

APPRAISING OCCUPATIONAL RADIATION PROTECTION IN MEDICINE AND THE NIGERIAN RADIATION SAFETY IN NUCLEAR MEDICINE REGULATION 2006

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Abstract

This paper seeks to appraise the Occupational Radiation Protection in Medicine and the Nigerian Radiation Safety in Nuclear Medicine Regulation 2006 and other issues connected thereto. It examines the extent to which the regulation governing radiation safety in nuclear medicine protects the health professionals whose work involves radiation exposure. The enabling law for the Nigerian Safety and Nuclear Medicine Regulation 2006 is the Nuclear Safety and Radiation Protection Act, No. 19 of 1995. Section 47 of the Act provides that: the Authority may, with the approval of the President make regulations, prescribing anything required to be prescribed under the Act, hence the adoption of the Nigerian Safety and Nuclear Medicine Regulation to provide for what the principal Act did not cover as it related to safety and the practice of nuclear medicine in Nigeria. The paper also appraises the administrative requirements and authorization of practice for nuclear medicine practitioners, renewal of authorization, personal accreditation, authorization of other activities related to nuclear medicine, inspection by relevant authorities, the issue of non-compliance and suspension or withdrawal of authorization. Other foci of this paper include radiation safety and protection requirements for nuclear medicine practitioners in Nigeria, quality assurance indicators measured against international standards, and implications of the regulation on radiation protection education and training. The paper concludes by identifying the gaps in the Nigerian Regulation if any and make necessary recommendations for the promotion of safer use of nuclear radiation in the health sector of Nigeria in line with international best practices.

1.0 Introduction

National regulatory agencies and medical facilities are aware of the potential risks of ionizing radiation and the need to ensure that exposure is avoided or minimized. Ionizing radiation safety is essential for the health and wellbeing of health workers, hence the need for law and regulations regarding the recognition of the occurrence and the need for the control of occupational health hazards associated with ionizing radiation. Satisfactory radiological protection is based on three core principles: (i) the principle of justification for exposure (ii) the principle of optimization of protection, and (iii) the principle of application of dose limits. Nigeria like other countries provide safety regulations for health workers exposed to nuclear radiation in the health sector in line with the guiding principles of the International Commission

on Radiological Protection (ICRP). The law is made to protect patients, workers and the general public from the risks associated with exposure to ionizing radiation in the course of nuclear medicine practice in Nigeria, and to assist licensees in meeting radiation safety and protection requirements in nuclear medicine practice for the attainment of adequate radiation protection and safety of patients. These regulations are applicable to all established uses of ionizing radiation sources employed in the practice of nuclear medicine, to the facilities where the sources are located and to the individuals involved. These regulations cover occupational, public, medical, potential and emergency exposure situations.

It is imperative that, there is urgent need for nations and organization to provide safety in the use of nuclear and radioactive substances in industries and health facilities. Despite the enormous gains associated with their uses, there are deleterious effects associated with their usage. According to the IAEA, the increasing use of medical procedures utilizing ionizing radiation and better access to this health technology resulted in rapid increase in the number of occupationally exposed workers in medicine over the years and substantial occupational exposure may occur in certain medical procedures. The organization further asserts that it is a continuing challenge, in particular for exposure control and training of healthcare professionals in radiation protection issues.¹ The recognition of this fact among other reasons demands that, in this paper, the authors will consider the multifaceted theoretical, scientific and legal issues of safety in the use of nuclear and radioactive substances in industries and health facilities and the way that the law regulate same in Nigeria.

2.0 Occupational Radiation Protection in Medicine

The World Health Organization's International Agency for Research on Cancer (IARC) recognizes radiation as a carcinogen.² Occupational exposure means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.³ Besides the risk of exposure faced by the general population daily, introduction of further exposure such as while seeking medical attention as a patient or working with ionizing radiation in the care of patients can increase the risk of contracting malignancies in the future. With the progressively increasing use of radiation in medicine, radiation protection is becoming equally increasingly crucial to safeguard healthcare workers in the line of duty. Medical applications currently

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¹IAEA, "Background, International Conference on Occupational Radiation Protection – Strengthening Radiation Protection of Workers – Twenty Years of Progress and the Way Forward", available at <https://www.iaea.org/events/occupational-radiation-protection-2022>, accessed 07 July, 2022

² IARC classifies radiofrequency electromagnetic fields as possibly carcinogenic to humans. Available at: https://www.iarc.who.int/wp-content/uploads/2018/07/pr208_E.pdf, accessed 09 July, 2022

³ Medical Dictionary for the Dental Professions. S.V. "Occupational Exposure." Available online at <https://medical-dictionary.thefreedictionary.com/occupational+exposure>, accessed 101 July, 2022

account for almost the totality of all non-natural sources of radiation exposure in the world, also representing the fastest growing source of radiation exposure worldwide.⁴ The goal of radiation protection in medicine continues to be focused on ways to lessen unwarranted exposure to radiation thereby curbing as much as possible the injurious consequences of ionizing radiation.

(a) Standardizing Occupational Radiation Protection

The principles and practices that embody radiation protection stem from a combination of science-based rationale and sociogenic values. The standard of radiation protection continues to evolve with the input of relevant bodies at the local and intercontinental level consistently applying scientific evidence to homogenize practice; along with the altruistic persuasion for the protection of human life which the society exerts. This drive towards achieving a standard agreeable to all stakeholders remains a source of complexity in the radiation protection space. Establishing a figure that will encapsulate the word reasonable is still subject to exegesis.⁵

Healthcare applications in particular have always presented a unique challenge, as estimating the risk of illness in relation to the dose of exposure and attempting to fix a blanket threshold for exposure remains an arduous task; since there cannot be one threshold for all the various applications of radiation in medical practice. Putting into consideration both scientific evidence and ethical values, standards are fixed on the premise that the benefits of employing radiation for diagnosis or treatment has to exceed the risk of exposure both for the patient and the health worker.

(b) Regulation of Occupational Radiation Protection in Nigeria

Personal monitoring of occupational exposed workers (OEWs), adequate records and routine evaluations remain vital tools for effective occupational radiation protection in medicine. The Nigerian Nuclear Regulatory Authority (NNRA) is the body authorized to supervise the application of nuclear matter and ionizing radiation in all sectors of the country. Since 2004, the NNRA carries out its functions by developing and communicating regulatory guidelines for those operating within her statute, including the health sector. The regulations align with the global ALARA (as low as reasonably achievable) philosophy, requiring that the use of radiation for medical purposes follow the principles of justification and optimization to guarantee safety of the health workers, the patients and the general public. With the adoption of the Nigerian Safety and Nuclear Medicine Regulation 2006, authorizations, licensing and accreditation requirements for obtaining and utilizing radiation in Medicine are clearly defined; as well as the mandated dose limits for occupational and public exposure. In keeping with IAEA safety standards, the recommended dose limits for occupational exposures in radiation

⁴O. Holmberg, and others, "The importance and unique aspects of radiation protection in medicine", (2010)(76)(1), *European Journal of Radiology*, 6-10. Available at: <https://doi.org/10.1016/j.ejrad.2010.06.031>. accessed 10 July, 2022

⁵ Jessica S Wieder *et al*, *J. Radiol. Prot.* 42 021513, 2022

workers was stipulated by the NNRA as 20 mSv per year.⁶ Besides continuous training of health workers and effective supervision of practice by relevant authorities, objective appraisal of essential legal frameworks guiding the statutory regulatory agencies can help highlight some of the critical challenges that should be addressed to ensure optimal radiation protection framework in Nigeria.

3. Legal Framework on Occupational Radiation and Nuclear Safety in Nigeria

There are two principal legislation dealing with issues of Occupational Radiation and Nuclear Safety in Nigeria and a subsidiary legislation. The Nigerian Atomic Energy Commission Act, enacted 27 August, 1976 and the Nuclear Safety and Radiation Protection Act of 1995. The subsidiary legislation are the Nigerian Nuclear Regulatory Authority (NNRA) of 1995 and the Nigerian Safety and Nuclear Medicine Regulation 2006. These legal frameworks shall be discussed hereunder.

(a) The Nigerian Atomic Energy Commission Act, enacted 27 August, 1976

The Nigerian Atomic Energy Commission Act, enacted 27 August, 1976 is the first legislation that addressed the issue of Nuclear Energy in Nigeria. It came into existence through the enactment of Decree No. 46 in August 1976⁷ leading to the launching of the national nuclear programme in Nigeria. The Act establishing the Nigeria Atomic Energy Commission for the development of atomic energy and its peaceful use was first enacted on 27 August, 1976⁸ and it provides that it shall have power to: prospect for and mine radioactive minerals, construct and maintain nuclear installations for the purpose of generating electricity, produce, use and dispose of atomic energy and carry out research into matters connected with the peaceful uses of atomic energy, manufacture or produce, buy, acquire, treat, store, transport and dispose of any radioactive substances as part of its corporate responsibility under the Act. The clause dealing with *the use and dispose of atomic energy* encompasses the use of nuclear energy for medical reasons.

(b) Nuclear Safety and Radiation Protection (NSRP) Act of 1995

The NSRP Act is the second legislation that addressed the issue of Nuclear Energy in Nigeria. Nuclear Safety and Radiation Protection Act of 3rd August, 1995⁹ established the Nigerian Nuclear Regulatory Authority (NNRA) in 1995. The function of this body shall include the control and regulation of the use of radioactive substances, material, equipment, emitting and generating ionising radiation. The establishment of a regulatory infrastructure is *sine quanon* towards developing a national nuclear energy programme that will not result in a national woe

⁶G.B Ekong others, "Enhancing Radiation Safety through Occupational Radiation Protection in Nigeria", Nigerian Nuclear Regulatory Authority Abuja, FCT, Nigeria. Available at: <http://elibrary.nnra.gov.ng/jspui/bitstream/123456789/848/1/Radiation%20Protection%20Oversight%20in%20Nigeria%20Through%20Occupational%20Exposure.pdf>, accessed 12 July, 2022

⁷Nigerian Atomic Energy Commission Act enacted 27 August, 1976, CAP. N90 LFN 2004.

⁸*Ibid*, Sections 1, 2(1)(a)-(e).

⁹Nuclear Safety and Radiation Protection Act of 3rd August, 1995

or calamity hence in 1995, the Nuclear Safety and Radiation Protection Act established the Nigeria Nuclear Regulatory Authority.

(i) Working Conditions Categorized as Exposed to Occupational Radiation under the NSRP

Radiation protection is the science and practice of protecting people and the environment from the harmful effects of ionizing radiation. The International Atomic Energy Agency (IAEA) defines radiation protection as: *“The protection of people from harmful effects of exposure to ionizing radiation, and the means for achieving this.* According to the IAEA, radiation protection can be divided into three groups: first, occupational radiation protection, which is the protection of workers in situations where their exposure is directly related to or required by their work, second medical radiation protection, which is the protection of patients exposed to radiation as part of their diagnosis or treatment and the third public radiation protection, which is the protection of individual members of the public and of the population in general.¹⁰

Section 28 of the NSRP, the following classes of working conditions as occupation that are exposed to ionizing radiation: Working Condition “A”; and Working Condition “B”.¹¹ Working Condition “A” exists where the annual exposure is likely to exceed the prescribed dose equivalent limit as specified in the Code of Practice, in which case the workers assigned thereto shall- be classified as Type “A” Exposed Workers; and be subject to special health supervision and individual assessment by individual monitoring for external radiation and internal contamination as appropriate or by indirect methods.¹² Working Condition “B” exists where the annual exposure is not likely to exceed three tenths of the dose equivalent limit as specified in the Code of Practice, in which case the workers assigned thereto are classified as type “B” Exposed Workers and the dose equivalent assessment is achieved by area monitoring. No person under the age of 18 years shall be employed in any work performed under Working Condition “A” as is defined in subsection (2) of this section.¹³

(ii) Categories of Radioactive Substances under the NSRP

Radioactive substance is a substance that radiates as a result of nuclear decay or transition of nuclear energy level, and has a specific radioactivity or a total activity exceeding the exemption level. It refers to a substance that contains one or more radionuclides the activity or activity concentration of which cannot be disregarded from a radiation protection point of view.¹⁴ It means any material which emits ionizing radiation, and the term ionizing radiation represents

¹⁰ Nick Connor, “What is Radiation Protection – Definition”, 2019 available online at <https://www.radiation-dosimetry.org/what-is-radiation-protection-definition/> accessed 06 July, 2022.

¹¹ Nuclear Safety and Radiation Protection Act of 3rd August, 1995, s 28(1)(a)-(b)

¹² *Ibid* s 28(2)

¹³ *Ibid* s 28(3)

¹⁴ Law Insider, “Radioactive Substance Definition”, available at <https://www.lawinsider.com/dictionary/radioactive-substance#:~:text=Radioactive%20substance%20means%20a%20substance%20that%20radiates%20as%20a%20result,activity%20exceeding%20the%20exemption%20level>, accessed 13 July, 2022

x-rays, gamma rays, alpha and beta particles, high speed electrons, neutrons and other nuclear particles¹⁵

The categories of radioactive substances, sources and practices under section 29 of the NSRP Act are classified as follows- Category I, X-ray, that is, gamma-ray sources and other sealed sources used in medical diagnosis and therapy;¹⁶ Category II, that is, unsealed radiation sources used in medical diagnosis and therapy, agriculture, industry and research;¹⁷ Category III, that is, nuclear research reactors and critical assemblies, nuclear power reactors, mining and milling of radioactive ores and other facilities of the nuclear fuel cycle;¹⁸ and Category IV, that is, non-uranium mines and mills having associated radio- active substances in concentration which can lead to significant radiation exposures to workers and the public.¹⁹

(iii) Nigerian Nuclear Regulatory Authority

The Nigerian Nuclear Regulatory Authority (NNRA) (hereinafter referred to as Authority) is responsible under the Act among others for nuclear safety and radiological protection regulation and it shall regulate the possession and application of radioactive substances and devices emitting ionizing radiation, ensure protection of life, health, property and the environment from the harmful effects of ionizing radiation, while allowing beneficial practices involving exposure to ionizing radiation, regulate the safe promotion of nuclear research and development, and the application of nuclear energy for peaceful purposes. The Authority shall perform all necessary functions to enable Nigeria meet its national and international safeguards and safety obligations in the application of nuclear energy and ionizing radiation.²⁰ The NNRA is the Agency whose action plan is targeted at protecting workers against exposure to ionizing radiation. Workers in this respect are those who encounter radiation or radioactive substances in the course of their job. This includes both health workers and their patients. Section 47 of the NSRP Act provides that: the Authority may, with the approval of the President make regulations, prescribing anything required to be prescribed under the Act²¹, hence the adoption of the Nigerian Safety and Nuclear Medicine Regulation to provide for what the principal Act did not cover as it related to safety and the practice of nuclear medicine in Nigeria

(c) Nigerian Safety and Nuclear Medicine Regulation 2006

The enabling law for the Nigerian Safety and Nuclear Medicine Regulation (NSNMR) 2006 is the Nuclear Safety and Radiation Protection Act, No. 19 of 1995.²²

¹⁵*Ibid*

¹⁶Nuclear Safety and Radiation Protection Act of 3rd August, 1995, s 29(a)

¹⁷*Ibid* s 29(b)

¹⁸*Ibid* s29(c)

¹⁹*Ibid* s29(d)

²⁰*Ibid*, s 4 (1) (a)-(d)

²¹*Ibid*, s 47

²² Nuclear Safety and Radiation Protection Act (1995 No. 19) Nigerian Radiation Safety in Nuclear Medicine Regulations, 2006

The NSNMR, 2006 (hereinafter referred to as Regulation) is a policy framework and is pivotal to Nigeria's ionizing radiation safety. It is essential for the safety, health and wellbeing of health workers, and the need for the control of occupational health hazards associated with ionizing radiation. The several objectives of the regulation are to: protect patients, workers and the general public from the risks associated with exposure to ionizing radiation in the course of nuclear medicine practice in Nigeria and to assist licensees in meeting radiation safety and protection requirements in nuclear medicine practice for the attainment of adequate radiation protection and safety of patients, worker and the public.²³ In terms of its scope, the Regulation is said to be applicable to all established uses of ionizing radiation sources employed in the practice of nuclear medicine, to the facilities where the sources are located *such as hospitals and their laboratories*, and to the individuals involved. On a wider range, the Regulation covered occupational, public, medical, potential and emergency exposure situations.²⁴

(i) Administrative Requirements and Authorization of Practices under NSNMR, 2006

Administrative Requirements and Authorization of Practices constitutes Part II of the Principal Requirements of the Regulation. The Regulation provides that: any legal person who intends to utilize radiation sources in nuclear medicine shall notify his intention to the NNRA and shall apply for authorization in the form of a licence for in vivo use and a registration for in vitro use. Such legal person apart from applying for an authorization, shall submit to the Authority the relevant information necessary to demonstrate the safety of the practice and is expected to refrain from carrying out any of the actions or such practices until the registration or licence has been granted.²⁵ Other administrative requirements expected in the application for authorization includes: the qualifications in radiation safety and protection of the medical practitioners who are to be so designated by name in the registration or licence, or a statement that only medical practitioners with the qualifications in radiation safety and protection specified in these regulations or to be specified in the registration or licence will be permitted to prescribe medical exposure by means of the authorized radiation source.²⁶

The Regulation mandates the registrant and licensee to comply with radiation safety requirements for the following stages of the nuclear medicine practice which includes: design and construction; operation (acceptance, commissioning, clinical use, and maintenance), modifications, and decommissioning (partial or total) and return or disposal of sources.²⁷ As a rider to "modification" under section 5(c), section 6 of the Regulations provides that where modification has possible implications for radiation safety of the nuclear medicine facilities of the type and activity of radioactive sources and of procedures or cessation of the practice, such

²³*Ibid*, s 2, Objective

²⁴*Ibid*, s 3 Scope

²⁵*Ibid*, s 4(1)(2)(3)

²⁶ *Ibid*, s 4(4)(a)-(b)

²⁷*Ibid*, s 4(5)(a)-(d)

modification shall require an amendment to the registration or licence.²⁸ This is to avoid modification or decommissioning exercise that has implications for safety and health without the knowledge of the regulatory agency, the NNRA.

(ii) Renewal of Authorization for the Utilization of Radiation Sources in Nuclear Medicine

Where authorization is granted to a legal person by NNRA for the utilization of radiation sources in nuclear medicine such action which is described in the Nigerian Basic Ionizing Radiation Regulations, the authorization of such licence or registration shall be renewed as determined by the Authority and it shall be made on a prescribed form issued by the Authority.²⁹

(iii) Personal Accreditation and Educational Requirements

The Regulation provides that all personnel upon whom protection and safety depends in occupational radiation certain shall be appropriately trained and qualified so as to understand their responsibilities and perform their duties with appropriate judgment in accordance with the laid down procedures.³⁰ Individuals whose sole responsibilities is the protection and safety and those who could substantially affect protection and safety by virtue of tasks involving manipulation of sources or operation of equipment, shall show documented evidence of educational qualification and training in nuclear medicine. These individuals include: medical practitioners working with radionuclides, for example nuclear medicine physicians and other appropriately trained clinical specialists; medical physicists in nuclear medicine (qualified experts in nuclear medicine physics); other health professionals involved in the clinical use of radionuclides are radiopharmacists, nuclear medicine technologists. Other categories are radiation safety officer and staff performing special tasks (e.g. type testing of equipment, quality control tests).³¹ Under this provision, competence and proper training is required for core professionals and allied workers or support staff because of the dangers inherent in nuclear radiation facilities and environments.

(iv) Requirements for Obtaining Personal Accreditation

To obtain personal accreditation in line with the NSNMR, the staff concerned under section 6(2)(a)-(e) of the Regulation above shall possess the following requirements, as applicable: university degree or academic qualification relevant to the profession, issued by universities, colleges of health technology, polytechnics and colleges of technology and other accredited federal institutions; accreditation to practice the profession granted by the relevant competent authorities or other professional or academic bodies recognized by the Authority; attendance at and passing of required examinations on a course on radiation safety for which the contents,

²⁸ *Ibid*, s 4(6)

²⁹ *Ibid*, s 5(1)-(2)

³⁰ *Ibid*, s 6(1)

³¹ *Ibid*, s 6(2)(a)-(e)

the methodology and the teaching institution are accredited by the Authority or by other professional bodies recognized by the Authority.

The Regulation further requires that the course shall be integrated in the curricula of the professional education under these regulations; on-the-job training supervised by professionals with accreditation by the Authority or other appropriate competent authorities.³² In addition to the staff needing formal credentials, the following staff shall be provided with specific instructions on radiation safety and protection: nurses attending patients under therapy; staff who do not belong to the nuclear medicine practice but need to enter controlled areas; and staff who transport radioactive materials within the institution.³³ These training records shall be kept for at least five years after the expiry of the corresponding authorization.³⁴ The provision of section 6 of the Regulation implies that all staff working in nuclear medicine practice, shall have appropriate academic qualifications and relevant practical training to avoid dangers from occurring.

Equipment servicing personnel shall have documentary evidence for the individual to perform maintenance of nuclear medicine equipment. The documentary evidence shall consist of the following: certification, ideally by the manufacturer, of having completed a training programme on the type of authorized equipment; course on radiation safety for which the contents, the methodology, and the teaching institution are approved by the Authority.³⁵

(v) Authorization/Inspection/Withdrawal of Authorization and other Activities Related to Nuclear Medicine

The import, distribution, sale, decommissioning or transfer of radiation emitting equipment; personnel monitoring; installation and maintenance of nuclear medicine equipment³⁶ shall require authorization in relation to nuclear medicine practice. The registrant and the licensee shall permit the Authority to inspect his facilities and records³⁷ and in the event of non-compliance. The Authority will suspend or withdraw the authorization granted. In the course of inspection, if they are breaches found regarding the licence condition, the registrant and licensee shall, as appropriate: investigate the breach and its causes, circumstances and consequences; take appropriate action to remedy the circumstances that led to the breach and to prevent a recurrence of similar breaches; communicate to the Authority, or to any relevant organizations where applicable, on the causes of the breach and on the corrective or preventive actions taken or to be taken; and take necessary actions as required by the Authority. The Regulation provides that failure to take corrective or preventive actions within a reasonable

³² *Ibid*, s 6(3)(a)-(e)

³³ *Ibid*, s 6(4)(a)-(c)

³⁴ *Ibid*, s 6(5)

³⁵ Nuclear Safety and Radiation Protection Act (1995 No. 19) Nigerian Radiation Safety in Nuclear Medicine Regulations, 2006, s 6(6)(7)(a)-(b)

³⁶ *Ibid*, s 7 (a)-(c)

³⁷ *Ibid*, s 8

time shall be veritable grounds for modifying, suspending or withdrawing any authorization that had been granted by the Authority.³⁸ Though, the Authority shall suspend or revoke an authorization when registrants and licensees are in serious breach of the conditions of the authorization set out by the Nigeria Basic Ionizing Radiation Regulations or the specific requirements of these regulations. In the event of suspension or revocation due to breaches the registrant or licensee shall reapply for authorization or apply for reconsideration of decision in order to resume operation.³⁹

(vi) Radiation Safety and Protection Requirements

With the advancement of cutting-edge technology, radiation-based applications continue to gain more ground in modern medicine. Occupational radiation exposure in the medical field occurs via two broad routes: diagnostic radiation and therapeutic radiation. In both cases, the patient and the health worker are at risk of undue radiation exposure. Hence, actualizing an effective occupational radiation protection mechanism is immensely beneficial for not just health workers involved in radiation medicine, but also patients who use these services. Irrespective of the dose, ionizing radiation exposure is dangerous to human health, and it is well acknowledged in literature that the impact of exposure is cumulative. Deleterious health effects from ionizing radiation exposure can be classified into two: deterministic effects – those that arise when a specified dose of exposure threshold is attained, for example skin burn, infertility, cataracts; and stochastic effects – those that are not dependent on any dose threshold including various types of cancers, and genetic mutations in fetuses. With deterministic effects, efforts on protective measures are geared towards dose limitation, but with stochastic effects we see that there can be no totally “safe” threshold dose and therefore, protective measures focus on keeping doses at a level as low as reasonably achievable (ALARA).

Radiation safety refers to safety issues related to radiation hazards arising from the handling of radioactive materials or chemicals and exposure to x-ray from x-ray machines, electron microscopes, particle accelerators, atomic energy plants, nuclear explosions or accidents etc. Radiation is extremely harmful to humans and animals. It can cause death or short to long-term radiation sickness by damaging organs and tissues.⁴⁰

(a) Types of Radiation: Non-Ionizing and Ionizing Radiation

There are two basic types of radiation. The first is the non-ionizing radiation such as visible light, microwave and radio wave do not do much harm to the tissues (unless concentrated). The second is the Ionizing radiation removes electrons from atoms and releases immense energy. This includes alpha particles, beta particles, x-ray and gamma ray and neutrons, which destabilize molecules in the cells and tissues, hence causing failure of organs, and ultimately

³⁸ *Ibid*, s 9(1)(a)-(d) and 2

³⁹ *Ibid*, s 9(3)-(4)

⁴⁰ Safeopedia, “What Does Radiation Safety Mean”, <https://www.safeopedia.com/definition/1056/radiation-safety-occupational-health--safety> accessed 15 July, 2022

death of the individual or long to short-term radiation sickness. Implementation of radiation safety in the workplace is, therefore, a statutory requirement for the employer (as low as reasonably achievable or ALARA). It is needed to make the workplace a radiation hazard-free zone and have positive control with maximum caution and preventions to protect the employees. Following is a list of possible sources of radiation in the workplace: Medical industry - x-ray machine, radio therapy and some radioactive chemicals used in cancer treatment. Food industry - some food contains radioactive materials. Some food processing use radioactive materials metal industry -ore containing radioactive material is released during processing Nuclear power plant - the reactor uses radioactive materials Nuclear weapons - the factory and the military personnel using nuclear weapons are at risk of radioactivity Astronauts - may receive x-ray and Gamma rays in the unprotected space Consumer products - smoke detectors, luminous watches and gas mantles etc.⁴¹ Though this paper concentrates or focuses on medical radiation safety.

(b) Uses of Radiation in Safety Treatments

Radiation safety is a combination of safe practices and precautionary measures put in place to promote safety when working with or near radiation.⁴² Radiation is utilized in a lot of medical treatments and equipment. Radiation therapy or radiotherapy is a cancer treatment that kills cancer cells and reduces tumors. Normal cells can heal and repair themselves while cancer cells cannot. Prior to this treatment, a patient will be requested to take a CT scan to locate the area of the cells that needs to be removed. The two types of radiation therapy are external beam and internal. The machine that administers external beams radiotherapy is called a medical linear accelerator. There are many external radiation therapies a patient can choose from such as three-dimensional conformal radiation therapy, intensity modulated radiation therapy, and proton beam therapy. Brachytherapy, an internal radiation treatment, is administered by directly placing radioactive sources on the target area inside the body.⁴³

(c) Safety and Protection *Simplicita* in Exposure to Ionizing Radiation

The act of protection and safety means the protection of people against exposure to ionizing radiation or radioactive substances and the safety of .radiation sources, including the means for achieving such protection and safety, such as the various procedures and devices for keeping peoples' doses and risks as low as can reasonably be achieved and below prescribed dose constraints, as well as the means for preventing accidents and for mitigating the consequences of accidents 'should they occur'.⁴⁴

⁴¹ *Ibid*

⁴² Safety Culture, "What is Radiation Safety", available at <https://safetyculture.com/topics/radiation-safety/#:~:text=Also%20called%20radioactive%20safety%2C%20radiation,as%20low%20as%20reasonably%20achievable.%E2%80%9D>, accessed 18 July, 2022

⁴³ *Ibid*

⁴⁴ Nigerian Radiation Safety in Nuclear Medicine Regulations, 2006, Part I, General Interpretation.

(d) Legal Requirements for Exposure to Radiation by Workers and the General Public

The law provides for radiation safety and protection requirements justified for practice, dose limitation, optimization, protection and dose constraints under Section 25 of the Nuclear Safety and Radiation Protection Act on one hand and Regulation 15 of Nigeria Basic Ionizing Radiation Regulations on the other which shall be applied in nuclear medicine. The dose limits for occupational and public exposure are reproduced in the first Schedule of the Nigeria Basic Ionizing Radiation Regulations.⁴⁵ Section 25 of the NSRPA which deals with control of exposure to radiation provides that the Authority shall, in the performance of its functions and for the protection of radiation workers and the general public, ensure that- no practice is adopted, unless its introduction produces a positive net benefit; and the dose equivalent to individual, shall in no way exceed the established limits prescribed by the Authority.⁴⁶

(vii) Occupational Exposure under the NSNMR, 2006

Occupational exposure means exposure for those involved in the performance of radiological procedures. Part IV of the NSNMR 2006 provides for radiation safety and protection requirements, responsibilities and conditions of service. The Regulation provides that workers shall: follow any applicable rules and procedures for protection and safety specified by the employer or licensee; use properly the monitoring devices and the protective equipment and clothing provided; cooperate with the employer or licensee with respect to protection and safety and the operation of radiological health surveillance and dose assessment programmes; provide to the employer or licensee such information on their past and current work as is relevant to ensure effective and comprehensive protection and safety for themselves and others; abstain from any willful action that could put themselves or others in situations that contravene the requirements of the Nigeria Basic Ionizing Radiation Regulations; accept such information, instruction and training concerning protection and safety as will enable them to conduct their work in accordance with the requirements of the Nigeria Basic Ionizing Radiation Regulations.⁴⁷ Furthermore, if for any reason a worker is able to identify circumstances that could adversely affect compliance with the Nigeria Basic Ionizing Radiation Regulations, the workers shall as soon as feasible report such circumstances to the employer or licensee. The management shall record any report received from a worker that identifies circumstances which could affect compliance with the Nigeria Basic Ionizing Radiation Regulations, and shall take appropriate action. If workers are engaged in work that involves or could involve a source that is not under the control of their employer, the registrant or licensee responsible for the source and the employer shall co-operate by the exchange of information and otherwise as necessary to facilitate proper protective measures and safety provisions.⁴⁸

⁴⁵ *Ibid*, s 10

⁴⁶ Nuclear Safety and Radiation Protection Act (1995 No. 19) s25

⁴⁷ Nigerian Radiation Safety in Nuclear Medicine Regulations, 2006, s 25(1)(a)-(f)

⁴⁸ *Ibid*, s 25(2)-(4)

(viii) Medical Exposure under the NSNMR, 2006

Medical exposure refers primarily to exposure incurred by patients for the purpose of medical diagnosis or treatment.⁴⁹ A medical exposure to ionising radiation is when a patient receives ionising radiation as part of their diagnosis or treatment. This could be an X-ray at a dentist, a CT scan at a hospital, a mammogram, or radiotherapy received as part of cancer treatment. It also includes exposure to radiation for medical or biomedical research purposes as well as carers and comforters exposed to ionising radiation while attending a patient.⁵⁰ Professional radiation exposure cannot be avoided in nuclear medicine practices. It can only be minimized up to some extent by implementing good work practices. Professional radiation exposure and exposure to the patient and the general public cannot be avoided in nuclear medicine practice, where open sources of radiation are handled and radioisotope is administered in the form of radiopharmaceutical resulting in the patient himself becoming a moving source of radiation.⁵¹

Part V, Section 35 of the NSNMR, 2006 addresses issues associated medical exposure to ionising radiation and places responsibilities on the registrants, licensees and medical practitioners. With regard to responsibilities for medical exposure, registrants and licensees shall ensure that: no patient is administered a diagnostic or therapeutic medical exposure unless the exposure is prescribed by a medical practitioner; medical practitioners are assigned the primary task and obligation of ensuring overall patient protection and safety in the prescription of, and during the delivery of, medical exposure; medical and paramedical personnel are available as needed, and are either health professionals or have appropriate training to discharge their assigned tasks in the conduct of the diagnostic or therapeutic procedure that the medical practitioner prescribes;⁵² for therapeutic use of radiation, the calibration, dosimetry and quality assurance requirements are conducted by or under the supervision of a qualified expert in radiotherapy physics; the exposure of individuals incurred knowingly while voluntarily helping (other than in their occupation) in the care, support or comfort of patients undergoing medical diagnosis or treatment be constrained as specified in Regulation 15 of Nigeria Basic Ionizing Radiation Regulations and training criteria are specified or subject to approval, as appropriate, by the Authority in consultation with relevant professional bodies.⁵³

Licensees shall ensure that for diagnostic uses of radiation, the imaging and Quality Assurance requirements are fulfilled with the advice of a qualified expert in nuclear medicine physics. Medical practitioners shall promptly inform the registrant or licensee of any deficiencies or

⁴⁹ Science Direct, "Medical Exposure", available at <https://www.sciencedirect.com/topics/engineering/medical-exposure#:~:text=Medical%20exposure%20refers%20primarily%20to,Module%20in%20Biomedical%20Sciences%2C%202021>, accessed 10 July, 2022

⁵⁰ Marty Whelan, Health Information and Quality Authority, (HIQA), "Medical Exposure to Ionising Radiation", available online at <https://www.hiqa.ie/hiqa-news-updates/medical-exposure-ionising-radiation-be-regulated-hiqa#:~:text=A%20medical%20exposure%20to%20ionising,as%20part%20of%20cancer%20treatment>, accessed 18 July, 2022.

⁵¹ Ashish Kumar Jha and others, "Radiation safety audit of a high volume Nuclear Medicine Department", (2014) (29)(4) *Indian J Nucl Med.* 227–234, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4228585/>, accessed 20 July, 2022

⁵² *Ibid*, s 35(1)(a)-(c)

⁵³ *Ibid*, s 35(1)(d)-(f)

needs regarding compliance with the national regulations concerning protection and safety of patients and shall take such actions as may be appropriate to ensure the protection and safety of patients.⁵⁴

The registrant and licensee shall ensure that workers (medical practitioner, medical physicist, technologist) follow any applicable rules and procedures for the protection and safety of patients, as established by the licensee; are competent in the operation and use of the equipment and sources employed in nuclear medicine, of the equipment for radiation detection and measurement, and of the safety systems and devices, commensurate with the significance of the workers' functions and responsibilities; and know their expected response in the case of patient emergencies.⁵⁵

(ix) Public Exposure Resulting from a Nuclear Medicine Practice

Public exposure is a form of exposure for members of the public, such as in waiting rooms. Public Exposure as defined under Part I dealing with General Interpretation of the NSNMR, 2006 to mean exposure incurred by members of the public from radiation sources, excluding any occupational or medical exposure and the normal local natural background radiation but including exposure from authorized sources and practices and from intervention situations.⁵⁶ Part VI, section 50 of the 2006 Regulation places responsibilities on registrant and licensee. Sub-section 1 provides that, the registrant and licensee shall be responsible for controlling public exposure resulting from a nuclear medicine practice. In order to control public exposures, the registrant and licensee shall be responsible, with respect to the sources under their responsibility, for the establishment, implementation and maintenance of: protection and safety policies, procedures and organizational arrangements for the usage, transport, storage and disposal of nuclear medicine sources to ensure their safety and security in accordance with the requirements of the Authority; measures for ensuring the optimisation of the protection of members of the public; measures for ensuring the safety of such sources, in order that the likelihood of public exposures are controlled; appropriate protection and safety training to the personnel having functions relevant to the protection of the public, as well as periodic retraining and updating as required, in order to ensure the necessary level of competence; appropriate monitoring equipment and surveillance programmes to assess public exposure; adequate records of the surveillance and monitoring as required by the Authority; emergency plans and procedures, commensurate with the nature and magnitude of the risk involved, and activate such plans and procedures in accordance with the requirements of the Authority.⁵⁷

⁵⁴ *Ibid*, s 35(2)-(3)

⁵⁵ *Ibid*, s 35(4)(a)-(c)

⁵⁶ Nigerian Radiation Safety in Nuclear Medicine Regulations, 2006, Part I, General Interpretation.

⁵⁷ *Ibid*, s 50(1)(2)(a)-(g)

Registrants and licensees shall: develop and implement use, storage and transport measures for ensuring the safety and security of radiopharmaceuticals to control public exposures in accordance with the requirements of the Authority; and control and maintain constant surveillance of radioactive sources that are not in storage for example when nuclear medicine sources are being transported or used for treatment and secure stored radioactive sources from unauthorized access, removal, or use (e.g., the storage facility shall be locked at all times). Registrants and licensees shall be responsible for ensuring that the optimisation process for measures to control the discharge of radioactive substances from a source to the environment is subject to dose constraints established or approved by the Authority.⁵⁸

It is important to state that medical exposure differs from occupational and public exposure in that persons (primarily patients) are deliberately, directly and knowingly exposed to radiation for their benefit. In medical exposure applying a ‘dose limit’ is inappropriate, as it may limit the benefit for the patient; consequently, only two of the radiation protection principles apply – justification and optimization.⁵⁹ Medical exposure show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct benefits to health of an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionizing radiation.⁶⁰ The principle of justification in general is invoked at three levels. First, nuclear medicine as a practice is a justified application of radiation, given the overall benefit to patients. Second, a specific type of examination must be justified on its merits. The third, and final, is the examination for an individual patient must be justified based upon a correct assessment of the indications for the examination, the actual clinical situation, the expected diagnostic and therapeutic goals, and how the results are likely to influence the diagnosis and the medical care of the patient.⁶¹ The nuclear medicine physician has the responsibility for the control of all mentioned aspects of the conduct and extent of nuclear medicine examinations, including the justification of the given procedure for a patient. He also should decide on the appropriateness of examinations, choose appropriate radiopharmaceutical, and determine the techniques to be used. There should be relevant compliance with relevant international and national guidelines. The principles of optimization of radioprotection are applied to nuclear medicine procedures that have been justified. For diagnostic administrations, the administered activity should be as low as possible while serving the clinical purpose, obtaining adequate image quality and respecting relevant diagnostic reference levels. For therapeutic examination, the goal is to

⁵⁸ *Ibid*, s 50(3)(a)-(b) and 4

⁵⁹ IAEA: “IAEA Safety Standards and Medical Exposure”, available at <https://www.iaea.org/resources/rpop/resources/international-safety-standards/iaea-safety-standards-and-medical-exposure#1>, accessed 20 July, 2022

⁶⁰ Tereza Kracmerova and Søren Holm, “Basics of Radioprotection”, *Reference Module in Biomedical Sciences*, 2021 available at <https://www.sciencedirect.com/topics/engineering/medical-exposure#:~:text=Medical%20exposure%20refers%20primarily%20to,Module%20in%20Biomedical%20Sciences%2C%202021>, accessed 21 July, 2022

⁶¹ *Ibid*

administer maximum activity to the organ of interest, while the activity in the rest of the body is kept as low as possible. The optimization of radiation protection includes the choice of radiopharmaceutical, amount of activity, procedure considerations, calibration, dosimetry and quality assurance.⁶² In a nutshell, the International Commission on Radiological Protection (ICRP) stated that the System of Radiological Protection is based on the following three principles: first, Justification. *“Any decision that alters the radiation exposure situation should do more good than harm.”* second, Optimisation of Protection, *“Here doses should all be kept as low as reasonably achievable, taking into account economic and societal factors.”* (Known as ALARA or ALARP)., third, Dose Limitation which requires that the *total dose to any individual ... should not exceed the appropriate limits.*⁶³

4. Who is Responsible for Applying Safety Standards?

There is a hierarchy of responsibilities within the framework for safety, from governments to regulatory bodies to the organizations responsible for, and the persons engaged in, activities involving radiation exposure. The government is responsible for the adoption within its national legal system of such legislation, regulations, and standards and measures as may be necessary to fulfil all its national and international obligations effectively. Specifically to medical exposure, the government has the responsibility to ensure that as a result of consultation between the health authority, relevant professional bodies and the regulatory body: the relevant parties are authorized to assume their roles and responsibilities; a set of diagnostic reference levels is established for medical exposures incurred in medical imaging, including image guided interventional procedures; dose constraints are established for exposures of carers and comforters, and exposures due to diagnostic investigations of volunteers participating in a programme of biomedical research; criteria and guidelines are established for the release of patients who have undergone therapeutic radiological procedures using unsealed sources or patients who still retain implanted sealed sources.⁶⁴

The prime responsibility for safety rests with the person or organization responsible for facilities and activities (hospital management). In the case of medical exposures, because of the medical setting in which such exposures occur, primary responsibility for protection and safety for patients lies with the health professional responsible for delivery of medical exposure. Only persons with the appropriate competencies are allowed to take particular roles and responsibilities; this applies in particular to persons undertaking the role of radiological medical practitioner, medical radiation technologist, or medical physicist.⁶⁵

⁶²*Ibid*

⁶³ ICRP, The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication (2007) (103) (37) Ann. ICRP 2-4.

⁶⁴IAEA: “IAEA Safety Standards and Medical Exposure”, available at <https://www.iaea.org/resources/rpop/resources/international-safety-standards/iaea-safety-standards-and-medical-exposure#1>, accessed 22 July, 2022

⁶⁵ *Ibid*

Other parties also bear certain responsibilities or can influence safety, e.g., suppliers of radiation generators and radioactive sources, technical standards associations, medical devices regulatory agencies, and health technology assessment agencies, health insurance or reimbursement companies and standards accreditation bodies. Government should be aware of these players in their country and utilize their influence to improve the practice of radiation protection and safety in medical uses of ionizing radiation.⁶⁶

5. Quality Assurance Indicators and Effectiveness of Regulatory Bodies

The quality assurance indicators and the effectiveness of a regulatory bodies are considered when an acceptable level of safety is being maintained by the regulatory organisations. This is done by taking appropriate actions to prevent degradation of safety and to promote safety improvements.⁶⁷ Regulatory bodies like the Nigerian Nuclear Regulatory Authority (NNRA) should perform its regulatory functions in a timely and cost-effective manner as well as in a manner that ensures the confidence of the operating organisations, the general public and the government. As regards Effectiveness of Regulatory Bodies the IAEA has set a benchmark on issues relating to maintaining competence which rest on giving the necessary authority the needed resources as prerequisites. The regulatory body is effective when it: ensures that an acceptable level of safety is being maintained by the regulated operating organisations, develops and maintains an adequate level of competence, takes appropriate actions to prevent degradation of safety and to promote safety improvements, performs its regulatory functions in a timely and cost-effective manner as well as in a manner that ensures the confidence of the operating organisations, the general public, and the government and strives for continuous improvements in its performance.⁶⁸

Furthermore, the quality assurance measured against international standards, the IAEA has produced the document on Quality Assurance within Regulatory Bodies, IAEA-TECDOC-1090, which provides information and good practices in the development and application of quality assurance to regulatory activities for effectively and efficiently fulfilling the requirements of its mandate. Utilising a systematic approach to regulatory processes it proceeds to look at management aspects, performance activities and assessment issues.⁶⁹ It is pertinent to state that a regulatory body is effective when it: ensures that an acceptable level of safety is being maintained by the regulated operating organisations and such organization develops and maintains an adequate level of competence. It must take appropriate actions to prevent degradation of safety and to promote safety improvements, performs its regulatory functions in a timely and cost-effective manner as well as in a manner that ensures the confidence of the operating organisations, the general public, and the government. Other measures of the

⁶⁶ *Ibid*

⁶⁷ OECD, "Improving Nuclear Regulatory Effectiveness", Nuclear Energy Agency, Organisation for Economic Cooperation and Development 2001, 10-11

⁶⁸ *Ibid*

⁶⁹ *Ibid*, 16

effectiveness of a regulatory body are that it must strive for continuous improvement in its performance and the effectiveness of any regulatory body in fulfilling its fundamental mission (to ensure a safe nuclear industry) can only be assessed indirectly, using Performance Indicators (PIs) that derive from, and depend upon, the performance of the licensees. Such indicators should ideally show the impact of the regulatory body on the levels of occupational and public radiation exposure, the number of significant events and near-misses on the plant. The “health” of the licensee’s safety culture and safety management systems and the minimisation of radioactive waste generation and environmental impact of the licensee’s plants.⁷⁰

6. Conclusion and Recommendations

The legal framework for occupational radiation protection in Nigeria is essentially embodied in the Nigerian Atomic Energy Commission Act 1976 and Nuclear Safety and Radiation Protection (NSRP) Act of 1995. The Nigerian Nuclear Regulatory Authority (NNRA) has established a sound regulatory framework to guarantee the safety of all workers involved in the use of ionizing radiation; there is a prescribed dose limit at par with international standards, and radiation exposure is maintained As Low As Reasonably Achievable (ALARA). Potentially, the Nigerian regulations governing radiation safety in the medical industry are adequate to protect the health professionals whose work involves radiation exposure; however, compliance and quality assurance should remain key areas of focus for optimum application. Nigeria like other countries has to contend with the challenges that come with the institution of an effective regulatory system that determines the confines of safe use of radiation in medicine as well as other aspects of this application. The Nigerian government should be aware of key stakeholders who bear certain responsibilities or can influence safety in the country and utilize their influence to improve the practice of radiation protection and safety in medical uses of ionizing radiation.

⁷⁰*Ibid*, 24-25