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RADIATION EXPOSURE CONSIDERATIONS IN RADIOIODINE THERAPY CASES

BY

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This thesis is submitted to the University of Ghana, Legon in partial fulfillment of the requirement for the award

of

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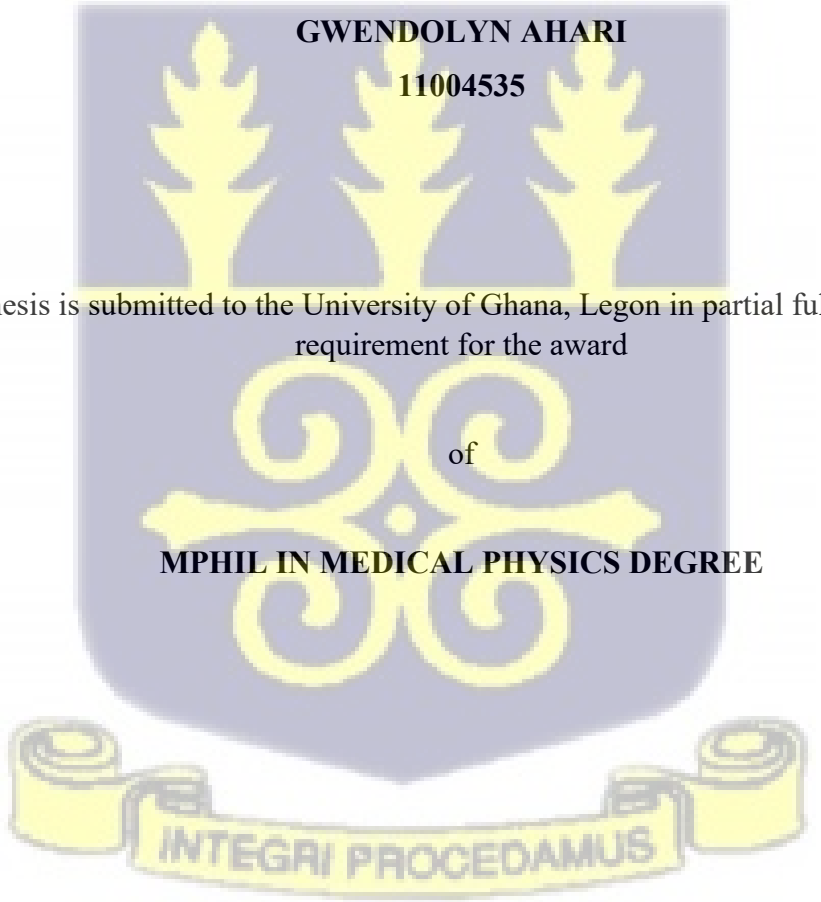

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DECLARATION

DECLARATION BY CANDIDATE

This study is the result of my own research, which I carried out under supervision in the Department of Medical Physics. I hereby declare that, except for references to other people's work, which has been duly referenced. This research presents finding original to me and has not been submitted either completely or in part for the award of any other degree in this or another University.

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DECLARATION BY SUPERVISORS

I declare that the practical work and presentation of this research were supervised by me in accordance with guidelines on supervision of thesis laid down by the University of Ghana.

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DEDICATION

This project is dedicated to my family for their support throughout the program.

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ACKNOWLEDGEMENT

I am grateful to the Almighty God for the strength and grace to go through this program successfully, and for His continuous blessing and favour upon my life.

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LIST OF ABBREVIATIONS

AAPM	-	American Association of Physicists in Medicine
ATA	-	American Thyroid Association
Cs-137	-	Caesium-137
CT	-	Computed Tomography
DTC	-	Differentiated Thyroid Cancer
EANM	-	European Association of Nuclear Medicine
Gy	-	Gray (unit of absorbed radiation dose)
I-131	-	Iodine-131
IAEA	-	International Atomic Energy Agency
ICRP	-	International Commission on Radiological Protection
ICRU	-	International Commission on Radiation Units and Measurements
KBTH	-	Korle Bu Teaching Hospital
MBq	-	Megabecquerel
mCi	-	Millicurie
MIRD	-	Medical Internal Radiation Dose
µSv/h	-	Micro sieverts per hour (unit of radiation dose rate)
NIST	-	National Institute of Standards and Technology
NRONMC	-	National Radiotherapy Oncology and Nuclear Medicine Centre
PET	-	Positron Emission Tomography
PPE	-	Personal Protective Equipment
SNMMI	-	Society of Nuclear Medicine and Molecular Imaging
SPECT	-	Single-Photon Emission Computed Tomography
Tc-99m	-	Technetium-99m

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ABSTRACT

This study was conducted to assess the external radiation exposure rates of patients undergoing iodine-131 (I-131) therapy and evaluate how well current practices align with radiation safety protocols, particularly at the National Radiotherapy Oncology and Nuclear Medicine Centre (NRONMC), Korle Bu Teaching Hospital. The study also verified whether the dose of I-131 administered to patients corresponded with the prescribed dose. These were necessary to identify possible gaps in protocol application and help minimize unnecessary radiation exposure to both the public and health professionals. A prospective cross-sectional design was used, with data collected from nineteen (19) patients made up of both inpatients (thyroid cancer cases) and outpatients (hyperthyroidism cases). Patient exposure rates were measured at specific time intervals post-administration using calibrated survey meters. Quality control tests—including linearity, accuracy, constancy, and geometry—were conducted on the dose calibrator prior to use to ensure measurement reliability. All QC tests passed within the internationally acceptable ±5% tolerance limit, validating the equipment for accurate dose measurement. Findings from the study revealed that while most patients were safely discharged, some had external exposure levels exceeding the recommended threshold of 30 μSv/h at discharge. Furthermore, although the majority of administered doses were within ±10% of the prescribed values, two patients exceeded this range with percentage differences of 19.5% and 27%, respectively. These discrepancies suggest the need for stricter monitoring of dose preparation and administration. In addition, while inpatients showed a predictable decrease in exposure over time, outpatients demonstrated inconsistent exposure patterns due to factors such as shared waiting areas and early discharge. The outcome of the study showed that although the centre has some safety measures in

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place, there are notable inconsistencies in practice and discharge decisions. The study concludes that there is a need for the development of localized and well-documented protocols to enhance consistency in patient management, especially for radiation exposure assessment and discharge criteria. It is recommended that routine QC checks be strictly enforced, patient isolation be improved, and staff training intensified to align with best practices and ensure optimal patient and public safety in I-131 therapy cases.

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CHAPTER ONE

INTRODUCTION

This chapter discusses the study's background, the problem statement, outlines of the study's objective, justifies its relevance and significance, and defines the research scope.

1.1 Background

Nuclear medicine is an integral and evolving field within the broader spectrum of medical science (IAEA, 2018). It has two main components namely; diagnostic nuclear medicine procedures (where radiotracers are used to visualize organs and their functions) and therapeutic nuclear medicine procedures (where radiation is delivered to target diseased tissues)(Society of Nuclear Medicine and Molecular Imaging, 2020). Additionally, it may also involve the use of molecular biology techniques (which involves studying biological processes at a molecular level mostly through imaging). The application of radioactive substances in this field enables clinicians to visualize, diagnose or treat various diseases with precision. Among its various branches, nuclear medicine's therapeutic applications have shown significant promise, particularly in the treatment of thyroid-related conditions through radioiodine therapy. This modality utilizes radioactive iodine isotopes, such as Iodine-131 (I-131), to treat thyroid disorders like hyperthyroidism and hypothyroidism which include Graves' disease, goitre, thyroid nodules, and thyroid cancer (Reiners & Schneider, 2002). Radioiodine therapy is a cornerstone treatment for both hyperthyroidism and thyroid cancer (American Thyroid Association, 2021). While surgery is often the initial approach for thyroid cancer, radionuclide therapy like I-131 is for eliminating residual thyroid

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tissue and preventing recurrence after the surgery. In hyperthyroidism, it effectively reduces thyroid hormone production.

Radioiodine therapy, specifically using I-131, has been a cornerstone in managing thyroid disorders, such as hyperthyroidism and thyroid cancer. According to Reiners and Schneider (2002), I-131 therapy involves the administration of a radioactive form of iodine drug to the patient, which selectively targets and destroys the thyroid tissue. This therapy works by exploiting the thyroid gland's natural propensity to absorb iodine, thereby allowing targeted delivery of radiation that selectively destroys diseased tissue while sparing most healthy cells. This approach has been widely accepted since its inception in the 1940s and continues to be a mainstay treatment modality (Bhatia *et al*., 2023). The clinical importance of I-131 therapy is underscored by its dependence in dual application: it is employed in relatively low doses for treating hyperthyroidism and in higher doses for ablating residual thyroid tissue or treating thyroid cancer post-surgery (Marinelli, Foote, & Quimby, 1948).

Despite its widespread use, I-131 therapy is not without risks, particularly concerning radiation exposure to the patient and those around them. Patients treated with I-131 emit radiation that poses potential hazards to family members, caregivers, and healthcare workers, necessitating rigorous safety protocols (Kochovska *et al*., 2017). To reduce exposure to patients, staff, family members, and others, healthcare professionals must follow precautions. With proper education and instructions, radiation exposure to patients, families, and the general public can be significantly reduced. The criteria used to determine when the patient may be discharged include an absolute retained activity, an absolute external dose rate from the patient, and a retained activity based on the potential radiation exposure to family members and the public (Yonekura *et al*., 2019).

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This research emphasizes the critical role of medical physicists in optimizing dosimetry, calculating and administering the precise radiation dose required to achieve therapeutic efficacy while minimizing side effects and radiation exposure to others. Moreover, the study seeks to address gaps in current practices in relation to patients' safety, particularly concerning the discharge of patients post-I-131 therapy. This is intended to provide the bases for comprehensive monitoring of radiation levels to ensure they remain within safe limits. In addition, this is to assess the adherence to established safety guidelines and/or protocols in the protection of patients and the public. Furthermore, this is to enhance treatment protocols and ensure that safety measures are both adequate and consistently applied in order to ensure the well-being of patients undergoing iodine-131 therapy for hypothyroidism and thyroid cancer (Luster *et al*., 2008).

1.2 Problem Statement

Radioiodine therapy is an effective procedure for treatment of hyperthyroidism and thyroid cancer. Despite this advantage, radioiodine therapy presents a significant challenge to patients in terms of patient discharge protocols and radiation safety management. The growing prevalence of I-131 therapy, particularly in developing countries including Ghana, has revealed critical gaps in both research and practice. The absence of localized protocols and adherence to international guidelines has resulted in inconsistencies in how patients are managed post- radioiodine therapy, particularly concerning the acceptance radiation exposure rates of discharged patients. This lack of standardization and well-documented protocols poses significant risks to patients, healthcare staff, and the general public. Without proper safety measures, individuals may be unknowingly exposed to unsafe levels of radiation from patients

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recently treated with I-131. The situation is further compounded by the high-energy gamma radiation emitted by I-131, which can penetrate through tissue and expose surrounding individuals to external radiation. Prolonged or repeated exposure—especially among vulnerable groups like children and pregnant women—can lead to cellular damage, increased risk of cancer, genetic mutations, or developmental defects in unborn babies. These potential outcomes highlight the critical need for strict, evidence-based discharge protocols and radiation safety practices. The absence of such measures defines the central problem of this study: the inconsistent management of post-therapy radiation exposure, which may compromise public and occupational health.

The problem is particularly pronounced in Ghana, where the absence of a documented local protocol exacerbates the challenges faced by healthcare providers in ensuring safe and effective therapy. This lack results in inconsistent discharge decisions, poor radiation monitoring practices, and increased risk of unintentional exposure to family members, healthcare workers, and the public. It also hampers the ability to enforce accountability, standardize care, and protect vulnerable populations, ultimately undermining the safety and quality of I-131 therapy delivery. This study addresses these issues by evaluating current practices, identifying gaps, and proposing evidence-based solutions for standardized patient discharge protocols, with the ultimate goal of minimizing radiation risks and ensuring safer treatment delivery, reduced complications, and greater protection for both patients and those around them.

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1.3 Relevance and Justification

The relevance of this study lies in its potential to significantly improve patient safety and effectiveness of radioiodine therapy, particularly in settings where existing

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protocols may be insufficient or inconsistently applied. The use of I-131, while effective, involves dealing with a radionuclide that poses both internal and external radiation risk. There are three sources of potential radiation exposure from radioiodine therapy. It includes external (photon) radiation emitted by the patient and any other source, internal contamination from ingestion or absorption of spoilt radioiodine-containing waste, and inhaled airborne contamination from volatilized iodine (IAEA, 2009).

The study is particularly justified given the strong gamma radiation emitted by I-131, which presents a significant risk of external exposure not just to the patient, but also to those in close proximity, such as family members, caregivers, and healthcare workers. Because of the strong penetration power and relatively high energy of gamma radiation emitted from I-131, radiation safety becomes a major concern. The high-energy gamma radiation can penetrate through the patient's body and can cause external radiation hazards to the persons around the patient especially to children and pregnant females, as they are more sensitive to radiation (Bhatia *et al*., 2023).

The study's focus on optimizing safety protocols and discharge practices is crucial in mitigating these risks. By controlling exposure through time, distance, and shielding, as well as by managing contamination risks through protective clothing and effective ventilation (IAEA, 2019), the study aims to provide a comprehensive approach to radiation safety. This is especially important in regions like Ghana, where the lack of localized guidelines may increase the risk of radiation exposure to both patients and the public.

While the study does not extend to the patient's journey home or their time at home, the implications of its findings are expected to have a lasting impact. By evaluating radiation levels and safety practices prior to discharge, the study seeks to minimize

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risks not just within the hospital setting, but also in the broader community, ensuring that patients, their families, and the public are protected from unnecessary radiation exposure.

1.4 Objectives of the Study

The main objective of this study is to assess and optimize the current external radiation exposure rates of patients undergoing I-131 therapy for hyperthyroidism and thyroid cancer.

The specific objectives of the study are to

1) verify the activity being administered to the patient as against the prescribed or intended activity to be given.
2) evaluate the radiation exposure rates of patients as a function of time following I-131 administration.
3) assess the adherence to Safety Protocols and guidelines during I-131 therapy.

1.5 Scope of the Study

This study was conducted at the National Nuclear Medicine and Radiotherapy Centre (NNMRC) of the Korle Bu Teaching Hospital. It focuses on patients undergoing low-dose I-131 therapy-refers to doses usually ranging from 10 to 30 mCi (370 to 1,110 MBq) for treating hyperthyroidism and high-dose therapy for thyroid cancer. The scope is carefully defined to include the period before patients are discharged from the hospital, with an emphasis on ensuring that radiation levels are within safe limits at the time of discharge.

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1.6 Summary of Introduction

At the end of the introductory chapter, it is clear that while I-131 therapy is an effective treatment for thyroid disorders, it presents significant challenges related to radiation exposure and patient safety. The chapter concludes by identifying the critical need for tailored, evidence-based protocols that minimize risks and standardize patient management practices post-therapy. This need serves as the foundation for the study's objectives to assess current practices and recommend improvements.

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CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

This chapter reviews the various literature underpinnings and historical evolution of I-131 therapy including understanding the fundamental principles of radiation physics, radiobiology, and nuclear medicine. These principles are key in understanding various protocol and procedures during I-131 therapy. Furthermore, this chapter discusses the key concepts and principles underlying I-131 therapy, including radioactive decay, radiation interactions with matter, absorbed dose, biological effects, and dose-response relationships. Additionally, a historical overview of I-131 therapy, encompassing early discoveries, the development of dosimetry techniques, and the transition to personalized approaches, will be presented. This comprehensive examination of the theoretical framework and historical context provides a solid foundation for understanding the current practices and challenges in I-131 therapy, ultimately paving the way for advancements in optimized dosimetry and clinical outcomes.

2.2 Theoretical Framework:

The theoretical framework of dose assessment in I-131 therapy is rooted in the fundamental principles of radiation physics, radiobiology, and nuclear medicine (Hall & Wuu, 2023). These principles are essential for the accurate calculation and optimization of I-131 doses leading to improved therapeutic efficacy and minimized adverse effects. Some of the key Concepts related to these principles are:

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- **Radioactive Decay:** I-131 is a radioactive isotope that undergoes beta-minus decay, emitting beta particles and gamma rays (National Institute of Standards and Technology, n.d.). The rate of decay follows an exponential law, characterized by the physical half-life of approximately 8.02 days (American Association of Physicists in Medicine, 2006).
- **Radiation Interactions with Matter:** The emitted beta particles and gamma rays interact with bodily tissues through various mechanisms, including ionization, excitation, and scattering (Attix, 1986). These interactions can result in both therapeutic and adverse biological effects (Hall & Wuu, 2023).
- **Absorbed Dose:** The absorbed dose is the fundamental quantity used to quantify the energy deposited in a given mass of tissue by ionizing radiation (International Commission on Radiation Units and Measurements, 2007). It is expressed in units of Gray (Gy), where one Gy equals one joule of energy deposited per kilogram of tissue (ICRU, 2007).
- **Biological Effects of Radiation:** The biological effects of I-131 therapy are complex and influenced by multiple factors, including absorbed dose, dose rate, tissue radiosensitivity, and individual patient characteristics (Hall & Wuu, 2023).
- **Dose-Response Relationships:** The relationship between absorbed dose and therapeutic or adverse effects is often represented by dose-response curves (Hall & Wuu, 2023). These curves help identify optimal dose ranges that maximize therapeutic outcomes while minimizing adverse effects.

2.2.1 Consideration in Application of I-131 Therapy

The theoretical framework outlined above provides the foundation for dose assessment in I-131 therapy. By applying the principles of radioactive decay, radiation

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interactions with matter, dosimetry models, and radiobiological effects, clinicians and physicists can:

- Accurately calculate the absorbed dose in target tissues (e.g., thyroid remnants, metastases) as described by the Medical Internal Radiation Dose (MIRD) schema (Hendricks, 1997).
- Optimize the administered I-131 activity to achieve the desired therapeutic effect while minimizing radiation exposure (American Association of Physicists in Medicine, 2006).
- Predict the risk of adverse effects such as salivary gland dysfunction and bone marrow suppression based on dose-response relationships (Hall & Wuu, 2023).
- Personalize treatment plans by considering individual patient characteristics, tumour properties, and pharmacokinetics (Behr & Beierwaltes, 2008).
- Evaluate the effectiveness of I-131 therapy and adjust treatment strategies as needed based on clinical outcomes and dosimetric assessments (American Thyroid Association, 2021).

2.3 Historical Overview of I-131 Therapy and Dose Assessment

The utilization of iodine-131 (I-131) in medicine represents a significant advancement in the field of nuclear medicine. Its evolution over the past eight decades is characterized by pioneering research, therapeutic breakthroughs, and ongoing refinements in dosimetry techniques (Behr & Beierwaltes, 2008).

2.3.1 Early Discoveries and Development of I-131Therapy

The inception of iodine-131 (I-131) therapy can be traced back to the 1930s and 1940s (Hertz, Roberts, Evans, & Hamilton, 1942). Seaborg and Livingood, researchers at the University of California, Berkeley, unveiled the unique properties of

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I-131 in 1938, recognizing its potential for medical applications due to its suitable half-life and emission of beta and gamma radiation (Seaborg & Livingood, 1938).

This discovery sparked extensive research, culminating in the first therapeutic use of radioiodine by Saul Hertz in 1941 to treat a patient with Graves' disease (Hertz, Roberts, Evans, & Hamilton, 1942). This pioneering work laid the groundwork for exploring I-131 in various thyroid disorders, ultimately leading to its widespread adoption. However, the initial stages of I-131 therapy were fraught with challenges, as dose assessments relied heavily on empirical observations and a limited understanding of radiation effects, resulting in inconsistent treatment outcomes (Marinelli, Foote, & Quimby, 1948).

2.3.2 Evolution of I-131 Therapy Dosimetry

The Medical Internal Radiation Dose (MIRD) schema, introduced in the 1960s, marked a significant advancement in I-131 therapy dosimetry (Loevinger, Budinger, & Budinger, 1988). This standardized framework provided a systematic approach for calculating absorbed doses in organs and tissues following radionuclide administration, including I-131. Prior to MIRD, dose assessments were largely empirical, leading to inconsistent outcomes and limited understanding of radiation effects (Marinelli, Foote, & Quimby, 1948). The MIRD methodology offered a rigorous and scientific approach, enhancing the accuracy and reliability of dosimetry calculations, thereby facilitating broader adoption of I-131 therapy through optimized treatment planning and delivery (Loevinger, Budinger, & Budinger, 1988).

Concurrently, the fixed-activity approach emerged as a standard practice in I-131 therapy (Behr & Beierwaltes, 2008). This method involved administering a predetermined I-131 activity based on patient weight or disease severity, offering a practical and convenient treatment delivery. However, its limitations in accounting for

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individual variations in I-131 uptake and kinetics became apparent. This led to the exploration of more personalized dosimetry methods aimed at tailoring I-131 activity to individual patient needs. These advancements, combined with the MIRD schema, contributed to the ongoing refinement of I-131 therapy, enabling more precise and effective treatments while minimizing adverse effects (Behr & Beierwaltes, 2008).

2.3.3 Advancement in Patient – Specific Dosimetry for I-131 Therapy

The 1980s marked a shift towards patient-specific dosimetry in I-131 therapy, driven by the recognition that a standardized approach was suboptimal (Behr & Beierwaltes, 2008). Clinicians and researchers sought to tailor I-131 activity based on individual patient characteristics and tumour properties, rather than relying solely on generalized protocols. This paradigm shift involved employing advanced imaging techniques, such as gamma camera scintigraphy, to estimate absorbed radiation doses in target tissues (Behr & Beierwaltes, 2008). By quantifying I-131 biodistribution and pharmacokinetics, clinicians could make more informed decisions about optimal treatment activity, potentially enhancing therapeutic outcomes while minimizing adverse effects.

Subsequent advancements in imaging technologies, including the integration of single-photon emission computed tomography (SPECT) and positron emission tomography (PET) with computed tomography (CT), revolutionized I-131 dosimetry (Behr & Beierwaltes, 2008). These hybrid imaging modalities offered more precise and detailed information on I-131 distribution and kinetics, enabling refined dose calculations and treatment planning. In addition to imaging advancements, computational modelling and simulation approaches have been increasingly adopted to predict I-131 dosimetry and optimize treatment planning (Behr & Beierwaltes, 2008). These models incorporate patient-specific data, including tumour

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characteristics, radiobiological parameters, and imaging information, to provide a comprehensive assessment of radiation dose distribution within the patient's body.

2.4 Current Practices in I-131 Dosimetry

Despite the advancements in personalized dosimetry, many clinical practices still rely on simplified or empirical approaches for I-131 dose administration. These approaches vary depending on the specific indication, disease severity, and institutional preferences.

2.4.1 Fixed-Activity Approach to Personalized Dosimetry

The administration of I-131 therapy has been a widely accepted approach for managing thyroid disorders, including hyperthyroidism and differentiated thyroid cancer (DTC) (American Thyroid Association, 2021). However, the traditional fixed-activity approach has faced scrutiny due to limitations in providing personalized dose assessment (Behr & Beierwaltes, 2008). For hyperthyroidism, such as Graves' disease and toxic multinodular goitre, the American Thyroid Association (ATA) guidelines recommend single treatment doses ranging from 10 to 20 mCi (370 to 740 MBq) for toxic multinodular goitre and 10 to 15 mCi (370 to 555 MBq) for Graves' disease. In DTC management, fixed activities ranging from 30 to 150 mCi (1,110 to 5550 MBq) are commonly used for remnant ablation and adjuvant therapy, depending on recurrence risk and metastasis (American Thyroid Association, 2021).

While standardized and simplified, the fixed-activity approach fails to account for individual variations in I-131 uptake and kinetics. This can lead to underdosing or overdosing, particularly in high-risk patients or those with comorbidities affecting I-131 metabolism. Moreover, the approach does not consider individual characteristics like thyroid gland size, radioiodine uptake, and factors influencing I-131 distribution

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and retention, potentially compromising therapeutic outcomes and increasing adverse effects (Behr & Beierwaltes, 2008).

Recognizing these limitations, personalized dosimetry approaches have emerged, tailoring I-131 activity based on individual patient characteristics and tumour properties. Advanced imaging techniques, computational modelling, and simulation methods provide comprehensive and accurate radiation dose assessments, potentially improving I-131 therapy effectiveness and safety (Behr & Beierwaltes, 2008).

As research and technology advance, integrating personalized dosimetry into routine clinical practice holds the promise of delivering more individualized and optimized treatment outcomes for patients undergoing I-131 therapy (Behr & Beierwaltes, 2008).

2.4.2 Efficacy and Limitations of Empirical Methods in I-131 Dosimetry

Iodine-131 (I-131) therapy has been a mainstay in managing thyroid disorders like hyperthyroidism and DTC (American Thyroid Association, 2021). However, determining appropriate I-131 doses has been challenging, leading to the exploration of various approaches, including empirical formulas (Behr & Beierwaltes, 2008). Some healthcare institutions have developed empirical formulas to estimate I-131 doses, considering factors like thyroid gland size, 24-hour radioiodine uptake, and desired therapeutic outcome (Behr & Beierwaltes, 2008). These formulas leverage institutional clinical experience and observations for personalized dose estimation.

While offering a practical solution, empirical formulas have limitations. One being the lack of a strong theoretical foundation, primarily relying on empirical data and observations rather than a comprehensive understanding of radiobiological and pharmacokinetic principles (Behr & Beierwaltes, 2008). Another applicability and generalizability may be restricted to specific patient populations and treatment practices within institutions, leading to inconsistent dosimetry practices and

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compromising overall I-131 therapy optimization and standardization (Behr & Beierwaltes, 2008). Additionally, empirical formulas may not account for individual variations in I-131 uptake, kinetics, and distribution, potentially resulting in suboptimal dose assessment and adverse patient outcomes (Behr & Beierwaltes, 2008).

As the field of nuclear medicine advances, the limitations of empirical formulas have become increasingly apparent. A shift towards more robust and personalized dosimetry approaches, grounded in a deeper understanding of radiobiology and incorporating advanced imaging and computational techniques, is gaining momentum (Behr & Beierwaltes, 2008). These advancements hold promise for delivering more precise and tailored I-131 therapy, ultimately improving treatment efficacy and safety.

2.4.3 Advancements in Personalized Dosimetry for I-131 Therapy

The management of thyroid disorders using iodine-131 (I-131) therapy has undergone significant evolution, with a growing emphasis on personalized dosimetry approaches. This shift is driven by recognizing the limitations of empirical formulas in accounting for individual variability in I-131 kinetics and distribution within the patient's body (Behr & Beierwaltes, 2008).

One key advancement is the increasing adoption of the Medical Internal Radiation Dose (MIRD) schema, focusing on calculating patient-specific absorbed doses based on individual organ masses, I-131 kinetics, and radiation emissions (Loevinger, Budinger, & Budinger, 1988). This personalized approach necessitates quantitative imaging techniques like SPECT/CT to accurately determine time-integrated activity in target organs (Behr & Beierwaltes, 2008). Complementing the MIRD schema, image-based dosimetry leverages advanced imaging techniques to quantify I-131 distribution and kinetics throughout the patient's body (Behr & Beierwaltes, 2008). This enables

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more tailored and personalized I-131 therapy by calculating absorbed doses in target organs and critical structures.

Personalized dosimetry offers numerous benefits. By considering individual patient characteristics, such as organ masses and I-131 metabolism, clinicians can tailor I-131 doses to optimize therapeutic efficacy while minimizing side effects, particularly valuable in high-risk patients, those with metastatic disease, or comorbidities affecting I-131 kinetics (Behr & Beierwaltes, 2008). However, implementing personalized dosimetry faces challenges, including time consumption, resource intensity, specialized expertise, and equipment requirements. Establishing standardized protocols and quality control measures is crucial to ensure accurate and reliable dosimetry results (Behr & Beierwaltes, 2008).

As the field of nuclear medicine advances, the adoption of personalized dosimetry approaches for I-131 therapy is poised to become the standard of care, delivering more targeted and effective treatment, ultimately improving patient outcomes and enhancing overall quality of care (Behr & Beierwaltes, 2008).

2.5 Challenges and Future Directions in Personalized I-131 Therapy Dosimetry

Recognizing the limitations of standardized I-131 therapy, the concept of patient-specific dosimetry gained prominence in the 1980s (Behr & Beierwaltes, 2008). To optimize treatment, clinicians and researchers sought to tailor I-131 activity based on individual patient characteristics and tumour properties (Behr & Beierwaltes, 2008). This shift incorporated advanced imaging techniques, such as gamma camera scintigraphy, to estimate absorbed radiation doses in target tissues, enabling more informed decisions about optimal I-131 activity (Behr & Beierwaltes, 2008). By

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quantifying I-131 biodistribution and pharmacokinetics, clinicians aimed to enhance therapeutic outcomes while minimizing adverse effects.

Subsequent advancements in imaging technologies, including hybrid modalities like SPECT/CT and PET/CT, further refined I-131 dosimetry (Behr & Beierwaltes, 2008). These imaging techniques provided more precise information on I-131 distribution and kinetics, facilitating accurate dose calculations and effective treatment planning. Additionally, computational modelling and simulation approaches were integrated to predict I-131 dosimetry and optimize treatment plans (Behr & Beierwaltes, 2008). By incorporating patient-specific data, these models offered a comprehensive assessment of radiation dose distribution within the body.

The integration of personalized dosimetry methods has transformed I-131 therapy into a more tailored and individualized approach. By considering unique patient characteristics, clinicians can optimize I-131 activity, potentially improving treatment efficacy and reducing treatment-related complications (Behr & Beierwaltes, 2008).

2.6 Radiation Exposure in I-131 Therapy

The use of iodine-131 (I-131) in medical treatments, such as thyroid disorder management, can result in significant radiation exposure for both patients and the surrounding environment. Radiation exposure from I-131 therapy can be categorized into internal and external radiation exposure (National Council on Radiation Protection and Measurements, 2011).

2.6.1 Internal Radiation Exposure in I-131 Therapy

Internal radiation exposure occurs when ingested or administered I-131 concentrates in the thyroid gland and other target tissues (National Council on Radiation Protection and Measurements, 2011). The emitted ionizing radiation from I-131 atoms within the

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patient's body leads to internal exposure. Absorbed radiation doses to the thyroid and other organs are influenced by factors including administered activity, I-131 biokinetics, and individual physiology (National Council on Radiation Protection and Measurements, 2011).

Iodine-131 biokinetics significantly impact internal radiation exposure. After administration, I-131 is rapidly absorbed into the bloodstream and selectively accumulates in the thyroid gland, where it is actively concentrated and retained (National Council on Radiation Protection and Measurements, 2011). This selective uptake and retention form the basis for I-131's therapeutic application in thyroid disorders like hyperthyroidism and thyroid cancer. However, the concentrated I-131 in the thyroid also leads to a higher absorbed radiation dose, potentially resulting in both beneficial and detrimental effects depending on treatment goals and patient condition (National Council on Radiation Protection and Measurements, 2011).

Beyond the thyroid, I-131 can be taken up and retained in organs like salivary glands, stomach, and bladder, contributing to additional internal radiation exposure (National Council on Radiation Protection and Measurements, 2011). While generally lower than thyroid doses, these non-target tissue doses contribute to the overall radiation burden and potential side effects.

2.6.2 External Radiation Exposure in I-131 Therapy

While the primary focus of I-131 therapy is targeted on internal radiation exposure, managing external radiation exposure from gamma ray emission by the patient's body is crucial for ensuring the safety of healthcare providers, family members, and the public (National Council on Radiation Protection and Measurements, 2011). External radiation exposure occurs when the patient's body emits gamma rays following I-131 administration (National Council on Radiation Protection and Measurements, 2011).

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This can potentially expose nearby individuals, including healthcare providers, family members, and the general public.

Administered I-131 for therapeutic purposes is selectively absorbed and retained within the thyroid gland or other target tissue; as it undergoes radioactive decay, it emits high-energy gamma rays that can penetrate the patient's body and reach the surrounding environment, potentially exposing individuals through direct patient contact, transportation, or shared living spaces (National Council on Radiation Protection and Measurements, 2011). Several key factors influence external radiation exposure rates from I-131 therapy patients, these include:

- **Administered Activity**: Higher administered I-131 activity generally results in higher external radiation exposure levels.
- **Distance from the Patient**: External radiation exposure decreases exponentially with distance from the patient, as described by the inverse square law.
- **Shielding Materials**: Appropriate shielding materials, like lead or high-density concrete, can effectively attenuate gamma radiation emitted by the patient, reducing external radiation exposure.
- **Duration of exposure**: Minimizing time spent in close proximity to the patient reduces overall radiation dose received by healthcare providers and family members.

Healthcare providers must carefully manage external radiation exposure by implementing appropriate radiation safety protocols and practices, including the use of personal protective equipment, maintaining safe distances, optimizing shielding, and limiting exposure duration (National Council on Radiation Protection and Measurements, 2011). In addition, accurate monitoring and documentation of external radiation exposure levels are also essential ways to ensure the safety of healthcare

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staff and the public. Furthermore, clear communication and education for patients and family members regarding external radiation risks and necessary precautions are crucial for effective I-131 therapy management and minimizing radiation exposure to the surrounding environment (National Council on Radiation Protection and Measurements, 2011).

2.6.3 Potential Impact of External Radiation Exposure

Understanding the potential impacts of external radiation exposure is crucial for implementing effective radiation safety measures and minimizing associated risks. The impact of external radiation exposure is felt by health workers, care givers and the public.

- **Healthcare Providers**: Healthcare providers including physicians, nurses, medical physicists, and medical technicians, are at the highest risk of external radiation exposure due to direct and prolonged contact with I-131-treated patients. Exposure to gamma radiation can increase the risk of deterministic effects like skin burns and stochastic effects like cancer. Adherence to strict radiation safety protocols, use of personal protective equipment, and maintaining safe distances are crucial for minimizing healthcare provider exposure and ensuring their safety.
- **Family Members**: Family members and care givers who are in close contacts of I-131-treated patients may also be exposed to external radiation during patient transportation, shared living spaces, or close physical interactions. Potential health risks for family members include increased risk of radiation-induced effects like cancer and genetic abnormalities. Comprehensive education and guidance for patients and family members are essential for understanding necessary precautions and minimizing external radiation exposure.

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- **General Public**: External radiation exposure from I-131-treated patients can extend to the general public, particularly in public spaces or during patient transportation. Although generally lower for the general public compared to healthcare providers and family members, the potential cumulative impact on a larger population cannot be overlooked. Appropriate radiation safety measures, such as shielding, restricted access to certain areas, and clear communication with the public, are necessary to mitigate these risks.

2.7 Radiation Safety Protocols and Guidelines in I-131 Therapy

A number of international organizations have developed comprehensive radiation safety protocols and guidelines for healthcare providers, patients, and the general public. These guidelines aim to ensure the safe and responsible use of I-131 therapy while protecting individuals from the harmful effects of ionizing radiation. Some of these protocols and guidelines, and the authoring organisations are discussed below:

2.7.1 International Atomic Energy Agency (IAEA)

The IAEA, as the global authority on nuclear technology and radiation safety, has established comprehensive guidelines for the safe use of radiopharmaceuticals, including I-131 therapy. The IAEA's "Radiation Protection and Safety in Medical Uses of Ionizing Radiation" (IAEA Safety Standards Series No. SSG-46) provides detailed recommendations for the implementation of radiation protection measures in medical facilities (IAEA, 2018). The guidelines address various aspects, such as patient management, staff protection, and public exposure control. Specific to I-131 therapy, the IAEA recommends the following safety protocols:

- Careful patient selection and informed consent procedures
- Strict control of the administered activity of I-131 to minimize radiation exposure

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- Appropriate shielding and containment measures to limit external radiation exposure
- Effective patient isolation and restricted access to patient rooms
- Comprehensive radiation monitoring and record-keeping for healthcare providers and patients.

2.7.2 Society of Nuclear Medicine and Molecular Imaging (SNMMI)

The SNMMI, a leading international organization in the field of nuclear medicine and molecular imaging, has published guidelines and recommendations for the safe use of I-131 therapy. The SNMMI's "Procedure Standard for Therapy of Thyroid Disease with Iodine-131 (Sodium Iodide)" provides detailed guidance on the clinical management and radiation safety aspects of I-131 therapy (SNMMI, 2019). The SNMMI guidelines emphasize the following radiation safety measures:

- Proper patient selection and informed consent, considering the patient's radiation exposure risk
- Careful calculation and administration of the optimal I-131 activity to minimize radiation exposure
- Appropriate shielding and contamination control measures during patient care and radioactive waste management
- Comprehensive training and education for healthcare providers on radiation safety protocols
- Effective patient isolation and counselling on radiation safety precautions for family members

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2.7.3 European Association of Nuclear Medicine (EANM)

The EANM, a leading European organization in nuclear medicine, has also developed guidelines for the safe use of I-131 therapy. The EANM's "Guideline on Radioiodine Therapy for Benign Thyroid Diseases (version 1.0)" provides recommendations for the clinical and radiation safety aspects of I-131 therapy (EANM, 2021). The EANM guidelines emphasize the following radiation safety protocols:

- Careful patient selection, considering the patient's radiation exposure risk and potential for compliance with safety measures
- Optimized I-131 activity administration to achieve the desired therapeutic effect while minimizing radiation exposure
- Effective patient isolation and implementation of radiation safety precautions for family members and the general public
- Comprehensive radiation monitoring and record-keeping for healthcare providers, patients, and the surrounding environment

2.7.4 International Commission on Radiological Protection (ICRP)

The ICRP, a leading international organization in the field of radiological protection, has developed principles and recommendations for the safe use of ionizing radiation, including I-131 therapy. The ICRP's "Radiological Protection in Therapy with Radiopharmaceuticals" (ICRP Publication 140) provides guidance on the implementation of radiation protection measures in the context of radionuclide therapy (ICRP, 2019). The ICRP's recommendations for I-131 therapy include:

- Adherence to the principles of justification, optimization, and dose limitation to ensure the safe use of I-131
- Appropriate patient selection and informed consent procedures, considering the patient's radiation exposure risk

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- Implementation of effective radiation shielding, patient isolation, and contamination control measures
- Comprehensive training and education for healthcare providers on radiation safety protocols
- Effective communication and guidance for patients and their families on radiation safety precautions

2.8 Guidelines for Safe and Effective I-131 Therapy Administration

The safe and effective administration of Iodine-131 (I-131) therapy requires a comprehensive approach that addresses various aspects, including patient selection, activity administration, patient management, and radiation protection measures. These recommendations are based on the guidelines and standards established by leading international organizations, such as the International Atomic Energy Agency (IAEA), the Society of Nuclear Medicine and Molecular Imaging (SNMMI), the European Association of Nuclear Medicine (EANM), and the International Commission on Radiological Protection (ICRP). This section will throw more light on the recommendations for patient selection, activity administration, patient management, and radiation protection measures.

2.8.1 Criteria for Patient Selection

Careful patient selection is crucial to ensure the safe and effective use of I-131 therapy. Healthcare providers therefore are to consider the following recommendations:

- **Evaluate the patient's radiation exposure risk**: Assess the patient's medical history, underlying conditions, and potential for compliance with radiation safety precautions

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- **Obtain informed consent**: Ensure the patient fully understands the risks and benefits of I-131 therapy, and that they are willing to comply with the necessary radiation safety measures.
- **Assess the patient's ability to follow radiation safety instructions**: Evaluate the patient's cognitive function, physical mobility, and access to appropriate support systems to ensure adherence to the required safety protocols (SNMMI, 2019; EANM, 2021).

2.8.2 Optimizing I-131 Activity for Safe and Effective Therapy:

The administration of the optimal I-131 activity is crucial to achieve the desired therapeutic effect while minimizing radiation exposure. Healthcare providers are therefore to follow these recommendations:

- **Carefully calculate the appropriate I-131 activity**: Determine the optimal I-131 activity based on the patient's condition, treatment goals, and established dosimetric models
- **Implement strict control measures during administration**: Ensure the accurate and precise delivery of the calculated I-131 activity, using appropriate shielding and contamination control measures.
- **Conduct post-administration monitoring**: Monitor the patient's response to the treatment and adjust the I-131 activity as needed, considering the potential for repeat or subsequent administrations (SNMMI, 2019; EANM, 2021).

2.8.3 Patient Management Strategies in Minimizing Radiation Exposure:

Effective patient management is crucial to minimize the potential for radiation exposure to healthcare providers, family members, and the general public. Healthcare providers area therefore to follow these recommendations:

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- **Isolate the patient**: Implement strict isolation protocols, such as the use of dedicated patient rooms, restricted access, and appropriate signage, to limit the potential for external radiation exposure.
- **Provide comprehensive patient education**: Educate the patient on the radiation safety precautions they must follow, including personal hygiene, waste management, and restrictions on physical contact with others.
- **Manage patient discharge and follow-up**: Establish clear guidelines for patient discharge, including residual activity thresholds, recommended isolation periods, and post-treatment monitoring requirements (IAEA, 2018; SNMMI, 2019; EANM, 2021).

2.8.4 Radiation Protection Measures in I-131 Therapy

Comprehensive radiation protection measures are essential to safeguard healthcare providers, family members, and the general public from the potential risks of external radiation exposure. Healthcare providers should implement the following recommendations:

- **Ensure appropriate shielding and containment**: Utilize appropriate shielding materials, such as lead or concrete, to minimize the external radiation exposure of healthcare providers and the public.
- **Implement effective contamination control**: Establish strict protocols for the management of radioactive waste, including the proper disposal of contaminated materials and the decontamination of work areas.
- **Provide comprehensive training and education**: Offer comprehensive training and education to healthcare providers on radiation safety protocols, the use of personal protective equipment, and emergency response procedures.

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- **Conduct regular monitoring and record-keeping**: Implement a robust system for radiation monitoring, including personal dosimetry, environmental monitoring, and comprehensive record-keeping to ensure compliance with regulatory requirements (IAEA, 2018; SNMMI, 2019; EANM, 2021)

2.9 Importance of Adhering to Protocols and Guidelines in I-131 Therapy

Strict adherence to established protocols and guidelines is essential to ensure the safe and responsible use of this therapeutic modality. Healthcare providers play a crucial role in the successful implementation of I-131 therapy and must be diligent in following the recommended best practices. Failure to adhere to these protocols can have serious consequences, including compromised patient safety, increased occupational radiation exposure, potential public health concerns, and legal and regulatory consequences.

- **Compromised Patient Safety**: Non-adherence to patient selection criteria, activity administration procedures, and patient management protocols can lead to suboptimal treatment outcomes, increased radiation exposure, and potential adverse effects for the patient.
- **Increased Occupational Radiation Exposure**: Inadequate radiation protection measures can result in elevated radiation exposure for healthcare providers, putting them at risk of developing radiation-induced health effects.
- **Potential Public Health Concerns**: Failure to properly manage radioactive waste and contain contamination can lead to the unintentional spread of radioactive materials, potentially exposing the general public to increased radiation levels.
- **Legal and Regulatory Consequences**: Non-compliance with established protocols and guidelines can result in legal and regulatory consequences,

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including fines, license revocation, and potential legal liability for healthcare providers and their associated institutions.

To mitigate these risks and ensure the safe and effective use of I-131 therapy, healthcare providers must demonstrate a strong commitment to adhering to the recommended protocols and guidelines. This is reflected in comprehensive training and education, robust quality assurance and continuous improvement, and effective interdisciplinary collaboration (IAEA, 2018).

By prioritizing the strict adherence to established protocols and guidelines, healthcare providers can significantly mitigate the risks associated with I-131 therapy, while ensuring the best possible outcomes for patients and safeguarding the well-being of healthcare providers, family members, and the general public. The importance of this commitment is crucial for the safe and responsible use of this therapeutic modality (IAEA, 2018).

2.10 Estimating Radiation Absorbed Dose in I-131 Therapy

Accurately estimating the radiation absorbed dose to these individuals is a critical component of the safe and responsible management of patients undergoing I-131 therapy. Radiation exposure to individuals near I-131 treated patients can occur through a variety of pathways, including external exposure to gamma radiation emitted by the radionuclide, as well as potential internal exposure if radioactive contamination is inadvertently spread. Failure to properly assess and mitigate these radiation risks can have significant consequences for the health and safety of family members, caregivers, and the general public. Accurate estimation of the radiation absorbed dose is essential for several reasons, some include:

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- **Ensuring Compliance with Regulatory Limits**: Most regulatory agencies have established dose limits for members of the public to protect them from the potential harmful effects of ionizing radiation. Estimating the radiation dose to individuals near I-131 treated patients is necessary to ensure compliance with these regulatory requirements and to implement appropriate radiation protection measures.
- **Optimizing Patient Discharge and Isolation Protocols:** The estimated radiation absorbed dose can inform the development of patient discharge criteria and isolation protocols, ensuring that patients are only released from the healthcare facility when the radiation levels pose a minimal risk to their family members and the public.
- **Guiding Radiation Protection Measures**: The dose estimation can help identify situations where additional radiation protection measures, such as increased shielding, decontamination, or restricted access, may be necessary to minimize the radiation exposure to individuals in close proximity to the patient.
- **Providing Accurate Risk Communication**: Precise dose estimates can facilitate the communication of accurate information to the patient, their family members, and the public about the potential radiation risks and the steps being taken to mitigate these risks.
- **Enabling Informed Decision-Making**: Accurate dose estimates can support healthcare providers in making informed decisions regarding the administration of I-131 therapy, weighing the potential benefits against the risks to the patient, their family, and the community.

To ensure the reliability and accuracy of these dose estimates, healthcare providers must follow established protocols and guidelines, such as those provided by the IAEA,

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SNMMI, and EANM. This involves the use of specialized software, computational models, and measurements to accurately predict and monitor the radiation levels in the patient's environment.

2.10.1 Direct measurements as a Dosimetric techniques in I-131 Therapy

Estimating the radiation absorbed dose to individuals near patients undergoing Iodine-131 (I-131) therapy is a critical component of ensuring the safe and responsible use of this therapeutic modality. Among the various dosimetric techniques available, direct measurements play a crucial role in providing accurate and reliable dose estimates.

Direct measurement-based dosimetry involves the use of specialized radiation detection equipment, such as handheld dose rate meters, portable survey instruments, and thermoluminescent dosimeters (TLDs), to directly measure the radiation levels in the patient's environment. This approach offers several key advantages including:

- **Accuracy and Precision**: Direct measurements provide a direct assessment of the actual radiation levels, rather than relying on theoretical calculations or models. This approach can account for factors such as the patient's specific activity distribution, shielding materials, and environmental conditions, resulting in more accurate and precise dose estimates (Bolch *et al*., 2009).
- **Real-Time Monitoring**: Direct measurements can be used to monitor the radiation levels in the patient's vicinity over time, providing healthcare providers with a dynamic understanding of the changing radiation environment. This information can be used to guide patient management decisions, such as adjusting isolation protocols or implementing additional radiation protection measures (Demir *et al*., 2011).

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- **Validation of Computational Models**: Direct measurement data can be used to validate and refine the computational models and algorithms used to estimate radiation absorbed doses, improving the overall reliability and accuracy of the dose assessment process (Maha *et al*., 2018).
- **Compliance Verification**: Direct measurements can be used to demonstrate compliance with regulatory dose limits for members of the public, ensuring that the radiation exposure risks associated with I-131 therapy are effectively managed (IAEA, 2014).

Accurate dose estimation through direct measurements is crucial in assessing the potential health risks to patients, their families, and the general public. By quantifying the radiation exposure levels, healthcare providers can implement appropriate radiation protection measures, such as adjusting isolation protocols, increasing shielding, or limiting the time spent near the patient, to minimize the risk of adverse health effects (IAEA, 2014). For example, direct measurement data can be used to demonstrate compliance with regulatory dose limits for members of the public, ensuring that the radiation exposure risks associated with I-131 therapy are effectively managed.

To effectively utilize direct measurements as a dosimetric technique, healthcare providers must be well-versed in the proper use and calibration of radiation detection equipment, as well as the interpretation of the collected data. This may involve comprehensive training, the development of standardized protocols, and the implementation of quality assurance measures to ensure the consistency and reliability of the measurement results (Divoli *et al*., 2009).

By prioritizing the use of direct measurements as a dosimetric technique, healthcare providers can demonstrate their commitment to the safe and responsible use of I-131

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therapy, ultimately safeguarding the well-being of patients, their families, and the broader community. Through the accurate estimation of radiation absorbed doses and the implementation of appropriate radiation protection measures, healthcare providers can minimize the potential health risks associated with I-131 therapy and ensure the continued safe and effective use of this important therapeutic modality (ICRP, 2019). Furthermore, the integration of direct measurement data with other dosimetric techniques, such as computational modelling and biokinetic analysis, can provide a more comprehensive understanding of the radiation exposure risks and enable healthcare providers to make informed decisions regarding patient management and radiation protection strategies (Stabin & Siegel, 2003). By combining different dosimetric approaches, healthcare providers can develop a more accurate and reliable assessment of the radiation exposure risks, allowing them to implement targeted and effective radiation protection measures.

2.11 Summary of Literature Review

At the end of the introductory chapter, it is clear that while I-131 therapy is an effective treatment for thyroid disorders, it presents significant challenges related to radiation exposure and patient safety. The chapter concludes by identifying the critical need for tailored, evidence-based protocols that minimize risks and standardize patient management practices post-therapy. This need serves as the foundation for the study's objectives to assess current practices and recommend improvements.

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CHAPTER THREE

METHODOLOGY

3.1 Introduction

This chapter outlines the method that guided the study, it includes the various key aspects such as the materials used for the study, the study design employed, the study population used, the sampling technique employed, the rationale for determining the sample size, the inclusion and exclusion criteria used, tools and procedure for data collection, management, and analysis, as well as ethical considerations.

3.2 Study Location

This research work was conducted at the National Nuclear Medicine and Radiotherapy Centre (NNMRC) of the Korle-Bu Teaching Hospital. It is the first and only public Nuclear Medicine centre in the country. The Centre houses a SPECT – CT, dose calibrator and radioactive sources such as Caesium–137, Technetium–99m and Iodine–131. The latter two radioactive sources are acquired on periodic basis when needed for diagnostic and/or therapeutic procedures and are kept under safety guidelines with adequate shielding. All data presented in this study were acquired following the approval of ethical clearance.

3.3 Study Design

The study is a prospective cross-sectional study in which a quantitative research approach was adopted to examine the dose optimization of radioiodine therapy. Data were collected from patient information, medical history, treatment details and, radiation exposure monitoring and subjected to statistical and comparative analysis

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using Microsoft Excel 2016. Patient information, medical history, and treatment details were extracted from the patients' hospital records, while patient radiation exposure was directly measured. All collected data were securely stored in a password-protected database accessible only to the research team, ensuring confidentiality and compliance with ethical guidelines.

3.4 Study Population

The study population included all thyroid cancer patients who were referred for radioiodine therapy at the Nuclear Medicine department of NNMRC from January to July, 2024; and satisfied the selection criteria. This study population was categorized into two groups: Inpatients – thyroid cancer patients undergoing therapy to remove residual thyroid tissue after total thyroidectomy; and Outpatients – patients with thyrotoxicosis disease especially patients with hyperthyroidism undergoing therapy to slow down the production of thyroid hormones.

3.4.1 Inclusion Criteria

1) Only patients referred for iodine therapy for the first time were considered for this study to ensure consistent treatment response, enhance generalizability and reduce variability in treatment outcomes.
2) A homogenous patient population was established by limiting the analysis to outpatient cases treated with a standardized low dose of 20 mCi radioiodine, the most common dose prescribed during my study (dose range: 20-30 mCi).
3) To ensure a consistent patient population, the analysis was restricted to inpatient cases treated with high-dose radioiodine therapy within a prescribed dose range of 100-250 mCi as anything lesser was considered low dose.

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3.4.2 Exclusion Criteria

Patients undergoing a second phase of iodine therapy were excluded from this study. Patients who require a second phase of therapy often have more complex disease or incomplete initial treatment response. Excluding them can reduce the variability in patient characteristics and disease severity, leading to a more focused and interpretable analysis.

3.5 Sampling Method

This study employed the simple random sampling technique to eliminate bias and guarantee a representative sample. Each patient was assigned a number, and a research randomizer was employed to select these numbers randomly.

3.6 Sample Size

The sample size used in this research was estimated using Slovin's formula. This method is widely recognized for determining sample sizes when the population size is known and when the study demands a specific margin of error. The formula is expressed as:

$$n = \frac{N}{1+Ne^2} \qquad (1)$$

Where: (n) is the estimated sample size, (N) is the total population size,

(e) is the margin of error, which for this study is set at 0.05, representing a 95% confidence interval.

For this study, data from case presentations over the last two years was used to estimate the sample size. The population size (N) was determined based on the average number of cases per year and extrapolated over the study period (2022 and 2023)., the total number of cases for 2022 and 2023 were 41 and 37 respectively.

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Therefore, N = $\frac{41+37}{2} = 39$. Thus, $n = \frac{39}{1+39(0.05)^2} = 35.33 \approx 36$

Therefore, if 36 patients : 12 months then, 7 months : x

Where $x = \frac{7\ months}{12\ months} \times 36 = 21\ patients$

Since this prospective study has been conducted over the last 7 months, my sample size is 21 patients. However, after considering the inclusion and exclusion criteria, a total of 19 patients made up of 7 males and 12 females were used in this study, with 2 patients excluded from the study. Out of the 19 patients, those receiving high doses (Inpatients) were 9 (3 males and 6 females) whiles those receiving low doses (Outpatients) were 10 (4 males and 6 females).

3.7 Materials

The materials used for this study include: a radiation survey meter, tape measure/1meter line, dose calibrator, radioactive sources (Caesium–137, Technetium–99m and Iodine–131), and personal protective equipment (such as: thyroid shield, Personal dosimeter, disposable gloves, nose mask). All documents such as radiation safety guidelines and protocols, localized procedure and protocol, checklists, patient records served as reference materials and protocols that guided in acquiring the data for this study.

3.7.1 Dose Calibrator

This is used to measure the radioactivity or the exact amount of a radioactive substance before it is administered to a patient. It is commonly used in nuclear medicine, and radiotherapy to ensure that patients receive the correct administered dose of a radiopharmaceutical. It measures the activity of radiopharmaceuticals typically in units of millicurie (mCi) or Becquerels (Bq). The device or instrument (shown in Figure 3.1) is regularly calibrated against known standard and thus gives

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highly accurate readings ensuring that the dose administered is as close as possible to the prescribed dose

Figure 3.1: A pictorial view of the Comecer Dose Calibrator

3.7.2 Survey Meter

This is a portable handheld device (figure 3.2) used to detect and measure radiation levels in the in an environment. It consists of a detector such as a Geiger – Muller (GM) tube or a scintillation detector, that detects radiation and converts it into electrical signals. These signals are processed and displayed on a digital readout providing the user with an immediate assessment of the radiation levels in the area. Survey meters are designed to detect different types of radiation, and measure in units such as micro sieverts per hour (μSv/h), milli sieverts per hour (mSv/h) or counts per minute (cmp). They also require regular calibrations to ensure accurate readings, especially when used in environments with varying radiation levels. The survey meter used for this work is a 9DP Model with Serial number, 25009/29.

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Figure 3.2: A pictorial view of the Ludlum survey meter

3.7.3 Personal Protective Equipment (PPE)

In iodine therapy the use of PPEs is very crucial in ensuring the safety of both the healthcare provider and patient. The PPEs used during the course of this study include:

- Disposable gloves: To protect hands from contact with radioactive materials and contaminated surfaces.
- Personnel radiation dosimeters: To monitor and record radiation exposure to ensure that it remains within safe limits
- Thyroid shield: To protect the thyroid gland from receiving some beta radiations emitted by the patient during exposure rate measurements
- Surgical masks: To reduce the risk of inhaling radioactive particles or aerosols
- Disposable gowns: To prevent contamination of clothing and skin

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3.7.4 Radioactive sources (Caesium–137, Technetium–99m and Iodine–131)

In iodine therapy, particularly in the treatment of thyroid conditions like hyperthyroidism and thyroid cancer, I-131 is the primary radioactive isotope used. However, other radiation sources like Cs-137 and Tc-99m also play roles in diagnostic and therapeutic procedures associated with iodine therapy. Each of these isotopes contributes to the overall process of diagnosing and treating thyroid conditions, with I-131 being central to the therapeutic aspect, Tc-99m aiding in diagnostic imaging of thyroid diseases, and Cs-137 for performing quality control tests on the equipment used. The table below shows some characteristics of these radioisotopes

Table 3.1: Characteristic and uses of radioisotopes used in I-131 Therapy

Radioisotope	Type of radiation emitted	Half - life	Classification and Use
Iodine–131	Beta particles Gamma rays	8 days	Medium lived Used for both diagnostic and therapeutic purposes
Caesium–137	Beta particles Gamma rays	30 years	Long lived Used in equipment calibration and medical therapy (brachytherapy)
Technetium–99m	Gamma rays	6 hours	Short lived Used for diagnostic imaging in nuclear medicine

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3.8 Procedure and Data Collection

3.8.1 Facility and Room Preparation

Before patients reported to the facility for the Iodine therapy, the rooms were prepped for their arrival by the Radiation Oncology Nurse and the Physicists which involves completely covering the surfaces of items in the room with a nylon bag while sockets and switches were covered with a duct tape. Anything else in the form of electrical appliances which may be in contact with patient such as; remote was put in a transparent zip lock bag for easy access. All these were done to reduce or possibly eliminate contamination to surfaces and electrical gadgets.

The hyperthyroidism patients (patients receiving low doses of Iodine 131), are detained for monitoring within a 24-hour timeframe, the room used for the quarantine was isolated and well aerated. In the case where thyroid carcinoma patients are involved (patients receiving high doses of Iodine 131), the rooms used for the isolation and monitoring are spacious enough to accommodate patient for a number of days until the exposure level are lower and appropriate for discharge.

3.8.2 Patient Preparation and Counselling

Written informed consent was taken from all patients undergoing radioiodine therapy following the detailed verbal and written explanation of the whole procedure and possible associated risks involved. During this stage, the patients to receive the radio-iodine therapy were given a list of "dos and don'ts" to follow after the administration of the iodine drug. This differed from patient to patient, based on the type of therapy they may be in for. The two types of therapy include the high dose therapy usually for the thyroid carcinoma patients and the other is the low dose therapy for the hyperthyroidism patients.

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3.8.2.1 Hyperthyroidism patients' preparation

After the Nuclear Medicine Physician was done talking to the patient and consent signed, the patient was met by the Physicist and given a set of instructions to be adhered to which includes;

- drinking adequate amount of water frequently after the drug is administered
- taking in solid foods an hour after drug administration if hungry
- to urinate frequently to prevent the irradiation of the bladder and also to flash about 2 or 3 times after the use of the water closet.
- to stay in the confined facility to prevent the unnecessary spread of radiation.

Finally on dose measurement, patients were informed of the dose reading that was to be taken at regular duration to help in determining the patient's exposure rate. This was useful in determining whether a patient is fit to be discharged or not. The essence of this was to make sure that patients do not expose close contacts to the radiation they may radiate. Patients were expected to be discharged if their external dose rate reading was below 30 μSv/h as per IAEA recommendations (International Atomic Energy Agency [IAEA], 2018).

3.8.2.2 Thyroid carcinoma patients:

With this category of patients, the set of instructions given to them included:

- taking in lime juice from time-to-time to prevent radiation induced damage to the salivary gland.
- drinking adequate amount of water frequently after the drug has been administered
- urinating frequently to prevent the irradiation of the bladder and also to flash about 2 or 3 times after the use of the water closet.
- taking regular showers and engage in exercise from time-to-time to help increase the rate of metabolism.

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- staying in the quarantined facility to prevent the unnecessary spread of radiation.
- wearing of gloves and changing them regularly to prevent contamination of surfaces.

Finally on dose measurement, patients were informed of the monitoring that would be done at regular duration to help in determining the patient's exposure rate. This was useful in determining whether a patient is fit to be discharged or not. The essence of this was to make sure that patients do not expose close contacts to the radiation they may radiate. Patient can go home if the external dose rate reading is around 30 μSv/h as per IAEA recommendations (IAEA, 2018). With high dose therapy, patients were detained and monitored for over 48 hours after intake of radio iodine capsule before discharged; this was to ensure that the exposure rate drops to acceptable levels as recommended by authorized bodies in Nuclear Medicine.

3.8.3 Quality Control on Dose Calibrator

The dose calibrator is essential for patient safety, as it ensures administered doses are accurate and align with prescribed treatments. Quality control tests—including constancy, accuracy, linearity, and geometry dependence—were conducted in accordance with the AAPM Task Group 56 and IAEA TECDOC-602 guidelines, which outline standardized procedures for verifying calibrator performance in nuclear medicine. The QC tests performed prior to data collection are summarized below:

- **Linearity Test**: In this test, the use of Technetium-99m (Tc-99m) activity was required. The source (Tc-99m) activity was measured using the dose calibrator, taking note of the time and date. The next steps included repeating the above process after every hour.

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- **Constancy Test**: In this test, a long-lived Caesium-137 activity was used. Firstly, the caesium source is placed into the dose calibrator and the I-131 button is pressed. The readings are recorded. This was repeated for 5 consecutive days.
- **Accuracy Test**: In this test, Tc-99m activity was required just as that of the linearity test. Here, the Tc-99m source was measured using the dose calibrator and readings were recorded and repeated after every 30 seconds consecutively for 3 times.
- **Geometry Test**: A 5 ml sized syringe was used for this test where 2 ml of Tc-99m activity was measured with the dose calibrator. This was diluted with 1ml distilled water until the containment of the syringe reached a 3 ml meniscus mark and measured. This was repeated till a 5 ml was reached and measured. This was done to make sure at different volumes, the dose calibrator measured the same value.

3.8.4 Cross-Calibration on Survey meter

To ensure accuracy in radiation exposure measurements, a cross-calibration of the Ludlum survey meter was conducted using a Bosean survey meter as the reference instrument. Both meters were exposed simultaneously to a long-lived Caesium source under controlled environmental conditions, at a fixed and equal distance from the source. Measurements were taken under identical geometric and temporal settings to minimize variability. The calibration factor was determined by calculating the ratio of the reference meter (Bosean) reading to the Ludlum meter reading.

From this procedure, the calibration factor for the Ludlum survey meter was determined to be 1.78. Prior to the cross-calibration, the Ludlum survey meter had a calibration factor of 1.62 and was due for recalibration on 17th February 2023. The Bosean survey meter used as the reference had a known calibration factor of 0.72, with its next scheduled calibration due on 29th September 2024.

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Figure 3.3: A pictorial view of the Bosean survey meter used for cross calibration

3.8.5 Data Collection

3.8.5.1 Verification of administered dose

This was done for all doses administered during the study duration; the verification process was done using the dose calibrator. It was ensured that all QCs were performed and all tests passed and, instrument was functioning properly before measurements were performed.

The appropriate settings were then selected based on the I-131 drug to be measured. The I-131 was then placed into the dose calibrator, and the activity reading was taken. After the activity was measured and recorded, the drug was administered to the patient and all other relevant details were recorded in the patients' medical records (folder).

The measured activity was then compared to the prescribed dose to ensure and verify the accuracy of the administered drug. A tolerance level of ±10% (recommended by the IAEA, EANM and ICRP) is accepted for safe administration of the radioiodine

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drug; and thus the formulae $\frac{measured\ activity - prescribed\ activity}{prescribed\ activity}\ x\ 100\%$ -----Equation (2) is used to calculate the percentage deviation of the administered dose from the prescribed dose.

Figure 3.4: A pictorial view of the researcher performing some measurement on dose verification

3.8.5.2 Monitoring radiation exposure rates

- **Low-dose Therapy**

Following the administration of the iodine-based radiopharmaceutical, the patient was isolated and monitored until radiation levels decreased to a safe discharge point. A survey meter was used to measure exposure rates at a 1-meter distance from the patient's neck, initially at the first hour and subsequently every two hours. Background radiation measurements were taken before the patient entered the room to ensure an uncontaminated baseline reading. To calculate accurate patient exposure

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rates, the recorded background value was subtracted from the measured readings, and the net exposure was then multiplied by the survey meter's calibration factor, as shown below;

$$Patient\ exposure\ rate = (exposure\ reading - background\ radiation) \times calibration\ factor$$ -----Equation (3)

This process ensured precise monitoring of radiation exposure during the iodine therapy.

- **High-dose Therapy**:

To monitor patient radiation exposure following the administration of an iodine-based radiopharmaceutical, patients were admitted to an inpatient facility and confined to a designated area. Radiation safety protocols were implemented, including instructions for reporting vomiting or contamination. A survey meter was used to measure external radiation exposure at a distance of 1 meter from the patient's neck, with measurements taken at regular intervals and recorded. The first exposure rate reading was taken 1 hour after drug administration, followed by additional readings at approximately 6-hour intervals. Background radiation levels were measured prior to the patient's entry into the isolation room to ensure accurate baseline correction. To obtain precise patient exposure rates, the background value was subtracted from the total measured exposure, and the net result was multiplied by the survey meter's calibration factor, as stated in Equation 3.

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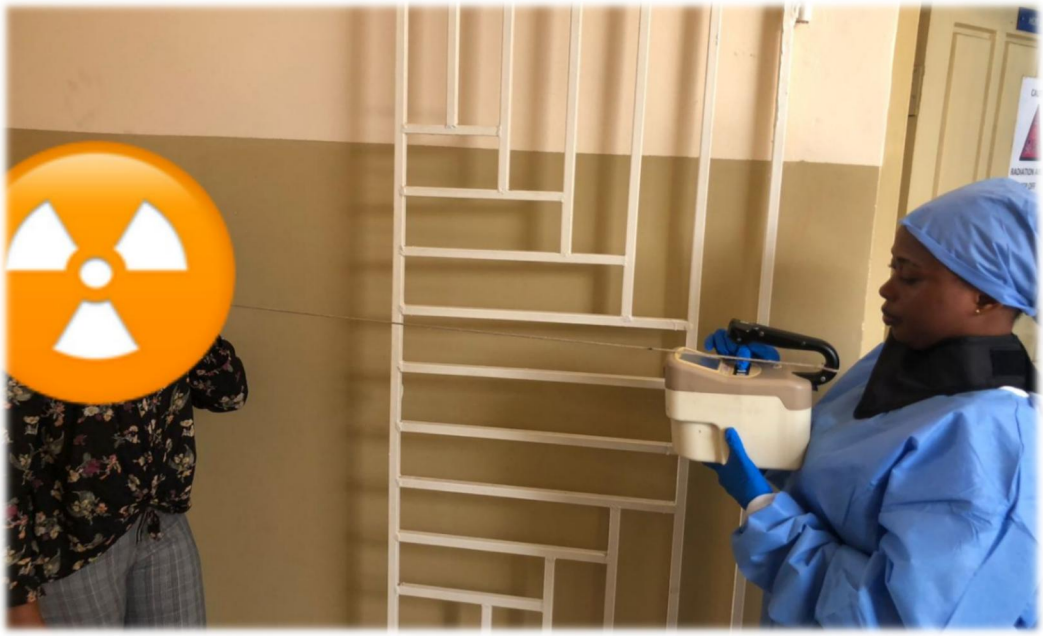

Figure 3.5: A pictorial view of the researcher measuring the exposure rate of a patient

3.8.5.3 Adherence to safety protocols

A comprehensive review of existing radioiodine therapy protocols and guidelines was conducted, encompassing international standards from IAEA, SNMMI, EANM, and ICRP. This was done using a checklist shown in Appendix 1 to evaluate the practices on key areas of radioiodine therapy in the centre. The key areas which were evaluated included as: patient evaluation and preparation, radiation safety measures, radiopharmaceutical preparation and administration, radiation exposure monitoring, post treatment follow-up, documentation and reporting, and patients discharge. The observed practices were noted and recorded based on the recommendations for each key area and conclusion were drawn accordingly.

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3.9 Statistical Analysis

Quantitative measurements were taken and evaluated for each patient; these measurements were compared to certain standards and deductions were made based on the findings. Also, descriptive analysis such as: means for the various exposure

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rates together with their standard deviations and range was carried out using Microsoft Excel 2019 version 2208 to give a wider perspective of the discharge rates of I-131 therapy patients. The findings were presented through tables, histograms and/or clustered charts were applicable.

3.10 Ethical Considerations

The ethical clearance for this study was sought from the Board of Ethics Committee for Basic & Applied Sciences of the University of Ghana which has been approved following a formal request. Furthermore, authorization was secured from the management of the National Radiotherapy Oncology and Nuclear Medicine Centre (NRONMC) at Korle Bu Teaching Hospital (KBTH) for the study. To maintain confidentiality and anonymity, patient identifiers were substituted with a three-digit code.

3.11 Summary of Methodology

The methodology chapter concludes by detailing the structured approach taken to ensure accurate dose administration, monitoring, and safety adherence in I-131 therapy. The outlined methods aim to provide reliable data on patient radiation exposure and protocol compliance. By employing stringent quality control measures and ethical considerations, the study's approach ensures validity and robustness in evaluating current practices and identifying areas for improvement.

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CHAPTER FOUR

RESULTS AND DISCUSSION

4.1 Introduction

The results of the experimental works are presented in this chapter and discussed within the framework of the stated objectives of the study and similar works in literature.

The overall aim of the study was to assess and optimize the current external radiation exposure rates of patients undergoing I-131 therapy for hyperthyroidism and thyroid cancers at the National Nuclear Medicine and Radiotherapy Centre of KBTH. This is achieved by establishing the results and discussions of the specific objectives as outlined in earlier sections of the work.

Results obtained from quality assessments of the equipment used for measurements are also thoroughly discussed since they form the basis of accurate results needed to achieve the objective of this study. As stated, the relevance of this study is to help address the current practice in relation to safety concerns in order to significantly improve the effectiveness of radioiodine therapy in Ghana.

4.2 Quality Control on Dose Calibrator

Before the main measurements were carried out certain quality control checks were performed on the dose calibrator to ensure its efficiency. The activity of various radionuclides was measured and also calculated using the decay formula: $A = A_0 e^{-\lambda t}$ -----Equation (4)

where, A = Calculated Activity, t = time taken and decay constant, $\lambda = \frac{\ln(2)}{t_{1/2}}$ -----Equation (5)

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Also, the percentage difference, pd was calculated for each of the measured activities and their calculated values, using $pd = (\frac{|Measured\ activity - Calculated\ activity|}{Calculated\ activity}) \times 100$ Equation(6)

These tests are discussed in the following subsections

4.2.1 Linearity test

The results obtained from this test showed that linearity was maintained within 3.5% across the operational range as shown in table 4.1 below. Also, a graph of measured activity versus calculated activity was further used to ascertain the linearity of the dose calibrator.

Table 4.1: Linearity Test on Dose Calibrator at an Hourly Rate

Measured Activity / (mCi)	Time/ (hr)	Calculated Activity/ (mCi)	Percentage difference/ (%)
5.10	0	5.10	0.00
4.46	1	4.54	1.86
4.00	2	4.05	1.19
3.58	3	3.61	0.72
3.16	4	3.21	1.62
2.77	5	2.86	3.21

From the results, the percent differences between consecutive readings are all within the typical ±5% linearity acceptance criteria, indicating good linearity of the dose calibrator as recommended by the IAEA-TECDOC-1583 (2007) which states that periodic linearity tests using multiple activity levels to ensure consistent performance within ±10%. The results are also in accordance with the SNMMI Procedure Standard NSN-1 (2018) which states that dose calibrators must exhibit linearity within ±5% across the clinically relevant range of activities. Both measured and expected activities show a clear decline over time, consistent with the radioactive decay of Tc-

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99m. However, slight deviations between the observed and expected values are seen, especially after 4-5 hours, but the percentage differences (all below 4%) remain within acceptable limits, indicating good calibrator performance.

Figure 4.1 below further helps visualize the agreement between the measured and calculated (expected) activity over the 6-hour test period. Overall, the graph demonstrates the dose calibrator's reliability in measuring Tc-99m activity over time.

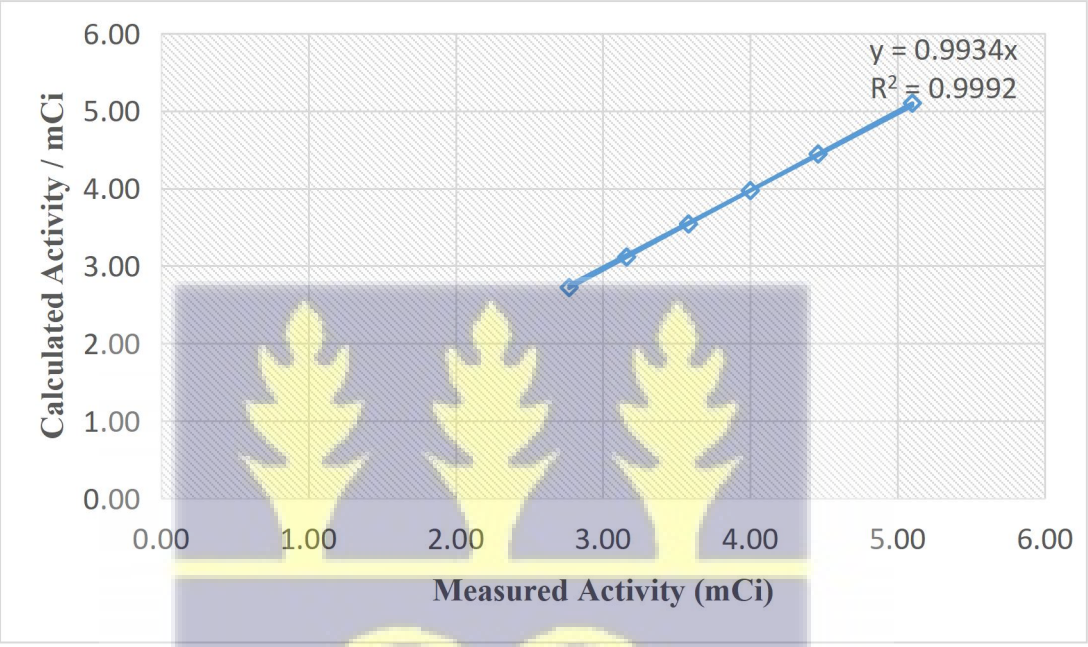

Figure 4.1: Graph showing the Linearity of the Dose Calibrator

4.2.2 Accuracy Tests

Accuracy refers to how closely the reading of the dose calibrator matches the true value of the radioactive material. An inaccurate dose calibrator may result in administering either a higher dose or a lower dose. Higher doses will increase radiation exposure risks, while lower doses may lead to ineffective treatment. From the results obtained (shown in Table 4.2 below), the dose calibrator exhibited excellent accuracy, with all percentage differences between the observed and true activities being significantly below 1%.

Table 4.2: Accuracy Test on Dose Calibrator Results

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Time/ (s)	Measured Activity/ (mCi)	Exact Activity/ (mCi)	Percentage Difference/ (%)
0	5.0	5.0	0.0
30	4.99	5.0	0.2
60	4.98	5.0	0.4
90	4.96	5.0	0.8

Typically, the accuracy should be within ±5% of the true value. SNMMI Procedure Standard, NSN-1 (2018) and IAEA-TECDOC-1583 (2007) recommend that dose calibrator readings should be within ±5% of the known standard. The results obtained were within the accepted values.

4.2.3 Constancy Tests

Constancy measures how consistently the dose calibrator gives the same readings over time when measuring the same source; and it ensures that the calibrator's performance is stable, detecting any drift in the device's functionality. From the results obtained (Table 4.3 below), the dose calibrator showed consistent performance over 5 days with minimal deviations from the reference activity, as all dose variation were within the ±5% acceptance threshold.

Table 4.3: Constancy Test on Dose Calibrator over a 5-day period

Days	Cs-137 Activity(µCi)	I-131 Settting(µCi)	I-131 Percentage Difference/ (%)
Monday	103	137	-0.58%

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Tuesday	104	138	0.15%
Wednesday	102	136	-1.31%
Thursday	106	140	1.60%
Friday	104	138	0.15%

Reference Values: I-131 Setting (µCi): 137.8 µCi (mean of the observed values)

This result is in accordance with both the SNMMI Procedure Standard, NSN-1 (2018), which advocates for constancy checks to ensure readings do not deviate by more than ±5% from baseline measurements; and AAPM Task Group 55 (2006) which recommends daily or weekly constancy checks with long-lived sources, ensuring deviations stay within ±5%.

4.2.4 Geometric Tests

Geometry evaluates the ability of the dose calibrator to give accurate readings regardless of the position or configuration of the radioactive sample. Inconsistent geometry can cause variations in dose readings, leading to incorrect dosing. The geometric test performed was to ensure that for different configuration of the radioactive sample (volume), the dose calibrator measured the same activity. It was observed from the results obtained that the dose calibrator showed consistent and accurate readings across different volumes, with variations due to geometry changes not exceeding 5%. (as shown in Table 4.4 below).

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Table 4.4: Geometry Test on Dose Calibrator using a Syringe

Sample Volume(ml)	Reference Tc-99m Activity(mCi)	Measured Activity(mCi)	% Deviation from 8.67 mCi

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2	8.67	8.67	0.0
3	8.67	8.48	2.19
4	8.67	8.37	3.46
5	8.67	8.28	4.5

The results indicates that the dose calibrator is performing well and is not significantly affected by the change in volume. The results align with established standards for geometry corrections, as outlined by both the SNMMI Procedure Standard NSN-1 (2018) and AAPM Task Group 55 (2006), which emphasize maintaining reading accuracy within ±5% across varying sample configurations.

4.3 Verification of Administered Activity as Against the Prescribed Activity

Table 4.5: Percentage difference in administered activities as against the prescribed activities

Prescribed Activity / mCi	**Administered Activity / mCi**	**% difference in Activities**
100	105	5
150	159	6
150	150	0
150	150	0
150	159	6
150	150	0
200	200	0
200	200	0
200	254	27

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200	239	19.5

Various international guidelines, such as those provided by the IAEA, SNMMI, EANM and AAPM, outline protocols for verifying I-131 doses. According to SNMMI guidelines (2018), the difference between the measured activity and the prescribed activity should be within ±5%; however, the IAEA-TECDOC-1602 (2008), EANM (2019), and AAPM recommends that the administered dose should be within ±10% of the prescribed dose for I-131 therapy.

From the results obtained (shown in Table 4.5 above), the administered activity were mostly the same as the prescribed activity except for 2 activities which were administered at higher doses of 27% and 19.5% than prescribed activity. The higher administered activities observed on those two days were most likely due to the radiopharmaceuticals arriving approximately 12–16 hours earlier than expected. Given the 8-hour half-life of I-131, this would result in less decay and therefore higher measured activity at the time of administration. Additionally, patients were admitted and prepared for treatment earlier than scheduled due to administrative and logistical adjustments, such as scheduling overlaps or delays in prior sessions. However, other potential causes cannot be ruled out, including the possibility of mechanical drift or calibration errors in the dose calibrator or even a minor undetected spill during dose preparation or transfer. These alternative possibilities highlight the need for continuous equipment monitoring and adherence to strict radiopharmacy handling procedures. Overexposure to radiation is a significant concern since high activities can lead to complications such as inflammation of salivary glands, radiation thyroiditis, and radiation exposure to non-target tissues such as bone marrow, lungs, or reproductive organs. The risk of adverse effects begins to increase significantly as the administered dose deviates further from the prescribed activity.

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4.4 Radiation Exposure Rates of Patients Undergoing I -131 Therapy

The recommendations of EANM and IAEA focus on monitoring the radiation exposure of patients, aiming to reduce radiation risks while maintaining effective therapeutic outcomes. In order to evaluate the discharge exposure rates of patients following I-131 administration, this study looked at both inpatients and outpatients, and the results are discussed below.

4.4.1 Outpatients

Outpatients are categorised as patients administered with 20 mCi of I-131 radiopharmaceutical. As presented in Table 4.6 below, it was observed that the mean discharge dose rate was 35.48 µSv/hr; this value is higher than the recommended discharge dose rate by both EANM and the IAEA (20 µSv/hr and 30 µSv/hr respectively). Also, the average time take for discharge was 4.2 hours, with the least time being 2 hours and the highest being 6 hours. The effect on the time taken before discharge is mainly attributed to the rate of metabolism and excretion of fluid from the patient's body; this determines the biological half-life of the I-131 radiopharmaceutical.

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Table 4.6: Representation of Outpatient exposure rate at different time points

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Physical half-life of I - 131 = 8 days = 192 hours

Patient ID	Age / yrs	Gender	Administered Activity / mCi	Discharge Dose rate / µSv/hr	Time Elapse / hr	Discharged Activity / mCi	Biological Half-life / hr	Effective half-life / hr	Effective half-life M Vs F
OUT-002	30	F	20	34.71	5	15.78	14.61	13.58	
OUT-003	32	F	20	38.72	5	17.60	27.11	23.76	
OUT-004	39	F	20	33.18	5	15.08	12.28	11.54	15.05
OUT-005	40	F	20	40.31	2	18.32	15.83	14.62	
OUT-008	46	F	20	30.36	5	13.80	9.34	8.91	
OUT-010	55	F	20	38.23	4	17.38	19.72	17.89	
OUT-001	28	M	20	31.69	4	14.40	8.45	8.09	
OUT-006	40	M	20	34.89	4	15.86	11.95	11.25	
OUT-007	45	M	20	36.10	6	16.41	21.02	18.94	11.38
OUT-009	52	M	20	36.61	2	16.64	7.54	7.25	
Mean Values				35.48	4.2	16.13	14.78	13.58	

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Further analysis to determine the effective half-life (combined physical and biological half-life) revealed that it takes an average of 13.58 hours for half the activity of the radionuclide to decay while in the patient's body. An observation of the data suggested that the mean effective half-life was longer in females (15.05 hours) than in males (11.38 hours). While this difference could be influenced by sex-related metabolic and physiological factors such as body composition and organ function, the small sample size and observed variability between individuals—both male and female—limit the strength of this comparison. Therefore, these findings should be interpreted with caution and regarded as preliminary observations rather than definitive conclusions. This observation may be partially explained by physiological differences, such as the typically higher proportion of body fat in females (Blaake, 2021), which can influence the distribution and clearance of radioiodine. Hormonal factors, including variations in thyroid hormone regulation, may also contribute to the differences observed between the sexes.

Figure 4.2 below further showed that none of the patients' discharge dose rate was consistent with any of the recommended discharge dose rates especially the adopted IAEA recommendation 30 µSv/hr; with the least dose rate prior to discharge being 30.36 µSv/hr and the highest being 40.31 µSv/hr. This inconsistency can be attributed to departmental challenges such as fixed operational working hours and inadequate human resource to work beyond operational hours. Also, some patients have very low metabolism and excretion rates and therefore spend longer time before their exposure reading reduce significantly.

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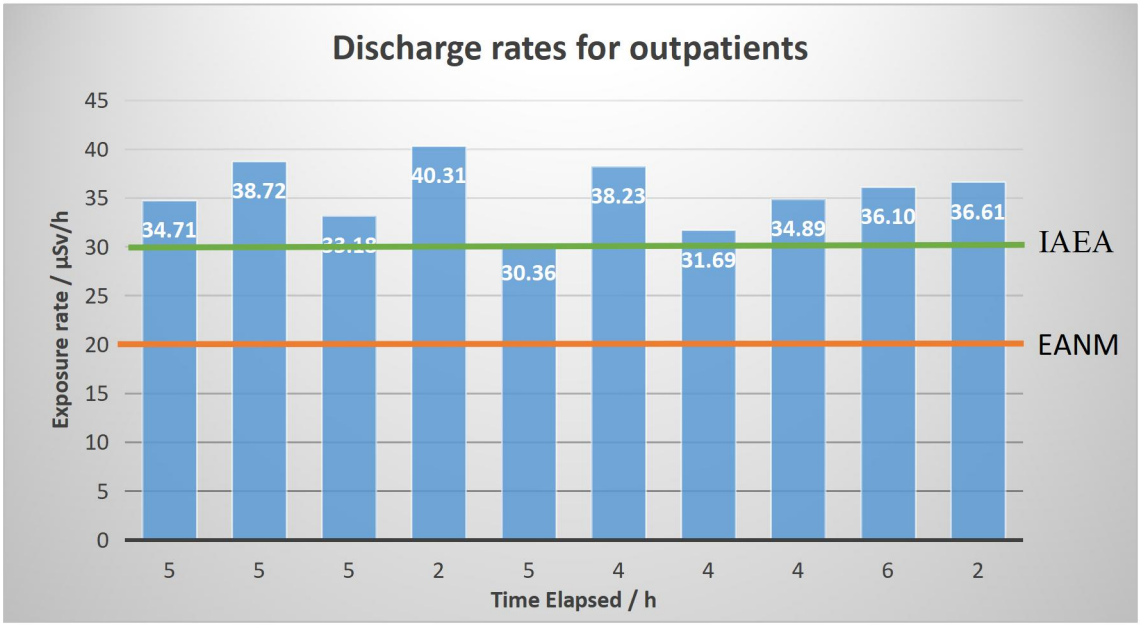

Figure 4.2: Graph showing the exposure rate against time elapsed for outpatients

4.4.2 Inpatients

In this work "inpatients" are categorised as patients administered with more than 100 mCi of I-131 radiopharmaceutical. As presented in Table 4.7 below, the mean discharge dose rate was 37.67 µSv/hr; this value is higher than the recommended discharge dose rate by both EANM and the IAEA (20 µSv/hr and 30 µSv/hr respectively). The average time taken for a patient to be discharged based on low exposure rates was 45.33 hours, with the least time being 32 hours and the highest being as high as 66 hours. As stated earlier the effect on the time taken before discharge is mainly attributed to the rate of metabolism and excretion of fluid from the patient's body, this determines the biological half-life of the radionuclide whiles in the patient's body.

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Table 4.7: Representation of Inpatient exposure rate at different time points

Physical half-life of I - 131 = 8 days = 192 hours								
Patient ID	**Age/ yrs**	**Gender**	**Administered Dose / mCi**	**Discharge Dose rate / µSv/hr**	**Time Elapse / hr**	**Discharged Activity / mCi**	**Biological Half-life / hr**	**Effective half-life / hr**
IN-002	14	F	159	21.14	32	9.61	7.90	7.59
IN-003	59	F	150	41.93	34	19.06	11.42	10.78
IN-004	69	M	239	37.51	41	17.05	10.76	10.19
IN-005	36	F	200	55.51	45	25.23	15.07	13.97
IN-006	67	F	105	49.09	46	22.31	20.59	18.59
IN-007	26	F	150	18.02	47	8.19	11.20	10.59
IN-008	42	M	150	23.36	48	10.62	12.56	11.79
IN-009	46	M	200	47.84	49	21.75	15.31	14.18
IN-010	48	F	159	44.61	66	20.28	22.21	19.91
Mean values				37.67		17.12		

Further analysis show that 3 out of 9 patients were discharged within recommended levels with a few being consistent with the adopted IAEA recommendation of 30 µSv/hr while most (representing 66.7 %) were inconsistent with the recommendation (Figure 4.3 below). These inconsistencies may be due to departmental challenges, such as inadequate weekend staff and a lack of dedicated space to admit patients for extended stays. Specifically, there are no specially designated rooms for prolonged patient admissions, as available facilities are often repurposed for other uses, including offices, brachytherapy treatment rooms, and similar functions.

Due to these challenges some contingencies are put in place to ensure patients exposure rates are within recommended levels before they are sent home by the

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hospital. One major contingency is to quarantine patients in a private facility (such as hotels) to further reduce exposure rate to the public. However, there is zero monitoring after patients are discharge from the hospital hence public safety is not guaranteed.

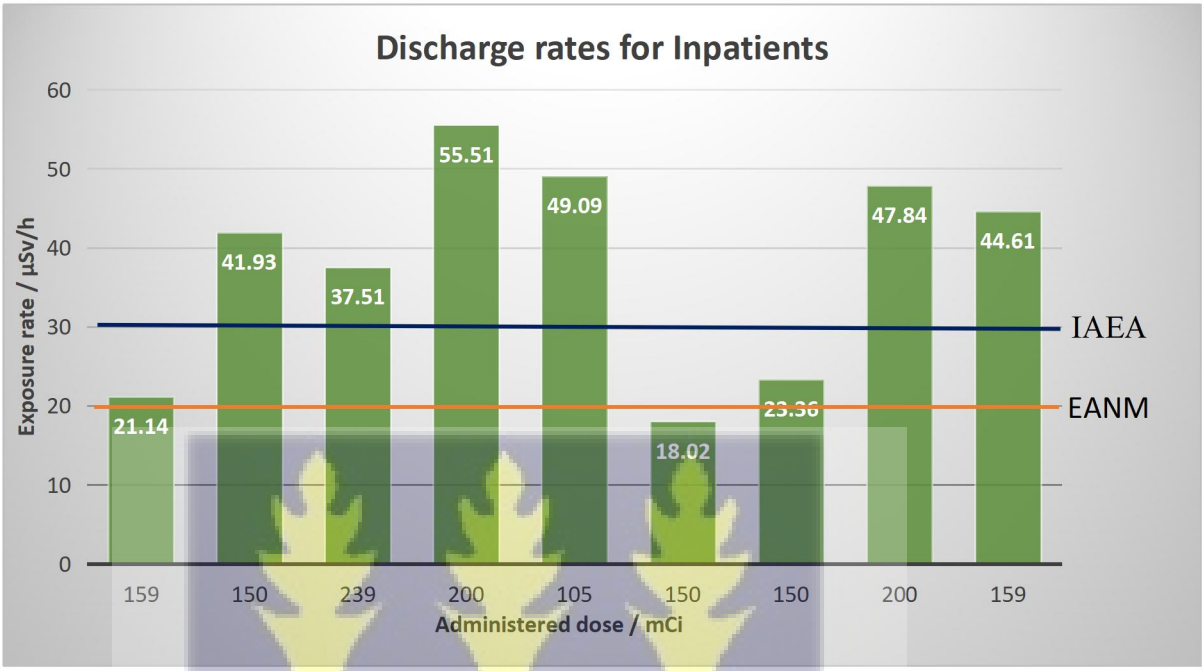

Figure 4.3: Graph of exposure rate against administered dose for inpatients

4.5 Current Clinical Practice and Adherence to Radiation Safety Protocols and Guidelines During I-131 Therapy

To assess adherence to radiation safety protocols, a checklist was used, adapted from the EANM Procedure Guidelines for Radioiodine Therapy of Differentiated Thyroid Cancer (2021) and the EANM Guideline on Radioiodine Therapy for Benign Thyroid Disorders (2022). The checklist outlined key areas and recommendations relevant to the safe use of I-131 in therapy. The checklist highlights several key aspects that are necessary for safe and effective treatment; and thus, the responses obtained from the major service providers in the institution is used to assess their clinical practice and

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adherence to radiation safety. The observations based on the responses obtained are outlined in Table 4.8 below and discussed extensively based on each key area.

Table 4.8: Radioiodine Therapy Checklist

Key Fields	Recommendations	Observed Practice
Patient Evaluation and Preparation	Verify the patient's diagnosis	Yes
	Get Thyroid Function Assessment Laboratory test	Yes
	Measure radioiodine uptake and clearance	Yes
	Ensure discontinuation of antithyroid medications as per protocol (e.g., Methimazole, Propylthiouracil).	Yes
	Inform the patient about the treatment process, potential side effects, and the importance of adherence to pre-treatment instructions.	Yes
	Patients should sign an informed consent form acknowledging their understanding of the procedure and its risks.	Yes
Radiation Safety Measures	Obtain necessary authorizations from the radiation safety committee.	Yes
	Ensure appropriate radiation shielding and containment measures are in place.	Yes

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	Patients' isolation for a specific period following radioiodine therapy, typically 2-3 days or until the radiation dose rate falls below a predetermined threshold.	Partially done
	During patient isolation period, access to the patient's room should be restricted to essential healthcare personnel. Visitors should be limited or avoided altogether.	Yes
	Provide detailed instructions to the patient and caregivers on radiation safety precautions.	Mainly done for inpatients
Radiopharmaceutical Preparation and Administration	Confirm the administered I-131 activity is within the recommended range	Yes
	Administer the I-131 dose using the appropriate technique.	Yes
	Record the actual administered activity and any deviations from the prescribed dose.	Actual administered activity recorded but not deviations
Radiation Exposure Monitoring	Monitor the patient's radiation exposure during and after administration.	Yes
	Measure radioiodine uptake and clearance at specified time points.	Yes
	Assess the patient's whole-body effective dose and organ-specific doses.	Only whole-body scan is done a week after administration

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		for inpatients only
	Maintain patient dosimetry records, including administered activity, biodistribution data, and calculated absorbed doses.	Aside the record for administered dose, the rest are not available to be assessed
	Staff dosimetry records, including personal dosimeter readings and cumulative annual doses.	Yes
	Records of environmental radiation monitoring in areas where I-131 therapy is conducted.	Done after inpatient discharge Not done after outpatient discharge
Post-Treatment Follow-up	Schedule appointments to monitor the patient's clinical response.	Yes
	Evaluate thyroid function and adjust the treatment plan as needed.	Yes
	Provide instructions on managing potential side effects.	Yes
	Work with the referring physician for ongoing patient care	Yes
Documentation and Reporting	Keep detailed records of the patient's treatment and relevant data.	Yes
	Report any adverse events or deviations from EANM guidelines to the appropriate authorities.	No
	Ensure compliance with institutional and regulatory requirements for I-131 therapy.	There is no institutionally documented

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		regulation
	Residual Activity: Confirm if the I-131 residual activity is 8 mCi or less for unrestricted release.	Yes
	Ensure that the total integrated exposure at 1 meter does not exceed release activity of 80 mCi.	*Not Applicable*
	Maintain distance greater than 3ft (1 meter) from others, except for brief necessary interactions if family members are over 45 years	Yes
Patients Discharge (NCRP Recommendations)	Enforce stricter precautions if family members are under 45 years: No contact within the same room. Maintain a distance of at least 9 ft for brief visits.	*Not Applicable*
	Apply restrictions based on calculated activity at discharge, particularly for higher initial activities.	Partially
	Patient discharge rate of 20 uSv/h for EANM, 30 uSv/h for IAEA, 20 uSv/h for ICRP and 25 uSv/h for NCRP all at 1 meter from patient	None is strictly adhered to.

4.5.1 Patient Evaluation and Preparation

Accurate patient preparation is essential for optimal treatment outcomes. The checklist confirms several important pre-treatment steps such as verifying diagnosis, performing thyroid function assessments (e.g., TSH, T3, T4 levels), discontinuation of

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antithyroid medications which can interfere with the effectiveness of I-131, as well as informed consent that ensures patients understand both the treatment and its potential risks, such as hypothyroidism, fertility issues, and secondary cancers; are all done before treatment.

It also revealed that administered doses are accurately recorded, and measurement of radioiodine uptake and clearance are done by measuring the exposure dose rates, however, there is the lack of documentation on the exact dose uptake and clearance measurement. This test helps predict how much of the administered radioiodine has been absorbed by the thyroid. Also, though patient education is being carried out well, there could be more emphasis on ensuring that they understand the instructions, especially since adherence to preparation (e.g., low-iodine diet) is crucial for treatment efficacy.

4.5.2 Radiation Safety Measures

Radiation safety protocols are in place to protect both healthcare staff and the public, following established guidelines such as those from the IAEA Radiation Safety Standards. The fact that necessary authorizations are obtained, and radiation shielding is in place shows an organized approach to radiation safety.

The checklist shows that, patients are isolated until radiation levels fall below a predetermined threshold, and during this time, strict access control is implemented. However, the isolation protocol is loosened when dealing with outpatients, since they are all kept in one room and thus leading to patient-to-patient exposure. The partial adherence to patient isolation suggests either inadequate facilities or inconsistent enforcement of isolation guidelines. This can lead to unnecessary radiation exposure to others, especially family members or healthcare workers.

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The checklist also revealed that radiation safety counselling is provided exclusively to patients, with limited or no formal guidance offered to caregivers. This gap is concerning, as uninformed caregivers may unknowingly expose themselves to radiation. It is essential that caregivers receive appropriate counselling, including instructions on proximity limits and clear behavioral guidelines to minimize exposure risk.

4.5.3 Radiopharmaceutical Preparation and Administration

According to the EANM Procedure Guidelines for Therapy with I-131(EANM, 2003), the administration of radioiodine should be precise, both in terms of dose and technique, it is crucial that the prescribed dose matches what is actually administered, and any deviations must be recorded.

It was observed that actual administered doses are measured and recorded but the deviations from the prescribed doses (if any), are not indicated in the patients' clinical notes. Also, radiopharmaceuticals are administered using the appropriate technique and the administered activity are within the recommended range on most occasions. However, failing to record deviations from the prescribed dose reduces accountability and can make follow-up treatments more difficult to plan. Proper documentation of administered doses is essential for assessing treatment efficacy and patient safety. In addition, calibration and quality assurance on dose calibrator should be performed regularly to prevent any discrepancies is the measurement of administered doses.

4.5.4 Radiation Exposure Monitoring

Monitoring radiation exposure during and after administration is crucial for ensuring the patient's safety and minimizing risks to others. Whole-body and organ-specific doses should be measured, and environmental radiation levels should be monitored.

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From the checklist, while whole-body scans are done a week after administration, organ-specific doses and detailed biodistribution assessments are missing. These are important for evaluating the radiation dose absorbed by the thyroid and other critical organs, such as the salivary glands, which can be affected by I-131. Also, the lack of environmental radiation monitoring during I-131 therapy is a significant gap. This could lead to unintentional exposure of healthcare staff or the public if radiation containment is inadequate. However, it was noted that environmental monitoring is done after inpatients are discharge, before and after clearing their room or ward; to ensure there is no radioactive spillage or contamination.

4.5.5 Post-Treatment Follow-up

Post-treatment follow-up includes monitoring the patient's clinical response, adjusting the treatment plan as necessary, and managing potential side effects like hypothyroidism or radiation-induced complications. The checklist indicated a total adherence to follow-up protocols, including thyroid function evaluation and side-effect management, indicates a robust post-treatment plan. This reduces the risk of long-term complications and ensures the treatment's effectiveness.

4.5.6 Documentation and Reporting

Maintaining comprehensive records of the patient's treatment, including any adverse events or deviations from the guidelines, is essential for ensuring patient safety and improving the quality of care. Failing to report deviations or adverse events as indicated in the checklist, is a critical gap. Regulatory compliance is important, and by not reporting adverse events, the institution may miss opportunities for improving its safety protocols. Also, the absence of specific institutional regulations for I-131 therapy highlights the need for developing clear policies that are in line with

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international standards such as the EANM and IAEA. Implementing institutional guidelines will help standardize procedures and improve safety.

4.5.7 Patient Discharge

The discharge of patients' post-therapy must be based on the residual radiation levels, and safety precautions should be in place to protect family members or the public. The recommended residual activity for discharge is 8 mCi or less according to the NCRP recommendations (Carey, Kumpuris, & Wrobel, 1995), and various international guidelines provide specific dose rate thresholds for safe release.

It was indicated in the checklist that residual doses of the iodine 131 containers and plastic dippers are checked and activity levels are ensured to be low before discharge. Discharging patients with residual activities above the recommended threshold (8 mCi or 20-30 μSv/h at 1 meter) increases the risk of exposing others to unnecessary radiation. This is a significant safety concern, particularly for vulnerable groups like children or pregnant women. The staff's lack of understanding regarding the total integrated discharge exposure limits of 80 mCi suggests the need for further training on radiation safety and regulatory requirements.

Additionally, though a distance greater than 1 meter away from others (family members, care givers and the public) is recommended for patients after discharge as well as no contact within the same room; there is no age limit to those who can get close except for children and pregnant women. However, the tendency of patients being discharged not adhering to distance recommendations from family members (especially those under 45 years old) is likely since there is no monitoring or supervision and thus increases the risk of exposure. These guidelines are in place to protect individuals from unnecessary radiation, particularly those who may be more vulnerable to its effects.

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4.6 Summary of Results and Discussion

The results and discussion chapter concludes by identifying significant findings related to dose accuracy, radiation exposure rates, and adherence to safety protocols. Variations in exposure rates among patients indicate inconsistencies in protocol application, highlighting areas where local practices can benefit from enhanced standardization. This chapter emphasizes that while current practices are effective, stricter enforcement and better training on international safety standards are essential to improve outcomes and reduce exposure risks.

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CHAPTER FIVE

CONCLUSION AND RECOMMENDATION

5.1 Conclusion

The aim of this research was to assess and optimize the current external radiation exposure rates of patients undergoing I-131 therapy for hyperthyroidism and thyroid cancers. In order to achieve this, certain specific objectives were carried out such as verification of administered activity, evaluation of patients' exposure rate and an assessment of the institutional adherence to radiation safety protocols and guidelines using a checklist.

The results from the four QC tests carried out on the dose calibrator shows a strong confidence in the dose calibrator used in this work since all tests were successful and within accepted tolerance levels. Also, all tests carried out were in accordance with internationally adopted standards, protocols, guidelines, and recommendations

From the measurements carried out and analysis of the results, it was observed that the administered doses were mostly within the recommended tolerance level of 10%, with few instances recording higher doses mainly due to institutional challenges such as drug importation and unrealistic treatment schedules. Also, mean average discharge dose rate were found to be 35.48 µSv/h for outpatients and 36.85 µSv/h for inpatients; these values exceed all the recommendations for discharge and thus indicates critical radiation safety issues to care givers and the public.

The checklist indicates that most of the necessary pre-treatment steps are being followed, such as thyroid function tests, discontinuation of antithyroid drugs, and obtaining informed consent. It also revealed that administered doses are accurately recorded, and measurement of radioiodine uptake and clearance are also done. These

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are essential to personalize dosing and ensure treatment efficacy as they form a crucial part of the treatment documentation. The checklist further showed that comprehensive follow-ups were adhered to, with regular appointments, thyroid function evaluations, and collaboration with referring physicians were being done.

The checklist further indicates that while there are good practices regarding radiation shielding and limited access during isolation, the partial adherence to patient isolation is concerning. Full isolation until the radiation level falls below a safe level is critical to protect others. A further limitation is the insufficient provision of radiation safety instructions, as these are typically directed towards patients only, neglecting caregivers. Again, the checklist revealed that, while monitoring after administration is done, the absence of organ-specific dose assessments and the lack of environmental radiation monitoring when patient is on admission are notable omissions. These practices are critical for tracking radiation exposure and ensuring safety for both the patient and the healthcare staff. Further deduction from the checklist indicates that although patient records are kept, adverse events and deviations from guidelines are not being reported. Lack of compliance with institutional or regulatory requirements for I-131 therapy could lead to patient safety risks or regulatory issues in the future.

Finally, the checklist shows the non-adherence to discharge criteria, particularly regarding residual activity and exposure rates. This was clearly evident in the second objective of this research where discharge rates were above adopted protocols and recommendations. This non-adherence presents a potential safety risk for the patient and close contacts, especially since discharge is happening even when rates exceed recommended limits.

It can therefore be concluded from this research that necessary authorizations are obtained, and radiation shielding is in place. Also, protocols and recommendations in

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key areas of radioiodine therapy such as Patient Evaluation and Preparation, Radiation Safety Measures, Radiopharmaceutical Preparation and Administration, Radiation Exposure Monitoring, Post-Treatment Follow-up are well adhered to. This shows an organized approach to radiation safety. However, the gaps in isolation protocols, lack of proper and accurate documentation and reporting, and most critically, high patients discharge rates undermine these efforts.

5.2 Recommendations

This research identifies several gaps in practice that could compromise patient safety and treatment outcomes, particularly regarding radiation safety measures and dose accuracy. To enhance the effectiveness and safety of radioiodine therapy, the following actions are recommended to the Nuclear Medicine and Radiotherapy Centre at KBTH as well as the research community:

1. Improve Calibration and Dosing: Address the inconsistencies in dose calibration and ensure accurate activity administration. Regular calibration of equipment and strict recording of deviations is essential.
2. Enhance Radiation Safety: Strictly enforce isolation protocols, provide comprehensive radiation safety instructions to both patients and caregivers, and implement continuous environmental radiation monitoring. Additionally, ensure proper ventilation of the I-131 drug using a functional laminar flow hood to remove harmful gaseous particles, thereby creating a safer environment for healthcare workers.
3. Expand Monitoring and Documentation: Include organ-specific radiation dose assessments and maintain detailed patient and staff dosimetry records. Accurate

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reporting of adverse events and deviations from the guidelines will improve compliance with international standards and ensure patient safety.

4. Discharge Planning and Safety: Adhere to the residual activity and dose rate limits for patient discharge, and ensure the staff is well-versed in these guidelines. This will reduce unnecessary radiation exposure to family members and the public.
5. Outpatient Monitoring and Safety: Start Iodine therapy for outpatients early to enable continuous monitoring and adequate time of decay before discharge. Also, ensure adequate spacing of at least 1 meter for outpatients that are isolated to prevent patient-to-patient exposure.
6. Education on Safety Protocol and Guidelines: Clinical and non-clinical staff should be properly educated on radioiodine therapy; the need for a Medical Physicist and/or a Radiation Protection Officer to supersede the implementation of the safety concerns and radiation measurement. Also, protocols and guidelines in radioiodine therapy must be summarised and displayed at visible points where everyone can see.
7. Research Community: Further research must go into the gender and age variations of discharge dose rates which will help in analysing the characteristics of radiation elimination from the body.

By addressing these issues, institutions can improve both patient outcomes and compliance with regulatory standards, making radioiodine therapy safer and more effective.

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5.3 Summary of Conclusion and Recommendation

In the final chapter, the study concludes that improved radiation safety and standardized discharge criteria are critical in I-131 therapy. Recommendations include

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enforcing safety protocols, investing in comprehensive staff training, and creating dedicated isolation facilities to enhance patient and public protection. By implementing these recommendations, healthcare facilities can ensure that I-131 therapy is both safe and effective, aligning local practices with global standards to better protect all involved.

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APPENDICES

APPENDIX 1: RADIOIODINE THERAPY CHECKLIST

Key Fields	Recommendations	Observed Practice
1. Patient Evaluation and Preparation	Verify the patient's diagnosis	
	Get Thyroid Function Assessment Laboratory test	
	Measure radioiodine uptake and clearance	
	Ensure discontinuation of antithyroid medications as per protocol (e.g., Methimazole, Propylthiouracil).	
	Inform the patient about the treatment process, potential side effects, and the importance of adherence to pre-treatment instructions.	
	Patients should sign an informed consent form acknowledging their understanding of the procedure and its risks.	
2. Radiation Safety Measures	Obtain necessary authorizations from the radiation safety committee.	
	Ensure appropriate radiation shielding and containment measures are in place.	
	Patients' isolation for a specific period following radioiodine therapy, typically 2-3 days or until the radiation dose rate falls below a predetermined threshold.	
	During patient isolation period, access to the patient's room should be	

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	restricted to essential healthcare personnel. Visitors should be limited or avoided altogether.	
	Provide detailed instructions to the patient and caregivers on radiation safety precautions.	
3. Radiopharmaceutical Preparation and Administration	Confirm the prescribed I-131 activity is within the recommended range	
	Administer the I-131 dose using the appropriate technique.	
	Record the actual administered activity and any deviations from the prescribed dose.	
4. Radiation Exposure Monitoring	Monitor the patient's radiation exposure during and after administration.	
	Measure radioiodine uptake and clearance at specified time points.	
	Assess the patient's whole-body effective dose and organ-specific doses.	
	Maintain patient dosimetry records, including administered activity, biodistribution data, and calculated absorbed doses.	
	Staff dosimetry records, including personal dosimeter readings and cumulative annual doses.	
	Records of environmental radiation monitoring in areas where I-131 therapy is conducted.	

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5. Post-Treatment Follow-up	Schedule appointments to monitor the patient's clinical response.	
	Evaluate thyroid function and adjust the treatment plan as needed.	
	Provide instructions on managing potential side effects.	
	Work with the referring physician for ongoing patient care	
6. Documentation and Reporting	Keep detailed records of the patient's treatment and relevant data.	
	Report any adverse events or deviations from EANM guidelines to the appropriate authorities.	
	Ensure compliance with institutional and regulatory requirements for I-131 therapy.	
7. Patients Discharge (NCRP Recommendations)	Residual Activity: Confirm if the I-131 residual activity is 8 mCi or less for unrestricted release.	
	Ensure that the total integrated exposure at 1m does not exceed release activity of 80 mCi.	
	Maintain distance greater than 3ft from others, except for brief necessary interactions if family members are over 45years	
	Enforce stricter precautions if family members are under 45years: No contact within the same room. Maintain a distance of at least 9 ft for	

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	brief visits.	
	Apply restrictions based on calculated activity at discharge, particularly for higher initial activities.	
	Patient discharge rate of 20uSv/h for EANM, 30uSv/h for IAEA, 20uSv/h for ICRP and 25uSv/h for NCRP all at 1meter from patient	

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APPENDIX 2: ETHICAL CLEARANCE

UNIVERSITY OF GHANA
ETHICS COMMITTEE FOR BASIC AND APPLIED SCIENCES (ECBAS)
P. O. Box LG 1195, Legon, Accra, Ghana

Ref. No: ECBAS 058/23-24

20th May, 2024

Ahuri Gwendolyn
Department of Medical Physics,
University of Ghana
Legon, Accra

Dear Ms Ahuri,

ECBAS 058/23-24: DOSE ASSESSMENT FOR PATIENTS RECEIVING I – 131 THERAPY

This is to inform you that the above referenced study has been presented to the Ethics Committee for Basic and Applied Sciences for a full board review and the following actions taken subject to the conditions and explanation provided below:

Expiry Date:	11/04/2025
On Agenda for:	Initial Submission
Date of Submission:	12/02/2024
ECBAS Action:	Approved
Reporting:	Annually

Please accept my congratulations.

Yours sincerely,

APPROVED
20 MAY 2024

Professor Dorcas Obeng-Sallo
ECBAS Chairperson

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APPENDIX 3: CALIBRATION CERTICATE FOR CS-137

Cs-137 STANDARD RADIONUCLIDE SOURCE CERTIFICATE

AEA TECHNOLOGY QSA

AEA Technology
QSA GmbH

Giesleweg 1
38110 Braunschweig
Postfach 11 37
38001 Braunschweig
Germany
Tel. +49 (0) 5307 932-0
Fax +49 (0) 5307 932-194

28 October 2005

CERTIFICATE

No. 93677 – NK 581

for a Sealed Radioactive Source

CE

Source Type: Dose Calibrator Reference Source

Product code	CDR562
Drawing	VZ-505/1
Source no	NK 581
Nuclide	Caesium-137

Measurement Data

Activity	9.21 MBq
Overall uncertainty*	3 %
Reference date	13 October 2005
Traceability*	Defined on page 2
Radioactive impurities	Related to Cs-137 (equal 100 %) the following radioactive impurities were detected: Cs-134 < 0.10 %

Leakage and Contamination Test/s

Test method/s*	I
Test/s passed on	18 October 2005

Additional Information

ISO classification*	C 22222

* see page 2 for explanation

AEA Technology QSA GmbH

i. A. [signature]
(Production Manager)

$T_{1/2} = 30.17\,y$

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