

DEVELOPMENT OF QUALITY MANAGEMENT SYSTEM FOR RADIOTHERAPY FACILITY

BY

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OUTLINE

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INTRODUCTION

- ▶ The quality of radiation therapy administered to patients is of great concern to national and international professional bodies and organisations
- ▶ Radiotherapy involves the use of radiation sources
- ▶ Radiotherapy is dynamic and multidisciplinary in nature
- ▶ To achieve optimum quality in treatment outcomes, QMS has to be established

INTRODUCTION

- Radiotherapy is a complex treatment modality

Causes of radiotherapy incidents/accidents

- lack of training, competence or experience
- poor design and documentations of procedures
- over-reliance on automated procedures
- poor communication and lack of team work
- Hierarchical departmental structure
- Working environment (Royal College of Radiology 2008)

INTRODUCTION

- WHO reported that a total of 3125 patients (USA, Latin America, Europe and Asia) were adversely affected by radiation therapy related accidents and incidents.
- 1.2% of this number of patients died
- 98.8% suffered either a deterministic or stochastic effects. Some might even had their disease recurring.

INTRODUCTION

- **Efforts to uphold radiotherapy quality service and continually improve it is so essential.**
- **This is why every radiotherapy facility must develop a QMS based on the ISO standards.**

OBJECTIVE

- The main objective of this presentation is to outline the means to develop a comprehensive Quality Management System for a radiotherapy facility being guided by the general principle stipulated in the ISO9001:2000.

SCOPE

- This covered organizational, technical, physical and clinical quality management system standards for Radiotherapy Facility with emphasis on linear accelerator.

DEFINITIONS

- **Quality is the degree to which a set of inherent characteristics of an object fulfills requirements (ISO9000:2015)**
- **Quality as the totality of features and characteristics of a radiation therapy process that bear on its ability to satisfy stated or implied needs of the patient” (Kutcher et al, 1994)**
- **QMS is a set of rules, which an organization uses internally to assure that product and services, which it delivers to its customers/clients satisfy their needs and expectations.**

PROGRESS IN QM IN RT

- The early QA programs in radiotherapy had a greater portion on equipment & computerised systems (WHO 2008, Hartman G., 2006)
- However, most of the earlier recorded accidents and incidence were as a result of human errors (WHO, 2008), hence the need not to limit QA only to physical and technical aspect of radiotherapy.
- Attention was shifted to QMS which included clinical, physical and Administrative aspect of RT (Synergy News, April 2017)

IMPORTANCE OF QMS

- QMS is a regulatory requirement (GSR Part 3)
- continuing quality improvement, increase of efficiency, chance for a cultural change, raised morale of personnel, reduction of the chance of litigation and increase of competitiveness (Hartmann G., 2006).
- QMS reduces the occurrence of incidents and accidents (Yang et al, 2014, Smith S. et al 2020)

FACTORS TO CONSIDER

- regulatory framework that exist in the country (Bogusz-Czerniewics, M.)
- the size and resources, equipment and technology available at the facility
- Quality Goals set by the facility (Kehoe T. and Rugg L.J)

ROAD MAP TO CONSIDER

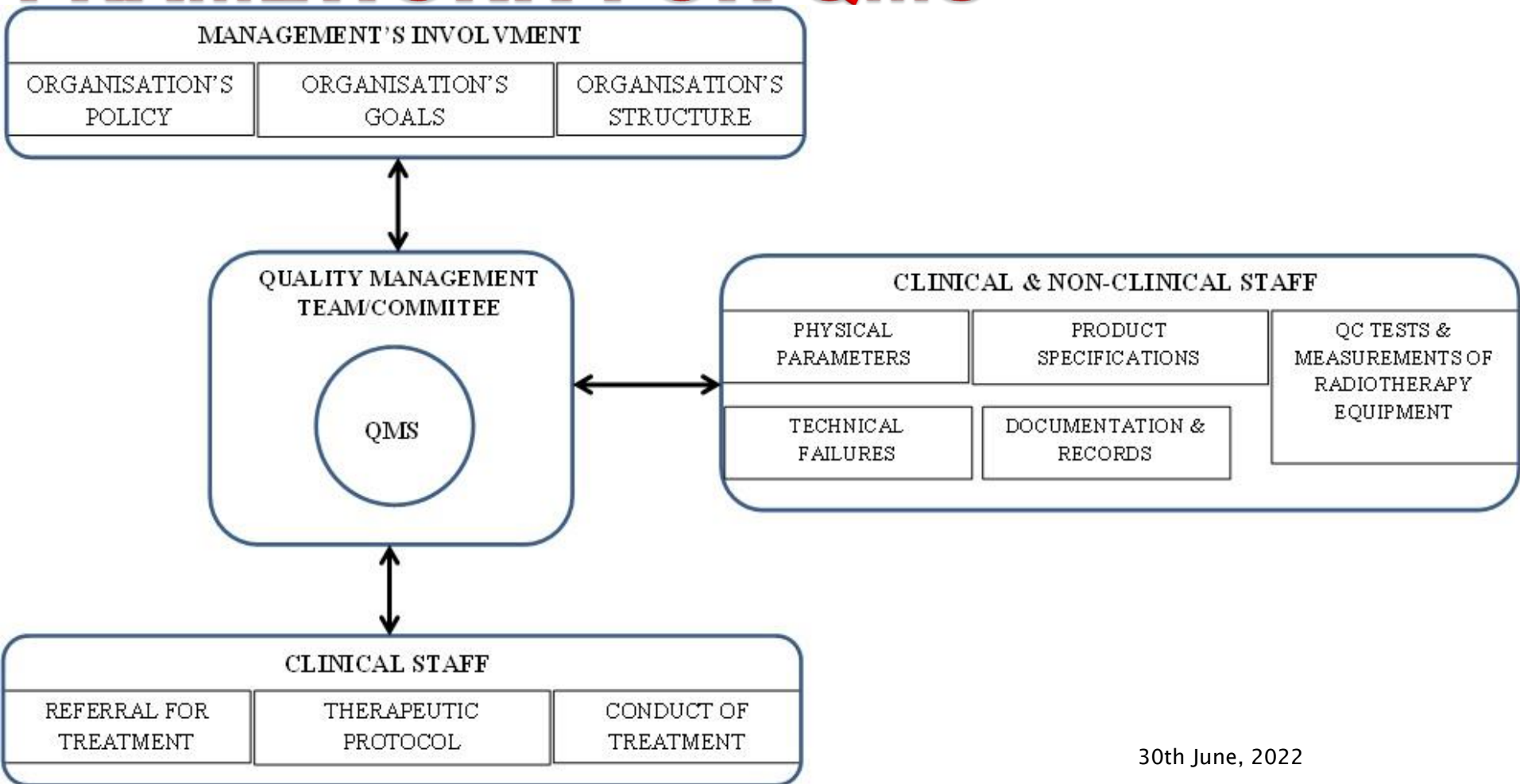
QA programme incorporating checks on very important aspect of the technical treatment delivery

Formal documentation on certified QA system focusing on the technical treatment delivery

Finally a comprehensive quality management system covering all parts of the radiation therapy



FRAMEWORK FOR QMS



FRAMEWORK FOR QMS

Category	No. of interventions
MANAGEMENT'S INVOLVEMENT	7
Organisation's policy	1
Organisation's Goal	4
Organisation's Structure	4
QMS Systemic Documentation	35
CLINICAL ASPECT	
Referral for Txt/txt decision etc	9
Therapy protocol	18
Conduct of treatment	14
PHYSICAL/TECHNICAL ASPECT	
Documentation & Records	14
Physical Parameters	3
Technical Failures	6
Product Specification	3
Quality Control of physical, technical, mechanical parameters	14

CONCLUSION & RECOMMENDATION

- The importance of quality management system was underscored and its development should be very systematic.
- Radiotherapy facility needs commitment and lots of effort from the quality management team to fully develop a QMS.
- However, a greater effort is needed by the entire workforce to ensure its implementation especially when the changes that will occur are drastic.
- The quality system will need constant reviews through quality audits which will lead to improvement of quality of service in radiotherapy

delivery

CONCLUSION & RECOMMENDATION

Hospital Authorities

- **must ensure that adequate resources are allocated for quality issues which will include training and retraining.**
- **There should be deliberate systematic attempt to fully develop and implement the quality management system**

CONCLUSION & RECOMMENDATION

The regulatory authority:

- must strengthen their regulatory regime to enforce requirements on quality management systems
- must take time to track and monitor licensees in their progress when it comes to developing and implementing QMS since it takes time to fully develop and implement

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ATTENTION**