discussed in Chapter Four (4.6) the monthly distribution of the reported adverse incidents during the period of the study were as follows (Figure 4.7): January 2 minor adverse incidents were reported; February 1 minor adverse incident reported; 2 minor adverse incidents were reported in March; April presented 4 reported minor adverse incidents; in May 1 minor adverse incident were reported and June had the highest reported amount with 5 minor adverse incidents.

Of the total of 15 reported adverse incidents eight originated at the pre-treatment units and seven at the radiation treatment units. As discussed in 4.8 the final responsibility to detect and prevent adverse incidents from occurring falls on the personnel at the radiation treatment units.

In January, March and April the planning unit was the point of origin of one of the monthly reported adverse incidents. The planning unit had only two radiation planning therapist in January, three in March, April and June and four in February and May (see Fig. 4.6). The months with the fewest number of planning personnel correlates with the months that the incidents originated in the planning unit. January also saw the highest workload in the planning unit.

In April and May the simulator was responsible for one reported adverse incident per month and for three adverse incidents in the month of June. The personnel distribution at the simulator was as follows: in January five radiation therapists; February and March seven radiation therapists; April and June six and in May five radiation therapists were allocated at the simulator. The productivity ranking of the months is January, May, February, June, March and April in descending order. Thus, no direct correlation can be made between personnel present, the workload and the occurrence of incidents at the simulator.

At the radiation treatment units February was the busiest with June, March, May, January and April following. The origin of incidents at the radiation treatment units were distributed as follows: in January, February and March there were one incident each month that originated at the radiation treatment units and in April and June two incidents each month. The personnel in attendance were, in descending order: 27 in February, 25 in March, 23 in January and April, 21 in May and 19 in June. The month of June had the least amount of personnel in attendance and the highest occurrence of reported adverse incidents. Figure 5.1 offers a depiction of the relation between workload, personnel in attendance and occurrence of reported adverse incidents. According to the Figure 5.1, there is no direct correlation between the workload, personnel and the adverse incidents.

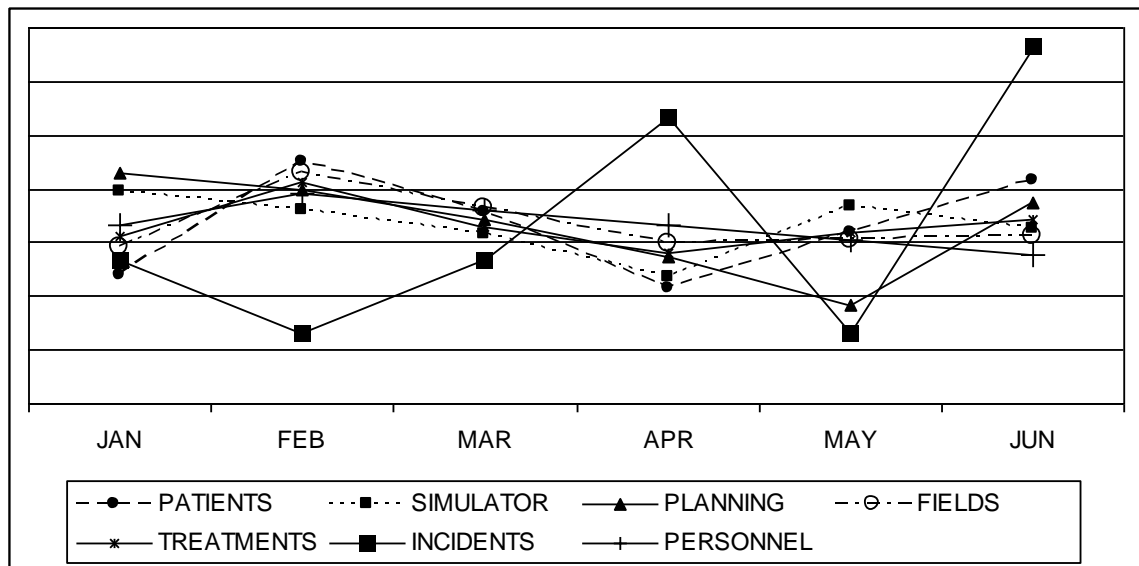


Figure 5.1 Relation between workload, personnel in attendance and occurrence of reported adverse incidents

5.4. THE QUALITY CONTROL PROCEDURE MANUAL

The information acquired from the monitoring of the adverse incidents and from the meetings held at the department, was used in conjunction with the information gathered from the literature consulted (See 1.9.6.), on radiation quality assurance and radiation quality control, to compile this quality control procedure manual in accordance with the specific quality control requirements of the department. Guidelines given by the AAPM Radiation Therapy Committee Task Group 40 in their report on Comprehensive Quality Assurance for Radiation Oncology (Kutcher *et al.*, 1994: 583-615), and recommendations by Thwaites *et al.*, (1995: 63) were especially useful in the compilation of the quality control procedure manual.

Once implemented, the quality control procedure manual will potentially provide a controlled and systematic evaluation mechanism for the quality control procedures, action criteria and responsibility and commitment to perform these procedures during the radiation therapy process at the department.

The quality control procedure manual may appear to be repetitive in the way that many actions are performed repeatedly, but repetition is part of the daily and weekly quality control process of radiation therapy at the department and there are continuous verification and controlling being performed in each area.

Every little detail regarding the patient's radiation treatment has to be checked, double-checked and checked again. Khan & Potish (1998: 37) state that radiation therapy cannot be metabolized, erased or revoked – once the dose of radiation is delivered, it cannot be removed. Thus, it is of the utmost importance that the radiation treatment should be administered accurately, meticulously and judiciously. There is little chance to rectify a

poorly planned or administered course of radiation treatment. One inaccurate radiation treatment can lead to paralysis, blindness, deafness or even death. Therefore, it is crucial that every little detail is repeatedly verified at all the different sections of the radiation therapy process.

A narration of the quality control procedure manual will now be presented according to the different sections in the manual. The sections follow the path of the cancer patient who enters the department to receive radiation therapy. Every section provides the quality control checks that should be performed with tick boxes present where the appropriate response can be ticked off (See Appendix 6).

5.4.1. SECTION A – THE SIMULATOR

5.4.1.1. Patient identification

When a patient arrives at the simulator, it is important to determine if it is the correct patient who is going to be simulated. Thus, the correct patient has to be identified. This must be done by asking the patient what his / her name is. If it is the correct name, the identification number and address of the patient has to be confirmed as well (Thwaites *et al.*, 1995: 68).

After the correct patient has been identified, the radiation therapist has to verify whether the patient signed a witnessed consent form, together with the oncologist, for all the procedures regarding the radiation therapy that are going to be performed.

5.4.1.2. Initial physical evaluation of patient and pertinent clinical information

Before any procedures can be performed on the patient, an initial evaluation of the patient file has to be performed for the assessment of the patient's diagnosis. The radiation therapist in charge of the simulation of the patient

has to determine whether the correct procedure is going to be performed. This evaluation includes the determination of the diagnosis of the disease and the stage of the disease as this influences the anatomical site of the patient to be simulated and whether the patient will be simulated for radical or palliative radiation treatment. It is important that there should be a history of the patient's disease, a pertinent pathology report and a positive histology report to corroborate the diagnosis and stage of the patient's disease (Thwaites *et al.*, 1995: 69) (Kutcher *et al.*, 1994: 608).

It is also important to be aware of the HIV status of the patient, as this can affect the radiation treatment option, as well as the side effects experienced by the patient during radiation treatment and the prognosis of the patient. The HIV status of the patient can affect the patients' tolerance of the radiation treatment regime, thus determining whether a patient with a radical staging might receive a palliative radiation treatment regime. The knowledge of the HIV status is important for the safety of the personnel as well. The assessment of the patient's physical condition is necessary, as radiation therapy can be very traumatic, stressful and invasive on the body. If a patient is to receive radical radiation treatment but his / her physical condition does not allow it, it could affect the radiation treatment option.

5.4.1.3. Previously treated or concurrently treated volumes in which dose can overlap with the current treatment volume

The patient's radiation treatment file has to be checked to determine if the patient has received previous radiation therapy. If s/he has received previous radiation treatment, the simulator films of the previously treated area have to be located and reviewed to establish any potential overlap with the current radiation treatment site. If present, the isodose distributions have to be reviewed as well, to establish potential overlap with current radiation treatment fields. If the current radiation fields are adjacent to the previous radiation fields, the departmental protocol states that there should

be a 0.5 cm separation between the adjacent radiation fields. A cumulative radiation dose calculation has to be done if the oncologist requests it, as well as in vivo measurements, where appropriate Thwaites *et al.*, (1995: 68).

5.4.1.4. Simulator Room Initial Set-up

When the radiation treatment of a patient is to be simulated at the simulator, the simulator room has to be prepared according to the localisation that is going to be performed. The simulator unit has to be placed in the standard set-up position that includes that the gantry should be on 0°, the collimator 90° and the couch rotation on 0°. The magnification factor used is 1.5 and this should be checked as well. The appropriate patient immobilisation devices are then chosen according to the anatomical area that is going to be simulated and the position in which the patient is set-up for the specified radiation treatment fields requested by the oncologist.

5.4.1.5. Simulation Set-up Notes

After the simulation of the patient is completed, it is very important to transfer all the information about the patient set-up, the field parameters and the radiation treatment regime, to the patient radiation treatment file, which will be handed to the radiation treatment unit where the patient receives radiation therapy. The following requirements for the patient treatment set-up should be noted and motivated where required: the precise patient positioning, the patient immobilisation devices used to ensure the patient treatment position and the general set-up instructions.

Together with the patient treatment set-up, the following physical treatment parameters have to be documented: the location of the radiation field; the anatomical location of the tattoos with references to anatomical landmarks, where possible; the radiation field size; whether there was any collimation rotation away from the standard 90°; whether the simulation was done

isocentric (SAD) or on a source surface distance (SSD) of a 100cm; and the separation of the anatomical area being treated.

If there is any shielding, MLCs or bolus required during the radiation treatment, it has to be noted together with their location and the thickness of the bolus. If the patient needs a bite-block or tongue depressor, it should be documented as well. The names of the radiation therapists responsible for the simulation of the patient have to be recorded as well. All of the documented information should be double-checked by the other radiation therapist present during the simulation of the patient (Kutcher *et al.*, 1994: 608).

5.4.1.6. Radiation Treatment Prescription

With the completion of the simulation of the patient, the radiation treatment prescription is completed, on the radiation prescription page in the patient's radiation treatment file, by the oncologist in charge of the patient. The completed radiation prescription has to be controlled by the simulator radiation therapist, before the radiation treatment file is handed over to the radiation treatment unit. The radiation treatment prescription should include the radiation treatment site; the radiation treatment mode and energy; a description of the radiation treatment field; the given radiation dose, which is the fractionation size and the percentage central dose. The field size has to be recorded and whether it is on a source surface distance of 100cm, or if it is isocentric. The daily radiation dose, total radiation dose and the fractionation scheme, have to be described. The radiation treatment prescription has to be signed and dated by the oncologist, as well as any radiation prescription changes that have been made. The radiation therapist has to verify that the radiation prescription coincides with the departmental guidelines and protocols. The radiation treatment protocol files at the simulator can be utilised for this verification (Thwaites *et al.*, 1995: 68) (Kutcher *et al.*, 1994: 595).

5.4.1.7. Radiation Monitor Units (MU) Calculation

For opposing radiation fields, the monitor units (MU) have to be calculated and checked before the radiation treatment file is handed over to the radiation treatment unit. The daily dose fractionation used has to be correct. The correct field size; modality; radiation treatment unit; radiation treatment energy and patient separation, have to be used in the calculation of the MU. The correct equivalent square has to be calculated and used. The correct source surface distance or isocentric, should be applied in the calculation of the MU. If beam blocking is extensive, the appropriate equivalent square calculations have to be made. If use of bolus is extensive, the appropriate separation has to be used (Kutcher *et al.*, 1994: 598).

5.4.2. SECTION B – PLANNING UNIT

5.4.2.1. The Scanner Form

When the CT images of the patient are received and transferred to the radiation treatment planning unit, there are several factors that should be controlled before, during and after the radiation treatment planning process.

The patient information has to be controlled. This includes the patient name, birth date and radiation therapy number (RT number). The patient orientation has to be controlled – whether the patient was positioned in an antero-posterior or postero-anterior position and whether the patient was scanned with his / her head entering the CT first or his / her feet entering first (Khan, 2007: 40).

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The information received from the simulator has to be controlled for the patient set-up. This includes the precise patient positioning, the patient immobilisation devices used to ensure the patient treatment position and the general set-up instructions. If the patient needs a bite-block or tongue depressor, it should be documented as well. This information should be

entered into the radiation treatment planning unit computer. The radiation treatment unit should be noted as well as whether the prescription falls within department protocol. It should be checked if a PTV was drawn in and signed by the consultant oncologist.

5.4.2.2. Treatment Planning Preparation

Before any planning can commence the patient identification and radiation therapy method has to be controlled. The planning directory where the patient is saved, the patient name and RT number has to be controlled. When it has been established that it is the correct patient, reference markers are placed on the tattoos.

5.4.2.3. Treatment Planning Process

When it has been established that it is the correct patient and the correct PTV the planning process can begin. The radiation beams are positioned and/or adjusted to deliver the required dose to the planning target volume while sparing the normal surrounding tissue and critical structures. The fields have to be described correctly according to their placement e.g. left lateral pelvis, the correct radiation treatment unit have to be selected as well as the treatment method – SAD / SSD. The field are then placed on the correct isocentric point. This placement can differ from patient to patient, depending on which treatment method is being used. The field sizes, gantry angle, collimator angles and wedges are then adjusted according to the shape of the PTV. When all the beams have been placed the dose are normalised to a point e.g. the isocentre point or a specific beam weight point. The correct isodose curves are selected to display the dose distribution. To obtain the required dose distribution, the necessary alterations are made according to the displayed dose distributions (Khan, 2007: 125 - 130).

5.4.2.4. Treatment Plan Evaluation

The isodose curves have to be meticulously controlled. At the department, the dose is usually normalised to the isocentre, but the prescription is done to the 95% isodose line, so that the whole PTV receives 100% of the prescribed dose. The minimum and maximum dose must be controlled. The hot spot - where the clinical target volume receives the highest dose - must not exceed 107% of the total dose. The minimum dose in the target volume must not be less than 5% of the prescribed dose. The dose received by the critical structures in the area of radiation must be controlled to verify that it is within the tolerance dose of the specific structure. The three dimensional conformal radiation treatment plans (3DCRTP) have to be viewed and authorised by the oncologist, before it is handed to the radiation treatment units (Kutcher *et al.*, 1994: 598) (Khan, 2007: 130).

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5.4.2.5. Dose Calculation

The dose delivered to the PTV is calculated according to the prescription and the isodose line selected by the oncologist to determine the treatment unit monitor units. The correct fractions are read in, then the isodose curve indicated by the oncologist is selected for prescription and the total dose are entered into the radiation treatment planning unit (Khan, 2007: 129).

5.4.2.6. Graphical Print-out Preparation

The printout has to include a graphical printout of the 3DCRTP, with the patient parameters and simulator set-up notes. If there is any shielding, MLCs or bolus required during the radiation treatment, it has to be noted, together with its location and the thickness of the bolus. All the physical beam parameters and a computerised MU calculation work sheet, have to be present as well. The prescribed isodose percentage has to be indicated, as chosen by the oncologist. The radiation therapist responsible for the design of the radiation therapy plan has to sign the printout of the radiation

treatment plan, which is given to simulator and radiation treatment units (Kutcher *et al.*, 1994: 590).

5.4.3. SECTION C – RADIATION TREATMENT UNITS

When the personnel at the radiation treatment unit receive the radiation treatment file from the simulator it should be thoroughly evaluated before the data is entered into the record-and-verify system of the radiation unit and the radiation treatment of the patient commences.

5.4.3.1. Simulator Set-up Page

The simulator / set-up page should be reviewed for each field, to determine whether the necessary information is accurately and clearly indicated. In the simulation set-up notes the patient parameters should be discussed in detail. All of this information is applied in the execution of the radiation therapy of the patient and it is vital that all necessary information is present and correct.

The information reviewed includes the precise patient positioning; the patient's immobilisation devices used to ensure this specific patient treatment position and the general set-up instructions. All the physical parameters have to be documented as well. The physical parameters include the location of the radiation field; the anatomical location of the tattoos with references to anatomical landmarks – where possible; the radiation field size; whether there was any collimation rotation away from the standard 90°; whether the simulation was done isocentric or on a source surface distance of a 100cm and the separation of the anatomical area being treated (NRC, 1995: 9).

If there is any shielding, MLCs or bolus to be used during the radiation treatment, it has to be noted, together with its location and the thickness of

the bolus. If a bite-block or tongue depressor / immobiliser were used in the simulation of the patient, it should be documented as well. The names of the radiation therapists responsible for the simulation of the patient have to be recorded as well (NRC 1995: 9) (Kutcher *et al.*, 1994: 608).

5.4.3.2. Radiation Treatment Prescription

The radiation treatment prescription, as received from the simulator, has to be controlled by the radiation therapist at the radiation treatment unit before the information is entered into the record-and-verify system. The radiation treatment prescription should include the radiation treatment site; the radiation treatment mode and energy; a description of the radiation treatment field; the given radiation dose, which is the fractionation size and the percentage central dose.

The field size has to be documented and whether it is on a source surface distance of 100cm, or if it is isocentric. The daily radiation dose, total radiation dose and the fractionation scheme has to be described. The radiation treatment prescription has to be signed and dated by the oncologist, as well as any radiation prescription changes that have been made. The radiation prescription coincides with the departmental guidelines (Kutcher *et al.*, 1994: 595) (Thwaites *et al.*, 1995: 69).

5.4.3.3. Radiation Monitor Units (MU) Calculation

Before the calculated monitor units are entered into the record-and-verify system of the radiation unit, it has to be reviewed. The daily dose fractionation used, has to be verified. The field size; modality; radiation treatment unit; radiation treatment energy and patient separation that were used to calculate MU, have to be controlled. The correct equivalent square has to be controlled.

The correct source surface distance or isocentric method, which was applied in the calculation of the MU, has to be controlled. If beam blocking is extensive, the appropriate equivalent square calculations have to be checked. If the use of bolus is extensive, the appropriate separation has to be controlled. The hot spots in treatment plans have to be checked to see if it is within acceptable limits. The MU indicated on the daily record for a particular field has to be checked for comparison to the correct MU calculation. If an electron beam radiation treatment or a single beam radiation treatment is given, the correct output factor has to be controlled.

All of the information above, regarding the patient set-up, the field parameters, the radiation monitor units and the radiation prescription, should then be meticulously entered into the record-and-verify system of the radiation treatment unit and controlled by a second radiation therapist working at that specific radiation treatment unit. No treatment should be given before all of the above checks have been performed twice (Kutcher *et al.*, 1994: 598,607) (Thwaites *et al.*, 1995: 69).

5.4.3.4. Initial physical evaluation of patient and pertinent clinical information

In accordance with the simulator, an initial evaluation of the patient file has to be performed for the verification of the patient's diagnosis and staging before any radiation therapy procedures can be performed on the patient. This must be done to determine whether the correct simulation procedure was performed on the patient and whether the correct radiation therapy procedure is going to be performed. The evaluation includes the determination of the diagnosis of the disease and the stage of the disease. It is important that there should be a history of the patient's disease, a pertinent pathology report and a positive histology report to corroborate the diagnosis and stage of the patient's disease (Kutcher *et al.*, 1994: 609).

The assessment of the patient's physical condition is necessary, as radiation therapy can be very traumatic, invasive and stressful on the body. If a patient were to receive radical radiation treatment but his / her physical condition does not allow it, it could affect the radiation treatment option. The radiation therapists performing duties at the radiation treatment units, have to continuously evaluate the physical condition of the patients to detect any serious deterioration during, or due to, the radiation therapy course (Kutcher *et al.*, 1994: 608).

It is important to be aware of the HIV status of the patient, as this can affect side effects experienced by the patient during the radiation treatment. The knowledge of the HIV status is important for the safety of the personnel at the radiation treatment units, as well.

5.4.3.5. Patient Identification

As with the simulation (5.4.1.1.), when a patient arrives at the radiation treatment unit on the first day of treatment, it is important to determine if the correct patient is to receive radiation treatment. Thus, the correct patient has to be identified. This should be done by asking the patient what his / her name is. If it is the correct name, the identification number and address of the patient has to be confirmed, as well.

On the first day of the radiation treatment, the radiation therapist in charge of briefing the patient has to inform the patient about the radiation therapy procedures at the radiation treatment unit and the necessary bathing instructions have to be explained to the patient, as well. A photograph of the patient is taken, which is then attached to the radiation treatment file, to facilitate in the identification of the patient (Kutcher *et al.*, 1994: 608).

Due to language barriers and the fact that some patients are in a hurry and want to be treated as soon as possible, it is probable that a wrong patient

may enter the radiation treatment room when a name is called. Thus, the identification of the patient has to be verified every single day, during the remainder of the radiation therapy course.

5.4.3.6. Radiation Treatment Execution

Before the patient enters the radiation treatment room, the identification of the patient has to be verified again. All the patient support and immobilisation devices, as described in the simulator set-up notes have to be controlled. The patient is then set-up in the described radiation treatment set-up position. The tattoo location has to be verified, together with the location of the radiation treatment field. The correct source surface distance has to be set-up and verified, whether it is isocentric or on a distance of 100cm.

The field parameters have to be checked and verified. These parameters include field size, gantry position, collimator position and table position. If there are any special treatment devices, like bite-blocks, tongue depressors, bolus or shielding, they have to be verified, checked and correctly applied. When all of the above checks have been performed and corresponds to the record-and-verify system, the radiation treatment may commence (Kutcher *et al.*, 1994: 597).

5.4.3.7. Electronic Portal Images (EPI)

With the first radiation treatment of each patient, an electronic portal image has to be taken of each radiation treatment field, to verify relative positional aspects of the treatment field. The image is created as a control image of the radiation treatment area to compare with the x-ray images supplied by the simulator during the simulation of the patient or with the digitally reconstructed radiographs (DRR) supplied by the radiation treatment planning unit, if the patient is receiving radiation treatment on a three-dimensional isocentric plan. The EPI image is verified by the radiation

therapist in charge and if it is within acceptable limits according to departmental protocol, the radiation treatment may be given (Thwaites *et al.*, 1995: 70) (Kutcher *et al.*, 1994: 611).

5.4.3.8. In Vivo Measurements

Within the first three radiation treatments, In Vivo measurements have to be done to control the given dose that the patient is receiving and the overall dosimetry of treatment delivery. The measurements are taken by attaching a diode to the skin surface of the patient directly in the centre of the radiation field. The given radiation dose is then measured during radiation therapy and recorded on the In Vivo forms. The medical physicist has to control the measured readings and verify that they are within acceptable limits (Thwaites *et al.*, 1995: 70) (Kutcher *et al.*, 1994: 599).

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5.4.3.9. Record Keeping

The record keeping in the radiation therapy file is essential, as it follows the progress of the radiation treatment that the patient is receiving. The daily and the cumulative dose have to be annotated. The radiation therapists who perform the radiation therapy on that day have to initialise the radiation treatment file.

There are two verifications that have to be done: a primary verification, which has to be performed within the first three days of the radiation treatment; the second verification that is a daily verification, has to be carried out every day. In the next section, both verifications will be briefly explained.

5.4.3.9.1. Primary Verification

A primary check has to be performed and recorded to establish if the names and initials of all the personnel who initial the radiation treatment file are present. Then it has to be verified, that the electronic portal images and the In

Vivo dosimetry were done and the images and In Vivo forms are present and signed by the oncologist and physicist, respectively. Where applicable, the form indicating that the check films for the MCPs were done and signed by the physicist and the oncologist, has to be controlled. The radiation treatment file has to be controlled and signed by the medical physicist, within the first three radiation treatments (Kutcher *et al.*, 1994: 609).

5.4.3.9.2. Daily Check

The daily records that have to be kept and performed include the documentation of:

- the radiation treatment unit;
- the radiation treatment modality;
- the radiation treatment energy;
- the daily and cumulative radiation dose, that the patient is receiving;
- the monitor unit settings for each field have to be checked for consistency with the simulator parameters, and recorded;
- the initials of the radiation therapists responsible for the radiation treatment on the day and for the completion of the daily record have to be recorded (Ali, Haselhorst & Foster, 1998:44) (Kutcher *et al.*, 1994: 609).

5.4.4. SECTION D – WEEKLY REVIEW

5.4.4.1. Overview

The radiation treatment file should be reviewed weekly. This weekly review is required to determine if all the necessary verifications and controls were performed and whether they were performed correctly, as will be described below. As part of the weekly chart review, the reviewer should determine if any new fields have been created, or any previously treated fields modified.

All modified fields as well as new treatment fields, should be carefully reviewed, as described in Section C. The date of the previous weekly review should be checked to see if the interval between the chart reviews is appropriate, or whether it should be brought to the radiation unit supervisor's attention. It is recommended that the same reviewer does not check a radiation treatment chart two weeks in a row, as this creates an opportunity for incorrect data to elude the quality control system (Kutcher *et al.*, 1994: 609). The following sub-categories should be checked as well:

5.4.4.2. Simulator / Set-up Page

The simulator / set-up page should be reviewed just as it was with the initial verification (5.4.3.1.). The set-up page should be reviewed for each field to determine whether the necessary information was accurately and clearly indicated. Bearing in mind that this information is applied in the execution of the radiation therapy of the patient, it is very important that the information presented is accurate and sufficient and interpreted and applied correctly, as well (NRC, 1995: 9) (Kutcher *et al.*, 1994: 610).

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5.4.4.3. Radiation Treatment Prescription

The radiation treatment prescription has to be reviewed continually during the weekly overviews. This weekly review should be done according to the initial radiation treatment prescription control that was performed (5.4.3.2.) (Kutcher *et al.*, 1994: 595) (Thwaites *et al.*, 1995: 69).

5.4.4.4. Radiation Monitor Units (MU) Calculation

The monitor units entered into the record-and-verify system of the radiation treatment unit have to be critically reviewed every week. This review has to be performed in the same way in which the initial verification was done (5.4.3.3.). This weekly review is performed to ensure that no incorrect monitor unit goes through the radiation treatment procedure, undetected (Kutcher *et al.*, 1994: 598,607) (Thwaites *et al.*, 1995: 69).

5.4.4.5. Electronic Portal Images (EPI)

It has to be reviewed whether the EPIs were done and whether they were within acceptable limits (5.4.3.7) and duly signed by the oncologist (Thwaites *et al.*, 1995: 70) (Kutcher *et al.*, 1994: 611).

5.4.4.6. In vivo Measurements

It has to be reviewed if the in vivo measurements were done and whether they were within acceptable limits and duly signed by the medical physicist (Kutcher *et al.*, 1994: 611).

5.4.4.7. Record Keeping

The weekly review is an overall review of all the previous controls that were expected to be performed. Thus, the recordkeeping has to be reviewed in the same manner as the initial review (5.4.3.9.). The record keeping in the radiation therapy file is crucial, as it follows the progress of the radiation treatment that the patient is receiving. Two checks, namely the primary verification and the daily verification are performed (Holmberg & McClean, 2002: 16).

5.4.4.7.1. Primary Verification

A primary check has to be performed and recorded to establish if the names and initials of all the personnel, who signed the radiation treatment file, are present. Then, it has to be verified that the electronic portal images and the In Vivo dosimetry were done and the images and In Vivo forms are present and signed by the oncologist and physicist, respectively. Where applicable, the form indicating that the check films for the MCPs were done and signed by the physicist and the oncologist, has to be controlled. The radiation treatment file has to be controlled and signed by the medical physicist, within the first three radiation treatments (Holmberg & McClean, 2002: 16) (Kutcher *et al.*, 1994: 611).

5.4.4.7.2. Daily Verification

The daily records that have to be kept have to be controlled, to ascertain whether the necessary information was documented on a daily basis (5.4.3.9.2.) (Kutcher *et al.*, 1994: 611).

The recurrent chart-checking theme is to verify that all parameters are consistent, from the radiation treatment prescription through to the radiation treatment plan, to the simulator sheet, to the MU calculation, to the daily radiation treatment execution and record keeping.

5.4.5. SECTION E – ADVERSE INCIDENTS

5.4.5.1. Discovery of an Adverse Incident

Upon the discovery of an adverse incident, the adverse incident report form has to be completed (3.2.1.). The adverse incident then has to be reported to the oncologist in charge of the patient. After discussion with the oncologist, the adverse incident has to be rectified where and if possible (Holmberg & McClean, 2002: 16).

5.4.6. SECTION F – REVIEW AT COMPLETION OF TREATMENT

5.4.6.1. Final Review

As a final review, before the chart is placed in a file, the following items should be checked. The total radiation dose delivered has to be checked, to ascertain if it matches the prescribed radiation dose. The chart has to be checked to see if all the proper documentation were done (record keeping). A printed radiation treatment summary of the radiation dose delivered has to be included (Kutcher *et al.*, 1994: 611).

This section of the chapter provided the narration of the quality control procedure manual. The next section of the chapter will provide the

limitations of the study, as well as recommendations and the final conclusion.

5.5. LIMITATIONS OF THE STUDY

Limitations experienced during this study, were definitely the availability of literature on this specific subject and the support of the personnel at the department. As stated in 2.1 several searches e.g. literature searches, internet searches and Nexus searches, were performed to locate related published studies. Although an abundance of literature information of general quality assurance in radiation therapy and quality assurance, specially aimed at radiation physics and physicists were identified, very few related published studies, specifically on the analysis of incidents during radiation therapy of cancer patients, were found. Only a total of six related published studies that were applicable on this study, were found.

Patton *et al.*, (2003: 50) support this statement by stating that there are many publications under the general label of radiation therapy errors, which do not address medical mistakes, but instead deal with set-up uncertainties during patient treatment: patient positioning, organ motion, set-up error, and radiation dose determination each possess an extensive literature. In contrast, reports addressing radiation therapy treatment mistakes, or incidents, are relatively few.

Another limitation could be ascribed to the attitude of the radiation therapists. The personnel at the department were very sceptical and negative about the study. They felt that the adverse incidents would be labelled to people and interpreted as mistakes. In addition, to worsen matters, their 'mistakes' would then be put under a magnifying glass. However, they soon realised that this was not the case. As stated by Leer, Corver, Kraus, v.d. Togt & Buruma (1995: 81) it is important that the

personnel as a whole becomes aware of the quality control process and that they are stimulated to participate. The first reaction to the study, the reporting of the adverse incidents and the discussions, were not always very positive, as was the case with Leer *et al.*, (1995: 81). Some personnel at the department felt that work methods were adequately organised as they were and that further regulations were not necessary and could even be counter productive.

In line with Leer *et al.*, (1995: 81) once the discussions actually started and the study came into affect, different opinions were detected and the process became clearer. This in turn, has led to the motivation of more frankness and can also lead to increased efficiency and improvement in the quality of radiation care that the patients are receiving at the department. The personnel also realised that high quality and correct work can be verified by consistent and regularly performed, physical quality control. The increased motivation during the work is to the ultimate benefit of the patient (Roth *et al.*, 1998: 87). Even though there was a positive change in the radiation therapists' attitude it is still possible that some adverse incidents are not reported.

5.6. RECOMMENDATIONS

To perform a study that focuses on the errs of human ways in their professional surroundings, in a manner of speaking, is not an easy feat. Moreover, if these professional surroundings are highly technological equipment that are utilised in specialised complex radiation treatment for cancer patients and the personnel has to identify and report the incidents, it can be a very sensitive study.

Thus, it was of utmost importance that the objectives and the goals of the study were communicated thoroughly and meticulously to the personnel

involved, before the study commenced. The aim of the study, the method of the study and the significance of the study, should be well known to all involved. It is also of utmost importance to stress the fact that the intended goal of the study is to confirm the effectiveness and quality of the radiation therapy received by the patient and furthermore enhance these aspects, if required. The personnel involved must understand that the purpose of the incident reports is to identify potential and actual risks of inaccurate radiation therapy, and to eliminate adverse radiation therapy incidents (Dunn, 2003: 63), and *not* to focus attention on mistakes that they might have made.

Management can play a very important role in the improvement of the existing quality system of a department. Enlightened leadership can instill the desire to improve quality care and can provide the means, in both structure and support, to accomplish this (Kutcher *et al.*, 1994: 582). The outcome of radiation therapy is dependant on effective teamwork because radiation therapy relies on a multi-functional, multi-disciplinary team. Management needs to focus on the organisation, structure and control of quality control tasks, to motivate innovation and improvement of the quality control system. Management also needs to encourage confidence amongst the radiation therapists and enhances an open-door policy, so that radiation therapists feel comfortable to discuss new ideas and solutions. All ideas, even those that fail, can create opportunity for knowledge and better understanding (Kehoe & Rugg, 1999: 284).

The outcome of this study was the compilation of the quality control procedure manual, specially designed for radiation therapists. The present study can be extended by the implementation of this designed quality control procedure manual. The influence of the quality control procedure manual on the flow and structure of the radiation tasks and procedures performed by the personnel can be monitored. The subsequent influence on

the incidence of the adverse radiation incidents and the overall quality of the radiation therapy received by patients can be investigated as a future research project.

5.7. FINAL CONCLUSION

The final objective of the study was to compile QC methods in a QC procedure manual. The manual was designed to minimise the occurrence and consequences of any events, which could subsequently lead to adverse radiation incidents, which could potentially affect the outcome of patient treatment (Leer *et al.*, 1998: 74).

The study contributed to the advancement of the quality control management system at the Oncotherapy Department, Universitas Annexe, Bloemfontein, with the focus on the radiation treatment delivery process. Information obtained from the study was used in conjunction with information obtained from the literature study, as a basis in the compilation and design of a quality control procedure manual for the department. Once implemented, procedures and / or protocols in this manual will be able to assist in more accurate, effective and higher quality, radiation treatment delivery.

This quality control procedure manual includes the responsibilities of radiation therapists regarding quality control procedures during the course of radiation treatment of a patient. This quality control procedure manual, together with the adverse incident report will provide the department with an effective method of reporting adverse incidents and finding ways of improving radiation treatment delivery, with the minimum number of adverse incidents.

Thus, in a combined effort from all the radiation personnel at the department, the research objectives were achieved, through the monitoring of the origin and frequency of the adverse incidents, adverse incident discussions and literature reviews. Through the execution of the study, the quality control procedure manual for radiation therapists at Universitas Annexe has been compiled to assist and guide in the delivery of radiation therapy of the highest standard at the Oncotherapy department.

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APPENDICES

APPENDIX 1

UNIVERSITEIT VAN DIE VRYSTAAT
UNIVERSITY OF THE FREE STATE
YUNIVESITHI YA FREISTATA




Departement Onkoterapie/Department of Oncotherapy
Fakulteit Gesondheidswetenskappe/Faculty of Health Sciences
Skool vir Geneeskunde/School of Medicine

January 2007

TO WHOM IT MAY CONCERN

I, Prof L Goedhals, Head of the Oncology Department at Universitas Annex, BLOEMFONTEIN, hereby grant Billyndè Kinsella permission to conduct research for her M.Tech studies in the above mentioned department.

Thank you


PROF L GOEDHALS
HEAD OF ONCOLOGY DEPARTMENT
/ss

Departementshoof/Head of Department: Prof L Goedhals

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APPENDIX 2

UNIVERSITAS ANNEXE RADIATION THERAPY

Adverse Incident Report

RT. Nr: _____

Date: _____

Modality + Energy: _____

Plan/ Opp /Single field

Prescribed Dose: _____

Number #: _____

Prescribing doctor: _____

• _____ •

Adverse incident reported to: _____

Description of adverse incident: _____

Reason: _____

Corrective actions: _____

Preventative action: _____

• _____ •

Adverse incident reported to doctor: _____

Reporting radiation therapist: _____

APPENDIX 3

Data Form

	<u>Treatment Unit Malfunction</u>		<u>Dose Calculation Error</u>		<u>Incorrect Field Positioning</u>		<u>Patient Positioning</u>		<u>Radiation Treatment Energy</u>		<u>Shielding</u>	
	<u>Major</u>	<u>Minor</u>	<u>Major</u>	<u>Minor</u>	<u>Major</u>	<u>Minor</u>	<u>Major</u>	<u>Minor</u>	<u>Major</u>	<u>Minor</u>	<u>Major</u>	<u>Minor</u>
<u>Jan</u>												
<u>Feb</u>												
<u>Mar</u>												
<u>Apr</u>												
<u>May</u>												
<u>Jun</u>												

APPENDIX 4

Monthly distribution of reported adverse incidents in the various categories.

<u>Month</u>	<u>Incident</u>	<u>Major/Minor</u>	<u>Correction</u>
<i>January</i>	1. DCE	Minor	√
	2. DTE	Minor	X
<i>February</i>	1. FP	Minor	X
<i>March</i>	1. DCE	Minor	X
	2. RE	Minor	X
<i>April</i>	1. TUM	Minor	√
	2. DCE	Minor	√
	3. DTE	Minor	√
	4. IP	Minor	X
<i>May</i>	1. DCE	Minor	√
<i>June</i>	1. DCE	Minor	√
	2. IS	Minor	√
	3. FP	Minor	X
	4. PP	Minor	√
	5. IS	Minor	X

data transfer error (DTE), dose calculation error (DCE); incorrect field positioning (FP); incorrect patient (IP); incorrect patient positioning (PP); incorrect radiation energy (RE); incorrect shielding (IS); treatment unit malfunction (TUM)

APPENDIX 5

MINUTES OF THE MEETINGS

1. MEETING HELD ON 7 MARCH 2007 (1/2007)

1.1. January 2007

1.1.1. Reported Adverse Incidents

Adverse incident 1: The dose calculation for the radiation treatment was done for 200cGy fractions while 180cGy fractions were prescribed. The patient received 5 fractions radiation treatment on this dose. A correction was made for the adverse incident by compensating for the additional dose.

Adverse incident 2: Due to a change in the patient's separation measurement, the dose monitor units were altered after the patient returned for the second course radiation. It went unnoticed at the treatment unit and the patient received seven fractions radiation treatment with this radiation dose. The patient completed this specific segment of his radiation treatment and no correction could be made.

1.1.2. Opinions of the radiation therapists on the factors influencing the occurrence of adverse incidents

The radiation therapists felt that the heavy workload and the shortage of personnel played a major role in the occurrence of adverse incidents. Due to the continuous heavy workload, some patients were only simulated for their radiation therapy in the late afternoon and then it was expected that they would start with their radiation treatment on the same day. The radiation therapists commented that the starting of a new patient in the last few minutes of a workday put extra pressure on the already overworked radiation treatment units and the personnel and created an environment for

adverse incidents to occur. Opinions were also aired that new students did not possess the required knowledge to perform duties accurately and needed constant monitoring, assistance and attention.

1.1.3. Preventative Steps

The radiation therapists decided that no patients are to start with their radiation treatment before all the necessary verification checks have not been performed. These verification checks include the dose calculation checks and the secondary checks on the information that was entered into the computerised record-and-verify system at the radiation treatment unit.

1.2. February 2007

1.2.1. Reported Adverse Incidents

A patient received a radiation treatment plan with electron fields. With the set-up of the patient during treatment, the collimation degrees were altered and did not correspond with the instructions received from the treatment planning unit on the patients' treatment plan. The patient received two fractions radiation treatment with the incorrect collimator angle. It was not possible to correct this adverse incident.

1.2.2. Opinions of the radiation therapists on the factors influencing the occurrence of adverse incidents

No explanation could be given for the occurrence of this adverse incident.

1.2.3. Preventative Steps

If there are any queries or doubts about a prescription or radiation treatment set-up at the start of or during the radiation treatment of a patient, the relevant personnel, be it the oncologist, the planning radiation therapist or the simulator radiation therapist, has to be contacted and consulted on the matter. This needs to be done to clarify any uncertainties regarding the radiation treatment of the patient.

2. MEETING HELD ON 9 MAY 2007 (2/2007)

2.1. March 2007

2.1.1. Reported Adverse Incidents

Adverse incident 1: A dose distribution was done for the isodose curve of 115% while the oncologist prescribed the radiation dose on the isodose curve of 110%. The patient received one fraction radiation treatment with this radiation dose. No correction was made for this adverse incident because the deviation from the prescribed radiation treatment was miniscule.

Adverse incident 2: The patient received orthovoltage radiation treatment. The patient received two fractions radiation treatment with 250KV radiation energy instead of the prescribed 100KV radiation energy. The adverse incident was atoned for by decreasing the total number of radiation fraction treatments, to achieve the same result.

2.1.2. Opinions of the radiation therapists on the factors influencing the occurrence of adverse incidents

The first incident was once again a case of a heavy workload, shortage of personnel and the rush to start the patients with their radiation treatment.

No comments were given about the second adverse incident.

2.1.3. Preventative Steps

Once again, if there are any queries or doubts about a prescription or radiation treatment set-up, or if the radiation therapist responsible for the carrying out of the oncologists prescription does not agree with the radiation treatment prescription, the relevant personnel, be it the oncologist, the planning radiation therapist or the simulator radiation therapist, has to be contacted and consulted on the matter, before any changes are made to the radiation treatment.

2.2. APRIL 2007

2.2.1. Reported Adverse Incidents

Adverse incident 1: The treatment unit did not call up the last field in the patients' radiation treatment sequence and the controller did not notice that all the radiation fields had not been given. The patient received one fraction radiation treatment like this. The adverse incident was rectified by delivering this radiation field at a later stage in the radiation therapy course.

Adverse incident 2: The dose calculation was done incorrectly at the simulator and it was not checked at the radiation treatment unit before the patient received his first radiation treatment. The patient received one fraction radiation treatment on this dose. The adverse incident was corrected the following day, by compensating for the imprecise radiation dose.

Adverse incident 3: The monitor units were erroneously entered into the radiation treatment unit record-and-verify system and were not checked before the patient received radiation treatment. The patient received one fraction radiation treatment on this dose. The adverse incident was corrected the following day, by compensating for the imprecise radiation dose

Adverse incident 4: The patient entered the radiation treatment room when another patient was called and the radiation therapist did not notice. The patient thus received one fraction radiation treatment on another patient's radiation treatment plan. No correction could be made for this adverse incident.

2.2.2. Opinions of the radiation therapists on the factors influencing the occurrence of adverse incidents

The shortage of personnel and the high workload played a role in the occurrence of these incidents as well. Another factor was all the public holidays like the Easter weekend and Freedom Day and the fact that many of the patients wanted to go home over these periods. This resulted in a situation where some patients were receiving radiation treatments twice daily and thus, putting even more strain on the personnel and on the radiation treatment units.

It was also noted that the occurrence of adverse incidents increased when one of the radiation treatment units broke down and the patients had to be distributed amongst the remaining radiation treatment units. The distribution of the patients between the radiation treatment units necessitated the calculation of new applicable doses and the patients' radiation treatment

information had to be entered into the newly allocated radiation treatment unit's computerised record-and-verify system.

They also observed that radiation therapist rotation on the radiation treatment units could affect the occurrence of adverse incidents. This could be attributed to the fact that the newly rotated personnel were not familiar with the patients or their radiation treatment set-up. The same scenario occurs when a radiation treatment unit breaks down and the personnel of the affected unit have to work on other units. Thus, the patients may be treated by radiation therapists who are not familiar with their radiation treatment set-up.

2.2.3. Preventative Steps

The radiation therapists working at the simulator should double-check each other on the simulator set-up instructions and the calculated monitor units before the radiation treatment files are passed on to the radiation treatment units.

Patient identification is very important. Make sure that there are photographs on the treatment files and control name and birth date.

No patient should start their radiation treatment before all the necessary verification checks have been performed. This is significant for patients currently busy with their radiation treatment course, but who have to be moved to another radiation treatment unit, due to radiation treatment unit malfunction. These verification checks include the dose calculation checks and the secondary checks on the information that was entered into the computerised record-and-verify system at the radiation treatment unit.

3. MEETING HELD ON 4 JULY 2007 (3/2007)

3.1. May 2007

3.1.1. Reported Adverse Incidents

Adverse incident 1: The monitor units were erroneously entered into the radiation treatment unit record-and-verify system and were not checked before the patient received radiation treatment. The patient received one fraction radiation treatment on this dose. The erroneous dose was compensated for in the next fraction radiation treatment.

3.1.2. Opinions of the radiation therapists on the factors influencing the occurrence of this adverse incident

The shortage of personnel and the high workload played a role in the occurrence of this incident as well.

3.1.3. Preventative steps

No patient should start radiation treatment before all the necessary verification checks have been performed. This is significant for patients currently busy with their radiation treatment course but who have to be moved to another radiation treatment unit, due to radiation treatment unit malfunction. These verification checks include the dose calculation check and the secondary check on the information that was entered into the computerised record-and-verify system at the radiation treatment unit.

3.2. JUNE 2007

3.2.1. Reported Adverse Incidents

Adverse incident 1: The monitor units were incorrectly entered into the radiation treatment unit RV system and were not checked before the patient received his first radiation treatment. The patient received one fraction radiation treatment on this dose. The adverse incident was corrected by compensating for this radiation dose at the next fraction radiation treatment.

Adverse incident 2: The patient received treatment with extra shielding as if he were being treated with off-cord fields, while he was supposed to be treated with normal big fields with lead shielding of the cerebellum. The patient received one fraction radiation treatment like this. The adverse incident was corrected by deducting one fraction radiation dose from the original prescription of this specific segment of his radiation treatment course.

Adverse incident 3: The isocentre coordinates were described incorrectly in the simulator instructions. The error was discovered with the electronic portal imaging. The patient received two fractions radiation treatment on this set-up. No correction could be made for this adverse incident.

Adverse incident 4: A child was marked for brain and spine radiation treatment. With the marking of the booster fields it was discovered that his radiation treatment set-up position differed slightly from the original position. This was due to the fact that the child was scared, stressed and crying during the marking and immobilisation process. As his radiation treatment course progressed he started to trust the process and relaxed. This caused an alteration of 5 mm in the position of his neck which in turn caused an important part of the target volume to be shielded. Two additional radiation

fields were given together with his booster fields over the target volume to compensate for the lost radiation dose.

Adverse incident 5: The lead shielding tray was made incorrectly. Too much of the target volume was shielded during the patients' first fraction radiation treatment. No correction could be made for this adverse incident.

3.2.2. Opinions of the radiation therapists on the factors influencing the occurrence of adverse incidents

The radiation therapists observed that the occurrence of the reported adverse incidents were at their highest in flu season when many of the personnel were ill or on sick-leave. They felt that illness could lead to a lack of concentration and a decline in productivity.

The shortage of personnel increased in June, due to the fact that the students were writing examinations. The fact that the radiation treatment units are under pressure to start the patients with their treatment, even if it's late in the afternoon, creates an environment for incidents to occur.

3.2.3. Preventative Steps

The radiation therapists working at the simulator should double-check each other on the simulator set-up instructions and the calculated monitor units before the radiation treatment files are passed on to the radiation treatment units. Once again, no patients should start with their radiation treatment before all the necessary verification checks have been performed.

Any shielding accessories e.g. lead blocks, MCPs and multi-leaf collimation have to be verified before the radiation therapy of the patient commences. When a new patient starts with radiation therapy, the radiation therapists

who do the first radiation set-up and treatment have to carry out the first radiation treatment completely. This is done to check for any irregularities during the radiation treatment session and between the individual radiation treatment fields.

APPENDIX 6

Quality Control Procedure Manual

For Radiation Therapists

**THIS MANUAL CONTAINS THE QUALITY CONTROL CHECKS
which will be continuously implemented by:**

Facility Name: Oncotherapy Department, Universitas Annexe, Bloemfontein

Address: Oncotherapy Department
National Hospital
Roth Lane
Willows
Bloemfontein
Free State
South Africa

Date Completed: 2009

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SECTION A

SIMULATOR

1. Patient Identification

When a patient arrives at the simulator it is important to determine if it is the correct patient who is going to be simulated.

- | | Y | N | NA |
|--|--------------------------|--------------------------|--------------------------|
| 1.1. Patient name | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 1.2. ID | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 1.3. Address | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 1.4. Signed and witnessed consent form | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

2. Initial physical evaluation of patient and pertinent clinical information

The initial clinical evaluation of a patient file and pertinent clinical information encompasses a thorough assessment of the patient's diagnosis to verify that the correct procedure is going to be performed.

	Y N NA
2.1. Diagnosis of disease	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
2.2. Stage of disease	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
2.3. History	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
2.4. Pertinent pathology report	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
2.5. Positive histology	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
2.6. HIV status	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
2.7. Physical condition	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

3. Previously treated or concurrently treated volumes in which dose can overlap with the current treatment volume

The patient's file has to be checked to determine if the patient has received previous radiation therapy. If s/he has received previous radiation treatment, the simulator films of the previously treated area have to be located and reviewed to establish any potential overlap with the current radiation treatment site.

	Y N NA
3.1. Review simulator films to locate potential overlap	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
3.2. Review isodose distributions to locate potential overlap	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
3.3. Determine max cumulative dose in the overlap region	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
3.4. 0,5 cm separation between adjacent fields	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
3.5. Calculate cumulative dose to any other special points	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

- 3.6. Request In vivo measurements where appropriate

4. Simulator Room Initial Set-up

When a patient is to be simulated at the simulator, the simulator room has to be prepared according to the localisation that is going to be performed. The standard set-up of the simulator unit has to be done and/or controlled.

- | | Y | N | NA |
|---|--------------------------|--------------------------|--------------------------|
| 4.1. Gantry 0° | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.2. Collimator 90° | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.3. Bed rotation 0° | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.4. Magnification factor 1.5 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.5. Correct patient support and immobilization devices | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.6. Correct patient positioning | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.7. Source surface distance 100cm | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.8. Isocentric treatment technique | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.9. Specified fields | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

5. Simulation Set-up Notes

After the simulation of the patient is completed, it is very important to transfer all the information regarding the patient set-up, the field parameters and the radiation treatment regime, to the patient radiation treatment file, which is given to the radiation treatment unit where the patient receives his/her radiation therapy.

- | | Y | N | NA |
|---|--------------------------|--------------------------|--------------------------|
| 5.1. Patient parameters | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5.2. Patient treatment position | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5.3. Patient support and immobilisation devices | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5.4. Setup instructions | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

- | | | | | |
|-------|---|--------------------------|--------------------------|--------------------------|
| 5.5. | Anatomical location of tattoos | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5.6. | All physical beam parameters | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5.7. | Field size | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5.8. | Separation | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5.9. | Source surface distance 100cm | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5.10. | Isocentric treatment technique | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5.11. | Lead blocks/MLC | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5.12. | Wax build-up | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5.13. | Bite-block / Tongue depressor | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5.14. | Radiation therapists | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5.15. | Double-check by another radiation therapist | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5.16. | Initials of simulation radiation therapists | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

6. Radiation Treatment Prescription

Upon the completion of the simulation of the patient, the radiation treatment prescription is completed by the oncologist in charge of the patient.

- | | | | | |
|------|------------------|--------------------------|--------------------------|--------------------------|
| | | Y | N | NA |
| 6.1. | Treatment site | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6.2. | Treatment mode | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6.3. | Treatment energy | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6.4. | Treatment field | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

- | | | | | |
|-------|--|--------------------------|--------------------------|--------------------------|
| 6.5. | Given dose / Fractionation | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6.6. | Central dose / percentage | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6.7. | Field size | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6.8. | Source surface distance 100cm | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6.9. | Isocentric treatment technique | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6.10. | Daily dose, total dose and fractionation scheme | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6.11. | Prescription has been signed and dated by oncologist | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6.12. | Prescription changes have been signed and dated | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6.13. | Departmental guidelines followed | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

7. Radiation Monitor Units (MU) Calculation

For opposing radiation fields, the monitor units have to be calculated and checked before the radiation treatment file is handed over to the radiation treatment unit.

- | | | Y | N | NA |
|-------|--|--------------------------|--------------------------|--------------------------|
| 7.1. | Daily dose fractionation calculated is correct | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7.2. | MU consistent with total dose / fractionation scheme | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7.3. | Correct factors and parameters used | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7.4. | Correct radiation treatment unit | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7.5. | Correct radiation treatment modality | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7.6. | Correct field size / calculated equivalent square | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7.7. | Correct radiation treatment energy | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7.8. | Correct patient separation | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7.9. | Source surface distance 100cm | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7.10. | Isocentric treatment technique | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7.11. | If beam blocking is extensive, the appropriate equivalent square calculations have been made | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7.12. | If use of bolus is extensive, the appropriate separation has to be used | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

SECTION B

PLANNING UNIT

Three Dimensional Conformal Radiation Treatment Planning

When the CT images of the patient are received and transferred to the radiation treatment planning unit, there are several factors that should be controlled before, during and after the radiation treatment planning process.

1. The Scanner Form

The scanner form is received from the CT unit and has to be controlled for all the information regarding the patient, the patient setup and the radiation treatment protocol.

	Y	N	NA
1.1. Patient name and identification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.2. Patient orientation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.3. Patient parameters	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.4. Simulator and setup instructions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.5. Radiation treatment unit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.6. Contours are drawn in	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.7. PTV drawn in	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.8. Consultant signature at PTV	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.9. Prescription within department protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Treatment Planning Preparation

Before any planning can commence the patient identification and radiation therapy method has to be controlled.

	Y	N	NA
2.1. Correct directory	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.2. Teletherapy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- | | | | | |
|------|------------------------------------|--------------------------|--------------------------|--------------------------|
| 2.3. | Correct patient | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2.4. | Control RT number and patient name | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2.5. | Place marker correctly on tattoo | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

3. Treatment Planning Process

The radiation beams are positioned and/or adjusted to deliver the required dose to the planning target volume while sparing the normal surrounding tissue and critical structures.

Y N NA

- | | | | | |
|-------|--------------------------------------|--------------------------|--------------------------|--------------------------|
| 3.1. | Correct treatment field description | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3.2. | Correct treatment unit | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3.3. | Correct treatment method – SAD / SSD | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3.4. | Correct placing of isocentre | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3.5. | Correct gantry angles | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3.6. | Correct collimator degrees | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3.7. | Correct fieldsizes | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3.8. | Correct normalization point | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3.9. | Correct isodose curves | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3.10. | Correct orientation of wedges | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3.11. | Correct application of shielding | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

4. Treatment Plan Evaluation

The plan must be evaluated to ascertain whether the PTV are covered accurately and adequately by the radiation dose.

Y N NA

- | | | | | |
|------|---|--------------------------|--------------------------|--------------------------|
| 4.1. | Adequate coverage of PTV | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.2. | Adequate coverage on superior / inferior slices | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.3. | Maximum dose \leq 107% of prescribed radiation dose | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.4. | Minimum dose \geq 95% of prescribed radiation dose | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

- 4.5. Dose to critical organs within tolerance

5. Dose Calculation

The dose delivered to the PTV is calculated according to the prescription and the isodose line selected by the oncologist to determine the treatment unit monitor units.

Y N NA

- 5.1. Correct fractions
- 5.2. Correct isodose line
- 5.3. Correct total dose

6. Print-out Preparation

After completion of the plan and approval by the oncologist a graphical print-out is made which is then given to the radiation treatment unit together with the patients' radiation treatment file.

Y N NA

- 6.1. Graphical print-out of 3DCRTP
- 6.2. Patient name and identification
- 6.3. Patient orientation
- 6.4. Patient parameters
- 6.5. Simulator and setup instructions
- 6.6. All physical beam parameters
- 6.7. Computerised MU calculation work sheet
- 6.8. Selected isodose percentage indicated
- 6.9. Additional bolus, MLCs, lead shielding indicated
- 6.10. Signed by planning radiation therapist
- 6.11. Oncologist authorisation

SECTION C

RADIATION TREATMENT UNITS

The radiation treatment file should be thoroughly evaluated before the data is entered into the record-and-verify system of the radiation unit and the radiation treatment of the patient commences.

1. Simulator / Setup Page

The simulator/setup page should be reviewed for each field to determine whether the necessary information is accurately and clearly indicated.

	Y	N	NA
1.1. Patient parameters	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.2. Patient treatment position	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.3. Patient support and immobilisation devices	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.4. Setup instructions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.5. Anatomical location of tattoos	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.6. All physical beam parameters	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.7. Field size	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.8. Separation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.9. Source surface distance 100cm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.10. Isocentric treatment technique	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.11. Lead blocks/MLC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.12. Wax build-up	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.13. Bite-block / Tongue depressor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.14. Initials of simulation radiation therapists	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Radiation Treatment Prescription

With the completion of the simulation of the patient, the radiation treatment prescription is completed by the oncologist in charge of the patient.

	Y	N	NA
2.1. Treatment site	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.2. Treatment mode	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.3. Treatment energy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.4. Treatment field	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.5. Given dose / Fractionation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.6. Central dose / percentage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.7. Field size	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.8. Source surface distance 100cm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.9. Isocentric treatment technique	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.10. Daily dose, total dose and fractionation scheme	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.11. Prescription has been signed and dated by oncologist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.12. Prescription changes have been signed and dated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.13. Departmental guidelines followed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. Radiation Monitor Units (MU) Calculation

Before the monitor units are entered into the record-and-verify system of the radiation unit, it has to be reviewed.

		Y	N	NA
3.1.	Daily dose fractionation calculated is correct	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.2.	MU consistent with total dose / fractionation scheme	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.3.	Correct radiation treatment unit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.4.	Correct radiation treatment modality	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.5.	Correct field size / calculated equivalent square	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.6.	Correct radiation treatment energy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.7.	Correct patient separation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.8.	Source surface distance 100cm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.9.	Isocentric treatment technique	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.10.	If beam blocking is extensive, the appropriate equivalent square calculations have been made	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.11.	If use of bolus is extensive, the appropriate separation has to be used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.12.	Hot spots 3D plans calculated and documented	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.13.	MU indicated on the daily record for a particular field corresponds to the correct MU calculation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.14.	Correct output factor used for electron beam treatments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.15.	Correct output factor used for single beam treatments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.16.	Beam and patient parameters used for the calculation are consistent with those listed on the simulator setup sheet and/or treatment plan	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.17.	MU calculations have been reviewed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.18.	Correct factors and parameters used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

This information should then be meticulously entered into the record-and-verify system of the radiation treatment unit and controlled by a second radiation therapist. No treatment should be given before all of the above checks have been performed twice.

When the patient receives his/her radiation treatment the following should be evaluated

4. Initial physical evaluation of patient and pertinent clinical information

Before any procedures can be performed on the patient an initial evaluation of the patient file has to be performed for the assessment of the patient's diagnosis and staging. This is to be done to determine whether the correct procedure is going to be performed.

	Y	N	NA
4.1. Diagnosis of disease	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.2. Stage of disease	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.3. Positive histology	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.4. Physical condition	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.5. Pertinent pathology report	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.6. HIV status	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. Patient Identification

When a patient arrives at the radiation treatment unit, it is important to determine if it is the correct patient who is going to receive radiation treatment.

	Y	N	NA
5.1. Patient name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.2. ID	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.3. Photograph	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.4. Bathing instructions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.5. Signed and witnessed consent form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. Radiation Treatment Execution

When the patient enters the radiation treatment room the following has to be checked.

	Y	N	NA
6.1. Correct patient	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.2. Patient support and immobilization devices	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.3. Patient setup position correct	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.4. Tattoo location	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.5. Location of treatment field	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.6. Source surface distance 100cm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.7. Isocentric treatment technique	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.8. Correct field parameters	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.9. Special treatment devices	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.10. Beam modifiers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. Electronic Portal Images (EPI)

Electronic portal images have to done on the first day of treatment to verify that the radiation treatment fields are within acceptable limits.

	Y	N	NA
7.1. Electronic portal imaging done as per protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2. EPIs within acceptable limits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8. In vivo Measurements

Within the first three radiation treatments, In Vivo measurements have to be done to control that the given dose the patient is receiving is within acceptable limits.

	Y	N	NA
8.1. In vivo measurements (diode) done as per protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.2. In vivo measurements within acceptable limits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.3. In vivo measurements signed by physicist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. Record Keeping

Primary Check

	Y	N	NA
9.1. File of initials of all individuals who initial the chart	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.2. Electronic portal images	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.3. In Vivo dosimetry records	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.4. MCP check film form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.5. Checked by physicist within first three treatments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Daily Check

	Y	N	NA
9.6. Correct radiation treatment unit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- | | | |
|-------|--|--|
| 9.7. | Correct radiation treatment modality | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |
| 9.8. | Correct radiation beam energy | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |
| 9.9. | Daily record documenting | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |
| 9.10. | Daily and cumulative doses | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |
| 9.11. | MU settings for each field consistent with data in
the simulator/setup parameters sheet | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |
| 9.12. | Radiation therapist signatures | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |

SECTION D

WEEKLY REVIEW

The weekly review is actually an inspection of all the checks that should have been carried out before and during the radiation treatment of the patient. As part of the weekly chart review, the reviewer should also determine if any new fields have been created or any previously treated fields modified. All modified and new treatment fields should be carefully reviewed as described in the previous section.

1. Overview

	Y	N	NA
1.1. The date of the previous weekly chart review	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.2. Interval between chart reviews appropriate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.3. Chart and the calculations reviewed by physicist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.4. Not the same reviewer two weeks in a row	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Simulation Set-up Notes

The simulator/setup page should be reviewed for each field to determine whether the necessary information is accurately and clearly indicated and entered as such into the record-and-verify system.

	Y	N	NA
2.1. Patient parameters	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.2. Patient treatment position	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.3. Patient support and immobilisation devices	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.4. Setup instructions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.5. Anatomical location of tattoos	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.6. All physical beam parameters	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.7. Field size	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.8. Separation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.9. Source surface distance 100cm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.10. Isocentric treatment technique	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.11. Lead blocks/MLC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.12. Wax build-up	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.13. Bite-block / Tongue depressor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.14. Radiation therapists	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.15. Double-check by another radiation therapist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. Radiation Treatment Prescription

With the completion of the simulation of the patient the radiation treatment prescription is completed by the oncologist in charge of the patient.

	Y	N	NA
3.1. Treatment site	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.2. Treatment mode, and energy are identified	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.3. Treatment field	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.4. Given dose / Fractionation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.5. Central dose / percentage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.6. Field size	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.7. Source surface distance 100cm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.8. Isocentric treatment technique	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.9. Daily dose, total dose and fractionation scheme	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.10. Prescription has been signed and dated by oncologist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.11. Prescription changes have been signed and dated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.12. Departmental guidelines followed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. Radiation Monitor Units (MU) Calculation

The radiation monitor units have to reviewed weekly

	Y	N	NA
4.1. Daily dose fractionation calculated is correct	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- | | | |
|-------|---|--|
| 4.2. | MU consistent with total dose / fractionation scheme | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |
| 4.3. | Correct factors and parameters used | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |
| 4.4. | Correct radiation treatment unit | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |
| 4.5. | Correct radiation treatment modality | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |
| 4.6. | Correct field size / calculated equivalent square | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |
| 4.7. | Correct radiation treatment energy | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |
| 4.8. | Correct patient separation | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |
| 4.9. | Source surface distance 100cm | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |
| 4.10. | Isocentric treatment technique | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |
| 4.11. | If beam blocking is extensive, the appropriate
equivalent square calculations have been made | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |
| 4.12. | If use of bolus is extensive, the appropriate
separation has to be used | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |

5. Electronic Portal Images (EPI)

Electronic portal images have to be present in radiation treatment file for radiation treatment units with these facilities.

- | | | |
|------|--|--|
| | | Y N NA |
| 5.1. | Electronic portal imaging done as per protocol | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |
| 5.2. | EPIs within acceptable limits | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |
| 5.3. | EPIs signed by oncologist | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |

6. In vivo Measurements

The in vivo measurement document has to be present in the radiation treatment file.

	Y	N	NA
6.1. In vivo measurements done as per protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.2. In vivo measurements within expected limits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.3. In vivo measurements signed by physicist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. Record Keeping

Primary Check

	Y	N	NA
7.1. File of initials of all individuals who initial the chart	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2. Electronic portal images	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.3. In Vivo dosimetry records	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.4. MCP check film form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.5. Checked by physicist within first three treatments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Daily Check

	Y	N	NA
7.6. Correct radiation treatment unit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.7. Correct radiation treatment modality	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.8. Correct radiation beam energy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.9. Daily record documenting	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.10. Daily and cumulative doses	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.11. MU settings for each field consistent with data in the simulator/setup parameters sheet	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.12. Record of blocks, wedges, bolus, MLCs, MCPs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.13. Radiation therapist signatures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The recurrent chart checking theme is to verify that all parameters are consistent from prescription to treatment plan to simulator sheet to MU calculation to the daily treatment record.

SECTION E

ADVERSE INCIDENTS

1. Discovery of an adverse incident

Upon the discovery of an adverse incident the following actions should be followed.

	Y	N	NA
1.1. Identify adverse incident	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.2. Complete adverse incident report form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.3. Report adverse incident	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.4. If possible, compensate for adverse incident	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

SECTION F

REVIEW AT COMPLETION OF TREATMENT

As a final review before the chart is filed, the following items should be checked:


1. Final Review

		Y	N	NA
1.1.	Prescribed dose delivered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.2.	Documented according to department policy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.3.	Treatment summary included	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

APPENDIX 7

'THE DEVELOPMENT OF A RADIATION QUALITY CONTROL MANUAL
BY ANALYSING THE PREVALENCE OF ADVERSE INCIDENTS DURING
RADIATION THERAPY AT UNIVERSITAS ANNEXE, BLOEMFONTEIN,'

By Billynde Kinsella. A language check has been completed on this Masters
Dissertation, by S. G. Crews (B.BIBL.)



S.G. CREWS

JUNE 2008