## A STUDY OF ADULT DIAGNOSTIC REFERENCE LEVELS (DRLs) FOR BONE AND THYROID SCINTIGRAPHY IN HOSPITAL PAKAR USM

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# SCHOOL OF HEALTH SCIENCES UNIVERSITI SAINS MALAYSIA

## A STUDY OF ADULT DIAGNOSTIC REFERENCE LEVELS (DRLs) FOR BONE AND THYROID SCINTIGRAPHY IN HOSPITAL PAKAR USM

by

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Dissertation submitted in partial fulfillment of the requirements for the degree of Bachelor of Medical Radiation (Honours)

June 2025

#### **CERTIFICATE**

This is to certify that the dissertation entitled "A Study of Adult Diagnostic Reference Levels (DRLs) for Bone and Thyroid Scintigraphy in Hospital Pakar USM" is the bona fide record of research work done by Ezzradyeana Mayang Anak Roddy during the period from October 2024 to June 2025 under my supervision. I have read this dissertation and that in my opinion it conforms to acceptable standards of scholarly presentation and is fully adequate, in scope and quality, as a dissertation to be submitted in partial fulfillment for the degree of Bachelor of Medical Radiation (Honours).

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#### **DECLARATION**

I hereby declare that this dissertation is the result of my own investigations, except where otherwise stated and duly acknowledged. I also declare that it has not been previously or concurrently submitted as a whole for any other degrees at Universiti Sains Malaysia or other institutions. I grant Universiti Sains Malaysia the right to use the dissertation for teaching, research and promotional purposes.

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#### LISTS OF ABBREVIATIONS

ADs Achievable Doses

ALARA As Low As Reasonably Achievable

CT Computed Tomography

DRLs Diagnostic Reference Levels

I-123 Iodine-123

I-131 Iodine-131

IAEA International Atomic Energy Agency

ICRP International Commission on Radiological Protection

keV Kiloelectron Volt

MIRD Medical Internal Radiation Dose

MBq Megabecquerel

MDP Methylene Diphosphonate

MOH Ministry of Health

MRSD Medical Radiation Surveillance Division

NM Nuclear Medicine

NRPB National Radiological Protection Board

PET Positron Emission Tomography

SPECT Single-Photon Emission Computed Tomography

SNMMI Society of Nuclear Medicine and Molecular Imaging

Tc-99m Technetium-99m

TSH Thyroid-Stimulating Hormone

USM Universiti Sains Malaysia

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# KAJIAN TAHAP RUJUKAN DIAGNOSTIK (DRLs) BAGI PESAKIT DEWASA UNTUK SKINTIGRAFI TULANG DAN TIROID DI HOSPITAL PAKAR USM

#### **ABSTRAK**

Pengenalan: Tahap Rujukan Diagnostik (DRLs) memainkan peranan penting dalam prosedur pengimejan perubatan nuklear, terutamanya dalam pemeriksaan yang kerap dijalankan seperti skintigrafi tulang dan tiroid. DRLs berfungsi sebagai penanda aras untuk meningkatkan keselamatan pesakit dan mengoptimumkan penggunaan radiofarmaseutikal. Namun begitu, tiada DRLs yang telah ditetapkan bagi prosedur ini di Hospital Pakar USM, mahupun di Malaysia. Pada masa ini, hanya Dos Boleh Dicapai (ADs) kebangsaan sahaja yang telah ditubuhkan bagi prosedur pengimejan perubatan nuklear, menyebabkan kefahaman yang terhad terhadap aktiviti radiofarmaseutikal yang diberi dalam amalan klinikal semasa di Hospital Pakar USM. Objektif: Kajian ini bertujuan untuk menentukan aktiviti radiofarmaseutikal yang diberi kepada pesakit dewasa yang menjalani skintigrafi tulang dan tiroid di Hospital Pakar USM, bagi mencadangkan DRLs untuk kedua-dua prosedur pengimejan ini. Perbandingan turut dilakukan antara DRLs yang dicadangkan dengan DRLs antarabangsa yang telah ditetapkan, serta antara ADs yang dicadangkan dengan ADs kebangsaan yang sedia ada. **Metodologi:** Reka bentuk kajian pemerhatian retrospektif telah dijalankan menggunakan data pesakit dalam tempoh lima tahun, bermula dari Januari 2020 hingga Disember 2024. Sebanyak 158 kes pesakit yang terdiri daripada 104 kes skintigrafi tulang menggunakan Tc-99m MDP dan 54 kes skintigrafi tiroid menggunakan Tc-99m pertechnetate telah

dikumpulkan. Aktiviti radiofarmaseutikal yang diberi telah dianalisis, diikuti dengan pengiraan persentil ke-50 dan ke-75 bagi kedua-dua prosedur pengimejan ini untuk mewakili nilai DRLs dan ADs yang dicadangkan. **Keputusan:** Bagi ADs yang dicadangkan, aktiviti radiofarmaseutikal yang diberikan dikira pada persentil ke-50 (median) ialah 763.68 MBq untuk skintigrafi tulang dan 187.71 MBq untuk skintigrafi tiroid. Bagi DRLs yang dicadangkan, aktiviti radiofarmaseutikal yang diberikan dikira pada persentil ke-75 ialah 793.28 MBq untuk skintigrafi tulang dan 196.08 MBq untuk skintigrafi tiroid. **Kesimpulan:** Kedua-dua nilai DRLs dan ADs yang dicadangkan dalam kajian ini adalah konsisten dengan piawaian antarabangsa dan kebangsaan, di mana nilainilai tersebut berada di dalam julat aktiviti radiofarmaseutikal yang boleh diterima. Kajian ini juga menyokong usaha berterusan ke arah pembangunan DRLs kebangsaan bagi prosedur pengimejan perubatan nuklear di Malaysia.

**Kata Kunci:** Perubatan Nuklear, Tahap Rujukan Diagnostik, Dos Boleh Dicapai, Skintigrafi Tulang, Skintigrafi Tiroid

### A STUDY OF ADULT DIAGNOSTIC REFERENCE LEVELS (DRLs) FOR BONE AND THYROID SCINTIGRAPHY IN HOSPITAL PAKAR USM

#### **ABSTRACT**

Introduction: Diagnostic Reference Levels (DRLs) are important in nuclear medicine imaging procedures, especially in commonly performed examinations such as bone and thyroid scintigraphy. DRLs function as the benchmarks to improve patient safety and optimize the use of radiopharmaceuticals. However, there are no established DRLs for these imaging procedures in the Hospital Pakar USM, or even in Malaysia. Currently, only national Achievable Doses (ADs) have been established for nuclear medicine resulting limited understanding administered imaging, regarding the radiopharmaceutical activities of the current clinical practices in Hospital Pakar USM. Objectives: This study focuses to determine the administered radiopharmaceutical activities in adult patients undergoing bone and thyroid scintigraphy in Hospital Pakar USM, in order to propose DRLs for these imaging procedures. The comparisons were carried out between the proposed DRLs and established international DRLs, as well as between the proposed ADs and established national ADs. Methodology: A retrospective observational design was conducted in this study using patient data within five years, starting from January 2020 to December 2024. A total of 158 patient cases, consisting of 104 bone scintigraphy cases using Tc-99m MDP and 54 thyroid scintigraphy cases using Tc-99m pertechnetate, were collected. The administered radiopharmaceutical activities were analyzed, followed by calculating the 50th and 75th percentiles for these imaging

ADs, the administered radiopharmaceutical activities calculated at the 50th percentile (median) for bone scintigraphy was 763.68 MBq, while for thyroid scintigraphy was 187.71 MBq. For proposed DRLs, the administered radiopharmaceutical activities calculated at the 75th percentile for bone scintigraphy was 793.28 MBq, while for thyroid scintigraphy was 196.08 MBq. Conclusion: Both proposed DRLs and ADs obtained for this study were consistent with international and national standards, where these values were within the ranges of administered radiopharmaceutical activities after the comparison had been made. This study also supports the ongoing efforts for the development of the national DRLs for nuclear medicine imaging procedures in Malaysia.

**Keywords:** Nuclear Medicine, Diagnostic Reference Level, Achievable Dose, Bone Scintigraphy, Thyroid Scintigraphy

#### **CHAPTER 1: INTRODUCTION**

This chapter presents an overview of the study, starting with the background of the study that highlights the important keywords. It also outlines the problem statements and objectives, as well as the significance of the study to provide a clear framework for understanding its purpose and scope.

#### 1.1 Background of Study

Nuclear medicine imaging has become a common practice in modern healthcare, covering approximately 90% of all procedures performed within the field of nuclear medicine (World Nuclear Association, 2024). According to the United Nations Scientific Committee on the Effects of Atomic Radiation (2010), nuclear medicine imaging is widely used compared to therapeutic purposes, with approximately 32.7 million procedures performed globally each year. In Malaysia, nuclear medicine has developed significantly since 2006 with the establishment of departments at both Hospital Pulau Pinang and Hospital Kuala Lumpur. The increased number of patient cases related to chronic diseases, especially cancer, has led to a growing demand for nuclear medicine imaging technologies (Hricak et al., 2021). This trend highlights their contribution to modern healthcare. As of today, there are 23 nuclear medicine centres in Malaysia, including facilities under the Ministry of Health (MOH), university hospitals, government-linked institutions, and private hospitals or institutions, reflecting an increasing number of patients (Ng, 2016). This significant prevalence highlights the need for standard reference values to manage internal radiation doses effectively.

In nuclear medicine, the focus is more on the internal radiation dose as it refers to the amount of radiation that is deposited within the body after the radiopharmaceutical is administered (Paquet et al., 2016). As with any form of radiation, it needs to be carefully balanced with patient safety while achieving high-quality diagnostic outcomes. This consideration has led to the need for Diagnostic Reference Levels (DRLs) as the standard reference values. Over the years, DRLs have been adjusted to fulfill the clinical practice requirements, which is then making them suitable for different healthcare settings (Almén et al., 2021). It is important to recognize DRLs as an optimization tool, as these values can be used to maintain consistency in the administered radiopharmaceutical activity to patients over time. Apart from that, another term of achievable doses (ADs) is also introduced. Both DRLs and ADs focus on the internal dosimetry of patients to improve radiation protection in nuclear medicine. However, their definitions and applications differ significantly. ADs focus on the continuous improvement that aligns with the "As Low as Reasonably Achievable" (ALARA) principle, which emphasizes to minimize radiation exposure while maintaining better diagnostic quality (Dudhe et al., 2024). The implementation of ADs supports ongoing advancements in radiation protection alongside the existing DRLs.

National and international regulatory organizations support the use of DRLs as part of the framework for radiation protection in healthcare institutions. The international organizations, such as the International Commission on Radiological Protection (ICRP) and the International Atomic Energy Agency (IAEA), are more directly involved in defining DRLs. According to Mohd Norsuddin et al. (2022), Malaysia has been working to develop its own national DRLs, taking on international recommendations such as those from the ICRP and IAEA. In Malaysia, the establishment and implementation of DRLs are strictly taken over by the Ministry of Health (MOH). By establishing DRLs, healthcare professionals are able to evaluate and compare their clinical practices against national and international standards to prevent inconsistent nuclear medicine imaging procedures performed on patients.

#### 1.2 Problem Statement

The increasing use of nuclear medicine imaging has raised significant concerns about the internal radiation dose, resulting from the administered radiopharmaceutical activity of to the patients. As the number of imaging procedures carried out increases, there is a need to monitor these administered activity levels by referring to the standard reference values for guidance. In Hospital Pakar USM, a major concern is directed toward bone and thyroid scintigraphy, as these two imaging procedures are the most commonly performed. According to Vañó et al. (2017), Diagnostic Reference Levels (DRLs) are widely known as established standard reference values for ensuring consistency in administered radiopharmaceutical activity for nuclear medicine imaging.

In 2013, the Malaysian Ministry of Health (MOH) established national DRLs for diagnostic radiology, focusing on imaging procedures such as mammography, general X-ray, computed tomography (CT), and fluoroscopy (Muhammad et al., 2020). However, DRLs for nuclear medicine imaging have not yet been established that resulting in no standard reference value for adult bone and thyroid scintigraphy in Hospital Pakar USM. Hence, there are no comparative surveys of DRLs between Hospital Pakar USM and the established DRLs from other countries. This gap highlights the need to assess current clinical practices in Hospital Pakar USM, considering that it is the only nuclear medicine centre covering a lot of patient cases within the East Coast region annually.

Although the MOH has provided data on Achievable Doses (ADs) for nuclear medicine imaging, there are also no surveys have been conducted for comparison for adult bone and thyroid scintigraphy (Ministry of Health Malaysia, 2013). As a result, there is a limited understanding of both DRLs and ADs for these imaging procedures in Hospital Pakar USM. Therefore, this study is needed to address these gaps by establishing standard reference values in evaluating current clinical practices.

#### 1.3 Study Objectives

#### 1.3.1 General Objective

To analyze the administered radiopharmaceutical activities related to adult bone and thyroid scintigraphy in Hospital Pakar USM for establishing Diagnostic Reference Levels (DRLs).

#### 1.3.2 Specific Objectives

- i. To establish Diagnostic Reference Levels (DRLs) and Achievable Doses (ADs) for adult bone and thyroid scintigraphy in Hospital Pakar USM.
- ii. To compare the Diagnostic Reference Levels (DRLs) for adult bone and thyroid scintigraphy in Hospital Pakar USM with established international Diagnostic Reference Levels (DRLs).
- iii. To compare the Achievable Doses (ADs) for adult bone and thyroid scintigraphy in Hospital Pakar USM with established national Achievable Doses (ADs).

#### 1.4 Significance of Study

This study is significant as it contributes to the future national data collection for Diagnostic Reference Levels (DRLs) in Malaysia. The studies on DRLs in Malaysia, especially for bone and thyroid scintigraphy are limited and not yet established, which supports the need to collect the data that represent actual clinical practices in Hospital Pakar USM. As a result, the comparisons between the proposed DRLs and the established international DRLs could be made to understand if there are any differences in patterns related to the data collection.

Furthermore, this study contributes to the optimization of radiopharmaceutical usage to ensure that the administered radiopharmaceutical activities are within an optimal range. By establishing DRLs specific to the imaging procedures, patient safety is able to be improved by ensuring that patients undergoing bone and thyroid scintigraphy receive safe and effective radiopharmaceutical activities. Therefore, DRLs are important to become the benchmarks to improve patient safety and optimize the use of radiopharmaceuticals so that the unnecessarily high internal radiation doses that increase the risk of radiation-induced side effects to the patients could be prevented.

The findings on DRLs and Achievable Doses (ADs) are directly supporting the improvements of clinical practices within the Department of Nuclear Medicine in Hospital Pakar USM. With the existing DRLs data, a comprehensive review for each nuclear medicine imaging procedure is carried out, specifically for bone and thyroid scintigraphy. Thus, this study is indeed helpful for healthcare professionals to systematically strategize for patient management.

#### **CHAPTER 2: LITERATURE REVIEW**

This chapter provides a comprehensive review of the several literatures related to the study. These include the main aspects that are highlighted, such as nuclear medicine, radiopharmaceuticals, bone and thyroid scintigraphy, followed by the term of the Diagnostic Reference Levels (DRLs). In addition, this chapter also describes the term of achievable doses (ADs), as well as, the radiation safety in nuclear medicine.

#### 2.1 Nuclear Medicine

Nuclear medicine is a field of modern medicine that applies the principles of radioactivity within clinical practices. It involves the usage of the small amounts of radiopharmaceutical compounds to diagnose and treat various health conditions. These radiopharmaceuticals emit different types of radiation, depending on their composition and targeted organ or tissue, which then determines whether they are used for imaging or treatment. For example, the radiopharmaceuticals that emit gamma rays are primarily used for diagnostic purposes, as they penetrate through the body and are detected by imaging systems, such as gamma cameras for single-photon emission computed tomography (SPECT) imaging or positron emission tomography (PET) scanners (Rushing, Pryma and Langleben, 2012). The accumulation of radiopharmaceuticals in specific organs or tissues provides information about their function, activity, or abnormalities after being administered into the body of the patient through injection, ingestion, or inhalation (Kane et al., 2022). Meanwhile, the beta particles are used for therapeutic purposes, as beta radiation delivers localized radiation to the target within millimeter ranges. This localized energy deposition minimizes the damage to surrounding healthy tissues while effectively treating health conditions such as hyperthyroidism and certain types of cancer (Welsh, 2007).

#### 2.2 Radiopharmaceuticals

Radiopharmaceuticals are radioactive compounds mainly used in nuclear medicine for both diagnostic and therapeutic purposes. These radioactive compounds consist of a radionuclide paired with a pharmaceutical compound, which is specifically designed to localize in targeted organ or tissue within the body (Calabria et al., 2023). For diagnostic radiopharmaceuticals, it is commonly associated with technetium-99m (Tc-99m) labelled compounds that are widely used due to their ideal physical properties, including a short half-life and pure gamma-ray emission of optimum diagnostic energy of 140 keV. These radiopharmaceuticals allow the imaging of physiological functions in organs to provide clinical information for early detection and further evaluation of health conditions (Kane et al., 2022).

#### 2.2.1 Preparation of the Radiopharmaceuticals

Radiopharmaceutical preparation involves the production within the nuclear research reactors or cyclotrons by irradiating specific targets to generate radioisotopes, which are then tagged onto molecules based on their biological characteristics (Dhoundiyal et al., 2024). There are several factors, such as pH, reaction time, and reducing agents, that contribute to determine the overall quality of the final radiopharmaceutical product (Nurhidayah et al., 2022). For isotopes with short half-lives, such as technetium-99m (Tc-99m), the preparation is usually conducted in hospital-based radiopharmacies under aseptic conditions. The labelling process with a cold kit is carefully handled to obtain high yield and purity. For isotopes with longer half-lives, commercial manufacturers manage the whole production and distribution process. These radiopharmaceuticals are often used for therapeutic purposes that require precise dosimetry calculations to optimize treatment for the patients (Dhoundiyal et al., 2024).

## 2.2.2 Factors Contributing to Variations of the Radiopharmaceutical Administration

Since nuclear medicine procedures involve the process of introducing a specific amount of a radiopharmaceutical compound into the body, one of the most important aspects that needs to be highlighted is the amount of administered radiopharmaceutical activity to the patient. Any variation in the administered radiopharmaceutical activity leads to inconsistent radiation doses delivered to patients, which is directly affecting patient safety (Marengo et al., 2021). This variability highlights the need to have standard reference values for these administered radiopharmaceutical activities for each nuclear medicine procedure that reflect actual clinical practices within healthcare institutions. According to a previous study (Kasalak et al., 2020), the findings have shown that the inconsistency of the radiation doses became the most common source of patient safety incidents in nuclear medicine, representing the majority of the 24.5% of all reported cases. It is stated that under this medication or intravenous fluids category, which includes the errors related to inventory management, unadministered or inaccurately measured radiopharmaceuticals, and incorrect administration schedules, directly contributes to the variations in administered radiopharmaceutical activities to the patient.

Kasalak et al. (2020) also found that the incidents under the clinical process and procedure category made up 18.4% of the cases and often involved incomplete or inadequate procedures. This category includes the imaging errors, such as missing important body parts from the scanning field, or delays when obtaining the results. Therefore, the accidental changes in administered radiopharmaceutical activities or repeated procedures are likely to occur, which further increases the internal radiation doses of the patients. These findings reflect the ongoing challenges in maintaining consistency and precision within clinical practices in nuclear medicine.

#### 2.3 Bone and Thyroid Scintigraphy in Nuclear Medicine

Bone scintigraphy is frequently performed using technetium-99m methylene diphosphonate (Tc-99m MDP), which is highly sensitive for detecting bone metastasis, any fractures, infections, and malignancies that commonly spread to bones such as prostate, breast, and lung cancer (Adams and Banks, 2019). This type of imaging procedure relies on the physiological uptake of the radiopharmaceuticals that are administered intravenously, which are then imaged using a gamma camera. It provides functional information on the skeletal abnormalities before any structural changes are detectable with conventional radiographs (Bartel et al., 2018). It can be performed as a whole-body study to assess systemic bone involvement or as a regional scan to focus on a specific area of interest (Adams and Banks, 2019).

Thyroid scintigraphy is another nuclear medicine imaging procedure that determines the functionality and structure of the thyroid. The process involves using technetium-99m pertechnetate (Tc-99m pertechnetate) or iodine-123 (I-123), which is actively absorbed by thyroid follicular cells (Mansour et al., 2024). The gamma camera is then used to obtain detailed images to provide information on the size, shape, position, and functional activity of the thyroid gland. Thyroid scintigraphy is important in the evaluation of thyroid disorders, including hyperthyroidism, hypothyroidism, thyroid nodules, and differentiated thyroid carcinoma (Muzahir and Grady, 2023). Its ability to differentiate between functioning and non-functioning nodules is beneficial for healthcare professionals, especially when it comes to manage thyroid cancer and toxic nodular goiter (Giovanella et al., 2022). Nowadays, thyroid scintigraphy continues to become a non-invasive imaging procedure that is most frequently performed on patients in nuclear medicine.

#### 2.3.1 Prevalence of Patient Demographics in Bone and Thyroid Scintigraphy

Patient demographics, including gender, age, and the clinical diagnosis of the patient, influence the patient distribution for nuclear medicine imaging procedures within the healthcare institutions. There are several studies have further discussed these demographic characteristics of patients undergoing bone and thyroid scintigraphy in order to identify the patterns of the patient distribution that reflect their actual clinical practices.

The differences based on gender become a factor in influencing the patient distribution for both bone and thyroid scintigraphy. The gender distribution in bone scintigraphy presents a more complex pattern, which is more influenced by the specific clinical indications for the imaging procedure. There is a study carried out by Donohoe et al. (2017) that highlighted that while bone scintigraphy is performed in both genders, the distribution varies depending on the evaluation of the primary malignancy. For instance, breast cancer bone metastasis evaluation predominantly affects women, while prostate cancer staging primarily affects men. Meanwhile, thyroid disorders are significantly more prevalent in women, resulting in a higher number of thyroid scintigraphy performed on patients among the female population. Haque et al. (2018) reported in their study that a wide gap in the difference between genders in thyroid disorders, with women being 5-8 times more likely to develop thyroid dysfunction compared to men. In addition, Al-Jabri et al. (2021) also further supported these findings in their study of thyroid scintigraphy patients, showing a large percentage, approximately 75-80% of patients undergoing this type of imaging procedure were female.

The age distribution of patients undergoing different nuclear medicine imaging procedures varies significantly. According to Wyngaert et al. (2016), bone scintigraphy is frequently performed in older patients because the aging process is associated with

higher risks of osteoporosis, chronic bone diseases, and malignancies that commonly spread to bone, such as prostate and breast cancer. In contrast, a study conducted by Kanwal et al. (2024) has reported that thyroid scintigraphy is more commonly performed in younger adult patients, especially those aged between 20 and 40 years. The pattern reflects the tendency of thyroid disorders, especially hyperthyroidism and Graves' disease that highly affecting younger adults.

In nuclear medicine imaging procedures, the clinical diagnosis also significantly influences the selection and characteristics of the patient population. When discussing about diagnosis of the individual patient, especially for bone scintigraphy, there are several studies conducted by Wang et al. (2013), Wilfred (2019), and Mohseninia et al. (2023) reported the similar findings, where the primary indication is contributed by metastatic disease, with breast and prostate cancers being the most common malignancies that require this type of imaging procedure. In thyroid scintigraphy, the indications include functional thyroid disorders that involve the assessment of thyroid uptake and distribution patterns. It is stated that Graves' disease has become one of the most common indications for thyroid scintigraphy, as well as hyperthyroidism. Muzahir and Grady (2023) also highlighted in their study that the importance of thyroid scintigraphy in evaluating abnormal thyroid function and nodular thyroid disease based on these diagnosis. Similarly, a study by Kanwal et al. (2024) stated clearly that Graves' disease became the main indication for thyroid scintigraphy that highly affects women. The consistent findings reported across multiple studies further emphasize the importance of understanding the clinical diagnosis for each imaging procedure to guide healthcare professionals in handling proper patient care.

# 2.3.2 Variation of Administered Radiopharmaceuticals Based on Clinical Diagnosis in Bone and Thyroid Scintigraphy

Since technetium-99m methylene diphosphonate (Tc-99m MDP) is introduced into clinical practices in 1975, it has become a standard radiopharmaceutical for bone scintigraphy (Subramanian and McAfee, 1971). Tc-99m MDP contains phosphonate groups that make it chemically similar to phosphate and interact with bone by binding to the bone mineral phase, which is hydroxyapatite, through a process called chemisorption (Wong and Piert, 2013). There is a study conducted by Wyngaert et al. (2016) that reported that in adult patients, the average administered radiopharmaceutical activity is approximately 500 MBq, with a range of 300 MBq to 740 MBq becoming common for various health conditions, including malignancies such as prostate and breast cancer. It is also stated that in cases where there is a need for increased sensitivity for patients with advanced tumors or those undergoing treatment monitoring, the administered radiopharmaceutical activity is adjusted accordingly.

According to Adams and Banks (2019), it is found that Tc-99m MDP accumulates in the bones based on the process of bone formation, which is also known as the osteoblastic activity. The uptake is higher in areas where the bone is being built up or repaired, which can be seen in health conditions related to bone, including fractures, infections, and malignancies. It is also mentioned that Tc-99m MDP uptake can also be seen in other less common diseases, such as Paget's disease, fibrous dysplasia, or osteoid osteomas. The diagnostic value of bone scintigraphy depends on the uptake pattern of the Tc-99m MDP based on factors like the extent of the bone involvement, the location of the affected bones, and the type of pathology. The amount of radiopharmaceutical activity administered in these cases is closely related to the clinical diagnosis, in which different health conditions produce different levels of osteoblastic activity.

For thyroid scintigraphy, the administered radiopharmaceutical activities are not the same for every patient. According to the European Association of Nuclear Medicine (2024), it is stated that radiopharmaceuticals are usually administered in activities of 10 MBq for imaging thyroid function, as it provides better imaging with low radiation. The image can be obtained after 3 hours, with normal uptake values when the thyroidstimulating hormone (TSH) is low, which is below 10%. If thyroid hyperfunction is suspected, uptake values greater than 20% to 30% are considered an indicator of the independently functioning thyroid tissue. However, for technetium-99m pertechnetate (Tc-99m pertechnetate), it is administered intravenously from 37 MBq up to 370 MBq (Liu et al., 2017; Kane and Davis, 2022). The images are then obtained 20 minutes after injection. Tc-99m is taken up by the thyroid through the sodium-iodide symporter within the body, but unlike iodine-123 (I-123) and iodine-131 (I-131), it is not stored inside the thyrocytes, so it is washed out of the thyroid (Giovanella et al., 2022). There are many types of radiopharmaceuticals used in thyroid scintigraphy, with the respective administered radiopharmaceutical activities, as shown in Table 2.1. Therefore, this variation highlights the need to identify the clinical diagnosis, as it contributes to determine the appropriate selection of administered radiopharmaceutical activities.

Table 2.1 Radiopharmaceuticals Used in Thyroid Scintigraphy (Giovanella et al., 2022)

	Na[131]]I	Na[123I]I	Na[99mTc]TcO4	[99mTc]Tc-MIBI
Administration	Oral	Oral or Intravenous	Intravenous	Intravenous
Activity (MBq)	0.15 - 0.37	7.4 - 14.8	74 – 111	185 - 370
Energy(keV)	364	159	140	140
Physical Half-Life	8.06 hours	13.2 hours	6.04 hours	6.04 hours

Na[<sup>131</sup>I]I: Sodium Iodide I-131, Na[<sup>123</sup>I]I: Sodium Iodide I-123, Na[<sup>99m</sup>Tc]TcO<sub>4</sub>: Technetium-99m Pertechnetate, [<sup>99m</sup>Tc]Tc-MIBI: Technetium-99m Sestamibi

# 2.3.3 Variation of Administered Radiopharmaceuticals Based on the Body Weight of the Patients in Bone and Thyroid Scintigraphy

The variation in administered radiopharmaceutical activity based on body weight of the patients is an important consideration for both bone and thyroid scintigraphy. The standard for adults is usually based on an ideal body weight of 70 kg due to the actual body weight potentially impacts the image quality, especially for obese patients (Hansen et al., 2006). This finding is further supported from studies conducted by Papanastasiou et al. (2019) and Sakin et al. (2020), which highlights that obese patients often require higher administered radiopharmaceutical activity than that used for individuals of ideal body weight to achieve acceptable image quality due to increased soft tissue attenuation. According to Bartel et al. (2018), there is a guideline provided related to the administered radiopharmaceutical activity in bone scintigraphy for adults, where it usually ranges from 500 MBq to 1110 MBq, with only slight adjustments applied that ranged from 11 MBq to 13 MBq per kg for obese adult patients. The similar adjustments are also applied for the underweight patients, where there is a need to reduce the administered radiopharmaceutical activity to avoid excessive internal radiation doses to the patients while still maintaining the image quality. However, when there is a need to increase the administered radiopharmaceutical activity based on the body weight of the patients in nuclear medicine procedures, the fixed formula is applied by using 11.47 MBq per kg for technetium-99m (Tc-99m), or the using the general equation as shown below (Ghanem, Kazim and Elgazzar, 2011; Sakin et al., 2020):

$$Patient \ Dose = \frac{Standard \ Dose \times Patient \ Weight \ (kg)}{Standard \ Weight \ of \ 70 \ kg}$$

#### 2.4 Diagnostic Reference Levels (DRLs)

Diagnostic Reference Levels (DRLs) have become a critical component in optimizing patient safety for any imaging procedure, whether in radiology or nuclear medicine. In nuclear medicine, it is important to ensure that patients receive appropriately administered radiopharmaceutical activities and minimize the variations that are caused by human errors. In 1990, the term of DRLs was introduced internationally for the first time and known as the benchmark for standard reference values used for imaging procedures in common clinical practices to identify whether the amount of radiopharmaceuticals administered is unusually high or unusually low (Damilakis et al., 2023). A few years later, in 1996, several aspects of DRLs are expanded to emphasize more specific recommendations on their use. These DRLs are calculated at the 75th percentile of dose distributions, which helps to guide healthcare institutions to investigate their clinical practices if they exceed these values. Unlike the measured quantities used in radiology imaging procedures, such as mammography, computed tomography (CT), dental radiography, and fluoroscopy, nuclear medicine relies on the administered radiopharmaceutical activity as the primary measured quantity, usually expressed in units of megabecquerel (MBq). Based on the data that are collected from various publications by the International Commission on Radiological Protection (2001), the measured quantities for each imaging procedure in radiology have been used interchangeably across multiple sources, as shown in Table 2.2. Meanwhile, a consistently measured quantity is mentioned for each imaging procedure in nuclear medicine, which is then highlighting the ease of comparing and evaluating administered radiopharmaceutical activities across different healthcare institutions.

Table 2.2 Comparison of Key Publications on Diagnostic Reference Levels (International Commission on Radiological Protection, 2001)

Publication	Term	Exam Type: Measured Quantity	Selection	Purpose
ICRP 73 (1996)  Radiological Protection and Safety in Medicine. ICRP Publication 73. International Commission on Radiological Protection (1996)	Diagnostic reference level	Diagnostic radiology: Absorbed dose in air or tissue-equivalent material at the surface of a simple standard phantom  Nuclear medicine: Administered activity	Professional medical bodies;  Percentile point on observed distribution for patients;  Specific to country or region	Form of investigation level, identify unusually low or high levels; Not for regulatory or commercial purposes; Not a dose constraint; Not linked to limits or constraints
CRCPD (1988)  Average Patient Exposure Guides. CRCPD Publication 88-5. Conference of Radiation Control Program Directors, Inc. (1988)	Patient exposure guides	Medical, mammography and dental radiography: Entrance skin exposure in mR (measurements in air with no phantom)	Derived from inspection of data from United States surveys; Reflect "state of current practice"	Non-regulatory; Tied to specific technique factors: patient thickness, source-to-image distance, grid, film speed, kVp (for dental)

IPSM (1992)  National Protocol for Patient Dose Measurements in Diagnostic Radiology.  Dosimetry Working Party, Institute of Physical Sciences in Medicine (1992)	Reference dose levels	Diagnostic radiology: Entrance surface dose in mGy; dose-area product in Gy·cm²  Average for at least 10 adult patients to avoid extremes in physique (70 kg ± 10 kg)	Rounded 3rd quartile values from United Kingdom surveys	Page 15: "could be construed as dose constraints that have been set at the national level"; "Achievement of doses below reference levels should not be construed as an indication of satisfactory or optimum performance"
IAEA (1996) International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources. Safety Series No. 115. International Atomic Energy Agency (1996)	Guidance levels	Diagnostic radiology: Entrance surface dose in mGy;  Computed tomography: Mean surface air dose in mGy;  Mammography: Average glandular dose in mGy;  Fluoroscopy: Entrance surface dose rate in mGy per minute;  Nuclear medicine: Activity in MBq	Derived from wide- scale surveys for typical adults	Corrective actions if doses fall substantially below levels with no useful information or medical benefit or if doses exceed levels

NRPB (1999)	Suspension level	Diagnostic radiology: Entrance	Reference doses:	Suspension level: If
Guidelines on Patient Dose to	(mammography);	surface dose in mGy for adult and	3rd quartile	exceeded, subject to
Promote Optimisation of	Reference doses;	entrance surface dose in µGy for	distribution of	immediate review of
Protection for Diagnostic	Achievable doses;	pediatric;	mean values;	practice;
Medical Exposures.	,	Mammography: Average glandular	Achievable doses:	Reference doses:
Document of the NRPB, Vol	Diagnostic	dose in mGy for standard breast	Values achievable	Investigation levels for
10, No. 1. National	reference levels	model;	by standard means;	internal review, not formal
Radiological Protection	(nuclear	<b>Dental radiography:</b> Intraoral patient entrance dose in mGy and	Diagnostic	regulatory tool;
Board (1999);	medicine)		radiology: Mean	Achievable doses:
ARSAC (1998)		panoramic dose width product in	value for facilities;	Supplemental to reference
Notes for Guidance on the		mGy·mm;	Mammography:	doses, promote practice
Clinical Administration of		Fluoroscopy: Dose area product in	Value based on	optimization;
Radiopharmaceuticals and		Gy·cm²;	good technique;	Diagnostic reference
Use of Sealed Radioactive		Computed tomography: Single	Diagnostic	levels: Pragmatic values
Substances. Administration of		slices of CTDI <sub>w</sub> in mGy and dose	reference levels:	based on accepted customs
Radioactive Substances		length product in mGy·cm;	Guidance for	and practice;
Advisory Committee,		Nuclear medicine: Administered	practitioners in	Thresholds above which
Department of Health United			United Kingdom	special justification is
Kingdom (1998)		activity in MBq		required

EC (1999)	Diagnostic	Diagnostic radiology: Entrance	Diagnostic	Diagnostic radiology:
Guidance on Diagnostic	reference levels	surface dose in mGy;	radiology: 3rd	Groups of standard-sized
Reference Levels for Medical		Fluoroscopy: Dose area product in	quartile values	patients or phantoms,
Exposures. Radiation		Gy·cm <sup>2</sup> – average for at least 10	from European	broadly defined types of
Protection 109. European		adults to avoid extremes in physique	surveys;	equipment;
Commission (1999);		$(70 \pm 3 \text{ kg});$	Nuclear medicine:	Levels expected not to be
Nordic (1996)		Mammography: Entrance surface	Administered	exceeded when good and
Nordic Guidance Levels for Patient Doses in Diagnostic Radiology. Report on Nordic Radiation Protection Co- operation No.5 (1996);  SSK (2000)  Diagnostic Reference Levels in Nuclear Medicine.		dose in mGy for a standard phantom;  Nuclear medicine: Administered activity in MBq	activity necessary for a good image during a standard procedure	normal practice is applied; When consistently exceeded, review procedures and equipment;  Nuclear medicine: "Optimum" national values; For children are a fraction of adult values
Recommendation of the Radiation Protection Commission (2000)				

#### 2.4.1 Establishment of DRLs

The imaging procedures for DRLs establishment are those that are frequently performed within a healthcare institution (Vañó et al., 2017). There are several studies have shown that established DRLs focusing on the most common nuclear medicine procedures within their respective healthcare institutions (Korpela et al., 2010; Dambele et al., 2021; Wachabauer et al., 2022; Albahiti et al., 2024). These common imaging procedures cover the majority of patient cases, which highlights that these values for DRLs are based on the current clinical practices. According to Rehani (2015), the criteria of patients selected in data collection for DRLs should be close to the standard body weight of 70 kg. However, several countries have applied slight adjustments to the patient body weight when establishing their DRLs. For example, Croatia (Debeljuh et al., 2020) considered the body weight of the patients from 50 kg to 90 kg, while Saudi Arabia (Albahiti et al., 2024) selected patients with body weight within 61 kg to 81 kg. France (Institut de Radioprotection et de Sûreté Nucléaire, 2019) and Sudan (Ali, Elawad and Ibrahim, 2016) both collected patients with body weights between 60 kg and 80 kg. Meanwhile, Ireland (Health Information and Quality Authority, 2023) selected patients with body weight from 55 kg to 85 kg, and Japan (Abe et al., 2020; Kanda et al., 2020) selected patients with body weight from 50 kg to 70 kg for their DRLs. These variations reflect the differences in average body weight based on respective countries. Kanda et al. (2020) highlighted that slight adjustments are made to the standard body weight of patients, as the average Japanese adult weighs approximately 10 to 20 kg less than the average European adult. In Malaysia, a study by Azmi et al. (2009) reported that the average body weight of adult Malaysians is 66.56 kg for men and 58.44 kg for women. Therefore, by selecting patients with a body weight between 50 kg and 70 kg is considered appropriate for DRL data collection in nuclear medicine imaging procedures in Malaysia.

#### 2.4.2 Data Comparison with Established International DRLs

According to a study by Abdulkadir et al. (2021), a lack of Diagnostic Reference Levels (DRLs) results in a limited understanding of the measured quantity for imaging procedures that involve a lot of patients. In nuclear medicine, the variation in the administered radiopharmaceutical activity across different healthcare institutions will always exist (Albahiti et al., 2024). However, it is both valid and recommended to compare proposed DRL values with established international DRL values, if national DRLs have not yet been established (International Atomic Energy Agency, 2012; Health Information and Quality Authority, 2023). There is a summary of recommendations for establishing DRLs in different types of imaging procedures, including those in radiology and nuclear medicine, as shown in Table 2.3.

Currently, there are several countries that have established their DRLs, including Australia (Australian Radiation Protection and Nuclear Safety Agency, 2017), Brazil (Willegaignon et al., 2015), Croatia (Debeljuh et al., 2020), France (Institut de Radioprotection et de Sûreté Nucléaire, 2019), India (Pandey et al., 2024), Ireland (Health Information and Quality Authority, 2023), Japan (Abe et al., 2020; Kanda et al., 2020), Korea (Song et al., 2019), Kuwait (Alnaaimi et al., 2021), Qatar (Fayad et al., 2022), Saudi Arabia (Albahiti et al., 2024), and Sudan (Ali, Elawad and Ibrahim, 2016). If proposed DRL values are extremely lower or higher than international DRL values, it indicates the need for overall investigations within the healthcare institution, which includes assessing the functionality of the imaging systems, the quality of radiopharmaceuticals, and the clinical practices of the healthcare professionals involved (Albahiti et al., 2024). Therefore, the comparison among established DRL values based on these respective countries, focusing specifically on administered radiopharmaceutical activities for bone and thyroid scintigraphy, is presented in Table 2.4 and Table 2.5.

Table 2.3 Recommendations to Establish Diagnostic Reference Levels (Vañó et al., 2017)

Type of Procedure	Diagnostic Reference Levels Recommended	Method of Assessment	
Mammography	Yes	Patient survey or phantom	
Intra-oral dental radiography	Yes	Output measurement using standard settings	
Panoramic dental radiography	Yes	Air kerma-area product	
Computed tomography (adult and paediatric)	Yes	Patient survey	
Trunk radiography	Yes	Patient survey	
Skull radiography	Yes	Patient survey	
Radiology (paediatric)	Yes	Patient survey	
Extremity radiography	Yes (lower priority)	Patient survey	
Mobile radiography	Yes (lower priority)	Patient survey	
Neonatal radiography	Yes	Patient survey	
Mobile radiography (paediatric)	Yes (especially for children's hospitals)	Patient survey	
Barium study	Yes	Patient survey	
Interventional radiology and cardiology	Yes	Patient survey	
Other fluoroscopy	Depend on the use	Patient survey	
Nuclear medicine (adult)	Yes	Administered activity or activity per body weight	
Nuclear medicine (paediatric)	Yes	Administered activity that adjusted for size or weight	
Bone densitometry	Yes (lower priority)	Patient survey	

Table 2.4 Established International Diagnostic Reference Levels for Bone Scintigraphy

#### Administered Radiopharmaceutical Activity (MBq)

_	Minimum	Maximum	Mean	Standard Deviation	Diagnostic Reference Levels
Australia (2017)	580	1110	863	94	920
Brazil (2015)	740	1480	1036	190	1110
Croatia (2020)	444	777	635	119	740
France (2019)	469	808	-	-	670
India (2024)	532	939	707	72	747
Ireland (2023)	576	800	658	82	680
Japan (2020)	-	-	-	-	950
Korea (2019)	555	1110	822	131	925
Kuwait (2021)	459	1110	927	171	944
Qatar (2022)	550	1050	722	79	740
Saudi Arabia (2024)	962	1184	1107	42	1110
Sudan (2016)	500	1110	-	-	777

Table 2.5 Established International Diagnostic Reference Levels for Thyroid Scintigraphy

#### Administered Radiopharmaceutical Activity (MBq)

_	Minimum	Maximum	Mean	Standard Deviation	Diagnostic Reference Levels
Australia (2017)	25	380	209	43	215
Brazil (2015)	9	1110	410	144	444
Croatia (2020)	37	241	167	67	200
France (2019)	54	202	-	-	110
India (2024)	66	192	147	31	166
Ireland (2023)	74	100	80	5	100
Japan (2020)	-	-	-	-	240
Korea (2019)	111	444	215	79	27
Kuwait (2021)	185	250	185	21	185
Qatar (2022)	95	350	189	45	195
Saudi Arabia (2024)	148	222	172	31	194
Sudan (2016)	75	222	-	-	185