



شبكة المعلومات الجامعية
التوثيق الإلكتروني والميكروفيلم

بسم الله الرحمن الرحيم



HANAA ALY



شبكة المعلومات الجامعية
التوثيق الإلكتروني والميكروفيلم



شبكة المعلومات الجامعية التوثيق الإلكتروني والميكروفيلم



HANAA ALY



شبكة المعلومات الجامعية
التوثيق الإلكتروني والميكروفيلم

جامعة عين شمس

التوثيق الإلكتروني والميكروفيلم

قسم

نقسم بالله العظيم أن المادة التي تم توثيقها وتسجيلها
علي هذه الأقراص المدمجة قد أعدت دون أية تغيرات



يجب أن

تحفظ هذه الأقراص المدمجة بعيدا عن الغبار



HANAA ALY

Failure Mode and Effect Analysis for Three Dimensional Radiotherapy at Ain Shams University Hospital

A Thesis

Submitted for partial fulfilment of Master degree in
Clinical Oncology and Nuclear Medicine

By

Gehad Sobhy Muhammad El-Benbawy
M.B.B.,CH, 2016

Under Supervisor of

Prof. Dr. Iman Aly Sharawy

Professor of Clinical Oncology and Nuclear Medicine
Faculty of Medicine, Ain Shams University

Dr. Khalid Nagib Abdel Hakim

Assistant Professor of Clinical Oncology and Nuclear Medicine
Faculty of Medicine, Ain Shams University

Dr. Ghada Refaat Meckawy

Lecturer of Oncology and Nuclear Medicine
Faculty of Medicine, Ain Shams University

**Faculty of Medicine
Ain Shams University
2022**

بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ

قالوا

سببنا انك لا تعلم لنا
إلا ما علمتنا إنك أنت
العليم العظيم

صدق الله العظيم

سورة البقرة الآية: ٣٢



Acknowledgments

*First and foremost, I feel always indebted to **Allah**, the **Most Beneficent** and **Merciful** who gave me the strength to accomplish this work,*

*My deepest gratitude to **Prof. Dr. Iman Aly Sharawy**, Professor of Clinical Oncology and Nuclear Medicine, Faculty of Medicine, Ain Shams University, for her valuable guidance and expert supervision, in addition to her great deal of support and encouragement. I really have the honor to complete this work under her supervision.*

*I would like to express my great and deep appreciation and thanks to **Prof. Dr. Hatem Mohamed Abdalla**, Professor of Clinical Oncology and Nuclear Medicine, Faculty of Medicine, Ain Shams University, for his meticulous supervision, and his patience in reviewing and correcting this work,*

*I must express my deepest thanks to **Dr. Khalid Nagib Abdel Hakim**, Assistant Professor of Clinical Oncology and Nuclear Medicine, Faculty of Medicine, Ain Shams University, for guiding me throughout this work and for granting me much of his time. I greatly appreciate his efforts.*

*I can't forget to thank with all appreciation **Dr. Ghada Refaat Meckawy**, Lecturer of Oncology and Nuclear Medicine, Faculty of Medicine, Ain Shams University, whom tirelessly and freely gave comments on various drafts of this piece of work. She really provided me a great support.*

*Special thanks to my **Parents** and all my **Family** members for their continuous encouragement, enduring me and standing by me.*

*✍ **Gehad Sobhy Muhammad El-Benbawy***

List of Contents

<i>Subject</i>	<i>Page No.</i>
List of Abbreviations.....	i
List of Tables.....	iv
List of Figures	vi
Introduction	1
Aim of the Work.....	3
Review of Literature	
Three-dimensional Radiotherapy	4
3-D Radiotherapy process	13
Risk Management.....	40
FMEA (Failure Modes and Effect Analysis)	56
Methodology	70
Results.....	103
Discussion	142
Summary	151
Conclusions	157
References	159
Arabic Summary	—

List of Abbreviations

<i>Abbr.</i>	<i>Full-term</i>
ACR	: American College of Radiology
ASTRO	: American Society for Therapeutic Radiology and Oncology
AAPM	: American Association of Physicists in Medicine
BEVs	: Beam's eye views
CNS	: Central Nervous System
CRT	: Conformal radiation therapy
CT	: Computer tomography
CTV	: Clinical target volume
D	: Lack of detectability
DRR	: Digitally reconstructed radiograph.
DRR	: Digitally reconstructed radiographs
DVH	: Dose Volume Histogram
EPID	: Electronic Portal Imaging Device
ESTRO	: European Society for Therapeutic Radiology and Oncology
EU BSS	: European Union Basic Safety Standards
FMEA	: Failure Modes and Effects Analysis
FMECA	: Failure mode effects and criticality analysis
FTA	: Fault tree analysis
GTV	: Gross tumour volume
HACCP	: Hazard analysis and critical control points
HFMEA	: Healthcare Failure Modes and Effects Analysis

IAEA	: International Atomic Energy Agency
ICRP	: International Commission on Radiological Protection
ICRU	: International Commission on Radiological Units
IGRT	: Image Guided Radiotherapy
ILS	: Incident learning system
IM	: Internal margin
IMRT	: Intensity modulation radiation therapy
ITV	: Internal Target Volume
IVD	: In-vivo dosimetry
MLC	: Multi-leaf collimator
MPRs	: Multi-planar reconstructions
MRI	: Magnetic resonance imaging
MUs	: Monitor units
NTCP	: Normal tissue complication probability
NTCP	: Normal tissue complication probability
O	: Occurrence
OARs	: Organs at risk
OD	: Optical density
PET	: Positron emission tomography
PRV	: Planning organ at risk volume
PTV	: Planning target volume
QM	: Quality management
RCA	: Root cause analysis
ROSIS	: Radiation Oncology Safety Information System
RPN	: Risk Priority Number

RT	: Radiotherapy
RT	: Radiation Technician.
RTPS	: Radiation treatment planning system
RTT	: Radiation therapy technologist
RVS	: Record and verify system
S	: Severity
SAD	: Source axis distance
SAFRON	: Safety in Radiation Oncology database
SBRT	: Stereotactic body radiation therapy
SPECT	: Single photon emission computed tomography
SSD	: Source skin distance
TCP	: Tumour control probability
MLC	: Multi-leaf collimator
TG100	: Task group 100
TLD's	: Thermo-luminescent dosimeters
TPS	: Treatment Planning System
TV	: Treated volume
3-D CRT	: Three dimensional conformal radiotherapy
3-D	: Three dimensional radiotherapy

List of Tables

Table No.	Title	Page No.
Table (1):	Past and Present in Radiotherapy.....	5
Table (2):	Classification of conformal therapy according to the methodology and tools associated with each step of the procedure.....	7
Table (3):	A collection of recommended radiotherapy risk management related terminology.	45
Table (4):	Key staff functions in clinical radiation therapy have been summarized in the following table	54
Table (5):	Descriptions of the O, S and D values used in the TG-100 FMEA.....	63
Table (6):	Terminology relating to severity as used in the TG-100 FMEA.....	65
Table (7):	The basis for assigning these scores and their numerical values according to	68
Table (8):	FMEA Questionnaire for Head of department.....	71
Table (9):	FMEA Questionnaire for Oncology Staff	75
Table (10):	FMEA Questionnaire for Assistant lecturers and residents.....	78
Table (11):	FMEA Questionnaire for physicists.....	89
Table (12):	FMEA Questionnaire for Technicians	94

Table (13):	FMEA Questionnaire for Engineers	98
Table (14):	Major processes of 3-D Radiotherapy, potential causes of failure, severity scoring, Risk priority number (RPN) and suggested preventive measures for each failure mode	120
Table (15):	Major processes of 3-D Radiotherapy, potential causes of failure (after affiliation), severity, occurrence & lack of Detectability scoring, Risk priority number (RPN), suggested preventive measures for each failure mode (after affiliation) and risk reassessment.....	133
Table (16):	Personnel Requirements For Clinical Radiation Therapy.....	148

List of Figures

<i>Figure No.</i>	<i>Title</i>	<i>Page No.</i>
Figure (1):	Radiotherapy from the past to the present.....	4
Figure (2):	Flow chart illustrating the steps in the EBRT process, starting with diagnosis and ending with treatment delivery	14
Figure (3):	Schematic representation of different possibilities to combine uncertainties to define the PTV from the GTV	24
Figure (4):	Illustration of typical data exchanges between the RVS and other pieces of equipment in a modern radiotherapy department.....	33
Figure (5):	Simplified illustration of the relationships of the main procedural concepts applied in risk management of 3D radiotherapy.	48
Figure (6):	High-level Flow chart illustrating major steps in 3D radiotherapy process.	114
Figure (7):	Detailed Process Map of Three Dimensional Radiotherapy at Ain Shams University Hospital.....	115
Figure (8):	Affinity Diagram for suggested preventive measures for 3D radiotherapy process at Ain Shams University Hospital	118
Figure (9):	Suggested process Map of Three Dimensional Radiotherapy at Ain Shams University Hospital	130

Introduction

The increasing complexity of modern radiation therapy planning and delivery challenges traditional prescriptive quality management (QM) methods, such as many of those included in guidelines published by organizations such as the AAPM, ASTRO, ACR, ESTRO, and IAEA. These prescriptive guidelines have traditionally focused on monitoring all aspects of the functional performance of radiotherapy (RT) equipment by comparing parameters against tolerances set at strict but achievable values. Many errors that occur in radiation oncology are not due to failures in devices and software; rather they are failures in workflow and process. A major source of quality and safety impairment arises from weakness or variability in radiotherapy processes. Whereas, for example, there are a limited number of linear accelerator designs, there is very little standardization of processes between radiotherapy clinics. The wide variability in processes requires a much higher degree of customization that has to be carried out by those with intimate knowledge of the processes themselves. A structured methodology for analyzing clinical processes and for developing clinic- and site-specific quality management programs that more effectively and efficiently address work practices in individual clinics is needed (*Huq et al., 2016*).

Moreover, radiotherapy technology advancements have led to an increase in the use of computers and associated electronic processes. However, the 2009 International Commission on Radiological Protection (ICRP) Report 112 indicates that new types of incidents are occurring due to increased sophistication of treatment processes and the omnipresence of computers with increasingly complicated software (*Ortiz-Lopez et al., 2009*).

The report highlights the need to not only learn from incidents but also to continuously and proactively anticipate potential errors and likelihood of their occurrence. The key advantage of using a proactive risk assessment is in identifying and anticipating potential errors and taking action before a radiation incident occurs. Failure Modes and Effects Analysis (FMEA) is a structured and logical analysis of a process to identify steps which are associated with the highest risk (*Huq et al., 2016*).

The benefits and feasibility of FMEA for radiotherapy intensity modulation radiation therapy (IMRT), stereotactic body radiation therapy (SBRT) and brachytherapy practices have previously been described. Radiotherapy process mapping and FMEA will assume more central roles in optimization of clinical processes to produce maximum safety and quality of patient care (*Mayadev et al., 2015*).