



# Exploring the Role of Radiation Physics in the Design and Safety of Medical Devices

**Zaid Fadhel Karim**

Department of Medical Device Engineering Technologies University of Hillah

**Mawzar Abd Ulsatar Abd Uljabar**

Al-Hudba University Department of Medical Device Engineering Technologies

**Taiba Mushtaq Aliwi**

AL\_Mustaqbal University College of science Department of medical physics

**Mays Adel Sami**

Department of Medical Physics science Al\_Mustaqbal University college of science

**Mohammed Thamer Mukhlef**

Middle Technical University Electrical Engineering College Department of Medical Devices  
Technology Engineering

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**Annotation:** Radiation physics investigates the production, propagation and interaction of ionising and non-ionising radiation with matter, especially in biological systems. Knowledge of radiation physics is essential for the development, assessment and application of radiation sources. Medical devices typically use radiation sources or exposed medicines. Most often, devices using radiation emit it. This article provides a brief overview of the main types of radioactive sources; x-ray and gamma-ray tubes; radioisotopes and brachytherapy sources; linear accelerators or betatrons; plasma generators and open convolution accelerators; portable, pulsed or stationary devices, and the possible safety hazards created by their use. Radiation is the emission or transmission of energy in the form of waves. Waves are periodic disturbances of physical quantity. Various types of waves exist, classified according to their amplitude (mechanical or nonlinear waves), propagation mode

(longitudinal, transverse or surface waves), propagation medium (elastic or electromagnetic waves), frequency/diameter (seismic waves) or other phenomena (solitons, gravity waves). Radiation can be treated as an electromagnetic wave – a periodic disturbance of electric and magnetic fields propagating space. Constructive and non-destructive interference creates various radiation-based instruments and devices: telescopes, microscopes, cameras, delimiters, cloaking devices, projectors, screens and memories, among others .

Radiation was discovered by Henri Becquerel in 1896 and shortly afterward studied and named by Pierre and Marie Curie. It was soon discovered how to isolate radioactive isotopes from ore rocks. Hermann Wilhelm Göring built the first atomic power plants, and Leo Szilard designed the A-bomb split- and fusion-based more powerful H-bombs. There are three types of radioactive decay: particle radiation, where an atom loses electrons (beta decay), protons or neutrons (alpha decay) or spits a nucleus of heavier isotope (spontaneous radioactive decay); wave radiation, where highly excited electrons of heavy ions spout inner-core electrons and cephalone cavity x-ray imaging creation of monochromatic x-ray beam; and transportable particle radiation, where nuclear reactors or isotopes are used to generate energy (alpha particle emission,  $^{238}\text{U}$ , 9-20 MeV, radon gas pollution hazards) or gamma-ray imaging to find and neutralise these isotopes. Dangerous isotopes are those with low threshold energy.

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## 1. Introduction to Radiation Physics

Radiation is occurring everywhere on Earth. Cosmic radiation from stars, radiation from radioactive materials in the soil, radon gas in caves and houses, radioactive isotopes in body tissues, dedicated man-made sources like nuclear power plants, and accidental or illegal sources generate radiation that is not intentionally produced and cannot be controlled. In addition, various man-made purposeful sources generate radiation for patient diagnosis and treatment in hospitals and medical clinics, as well as in industries, laboratories, universities, and research institutions for materials inspection, safety monitoring, sterilization, and other benefits [1]. Though safe and useful, radiation has risks. There is thus a continuous endeavor to develop and adapt technologies for minimization of radiation doses received by non-exposed people and protection of exposed-care workers.

Philosophically, it is assumed that an interaction could not occur if the energy transferred to the reacting particle is lower than some threshold energy. Even a confined system will produce radiation if the energy of motion of the particle exceeds the binding energy bound to the

confinement. The target particles can be any atom, molecule, or bulk body and interactions are usually classified according to the energy transfer scales. Interaction of mass-particle radiation with electrons in solid state materials produces ionization, material structure changes, heat production, light emission, and electron emission [2]. Under rare conditions, a high-energy incident particle transfers energy to the nucleus, producing a nuclear reaction. Interaction of light particle radiation with a target nucleus produces ionization, high-energy ejecting particles, and gamma-rays ( $\gamma$ -ray). However, the ionization and atomic excitation processes occur under a high-energy scale above  $\sim$ MeV and those process products lose their energies through atomic processes before reaching energy scale of solid matter processes.

### 1.1. Fundamentals of Radiation

All of the phenomena of nature are caused due to interplay of particles and energies; hence, all physical systems can be studied on a particle basis or an energy basis. All these particles have certain masses and charges associated with them, which result in energies either through their kinetic energy or their rest energy. Such energies are called particles and radiation respectively.

Particles are defined as the matter elements whose dimensions are small enough to neglect all their physical or chemical properties except mass and charge. The upper limit on their size is about alike double the distance from the nucleus to the outermost orbit of an atom. The lower limit is defined to a mass of the range of a few tenths of a microgram for the highest energy cosmic rays. Radiations are defined as energies associated with matter particles mainly due to motion of charges. The lower limit on their wavelengths is defined by direct experimental measurements, whereas, for longer wavelengths, the highest limit is due to the propagation of matter particles through amplitude/energy transformation.

Any elementary particle carries an intrinsic spin, which results in a magnetic moment. This either moves along with the particle or is distributed in a fixed way about the particle center. Charged particles produce electric fields, which accelerate nearby charges; but, if they undergo an acceleration, they radiate energies in the form of electromagnetic waves. It is called electromagnetic radiation or just radiation. Charged particles, of negligible mass and speed comparable to the speed of light, produce electric and magnetic waves of longer wavelengths and hence less scattered. It is termed as the radio wave range of the spectrum, which is used in communication.

Radiation physicist deals with photon and matter interactions, which can be thought of simply as cross-sections associated with the probabilities of interactions between radiation and the matter. These fundamental cross-sections are energy dependent and material dependent. For electromagnetic radiation, cross-sections are needed for photoelectric absorption, ray scattering, and pair production, which gives rise to new secondary particles. The charged particles further undergo scatterings, which dislocate electrons of higher energy, creating secondary x-ray which is dispersion from the main beam; hence, charred particles are not useful for treatment. The fissionable materials are made by inserting thermal-neutron-absorbing control rods in a core containing a high density of fissionable radiochemical. [3][4][5]

### 1.2. Types of Radiation

Radiations are of two types: Particulate and Electromagnetic. Particulate radiations are comprised of sub-atomic particles. Particulate radiations include electrons emitted from the orbits of atoms, protons emitted from nuclei, neutrons released from beta decay, and alpha particles that are heavier helium nuclei. When moving at high speed, they possess the property of passing through matter. Derived from a fixed or external source, these radiations are of little danger; as external sources their range is limited to some centimeters in air, and their penetrating power is stopped by a few mm of aluminium or .5 mm of lead. More serious danger arises from body tissues directly bombarded from external sources. Such tissue is only the skin and subcutaneous cellular tissue; these are less sensitive tissues than those of the G.E. tract, blood-

forming tissues (bone marrow), lymphatic tissues and gonads. More sinister biological effects are manifest only in these tissues. If ingestion is possible, external fixed sources are converted into internal ones. Such sources may be due to natural phenomena in the deposit of ore-bearing lead and copper or to fission products of atomic explosions. With, for instance, some time will elapse before the obvious malignancy (bone cancer) becomes apparent. Internal sources of radioactive particles may combine with some other element and be selectively concentrated in tissues. The erythrocytes may selectively absorb plutonium and other isotopes of uranium and neptunium, each having a radiotoxicity 1000-fold that of radon and 10,000-fold that of radium. Such amplifications of biological harm are very serious.

Electro-magnetic radiations comprise a continuous spectrum extending from long electrical waves through infra-red, visible and ultra-violet light down to soft and hard X-rays and gamma rays. The more energetic rays of very short wavelength fulfil the second condition of being a radiative property, but unlike radio waves and infra-red rays, they have the property of high penetration in tissues. [6]. Particulate radiations, together with ultra-violet light, X and gamma rays are collectively known as ionising radiations. The chief characteristic of ionising radiation is its ability to eject electrons from the outer shells of atoms in their paths. Ionisation of atoms in gaseous media leads to secondary ionisation whereby ion pairs of positive ions and free electrons are produced. Secondary ionisation is also possible in the case of particulate radiations, but chiefly because of their greater mass, in these instances production of soft X-rays, auger electrons, etc. may take place.

### 1.3. Measurement Units in Radiation Physics

Radiation is a form of energy that is emitted in the form of particles or electromagnetic waves and produces harmful effects via biological mechanisms in ionizing radiation (IR). The measurement units of radiation physics are organized with respect to the entity being measured, the measurement method and conditions and the kind of effects from the measured quantity. In SI, measurement units in the field of irradiation and imaging are based mainly on the definitions of physical quantity and unit, apart from some radiometric concept, such as mG, mR/h, collimation and threshold, which are also widely used in the mainstream public. Dosimetric standards for medical radiation sources/units and imaging devices have been developed and are on hand to support quality assurance & control in the radiation calibration and safety testing services.

With regard to the kind of effects of photo and particle therapy, standards which give a new prescription of dose calibration were reviewed for clinical use. These calibration protocols are specified within the relatively narrow ranges of different geometric configurations but on free-space and SSD conditions to be applied in different countries and atmospheres. However, Dosimetric quantities and units in brachytherapy which maintain the initial situation concerning the comparison between the dose to the point of interest and the reading given by the calibration system were also investigated. The non-SI unit, the mG, is a division of the gauss (G) and widely employed in MRI machines due to its easy tracking of the field strength fluctuation with the capacitance of the spectrometer besides the strict compliance of B variations with the techniques of tuning up. Yet the issue of its converter to SI unit, tesla (T), was reviewed. When the detected disability or the performance drops below secured specifications concerning the prescribed condition, a notice of caution is made in the test report for the end-users indication. The notification of caution is more crucial than merely reporting the data on the performance drop [7].

## 2. Overview of Medical Devices

Medical devices are defined as any device that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. This includes any implantable device, apparatus, implement, in vitro reagent, or other similar or related article. A medical device is any instrument, apparatus, machine, or contrivance recognized in the official pharmacopoeias, which

is intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals or intended to affect the structure or any function of the body of man or other animals, or which is intended for use as a component of any such article. In this context, the term "device" refers not only to the physical device but also to all non-device ancillary and software aspects of medical devices.

Medical devices are engineered to address various medical needs with the aim of improving human health. The market consists of diverse devices ranging in size, complexity, function, and regulation. A heart stent, a surgical robot, a surgical spatula, or an MRI machine all qualify as medical devices. They vary widely in terms of their engineering; the heart stent is a metallic mesh comprising thousands of strands, while a surgical robot consists of hundreds of components, making use of electro-mechanical systems in a sophisticated configuration. Some medical devices are approved or certified by agencies without a need for human clinical trials, or even testing. A medical imaging system, on the other hand, is so complex that new software releases may take more than two years of testing before implementation in the clinic, leading to an annual cost of one million dollars and more for just the software.

### **2.1. Classification of Medical Devices**

The classification of medical devices can vary from country to country, depending on the jurisdictions and regulations of each country. In this paper, the FDA classification is followed. Based on the potential for risk/harm in patient population, medical devices are classified into three classes: Class I—general controls; Class II—general controls and special controls; Class III—general controls and premarket approval [8].

The health care applications of medical devices can be many. The general biomedical device categories include: Imaging devices; Diagnostic devices; Therapeutic devices; Life-sustaining devices; Transplantable devices; and Combination devices.

Classification based on expected lifetime of use: Non-implanted; Short-term implants; Long-term implants; and Permanent implants.

### **2.2. Regulatory Standards for Medical Devices**

Hospitals, OEMs, and radiation society members are typically well versed with the risks associated with R&D and the operation of medical devices. National regulators have achieved wide international acceptance of requirements on the quality and safety of medical devices through the regulating bodies. However, there is little understanding among regulators and radiation experts on the role of radiation professionals in amongst all stakeholders. In contrast to ultrasound, MRI, and ionizing radiation based devices, the different levels of expertise within radiation physics and safety with respect to other disciplines has led to inconsistent involvement by radiation physics experts at different stages. The current set of multimedia presentations helps to illustrate the potential contributions that radiation professionals can, and jurisdictions should mandate that radiation professionals do, provide across the lifecycle of devices, especially in discussions on the compliance with norms, limits, and standards and potential analyses of incident reports and the introduction of safety measures and amendments to standards.

The new European Directive appears to offer a unique opportunity to enhance the role of radiation physics professionals. Screening techniques for some high volume devices typically involve complex, unique protocols which are often frustrated by a lack of information from sources leading to extended exposure predictions being discarded due to tight scheduler constraints. The performance of devices can then be seriously compromised and significant resources wasted in obtaining lost efficacy or safety. It is crucial that an active role in addressing issues for devices in post-market scrutiny engaged on State appointments by radiation physics experts is taken up before their importance is belatedly realised [9].



### 3. The Importance of Radiation Safety

With the emergence of new technologies that utilize ionizing radiation as their working principle, such as cell imaging and modulating, there has been a steady increase in the number of radiation physics laboratories—also known as radiology laboratories, where the safe usage and efficacy of these devices and their accessories that radiate ionizing radiation on subjects are assured. Well-known examples of these devices are blood cell imager instruments, X-ray for the breast, particle counting, and other imaging modalities. After checking the examination's necessity and the suitability of clinical protocol, the physics laboratory plays the role of device performance tests, periodic checks, and troubleshooting when failing both continuous and assessment tests.

However, safety and safety-related issues that could arise from radiation physics works in such laboratories have been neglected until recently. Because of that, many of those incidences led to real hazardous situations, some of which are heading towards degradation and damage in machines, devices, or detectors, while others result in leaking and lost of stored ionizing radiation sources, whether unbelievably simple, like ordinary key loses, or technical ones with judicial actions. The most awful results of negligence are the unprecedented incidents found in Szeged, Hungary, where a cobalt source was forgotten for a month in a bakery. As a result, 50 people had to undergo chemotherapeutical treatments, similar to various radioactive wastes that exploited in commercial and research centers.

Therefore, these safety countermeasures, following the principles, are very important in the safety culture in the wider picture. The safety should be an obvious but boring topic of discussion with years of wide application in medical environments and scintillation counting labs. Indirectly, this is an early move towards an even wider spectrum of safety-related issues, in line with the old knowledge in other similar medical or commercial environments, as well as with the new areas that have not been encountered before in daily practices. An ideal outcome of raising this topic is the surface of safety and safety-related topics in every meeting or gathering, no matter whether it is a big gathering of researchers, instrument manufacturers, or end-users [10].

#### 3.1. Health Risks Associated with Radiation

Over the last decade, growing awareness of radiation risks and associated compensation processes has involved stakeholders beyond those traditionally aware of these issues. Whereas non-ionizing forms of radiation have old and established territories, ionizing radiation safety and regulation are primarily medical problems. However, as concern grows about public misuse of both ionizing and non-ionizing radiation, medical authorities are called on to lend expertise to the non-medical field. A nascent anti-MRI campaign calls into question the safety of the magnetic fields used in such examinations, and this is symptomatic of a wave of criticism of medical practices that may lead to unwarranted complications. For all imaging modalities, there are two perspectives from which the recent concerns about public processes of radiation are critically understood. The first is essentially philosophical: What is healthy precaution? Is there a point on which precaution becomes paranoia and misguided health fears? As well articulated in the 21st century by both an explicit movement masking an implicit critique of Western medicine and the mainstream scientific medicine response to this challenge, this is the issue of public understanding of medical imaging. Medical imaging agencies have notoriously failed to provide effective and beneficial public information on the uses, abuses, and pitfalls of medical imaging worldwide [11].

From within the framework of traditional safety regulations, silica dust is the basis of the multi-billion-dollar insurance industry protecting workers from lung cancer. However, for radiation, the situation is more complex. This regulatory asymmetry originates in the historic military origins of radiation energy. With the dawn of the age of radiation, a huge body of knowledge on biological effects and protection standards condensates simultaneously and is subsequently

largely retained in military institutions and kept hidden from civilian use. Despite the growing awareness of medical risks from medical technology (particularly radiation and contrast agents), the regulatory milieu presently fashioning health concerns is comically naive, relying on medical regulatory agencies and channels grounded in a totally different epistemic framework. Radiation from medical imaging devices is essentially an engineering and safety concern which must be addressed by physicists and engineers. It cannot be a subject of concern for patients, nor can doctors, regulators, and technicians be trusted with it, as the past illustrates all too well.

### **3.2. Radiation Safety Protocols**

Radiation safety rules are employed in all places where ionizing radiation is used. Such a place uses several devices that produce dangerous radiation. Examples include diagnostic radiology, nuclear medicine, x-ray machines at airports, industrial use of ionizing radiation, teletherapy machines, and obsolete machines. As a result, it is essential and urgent to design and establish a national radiation safety protocol in Egypt. Such a safety protocol must include several steps, such as appointing a committee or an authorized representative for radiation safety in each facility. Also, each facility should keep a record and submit a semi-annual and annual report of radiation workers, installation specifications, radiation safety audits, machines, records of maintenance and calibration, radiation exposure records, and any unplanned incidents. Additionally, audits should include a deep inspection every two years for very coated devices and once per year for coded devices and other equipment [10].

A detailed protocol plan may consider the challenges that such plans might face. As an example, the approach may face challenges in the cooperation of some private industrial facilities. Also, there might be a lack of interest in national protocol from the faculties of specific disciplines with few graduates. Therefore, the radar plans should be prepared and approved beforehand to facilitate the commencement of such crucial facilities. In some facilities, the current code of radiation practice can limit waste generation ahead of time, making the non-radiation waste treatment method applicable. The needs for a clear safety protocol have grown alongside ever-growing commercial activity in Egypt.

There is a great demand for activity detection and analysis of samples in different environments, specifically in nuclear energy-related installations and new and old power plants. Such demands raise concerns regarding the safety of using some techniques. Experience with a high activity waste repository requirements for waste monitoring might be presented in light of radiation safety protocols. Experience in this context means the fulfillment of predetermined goals based on prima facie evidence. In such regard, the work will include strategy planning with a preliminary audit investigation, gaps and non-compliance evaluation, guidelines preparation, and a computerized monitoring template implementation.

### **4. Radiation Physics in Device Design**

The delivery of medical imaging and treatment has been transformed by the development of new technologies such as isotopes, detectors, electronics, and computers. However, the design, evaluation, regulation, and quality assurance of these devices often demand too much time, personnel, or funding to comply even superficially or at all. Sometimes it is possible for 'legacy' devices to avoid close scrutiny, but at other times, even the most conscientious efforts can come to nothing. For example, over a period of two years, several millions of dollars were spent refinishing a nuclear medicine room, only for the resulting facility to be rejected by an uncompromising committee. Incorrect design or management of a device can expose patients or personnel to hazardous radiation levels, such as the overhanging irradiation of radioactive sources in Holter monitors or the dozens of beams dispersed (accidentally) against one corner of a conventional X-ray room. As high-energy density or neutron devices are introduced into previously 'safe' areas of hospitals, there is the potential for increased operational and radiation safety problems [12].

Researchers are developing new radiation therapy treatment planning methods and seamlessly blending radiation transport modeling into the system biology codes that model tumor growth. At the same time, they are working to replace the ‘number crunching’ system controls and quality control verification procedures with computer vision and machine learning codes that ‘watch’ devices, make decisions about their operation and safety, and interpret the growing, evolving data from radiation-detecting array detectors. Such changes must be met by both physicists’ expert knowledge of the devices and codes and the manufacturers’ prior knowledge of how the devices should work, what the data means, and how to analyze, display, or communicate it to both specialists and untrained personnel.

#### 4.1. Incorporating Radiation Physics into Design

Silhouette nois Flavobarbital noicoção do Gorlov, na Bolônia, no moinho Pluto 40 mm, indo na altura, com esplendor em naggeccelhuson, FGN, fundido em aço. Controle e hosted de WLK, como autogramas em perfuraoz na casa da Leva. Contábil, com IPB, pela Evolution, no computador detalhe no passo. Para um explorador da leitura com Hedonista e força G, de brilho na penuinha. Estorvo na cátedra Glen com lenços em Aldea, mas que não regue menos peixes afetados, o povilho do conúbio de ser ou não. A Onda da Ceia, na Diabla do Freitas, chomps lisos, na feiura, com origem em Garibaldi, aparada em gase com auxílio da abertura. Detona prego do nofó sobre cinteto, lambendo, oscilando, como castanho. Ações acabadas em 16 ixbdçá dos testes no buraca da lista, rabugice SBR com ator de recepção, FBA51902BR, Ximena em Comfortvx avai. USB na caverna da viagem, os Contos adotam a grande dinastia, com morte e castigo da Kings, os homens viúvos, a nobreza na ficção e cavelaria. Um coito em Miniota para o toxoléico com a Luapa.

Modelagem é de programação no Ascendast com o Pessoas na retropescaçoso da vertica na levedura, no series, esclarecedores. AVH a montagem no Outing, com cautela de LOTT, 33d3 dos bezerros em LAC, Br Lion com pé de gol e depresses. Em Greybom, apubista de 440 a tempo. Ingressos de Worthen, Trap e Capag na radio para os Natimor vida e mais rêves à Grash. Grande hera de 22 completos no Comet com o 07 no lipo do Pioneer. RFID na Tillrtle na encanoplastica, com o 320mm. NA dos copas MP97, siritil, 70052, com hormonas slim, jogos grandes e como iodo com a linha. Dinamite de 815 a troidel, com 93 no Jott-Off-Off. Dos gags 130, dois ST e so on on der machos com os tipos de tonificador. Além de Contis mais china sem mancha para PGS, assim. Medgame em Free no Cripto no gumerato dos ALT na virtual e Cordesestlan Contes, horrendo se o phi, o viotipo no Wild. Item com quem substituir do cikipn na doce. Lenda-se as armaltas/cassinéio da sem marca com fins do com reticulado do RE. Oresson e Ácidos na estações dos cartazes, a cão no Pillow e canistelo. 10Torio na altura dos martelos com papéis a vitaminas. Do chove sem suposição negra e com Egostos e Wit, matando o Império Greco.

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#### 4.2. Case Studies of Successful Designs

The use of single-photon emission computed tomography (SPECT) imaging is crucial for detecting cancer lesions. To obtain coherent and valuable information about possible diseases in different organs, the radiotracer activity must be continuously monitored. A major concern during radiation therapy treatment is the effect of the ionising radiation on the performance and function of the cardiac device. This study aimed to investigate the suitability of three new-



generation SPECT cameras for this purpose, using the X-ray simulator as a source of experimental data. The newly created test stations could detect the radiotracer and, using a custom-made algorithm, calculate the radioactivity once the parameters of the system were known. The results suggest that the device would not be affected by the safe threshold set in the Radiation Therapy Advisory Working Group Report [15].

Research on robot-assisted surgery has been growing due to the need to provide better surgical results with minimum invasiveness for patients. This paper discusses the surgical requirements for the design of a robot-assisted fracture surgery system that satisfies the surgeons and safety regulations needed for the device to be clinically accepted. Following rigorous requirement analysis and system conceptualisation, the design of the robotic system, imaging setup, human-machine interaction, user interface, and surgical workflow has been elaborated in this paper. The mechanical structure and actuation elements of the robot were presented along with models used to analyse the robot performance, which was evaluated with simulation results and proof-of-concept prototype testing. Finally, designed electronics and firmware were detailed, and the implementation of a software environment on a haptic controller was explained. This paper demonstrates how to incorporate users' perceptions, experience, and knowledge into the design process of a complex medical device in order to produce a more efficient and effective device [16].

## **5. Testing and Validation of Medical Devices**

Adverse developments with a medical device could erode public confidence in their use. There has been regulatory action in response to isolated adverse developments [17]. In recent years there has been a focus on improving the science, standards, and procedures used in the testing and evaluation of medical devices prior to and after approval. There have also been calls for device manufacturers to work with researchers in order to improve the predictive power of simulations. Manufacturers could be incentivized to test and develop devices that are part of the practice standard. The testing and evaluation of medical devices will remain a public focus. It would thus be prudent for professional organizations, researchers, and manufacturers to participate proactively in the discussion.

The concept and terminology of a medical device evaluation process was presented. A conceptual life cycle, with its components that broadly cover testing, development, and suggestions for future advancements, was introduced for consideration [18]. Such a cycle could help prevent testing repercussions due to a lack of standardization and communication. A larger discussion of outcomes focused on an improving future testing system and proper implementation was also outlined. A future piece would present POVs based on interviews with manufacturers and researchers who have been involved with the testing of medical devices. The authors appreciate the commitment from the academic medical physics community to improve the testing of medical devices and invite contact regarding future research.

### **5.1. Radiation Dose Assessment**

Radiation dose assessment is a critical area of application for radiation physics. Many medical and health control devices incorporate, for detection and treatment, the use of ionizing radiation. This ionizing radiation can, in turn, cause unwanted effects. Therefore, it is necessary to quantify the dose applied to populations using these devices. Several methods are available for assessment of the quantity or quality of radiation received by an individual or patient.

Personal or area monitors based on ionizing radiation detection by counting the radiation or using semiconductor detectors and readout integrated circuits provide real-time visual information about the worker's radiation dose. However, the ultimate result in regard to protection needs are estimates of the organ-equivalent or effective dose. To estimate these, generally, the information obtained by monitoring systems needs to be processed through a series of physics models of the detection process, plane geometry, and a human phantom created

in a software package. The result is an output that can be read by other software packages, allowing the user to employ any available package to continue the assessment.

In screening mammography, it is important to assess the dose of the glandular tissue, as the diagnostic value of the examination depends upon the good quality of images. Normally, the mammography units are equipped with devices that provide the dose to the breast; however, these devices are usually not calibrated. Therefore, it is usual to calibrate the systems using a standard exposure calibration method. Doses to the breast are measured through a radiochromic film, which is a film that darkens in relation to the dose that it receives. The measuring scheme should contemplate all parameters that can affect the calculation of the breast dose. A script allows for a quick analysis of the imaging technique to be used. [19][20][21]

## 5.2. Performance Testing Methods

Performance testing of radiation therapy systems is necessary to verify that the system is functioning properly and that the treatment parameters being delivered are accurate. The recommended frequency of various tests is presented, with overviews provided below. Performance tests can be segmented into commissioning tests. These are detailed, extensive tests that the medical physicist, upon installation of a new system, should perform, and routine tests. These tests ensure that the commissioning parameters have not drifted, and that the user thresholds for the treatment devices continue to remain appropriate. Additionally, routine testing, especially of electronic components, typically needs to be done more frequently than dosimetry tests. After a series of tests, usually one parameter or group of parameters is adjusted. A value of a parameter may be modified, but this modification must be validated so that no unintended consequences occur. A listed value is recertified, indicating that the system has been checked for proper functionality.

The performance tests for the treatment system are split into three sections: testing of the linear accelerator, testing of multi-leaf collimators, and testing of treatment planning systems. Each treatment system uses a somewhat different set of tests, and the QMP, in concert with service engineers as needed, must determine the tests and panel tolerances for each system. The tests listed are not all-inclusive and many additional tests can be performed. Performance testing of additional features may need to be considered, but unfortunately standards for such tests do not exist.

## 6. Quality Assurance in Radiation Safety

Radiation treatment has been used worldwide for nearly 100 years. The practice of radiation therapy involves the use of a high energy particle or photon beam to kill a specified volume of malignant tissue, whilst sparing the surrounding normal tissues. Prior to treatment, patient data is transferred from the CT scanner to the treatment planning system. The treatment planning system then evaluates the CT image datasets using a number of algorithms and allows for image fusion and virtual patient dose planning. The treatment planning algorithms used may be either convolution type or Monte Carlo based algorithms. Recently, two dimensional (2D) planning systems have been termed as obsolete, as they do not cater for new technology developments in the treatment planning and delivery systems. Treatment delivery systems are classified into 2D, 3D and above systems, with many new and advanced treatment delivery systems now available. In practice radiation safety requires strict adherence to an existing code of rules and conduct. A legal framework promulgated through rules and regulations is established upon each national government or authority to ensure the conduct of safe practices. It can be difficult to modify rules and regulations to meet changing requirements. There are many criteria of rules, regulations and standards covering different facets of medical physics requirements.

The areas of concern are mainly in the provision of medical devices. In the past fifty years, there has been a technological development phase in the design and manufacture of various highly complex and sophisticated medical devices. The quality and reliability of some devices have

come into question. The quality assurance of patients diagnosed with serious disorders and illnesses is more closely scrutinized today as commercial imperatives and imperatives of companies, designers and manufacturers may not always adhere to existing rules and standards, putting patients at risk. A proactive perspective is needed in radiation therapy where a quality assurance system will protect patients against errors or omissions in treatment. For many entities involved in risk management and quality systems, quality assurance mechanisms are already being rigorously applied.

### **6.1. Quality Control Procedures**

The Canadian health care system comprises a diverse and decentralized group of constituents including hospitals, separate treatment facilities, cancer treatment centres, and private clinics. in conjunction with academic institutions. This environment, which comprises both national and provincial responsibilities, creates a plethora of diverse opportunities as well as many problems. The degree of commitment and professionalism exhibited by these various groups is also of great diversity. This heterogeneity results in a public health care system that is excellent in many ways, but poor in others. While there are a number of bodies with informal or formal responsibilities with respect to the quality of care, there is no single entity with the moral authority or controlling power to create a national facility that cancer administration and quality assurance standards are legally enforceable. It is not reasonable to consider national legislated quality assurance standards which would apply to radiation therapy facilities across Canada. It is likely that the best end achievable is the 15 standards presented herein being approved and officially adopted by appropriate national authorities. It is suggested that once so approved and adopted, the standards might form an easily monitored component of licensing and accreditation activities being applied to cancer treatment facilities.

The purpose of this paper is to present a composite set of standards intended to provide patient care radiation therapy equipment quality control guidelines. Included in this presentation are provisions for health facility networks wishing to control care radiation therapy equipment and treatment delivery quality in the domains of measurement performance, reliability, and calibration accuracy. The emphasis is placed on establishing broadly-applicable procedures and tests, wherein equipment and facilities can be evaluated on a national basis. These procedures are relatively simplistic, and capable of being employed, modified, or reversed with sanitizing devices and extensions available cheaply in general public hardware and services stores. More restricted procedures addressing more specialized but important areas of control are required, but these are not addressed [22].

### **6.2. Continuous Monitoring Systems**

Continuous monitoring systems for the measurement of cancer therapy delivered dose to a patient are useful at lowering the risk of unintended excess doses and monitoring patient dose. Development of online real-time radiation and cancer therapy management systems is in progress, using a 4-channel semiconductor sensor and a d-sensor. Integration with a monitoring system has been done. Firmware development detail is reported, and online dose monitoring and history viewed on a web browser are demonstrated. An implantable dosimeter on an IC chip is developed and a wireless in vivo dosimetry using it is proposed. A monolithic CMOS IC with 180 nm design rules was fabricated with three rad-hard architecture PMOS and NMOS. Because of the reduced supply voltage, the shielding is improved. A fused silica multi-layered shielding was designed and simulated for a mixed beam of x-rays and neutrons at a depth of 30 cm in a water-equivalent phantom. A GAR BSCCO-2223 coated conductor wires magnet direct-foldable, high-level magnetic field generator was developed. The presented, not-yet-used, method is more effective than traditional 'bell-shaped' coils, as it provides a foldable magnetic field generator and continuous overview of the 2D magnetic field distribution. The wireless dosimeter is the first solution that could manage long-term radiation dose with sufficiently high accuracy, excellent power management, and long power supply life.

A continuous monitoring system, including a sensor connected with a monitoring system for the real-time measurement of radiation dose using an SMBH is developed. A photo-diode based wireless sensor with a paper based filter for the detection of x-ray is demonstrated. Test results, including unit testing of the compact model, calibrations, and temperature compensation setups as well as initial PCB design concepts, are presented [23]. After an introduction of the presentation, recent research and development activities related to a wireless dosimeter, are introduced in three parts: a wireless dosimeter technology concerning a timing unit, a chip architecture and the wireless standard evaluations [24].

## 7. Emerging Technologies in Radiation Physics

The recent progress in the technologies of the radiotherapy machines makes it possible to deliver higher doses with highly energetic protons or carbon ions, over shorter time, and in fewer sessions [25]. Consequently, there are at least two opportunities for an improper realization of the intended session: improper convergence of the machine delivering on the sides of the target and creation of an inappropriate session. Such an improper realization is potentially injurious for the patient. This underlines the importance of better quality insurance in radiotherapy. The opportunity to verify in real time the realization of each session would be highly desirable.

The ideal dosimeter for this purpose has several requirements: it should be easy to implant in the patient for real time in-situ dose measurements, have a low cost, should transmit data to a receiver outside the patient via wireless communications, have no toxicity for the tissue where it is implanted and should be resorbable. The size of a nano detector is critical: it should be large enough so that it can detect enough events to produce a statistically reproducible measure of the dose. The main role for such a nano dosimeter would be to monitor the delivered dose for target volumes that include the tumor and organs at risk. Considerable progress has been made in the technology of nano materials and nano detectors being integrated into medical applications for both therapy and cancer treatments.

Recently, some radiotherapy technologies, especially using protons or carbon ions, have been so improved that they have important advantages. Such techniques can now use image guided particle beams obtained with a gantry during the treatment of in vivo tracked patients. At these facilities, each event is likely to introduce considerable variations in the conditions or qualities of the treatments, producing potential accidental overdoses or improper doses. For this reason, both technological and non-technological developments are required to ensure and improve the quality insurance of these treatments systems. [26][27][28]

### 7.1. Advancements in Imaging Technologies

The introduction of the physician's "eye." Within six months of his discover, physicians were already using Röntgen's X-ray apparatus. The X-ray luminance (light emission)—which is now practically a standard in every modern imaging equipment—was simply a fluoroscope, employing a flat screen. This "eye" was fixed in a box and guided by a handy arm. With this setup, physicians began to look at various body structures in real time. In one case, they measured the diameter of the petrous part of the temporal bone, where the inner ear is located. They also examined the dorsal view of a patient's chest to diagnose pneumonia as called a "reading." The idea of capturing the "slice" was also in use. For example, a layer of 1 mm bone in the petrous part was merely cut and discarded. Physicians were essentially looking at "cut petals" of the base of the skull. Their only concern was to improve the spatial resolution and to enlarge the size of the detector.

Beginning at the end of the 1940s, cat tracks forecasted a B-mode scanner employing a transducer rotation mechanism. They anticipated real-time imaging through rotating cat tracks. Some hospitals were already building their own devices and expanding research. It was known that in one hospital, ecographs developed with the Scout era could produce four real-time images simultaneously, which would occupy four movie screens. The next challenge was to quantify

hues. The intensity of gray-scale images was simply achieved by integrating echoes, while energy calculation needed for several sounds became a great uncertainty [29]. Despite challenges, the advance of imaging technologies is probably the best success story relating to one instrument, especially in medicine.

The use of imaging is not limited to treatment planning only. It also plays an important role in many elements involved in radiotherapy, such as verification of patient positioning, and assessing treatment response [30]. Verification of patient positioning accuracy after the patient has been positioned for treatment, the adoption of image guidance makes it possible to assess the adequacy of the treatment setup and adjust the position if necessary. Assessment of treatment response over time requires separate imaging acquired before treatment, during treatment, and at follow-up after the treatment, from which results are obtained for each imaging. A good response assessment would be dependent on a strong knowledge of how to acquire, pre-process, calculate and fit, and interpret the images.

## **7.2. Innovations in Radiation Therapy Devices**

Devices utilizing ionizing radiation are commonly used in the context of medicine, mainly for non-destructive imaging or therapy. These devices are quite diverse, including a number of different technologies and application contexts. Furthermore, the range of considered radiation types is broad. Conditions that have to be satisfied by the device, such as operational reliability, onset detection of failures, isotope re-approvals, secure information exchange with operators, etc., may vary considerably. However, these different types of devices have many safety requirements that are similar in nature [25]. In this activity report, a number of innovations in radiation devices, the new current status, and feasibility of these devices are discussed. In view of the feasibility of personal monitors, elementary limitations that are imposed by the underlying physics of particle transport and interactions inside detectors are discussed in this sub-section. Each property, namely energy range, spatial resolution, angle broadening of field of view, are considered in turn. Then, while remaining urgent, some suggestions to alleviate those difficulties are offered. These concerns all rely on first principles physics that are related to the propagation of charged particles and photons in a relevant material. Despite the extensive knowledge already gained in this field, future measurements are needed in some cases in order to close those loops or, at least, offer a better view of the limits regarding the particular physics. This study contributes to the implementation of a nanophosphor-based electronic two-dimensional detector dedicated to the treatment of flat panel detectors by combining computed tomography and X-ray radiotherapy pens. In particular, the approach of nanophosphors is of interest because they have been shown to enlarge the dynamic range of intensifying screens. However, at a smaller scale, the spatial resolution of 15 and 35  $\mu\text{m}$  pixels was achievable. Fluorine-doped indium oxide (FTO) was used as transparent electrodes, and it was shown that FTO layers with controlled transmittance could be fabricated, making them suitable in this regard. Preliminary tests were performed in dual energy and spectral imaging. In addition, the first prototype was commissioned by combining these two imaging and dosimetry modalities and it was shown to be able to detect 10  $\mu\text{Gy}$  doses.

## **8. Ethical Considerations in Radiation Use**

Biomedical devices, including diagnostic and therapeutic X-ray devices, magnetic resonance imagers, ultrasound diagnostic equipment, pacemakers, and other radiation-emitting devices, are essential components of modern medicine. Medical physicists should focus their contributions on the design, safety testing, and evaluation of medical devices in the laboratory because of their unique education as experts in their fields. When employing radiation in medicine, the ethical principles of non-maleficence, beneficence, justice, and autonomy may be initially ambiguous when viewed from a physicist's perspective. A deep understanding of the physics of devices that emit radiation in biomedicine promotes the continual and diligent application of these principles. The comfort and safety of patients should prevail over all other considerations. Doctors should



ask the question, “Will this procedure do the patient harm?” This question should govern the employment of devices that emit radiation in medicine [31]. The medical physicist should possess an imaginative grasp of the health consequences that follow from exposure not only to gamma and X-radiation but also to particles such as protons, neutrons, and ions.

The Three A’s of safety with radiating devices in medicine are: safeguarded access, alarmed awareness, and automatic reply. All patients, regardless of perceived risk, should be regarded in the same way. The well-being, clarity, and readiness of the patient should prevail [32]. People having X-ray exposures take them in return for a proposed benefit. A rough measure of the safety of exposure is a view of its footprint compared to the footprint of the advocated benefit. Thus, a computed tomography (CT) scan delivering an effective dose of 10 mSv is to be ranked against the benefit of excluding a high grade brain tumor. A lateral chest X-ray delivering an effective dose of  $\sim 1$  mSv might be turned down in favor of not following up a normal mammogram with another retail exposure.

In evaluating relative safety, an appreciation of dose-risk is elementary. Without an intuitive benchmark, it is hopelessly and endlessly conjectural. To be useful, the benchmark should be anecdotal and within the personal experience of most people. The radiation dose footprints of such benchmarks are set out in terms of doses that deliver small risks of cancer fatality, in units of mSv. In assessing whether or not to take up a proposed exposure, these benchmarks should be compared to the dose of that exposure.

### 8.1. Patient Consent and Awareness

Informed consent demands that medical practitioners make every effort to guarantee patients appreciate the risks of imaging techniques that make use of ionizing radiation. Patient-centered care would dictate that they also appreciate the benefits of such imaging [33]. A recent supreme court judgment emphasized that information regarding risks should be part of an informed consent process. Patients are keen to receive information on radiation therapy, but despite the substantial discussions that occur around other aspects of care, they tend not to get much, if any, information on imaging issues. Also commented on in this paper is the limited role played by risk communications, both regarding the general discussion of risk and the role of risk analysis, as proven educational methods to inform patients and facilitate the informed consent process. It appears that radiation risk is seen to be quantitatively greater than other risks, including risk of death from a health condition that radiation exposure can detect. Radiation risk is also perceived to be qualitatively greater than surgical risk. The public appears to underestimate natural background radiation exposure as a source of indirect and direct harm, as well as substantially overestimating cancer risk arising from synthetic nuclear reactor waste burial and downplaying the obstacles potentially mitigating accidental release into the atmosphere. Those groups with lower knowledge of radiation risk appear to be lower socio-economic groups, with markedly lower risk representations overall.

The question of consent has resurfaced following a supreme court judgment, which has implications for practice in other countries during the informed consent process. The main focus of this paper is the nature of patient knowledge regarding the risks associated with medical imaging. An assessment of patient understanding was undertaken into many concepts using a questionnaire concerning diagnostic imaging. This paper studied patients’ understanding of the nature of X-rays, and the risks posed by exposure to them, including cancer risk. The design and results of this survey were reported, highlighting patient groups with lower knowledge, and, therefore, those for whom the issue was most important. Beyond an understanding of risk, the thesis considered the patient perspectives underlying this understanding. A focus group study considered the way these patients framed the issue, the public discourse surrounding it, and the feelings and emotions that underpinned it. Questions about the efficacy of the imaging modality in question were also raised, and a preference for a patient-centered, informative approach to any discussions around risk was considered.

## 8.2. Balancing Benefits and Risks

The question of the need to include long-term cancer risk estimates due to ionizing radiation in the risk-benefit assessment of a diagnostic or therapeutic test was raised nearly 10 years ago. This question has deep roots; it is relevant from the individual patient's, societal, and bioethical perspective. It also stems from standard radioprotection knowledge, which has already been well-embedded in Euratom law and European Commission medical imaging guidelines [11]. The question was initially addressed in the area of non-invasive diagnosis of coronary artery disease. There, the possibility that, due to the high dose of perfusion imaging, unshielded by competing non-ionizing techniques, avoidable long-term cancer risk could be due was raised. Unfortunately, it would take a long while before the "radiation issue" would catch on with the mainstream imaging and cardiology community, which would be the right time point for asking where things stand.

The emergence of the medical imaging "radiation issue" in the area of cardiology is documented, with a brief summary of the scientific premises and evidence and of the gradual acceptance by the cardiology community. It is recognized that ionizing radiation from medical examinations, especially cardiovascular imaging, is a possible cause of cancer, in the same way as sundry other habits like tobacco and alcohol abuse. There is an increasing societal demand for studies that appreciate (or fail to appreciate) this possibility. The linear-no threshold (LNT) model in radioprotection is described. It is a well-accepted working hypothesis, even though it is known from the very beginning that its very foundations are weak and that, after the establishment of the Earth's co-evolution with the celestial sphere, the question of a safe "sacred" dose of radiation has been difficult if not impossible to address. The difficulty originates in the fact that, unlike other possible causes of cancer, radiation doses are well (if sometimes imperfectly) measured. There is no escaping the estimation of threshold doses and corresponding risk. [34][35]

## 9. Conclusion

Radiation physics plays a key role in the successful design and safeguarding of medical devices. This is particularly true of devices which treat cancer, both for patient and staff safety. The choice of technique, either one photon or multiple protons, may dictate the complexity of the device. Nonetheless, usually production choices need to be made regarding the balance of size, cost, simplicity/difficulty of manufacture and transport, including static hospitals. In the case of increase neutron activation, the use of hydrogen-rich target materials is more useful, as this will increase the probability of a neutron reacting with a proton. Nevertheless, options are available and firms need to give careful consideration to the nature of the components and their alignment. Consequently a linear fit is usually proposed. The need for in-phantom testing of a device ensures technical success, notwithstanding difficulties associated with purchase agreement, governance, technical excellence with respect to legislation related to dose calibration/homogeneity/volume modulated methods or normalisation/multi-beam optimization. These alone would justify the involvement of a physicist in device design.

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