

# Roundtable A

How are we strengthening radiation  
safety culture in healthcare?

## Implementation and Compliance level of FANR Radiation Safety Regulations in Medicine for the International Conference on Radiation Protection in Medicine

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### Abstract

The implementation of radiation safety and protection regulations particularly in the medical field including optimization for patient protection raises challenges for all regulators, health authorities, and users. In view of this, the UAE government established Federal Authority for Nuclear Regulation (FANR) in 2009 and adopted international radiation safety regulations for medical and other fields to ensure protection of public, radiation workers, patients and environment. The goal of the paper is to demonstrate how FANR endeavoured to achieve compliance with the radiation safety and protection regulations by the licensees in medical fields and to see the improvement of radiation safety culture in the UAE. Over the period of eight years, FANR is utilizing certain regulatory tools to ensure compliance of regulations by licensees. FANR started introducing licensees to regulations through 'Meet your Regulator Workshops', then performing inspections, forming radiation protection committee, introducing radiation safety advisory documents, development of national radiation safety training strategy, and applying enforcement actions. In addition to collaboration with IAEA and other international radiation safety organizations. As a result of compliance, the number of violations are decreasing, and the radiation safety awareness level noticeably improved among medical users

### 1. INTRODUCTION

In 2009 FANR was established as the regulatory body to oversight the nuclear sector in the UAE under Federal Law by Decree No 6 of 2009 Concerning the Peaceful Uses of Nuclear Energy (The Law). FANR is conducting regulatory programmes in safety, security, radiation protection and safeguards, which fulfill key objectives in licensing and inspection in accordance with best international practices. FANR's Radiation Safety Department (RSD) is regulating radiation sources used for medical and non-medical purposes in the country. Since 2009, FANR issued two regulations and three regulatory guides related to radiation protection in medical and non-medical fields. After publishing regulations, FANR officially requested all radiation sources users to comply with the regulations and to obtain FANR license. FANR started to issue licenses to conduct regulated activities and perform inspections for all medical facilities to ensure that all user of radiation generators are complying with FANR requirements. By 2011, FANR started to hold "Meet Your Regulator Workshop" on annual basis as an interactive tool between FANR and its licensees. In the same year, FANR established the Radiation Protection Committee (RPC) that meets with local health authorities and stakeholders on quarterly basis to discuss radiation safety issues related to medical applications in the country. Part of FANR obligation and strategy is to manage the National Sources Register, as well the Orphan Sources Register. FANR regularly invites the IAEA to carry out certain appraisal missions to strengthen and enhance the effectiveness of the UAE regulatory infrastructure for nuclear safety, radiation protection, radioactive waste and transport safety.

### 2. Method

From the date of establishment, FANR qualified team started to build up a solid regulatory frame work via adopting IAEA regulations, regulatory guides and regulatory advice that can be followed clearly by medical radiation sources users and other stakeholders. In 2010, FANR started to receive license applications for facilities that use radiation source for medical purposes, FANR licensing team comprised of a group of qualified health physicists that are capable to evaluate the applications and provide recommendations to FANR management to issue licenses for facilities that meet FANR's radiation safety requirements for the medical field. Based on that, FANR licensees underwent an inspection programme run by a team of qualified inspectors to verify the arrangements of radiation protection. Moreover, FANR uses other effective regulatory tools to raise the level of compliance and build a strong radiation safety culture by holding regular international and local workshops that allow FANR to update and share with the licensees the major changes in regulatory requirements and analyze licensees' feedback for future improvements. In July 2011, FANR's Board of Management issued Resolution No. (4) For "Establishing the Radiation Protection Committee (RPC) in the State and Determining its Authorities and Work Policy". The RPC main goal is to provide recommendation on

how to improve the radiation protection infrastructure in the UAE. Additionally, FANR requested support from IAEA to provide appraisal missions like Integrated Regulatory Review Service (IRRS), Occupational Radiation Protection Appraisal Service (ORPAS), Education and Training Appraisal (EduTA). These missions help to ensure effectiveness of UAE regulatory infrastructure for radiation protection.

## RESULTS

Implementation and compliance level of FANR's radiation safety regulations in medicine improved remarkably over the seven years of operation. This was achieved by the existence of radiation safety regulations and guides, holding regular workshops with licensees, conducting regular inspections; all of which helped to organize and control the use of radiation sources and radioactive waste in medicine. At present, all radiation users have essential radiation safety resources and are more educated about radiation safety and security of radioactive materials than the past, which is reflected into the patient and public protection. By 2015 there was a large decrease in number of violations, and radiation incidents started to decrease notably. The formation of RPC resulted in the establishment of a Workgroup for a National Program for Radiation Safety in Medical Applications, which are currently involved with multiple projects for developing a national Dose Reference Levels (DRLs), national quality control testing criteria for X-Ray machines and a National Strategy for Education and Training in Radiation Protection. Moreover, the IAEA appraisal missions made recommendations and suggestions on actions to be taken to achieve improvements on the overall radiation protection infrastructure in the fields of patients' protection, radioactive waste management, emergency preparedness and response, education and training in radiation protection. In all the appraisal missions, FANR received a positive feedback from IAEA's expert for the amount of work done to achieve a robust regulatory control system in such a short time.

## DISCUSSION

### 2.1. (a) FANR Regulations

As a part of regulatory control on the medical practice, FANR issued two regulations and two regulatory guides. These regulations and regulatory guides were adopted from IAEA International Basic Safety Standards of General Safety Requirements Part 3 and IAEA Safety Requirements (TS- R -1). FANR Regulation 24 titled "Basic Safety Standards for Facilities and Activities Involving Ionising Radiation Other Than in Nuclear Facilities", defines the requirements that all licensees must comply with and follow in relation to the conduct of any regulated activity in the UAE.

FANR Regulation 13 titled "Safe Transport of Radioactive Materials", establishes the requirements for the safe transport of radioactive materials as defined in the IAEA Safety Standards Regulations for the Safe Transport of Radioactive Material within the UAE by road, rail, and waterways, and under the jurisdiction of the UAE. Nuclear medicine and radiotherapy licensees are required to follow and apply FANR Regulation 13 during transportation of radioactive sources.

FANR Regulatory Guide 007 "Radiation Safety" and Regulatory Guide 006 "Transportation Safety Guide" were issued to describe methods and/or criteria acceptable to FANR for meeting and implementing specific requirements in Regulations 24 and 13. Regulatory Guides 007 and 006 are not substitutes for Regulations 24 and 13, and compliance with them is not required. In some cases, licensees' methods of complying with the requirements in Regulation 24 and 13 deviates from the guidance set forth by the regulatory guide, which can only be acceptable if the alternatives provide assurance that the requirements are met.

### 2.2. (b) FANR Inspections

To ensure compliance with regulations and FANR's license conditions, a group of inspectors conduct announced and unannounced inspections for the medical licensees. The frequency of inspection depends on the level of the potential radiation risk and the licensee's inventory of radiation sources. See table 1

TABLE 1. Number of conducted inspections

Year	2010	2011	2012	2013	2014	2015	2016
No. of medical inspections	4	117	223	172	260	214	214

### 2.3. (c) Regular workshops with licensees

“Meet You Regulator Workshop” is an essential tool for communication and improvement that helps to raise the radiation safety awareness level of licensees. It is conducted on annual basis to update FANR’s licensees with changes in regulations, guides, licensing, inspections and penalties. It also aims to discuss some major inspection findings, emergency cases and radiation indicants; as well to share the feedback related to previous workshop, and to explain the lessons learnt from licensing, incidents and inspections, and to discuss important issues that all licensee must be aware of. Additionally, these workshops provide an opportunity for other local health authorities to present their requirements to medical licensees, to show the cooperation and consistent work between federal and local authorities regarding radiation safety regulations, and to pave the regulation path for the licensees to comply with radiation safety requirements from both regulatorybodies.

### 2.4. (d) FANR’s Radiation Protection Committee(RPC)

On 20<sup>th</sup> of July 2011, FANR’s Board of Management issued Resolution No. (4) Of 2011 “Establishing the Radiation Protection Committee in the State and Determining its Authorities and Work Policy.” The Radiation Protection Committee (RPC) purpose was to provide recommendation to improve the radiation protection infrastructure in the UAE and to provide advice on means to increase the awareness of radiation protection and to enhance the radiation safety culture. The RPC members includes representatives of 13 stakeholders of FANR that have impact on Radiation Protection, to date the RPC had a total number of 14 meetings.

One of the workgroup under the RPC is the National Program for Radiation Safety in Medical Applications Workgroup, which is comprised of members from all the health authorities in the UAE. The workgroup was established to implement a national program that emphasizes optimization of patient protection in medical applications. Thus, the workgroup has expanded on the work done by Dubai Health Authority in establishing the national diagnostic reference levels (DRLs) for specific X-Ray procedures. Moreover, the workgroup identified an action plan for the development of medical radiation protection infrastructure, such as quality control criteria for X-Ray machines. In addition to that, another workgroup was established for the National Strategy for Education and Training in Radiation Protection Workgroup, which focuses on implementing a national strategy, setting a criteria for interim recognition of qualified experts, and analyzing the present status and needs in Radiation Protection.

### 2.5. (e) IAEA appraisal missions

IAEA’s appraisal missions are excellent tools to improve the regulatory framework and the radiation protection infrastructure, by providing a space for the exchange of scientific and technical information; encouraging development of a national framework for competence; as well as identifying areas where performance should be improved to meet international standards. FANR completed three IAEA appraisal missions, which are: Integrated Regulatory Review Service (IRRS) in 2011 (and follow up mission extended to include a review of the transport of radioactive material in 2015), Occupational Radiation Protection Appraisal Service (ORPAS) in 2015, and Education and Training Appraisal (EduTA) in 2017.

The IRRS Team concluded that the recommendations and suggestions from the 2011 IRRS mission have been systematically implemented using a comprehensive action plan. Significant progress was made in many areas and many improvements were carried out following the implementation of the action plan. The ORPAS team delivered a preliminary report of its review, covering important findings identified during the mission, some of which were recognized as good practices.

### (f) Workshops and training

FANR conducted workshops and training for different UAE stakeholders in various areas of radiation protection. Below is a list of some workshops and training sessions.

- IAEA National Workshop on the Implementation of the IAEA General Safety Requirements Part 3 - Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, 1<sup>st</sup> to 3<sup>rd</sup> of June 2015
- IAEA regional training course on Train the Trainer 4<sup>th</sup> to 8<sup>th</sup> of October 2015.
- National workshop on Roles and Responsibilities of Qualified Expert and Radiation Protection Officers, 11<sup>th</sup> to 14<sup>th</sup> of October 2015.
- IAEA Expert Mission to review regulation and regulatory guide on disposal of radioactive waste 18<sup>th</sup> to 22<sup>nd</sup> of October 2015.

#### CONCLUSION

FANR controls the regulated activities in the UAE for medical licensees and other purposes. The existing Law, regulations, guides, instructions, and educated licensees immensely helped to build a strong radiation safety infrastructure in the medical field. The cooperation among local health authorities and establishment of Radiation Protection Committee resulted in forming certain workgroups that are focused on implementing national DRLs, national criteria for quality control testing, and national radiation safety educational and training strategy. The support of the IAEA appraisal missions identified areas where regulatory body performance should be improved to meet international standards.

## RADIATION AWARENESS AT UAE DURING THE NATIONAL DECLARATION: THE YEAR OF GIVING

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### Abstract

In 2016, United Arab Emirates President declared 2017 as “The Year of Giving”. Three key pillars for ‘giving’ are highlighted throughout the year: Corporate Social Responsibility (CSR), Volunteering, Serving the nation. UAE president message is: “The Year of Giving develops citizens’ sense of social responsibility, and helps individuals to release their talents by participating in positive activities that have an everlasting positive impact on society in the heart of the nation”. UAE medical radiation professionals are contributing in the Year of Giving through launching a radiation safety campaign as part of the ArabSafe program within Arab regions. The *ArabSafe\_UAE Chapter* intend to focus on students of different ages: Elementary, Secondary and Universities and Colleges levels. The aim of the current campaign 2017- 2018, to provide public awareness related to the beneficial uses of radiation in medicine and the means of avoiding unnecessary radiation exposure. This paper aims to present the activities of this campaign as *ArabSafe\_UAE Chapter* contribution in the global radiation safety approach. In addition, the future step is to expand ArabSafe throughout Gulf Cooperation Council (GCC) to introduce activities related to *ArabSafe\_GCC Chapter* in a challenge to establish active radiation safety teams within the Arabian Gulf regions.

### 1. INTRODUCTION:

“Giving” is the action that been encouraged through the history of the United Arab Emirates culture. Currently in 2016, UAE President declared 2017 as “The Year of Giving”. Throughout the 2017 year, three key pillars for ‘giving’ are highlighted: Corporate Social Responsibility (CSR), Volunteering and Serving the nation. HH Sheikh Khalifa bin Zayed Al Nahyan, UAE President, believe that “The more we have increase our help and given others, the more we get grace, stable, safer and more comfortable from our God ". The UAE message is: “The Year of Giving develops citizens’ sense of social responsibility, and helps individuals to release their talents by participating in positive activities that have an everlasting positive impact on society in the heart of the nation”. This reflects the UAE vision to build ambitious generations, proud of its identity and a focus of responsibility and generosity from the UAE people to help others by providing comfort and happiness in society [1-3].

His Highness Sheikh Mohammed bin Rashid Al Maktoum, UAE Prime Minister – Ruler of Dubai, started to implement the directives of His Highness the UAE President by setting a framework for activating the "Year of Giving / Year of Goodness" identifying targets and consolidating the efforts of volunteerism and establish social responsibility for both public and private sectors. According to that, he said that **we can achieve our excellence by upgrading our education system and by using modern technologies for education**. Moreover, providing an educational environment promotes scientific research to be aware to improve our thought and knowledge by having more experience by benefit others in our environment [2].

Dubai Health Authority- Department of Medical Education - is considering to contribute in the nation “Giving” approach through a voluntary work to raise awareness and to promote research in the Radiation Medicine fields. ArabSafe campaign and program been announced at the UAE medical community with the aim to encourage other UAE governmental and private sectors to participate and join the campaign activities. Students at schools and universities are the targets to raise awareness and to educate them in the field of radiation medicine and safety. The aim is to launch this campaign at UAE as ArabSafe\_UAE Chapter and to cooperate with our colleagues at the Arabian Gulf and the Arab World levels. The successful worldwide radiation protection programs and campaigns are valuable experiences for the ArabSafe activities to follow and to gain knowledge.

## 2. WORLDWIDE RADIATION PROTECTION PROGRAMS:

The global awareness radiation safety approaches supported by scientists in international administrations (mainly by WHO and IAEA) and by professional organizations; these include: EuroSafe, Image Gently and Image wisely at the USA, AfroSafe, Latinsafe , JapanSafe, CanadaSafe, ..etc. These are active movements to enhance the radiation safety for patients, public and staff. The joint statement of position of the IAEA and WHO known as **Bonn Call-for-Action** was the result of an international conference on radiation protection in medicine in December 2012. This statement encouraged professionals to be part of the global radiation safety initiatives and to establish their local campaigns to implement the international radiation safety practices.

ArabSafe group is aiming to promote radiation safety in the Arab world. It was established recently in January 2017 during the Arab Health Conference in Dubai, UAE, where a meeting was held among Arab medical professionals (Radiologists, Medical Physicists, Radiographers, Nuclear Medicine professionals, Healthcare Administrators). The meeting was enriched by the valuable attendance and support of Sheikh Hamdan Bin Rashid Al Maktoum Award for Medical Sciences and regulatory professionals from Saudi Arabia Food and Drug Department (SFDA, National Radiation Safety Committee) and UAE Federal Authority for Nuclear Regulation (FANR). This first meeting was supported by the valuable attendance of representatives from EuroSafe (European Society of Radiology) and AfroSafe to share their rich experiences. UAE professional association represented by Emirates Radiology Society (ERS) and Emirates Medical Physics Society (EMPS) contributed in organizing and attending the meeting. The meeting was followed by a session dedicated to radiation safety held within the scientific program of the Arab Health Total Radiology Conference in Dubai where a presentation was delivered on the ArabSafe campaign. Speakers from Saudi Arabia, EuroSafe, UNSCEAR, FANR and DHA contributed with their experiences and results of medical radiation safety activities.

ArabSafe was further inaugurated on 5 May 2017 during the Pan Arab Radiology Conference held in Marrakesh with the aim to promote medical radiation safety in the Arab region, Fig.1(5). ArabSafe aims are succeeding the strategic objectives of the worldwide campaigns which are linked to the implementation of the ten actions of the Bonn Call for Actions to promote and encourage compliance with standards, policies, strategies and activities for the promotion of radiation safety. Through the ArabSafe\_UAE Chapter activities, awareness on the beneficial uses of radiation in medicine and the means of avoiding risks and unnecessary radiation exposure are the targets to be achieved.

## 3. ArabSafe\_UAE Chapter Activities:

Based on the UAE vision to build ambitious generations, proud of its identity and to focus of responsibility towards spreading and sharing technology, sciences and research, the campaign aims to address students of different ages: Elementary, Secondary and Universities and Colleges levels on radiation benefits and safety implemented in the medical fields. The local approach to present generosity from the UAE people to help others by providing comfort and happiness in society will be reflected in one of the ArabSafe\_UAE Chapter aims; presented as a theme of: “**We aim to have Radiation for Mankind Happiness**”, Fig.2. This will aim to implement the radiation safety culture statement of the **Bonn Call for Action** and to highlight radiation in medicine benefits to UAE public environment.

During the ArabSafe\_UAE chapter activities, children group is among the awareness targets. We intend to visit schools to deliver a children story, in Arabic language titled as “**Shuaa Family**”. The story is of cartoon

characters on radiation types and uses in medical applications. Characters drawings will be included to simplify the presentations of radiation types commonly used in medicine, Fig. 3.

To reach a wider level of public, the UAE ArabSafe team intend to participate in the Dubai Health Authority (DHA) social media activities such as Instagram. The content of social media will be general information on radiation in Arabic; as videos on the following subjects:

- (a) What is radiation (radiation basics);
- (b) Types of radiation;
- (c) Benefits of radiation (uses of radiation in medicine);
- (d) Risk and safety of Ionizing Radiation (How to avoid the risk and maximize the benefits.).



FIG. 1: ArabSafe Secretary General Prof. Boudjema Mansouri and Deputy Secretary General Dr. Sarah Hagi during the inauguration ceremony. Photo and courtesy of the ISR Quality and Safety Alliance, a convener of the global radiation safety organizations ([http://www.isradiology.org/2017/isr/quality\\_arabsafe.php](http://www.isradiology.org/2017/isr/quality_arabsafe.php)).



FIG. 2: Theme used within the ArabSafe \_UAE Chapter.





FIG. 3: The ArabSafe\_UAE Chapter cartoon characters executed in children story.

#### 4. Conclusions

The UAE made a choice of 2017 as a “Year of Goodness”. It reflects a vision to build ambitious generations, proud of its identity and a focus of responsibility and generosity from the UAE people to help others by providing comfort and happiness in society. To promote radiation safety awareness, Dubai Health Authority (DHA) professionals specialized in Radiation in Medicine and concern with radiation safety intended to combine their activities in the ArabSafe campaign and program (UAE\_Chapter) with the UAE Year of Goodness to voluntarily service the UAE society.

The DHA professional teams of the ArabSafe\_UAE Chapter are introducing in the 2017 -2018 campaign: lectures on radiation in medicine to the employees in governmental organizations and to students. The DHA teams also introducing a children story in cartoon characters holding radiation names and signs to teach schoolchildren on radiation benefits and uses in medicine. Furthermore, the team intend to contribute in a video show on radiation in medicine to be presented on the DHA social media. These ArabSafe\_UAE Chapter activities are harmonized with the leadership by H. H. Sheikh Mohammed, UAE Prime Minister – Ruler of Dubai, who called all community to participate in this national plan by contributing special ideas and observations and activating of individuals in community volunteering and inspiring partisanship in a practical way in the new generations by social media or other technologies.

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# **THE RADIOLOGICAL PROTECTION IN THE FORMATION OF GENERAL PHYSICIAN AND THE RADIOLOGIST IN VENEZUELA**

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## **Abstract**

Within medical examinations for the diagnosis of diseases, X-rays images have a fundamental role; however, they have their indications. In order to avoid unnecessary radiographic examinations of patients, it is required that physicians and radiologists have the necessary knowledge about the effects of ionizing radiation and the radiological protection of the patient. This knowledge should be reflected in their study programs. A fundamental element in these Topics are their inclusion in the training of these professionals and from there the importance of evaluating whether these issues are addressed, and their level of complexity both theory and practice. This work evaluates the teaching of these themes in the training of the general physicians and radiologists, and makes the recommendations of the case In Venezuela there are eight Medical Faculties with twelve Medical Schools and ten postgraduates in Medical Images. Has been evaluated under the content the programs in general those that include content on aspects related to these aspects At the undergraduate level only one medical school has a radiology department where contents are taught on radiological physics, effects of ionizing radiation and radiation protection. With the training of radiologist physicians it was obtained that six postgraduate has these topics

## **1. INTRODUCTION**

Within medical examinations for the diagnosis of diseases, X-ray images are the most indicated, but have warnings and contraindications. As reported in the publication ICRP 104, the diagnostic use of radiation requires a methodology that guarantees high diagnostic gains, while minimizing possible harm [1] In this regard, the Spanish Society of Medical Radiology (SERAM) notes that in "Medical examinations for the diagnosis of diseases, X-ray images play a key role. However, the harmful effects of radiation used for medical purposes, and especially probabilistic ones, such as the induction of cancer, are frequently underestimated by health professionals"[2]

In this regard, in order to avoid unjustified radiographic examinations, and therefore unnecessary radiation of patients, physicians, and in particular radiologists, are generally required to acquire knowledge about the biological effects of radiation. Ionizing radiation and radiation protection, in particular, from the patient. In this direction, the International Atomic Energy Agency (IAEA) held the "International Conference on Radiation Protection in Medicine: Setting the Scene for the Next Decade". Of the ten main actions recommended at the conference, action 4 is aimed at Strengthen radiation protection education and training of health professionals, and in particular, prioritize radiation protection education and training for health professionals globally, targeting professionals using radiation in all medical and dental areas; and integrate radiation protection into the curricula of medical and dental schools, ensuring the establishment of a core competency in these areas [3]

This knowledge should be reflected in their curricula of medical schools, therefore, a key element in learning these subjects is their inclusion in training programs. Regarding this theme, the "Iberian-American Conference on Radiological Protection in Medicine", held in Madrid in 2016, aimed to identify problems for the implementation of these actions, propose possible solutions and define indicators of progress, and identified problems related to the significant number of unjustified radiological procedures, and the lack of continuing education and training programs in RP. Among the solutions proposed were: the introduction and integration of RP into pre and postgraduate education and, as indicators of progress, suggested: annual number of educational programs and activities [4]

The aforementioned is particularly relevant in the evaluation of the undergraduate education of the medical surgeons and Postgraduate radiologist who is taught in the universities and in particular in the contents of the subjects that make up the curriculum of medical schools. In order to evaluate the inclusion of

topics such as: a) physical fundamentals of techniques used in medical imaging, b) principles of operation of equipment used in medical imaging, c) biological effects of ionizing radiations, and d) fundamentals of the protection against the risks arising from exposure to ionizing radiation. Also, their level of complexity, both in theoretical training as in practice and related to the jobs they perform and specific roles. To this end, can be taken the Guidelines on Radiation Protection Education and Training of Medical Professionals in the European Union [5] and / or ICRP publication 113 “Education and Training in Radiological Protection for Diagnostic and Interventional Procedures” [6]

The present study evaluates, in the curricula of medical schools and postgraduate of medical images, in Venezuela, if there are subjects explicitly dedicated to discuss the topic mentioned in the previous paragraph or if, in any of the subjects that make up the curriculum of the medical schools, included contents on those themes. In addition, if in particular at the undergraduate level, there was a subject dedicated exclusively to treating student education in medical imaging

## **2. MATERIAL**

In Venezuela there are eight public universities with fourteen medical schools that grant the title of medical surgeon. These universities are listed below and the city where the medical schools are located: 1) Central University of Venezuela (UCV) with two headquarters in Caracas; 2) University of Carabobo (UC) with two headquarters: Valencia and Maracay; 3) National Experimental University Rómulo Gallegos (UNERM) with three headquarters: San Juan de Los Morros, Valle de la Pascua and Calabozo; 4) University of Zulia (LUZ) in Maracaibo; 5) University of Los Andes (ULA) with two headquarters: Mérida and Táchira; 6) Centro Occidental University “Lisandro Alvarado” (UCLA) with a headquarters in Barquisimeto; 7) National Experimental University “Francisco de Miranda” (UNEFM) with a headquarters in Coro; And 8) University of Oriente (UDO) with two headquarters: Anzoátegui and Ciudad Bolívar. Information published on the website of the Office of Planning of the University Sector (OPSU) [7] Each of the headquarters has its curriculum which are published in the web pages of these universities [8-19]

There are also ten postgraduate in Radiology distributed in the UCV, ULA, LUZ and UCLA. Their curriculum are also published on the websites of these universities [20-22]

## **3. METHODS**

A survey was applied to the resident physicians of the medical image postgraduates that are developed in the hospitals of Caracas, on their undergraduate studies. This survey was based on a checklist format with 28 questions, which could be answered on a scale valued with different degrees of compliance: 0 = Full absence of relevant information, 1 = Explicitly related irrelevant information, 2 = Information Relevant information implicitly, 3 = Explicitly related relevant information. The survey also asked the resident doctor about the University where he studied, the geographical location and the year of culmination.

In this sense, it was asked if there was any subject in the curricular design dedicated exclusively to developing the topics on: a) Diagnosis with medical imaging, b) physical fundamentals of techniques used in medical imaging, c) Principles of operation of equipment used in medical imaging, (d) biological effects of ionizing radiation, and (e) the basis of protection against the risks arising from exposure to ionizing radiation.

Likewise, specific questions were asked as to whether any of the subjects that make up the curriculum contained information related to: i) acquisition of skills in the localization and identification of the Radiological anatomy of the different imaging techniques based on clinical exploration and Pathophysiology reasoning, knowledge and understanding of the images of the human body, relationship between the morphology and structure of a medical image, the differences between normal and pathological images; ii) physical fundamentals of X-ray, ultrasound, CAT and MRI imaging; (iii) operating principles for medical X-ray equipment, ultrasound, CT scan, MRI; (iv) effects of radiation on the cell, systemic response to radiation, early effects and delayed effects of radiation, radiation and pregnancy; V) magnitudes and units in radiology, radiation detection and measurement, occupational exposure, medical exposure and exposure to the public.

The same list of questions was used to evaluate whether in the curriculum, both undergraduate medical and postgraduate radiologists, there were subjects dedicated exclusively to the topics mentioned and if these topics are implicit in some of their subjects that make up the curriculum.

#### 4. RESULTS

At the undergraduate level: 1) in relation to the subjects exclusively dedicated to developing the subjects evaluated, it was observed that one medical school has a teaching department of radiology attached to the University, from which a subject on diagnostic imaging, dictated in the 4th year, with a duration of one year and which is composed of two modules: the first one, with a duration of 3 months and dictated by a medical physicist, which deals explicitly with the topics of radiological physics, principles the operation of equipment used in medical imaging, the effects of ionizing radiation and radiation protection. The second module has duration of 6 months and is dictated by radiologists, which addresses the part corresponding to the diagnosis by medical images. 2) With regard to the answers to the questions on whether in any of the subjects that he had undergone undergraduate medicine had received information related to the topics mentioned in the questions, regarding medical imaging there was relevant information implicitly in different clinical services within their activities are diagnosed with medical images. (3) As regards questions relating to the physical fundamentals of techniques used in medical imaging, the principles of operation of equipment used in medical imaging, the biological effects of ionizing radiation and the protection fundamentals against the risks arising from exposure to ionizing radiation; the response had between the complete absence of relevant information and explicitly related irrelevant information.

With reference to the postgraduate program, when evaluating the curriculum for the formation of radiologists it was obtained that the entire postgraduate program in medical images that are dictated in Venezuela, have relevant information implicitly and/or explicitly, on these topics. It was possible to determine that everyone has among his subjects radiological physics; three universities have a subject dedicated to radiobiology and radiological protection and one has a subject on physical fundamentals and equipment in ultrasound and magnetic resonance. In one of the universities a medical physicist dictates the subjects during the three years of the postgraduate program. Three universities could not determine the programmatic content and therefore the level of depth the information imparted, nor the profession of the professor who dictates it. This is a pending task.

#### 5. DISCUSSION AND CONCLUSIONS

From the results obtained at the undergraduate level of medicine, it was observed that except in a medical school, the themes of radiological physics, biological effects of ionizing radiation and radiological protection, are absent from the curriculum in Venezuela.

In this sense, it is necessary to establish a subject with these topics in the education of the doctor and for this can be taken as an example the course of medical images that is dictated in that medical school, within which is a module with basic information on the basis of the biological effects of ionizing radiation, the principles of radiological physics and the fundamentals of radiation protection. This agenda largely coincides with that proposed in the publication ICRP 113, which includes the different groups of topics and the level of training recommended for the various categories of medically qualified personnel and other health care professionals [6]

Another element to emphasize from the evaluation on the dictation in that medical school is that this module was in charge of a medical physicist, which entails recommending that the module professor should have sufficient training and experience in the management of these topics.

With regard to the postgraduate course in Venezuela, for the training of physicians in medical imaging, the programmatic content of the postgraduate course of the Central University of Venezuela could be used as reference. Here physics of medical images, radiobiology and radiological protection are independent subjects that are part of the curriculum, distributed throughout the years of the postgraduate program, with sufficient depth and duration for the graduates to have a solid education in these aspects. Again it is recommended that a professor with sufficient theoretical training and practical experience carry out these subjects.

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# **IDENTIFIED ISSUES OF IMPLEMENTING NEW LEGISLATION INTO PRACTICE IN CZECH REPUBLIC**

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## **Abstract**

The new Atomic Act, Act No. 263/2016 Coll., and related implementing regulations, were adopted in the Czech Republic at the beginning of 2017. The new atomic law improves the legal regulation and brings some new elements focusing on increasing the level of radiation protection in the Czech Republic. The new Atomic Act transposes the latest EURATOM regulations and responds to the guidelines and other IAEA documents. As the subject some topics were selected topics that imply organizational changes, changes in procedures, or the introduction of new processes for users of ionizing sources, namely planning and verification of target volume irradiation at each medical exposure including radionuclide therapeutic applications, security of radionuclide sources and accidental exposures. The State Office for Nuclear Safety closely cooperates with experts across disciplines, with professional societies, in the implementation of the new legislation, and makes a number of guidelines to simplify the implementation of the new legislation into practice.

## **1. INTRODUCTION**

### **Dosimetry:**

Pursuant to the provisions of Section 8 (2) of Decree No. 422/2016 Coll., on Radiation Protection and Security of a Radioactive Source: Exposures of target volumes shall be individually planned for every person undergoing the treatment of medical exposure of patients for radiotherapeutic purposes, including the therapeutic applications of radionuclides. The target volume delivery should be appropriately verified, taking into account that doses to non-target volumes and tissues shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure. This paragraph is implementing the requirement of 59/2013 EURATOM Article 56.

According to the above-mentioned, provision dosimetry, planning and verification must be put into practice in therapy with unsealed radioactive sources or targeted radionuclide therapy. For each type of radical (curative) therapy, it will be necessary to develop a procedure for performing dosimetry, or to determine if it can be done at all.

The issue of dosimetry in the Czech Republic has never been dealt with in a comprehensive way. Several studies are currently being developed on this subject abroad and large-scale scientific teams are working on them. In the Czech Republic this issue is dealt with by experts from the Motol Faculty Hospital, who are also involved in international activities in this field, and cooperate with the State Office for Nuclear Safety to solve this problem.

### **Security of radionuclide sources:**

The existing legislation (Act No. 18/1997 Coll.) talked about the general conditions of safe operation of ionizing radiation sources. The licensee have an obligation under the quality system to establish and implement procedures so that unauthorized radiation, disposal or loss of resources can not occur.

The new legislation on radionuclide resource security focuses more on the precise responsibilities of the licensee, with a differentiated approach based on resource categorization. Within this graded access, 1. to 5.

Security category. The New Atomic Act provides the obligation to make security of radionuclide source 1 . up to 3. security category.

#### **Accidental and unintended exposures:**

The system of prevention and management of accidental and unintended exposures (further as accidental exposures) in radiotherapy was introduced in the Czech Republic in 1999, when the State Office for Nuclear Safety issued Recommendation *Accidental and unintended exposures in radiotherapy*, extended in 2008.

Although these procedures were not binding under current legislation (Act No. 18/1997 Coll.), the Accidental exposures in radiotherapy were recorded, classified, analyzed and reported to the State Office for Nuclear Safety in the years 2005-2016.

The term of accidental exposures means the incorrect exposure of a patient, the term radiological event is also used in the Czech Republic.

## 2. METHODS

#### **Dosimetry:**

The State Office for Nuclear Safety is very interested in the smooth implementation of dosimetry in practice and is aware of the lack of methodology and procedures. For this reason, the State Office for Nuclear Safety made an order to research targeted radionuclide therapy with unsealed radioactive sources. The aim of this study was to get a comprehensive overview of the state of this dosimetry issue both in the Czech Republic and internationally.

The next step was an order for processing of procedures for the determination of bio kinetics and absorbed doses in targeted radionuclide therapy for selected modalities. At the same time, an order was made to verify the established procedures in clinical practice and to consult the proposed procedures with other experts in clinical practice in the field of nuclear medicine.

#### **Security of radionuclide sources:**

The implementing legal regulation, which is Decree No. 422/2016 Coll., on radiation protection, sets out the requirements for the way of securing the radionuclide source. These requirements include the creation of a physical protection system and a response system to detect unauthorized admission. As part of the documentation submitted, when applying for a license, the applicant must submit a documentation named Plan of the Security, which must include a description of all elements of the security system. Due to the correct and simpler implementation of the requirement for the safety of radionuclide sources, the State Office for Nuclear Safety has prepared a guideline that includes issues in a general context for all types of workplaces with sources of ionizing radiation, including the ionizing sources used for medicalexposure.

#### **Accidental exposures:**

The requirements of the Directive 59/2013 EURATOM, Article 63, *Accidental and unintended exposures* have been implemented in new legislation not only for radiotherapy but also for nuclear medicine, radio diagnostics and interventional radiology. The law establishes the license holders an obligation to minimize the probability of accidental exposures occurrence, to carry out a risk analysis of the occurrence of accidental exposures in radiotherapy, to investigate and to take measures. License holders are also required to inform the patient or his or her legal representative, and the State Office for Nuclear Safety in case of serious accidental exposure.

The accidental exposures are classified according to their severity, for the reason of graduated approach in investigation, recording and reporting. Radiological events shall be classified with respect to their seriousness into categories A, B and C. The criteria for radiological event classification are specified in in the Decree No. 422/2016 Coll., on Radiation Protection and Security of a Radioactive Source. Category A or B radiological events refer to serious radiological events.

### 3. RESULTS

#### **Dosimetry:**

In the first phase of dosimetry preparation procedures for targeted radionuclide therapy, individual treatment modalities and possible dosimetry procedures have been identified and described based on the experience of practitioners and foreign available materials and studies.

These are the following methods of radionuclide therapy:

$^{131}\text{I}$  NaI treatment of thyroid gland disorders,  $^{131}\text{I}$  NaI treatment of differentiated thyroid carcinoma,  $^{90}\text{Y}$  treatment of non-Hodgkin's lymphoma,  $^{90}\text{Y}$  treatment of hepatocellular tumors and  $^{131}\text{I}$  mIBG treatment of neuroblastomas,  $^{131}\text{I}$  mIBG treatment of neuroendocrine tumors in adults,  $^{177}\text{Lu}$  labeled radiopeptides - treatment of neuroendocrine disorders of adults, radiosynovectomy, treatment of metastases,  $^{223}\text{Ra}$  treatment of bone metastases of castrationally-resistant prostate cancer.

Another output of this study was an estimate of the financial and personnel costs of the methods considered. Methods of treatment have been identified for dosimetry according to current possibilities.

The next step was to make an order for processing of procedures for the determination of biokinetics and absorbed doses in targeted radionuclide therapy for selected modalities. The method will be processed for planning and verification of the absorbed dose in the target tissue for the treatment of benign thyroid diseases with  $^{131}\text{I}$ , methods for determining the whole body absorbed dose (diagnosis and therapy of differentiated thyroid gland with  $^{131}\text{I}$ , therapy with  $^{131}\text{I}$ -mIBG), methods for determining absorbed dose in lesion (diagnosis and therapy of differentiated thyroid gland with  $^{131}\text{I}$ , therapy with  $^{131}\text{I}$ -mIBG), methods for determining absorbed dose in blood (diagnosis and therapy of differentiated thyroid gland with  $^{131}\text{I}$ , therapy with  $^{131}\text{I}$ -mIBG), methods for planning of therapy and verifying the absorbed dose in therapy of hepatocellular carcinomas with  $^{90}\text{Y}$  microspheres. At the same time, it will be verified whether the established clinical practice procedures are feasible. Proposed procedures will be consulted with other doctors in the field of nuclear medicine.

Based on the results of all the studies, the State Office for Nuclear Safety will issue a certified dosimetry methodology for target radionuclide therapy with unsealed radioactive sources for selected modalities. Publication of these methodologies is expected in 2018. In the following years, we will continue to address this issue and will make other orders of other therapeutic methods.

#### **Security of radionuclide sources:**

The Recommendation on "*Security of Radionuclide Sources*" states the exact procedure for licensee to perform security at each type of workplace; how to define a security category, how to ensure all the functions of the physical protection system (deterrence, detection, delay, response), how to make administrative, personnel and organizational steps and how to prepare the documentation (Plan of the Security). The requirements for ionizing sources are used in brachytherapy, radionuclide irradiators or blood irradiators, for example.

Although there has not yet been a case of intentional theft of ionizing radiation sources for terrorist or other purposes in the Czech Republic, it is important to maintain and implement a policy of safety and security in the use of ionizing radiation sources.

#### **Accidental exposures:**

The Accidental exposures prevention and management system will be part of the *Management system programme* or *Radiation protection assurance programme*. In order to facilitate the introduction of the requirements of the new legislation in practice, the State Office for Nuclear Safety is preparing a new *Recommendation - Accidental exposures* in cooperation with experts from the National Radiation Protection Institute. This Recommendation will include, in particular, an explanation of Accidental exposures procedures and classification in nuclear medicine, radio diagnostics and interventional radiology (including Accidental exposures reoccurring cases). An important part will be devoted to accidental exposures prevention, risk analysis methods, e.g. Failure Mode and Effect Analysis- FMEA.



#### 4. DISCUSSION AND CONCLUSIONS

The new Atomic Act, Act No. 263/2016 Coll., and related implementing regulations, were adopted in the Czech Republic of the beginning of 2017. The new atomic law improves the legal regulation and brings some new elements focusing on increasing the level of radiation protection in the Czech Republic. The new Atomic Act transposes the latest EURATOM regulations and responds to the guidelines and other IAEA documents. As the subject some topics were selected topics that imply organizational changes, changes in procedures, or the introduction of new processes for users of ionizing sources, namely planning and verification of target volume irradiation at each medical exposure including radionuclide therapeutic applications, security of radionuclide sources and accidental exposures. The State Office for Nuclear Safety closely cooperates with experts across disciplines, with professional societies, in the implementation of the new legislation, and makes a number of guidelines to simplify the implementation of the new legislation into practice.

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# EVALUATION OF CT SCAN PRACTICES AMONG CT SCAN RADIOGRAPHER IN TERTIARY CARE CENTERS OF NEPAL

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## ABSTRACT

**Introduction:** CT scan practices should be optimized for patient radiation dose reduction; a survey among those involved populations for their practices will provide the valuable data for interpreting the current scenario and also gives feedback for concerned authorities. **Methods:** A descriptive study was carried out with questionnaire survey among sixty four radiographer of different hospital of Nepal in order to determine the knowledge, attitude and practices on different aspects of patient radiation protection during CT Scanning. **Results:** Total of 64 participants were involved for the study all were aware about their equipment condition but most of them lacked proper practices regarding patient dose reduction, 71.8% perform regular triple phase abdominal scan, and only 7.8% respondent found to modify scanning parameter regularly, 75% of them didn't change the start and end location during different phase of scan and almost 6.2% of them perform water phantom test .Only about 25% population have idea of DRL and recommended effective dose. **Conclusions:** Some corrective measure should be initiated to change the practice pattern of technologist. Mainly their habit towards tailoring of scanning protocol with anatomical and pathological indication is needed, so that patient dose can be minimized.

**Keywords:** CT, practices, radiation protection, tertiary care, Nepal

## INTRODUCTION

Radiation hazard from Computerized tomography scan is an important issue because it is high radiation dose procedure. As compared with plain-film radiography, CT involves much higher doses of radiation, resulting in a marked increase in radiation exposure in the population[1,2]. Commonly protocol driven CT technique is used and the technical parameters (kVp, mAs, pitch & SL) are typically constant and not adjusted according to different body habitus of patients. Automatic mA, auto kV and shielding the superficial organs can play an important role in dose optimization during CT scanning. [3,4] The CT image quality is influenced by scanning parameters. Clinically acceptable image quality with minimal possible dose is of prime importance for radiation protection purpose. [5]

Scanning the arterial phase in low kVp is one of the methods for dose reduction. In addition the use of low kilo voltage has various advantages in post contrast studies like better CNR and better contrast enhancement with effective utilization of k-edge absorption of iodine contrast [6] Modern CT scanners present dose awareness features, since they offer a direct display of dose information, such as the CTDI<sub>vol</sub> and the DLP [7] This feature could potentially contribute to the reduction of patient doses, since the DLP values are readily available prior to the actual scanning and, thus, the examination protocols can be appropriately adjusted in order to offer

the required image quality with the smallest possible patient dose.

The multiphasic scanning protocol is more often used in abdominal imaging. Radiation sensitive organs like gonads and other viscera are located in abdomino-pelvic region. Hence these organs receive more exposure from radiation in multiphase study. Radiation dose delivered in such protocols be according to ALARA principle. Hence if possible the dose should be modified and adjusted according to patient's physical and clinical condition. [8]. CT manufacturers generally optimize the CT protocols with radiation doses in higher range for better image quality and clarity. Radiologic technologists should also be aware of the amount of radiation delivered for dose reduction purposes. So in our context, exposure condition should be modified according to the Nepalese body standards.

There are various ways to reduce the overall radiation dose delivered to patient from CT.[9] Reducing peak kilovoltage, tube current modulation, Iterative reconstruction, proper filtration, reducing multiphase study and proper education to physician and radiologic technologist helps in reducing the overall radiation dose. In our study we made a survey for finding the technologist performance and knowledge for reducing radiation dose to patient. Important technical parameter

were questioned and reviewed to find out the actual performance status in tertiary care center.

It is known fact that the estimated risk of radiation induced cancer and other effects are also linked to radiation dose and hence dose reduction is very essential. Radiological technologist have pivotal role for patient dose reduction. A survey was conducted among the CT radiographers about their practical knowledge on patient radiation protection, which will provide a feedback for current practice in tertiary (major) care center of Nepal and will provide valuable data for concern authorities. Furthermore such a studies will help to design a training program for respondent in national and international context.

### METHODOLOGY

To achieve the objectives, review questions and questionnaires were developed. In order to understand the level of existing practices, fourteen review questions were studied under following headings. Response was analyzed (proper response or improper response and the response between them was categorized as partial answer). by using descriptive analysis to generate results and conclusion.

1. Equipment condition
2. Education status
3. Dose modulation
4. Knowledge regarding patient protective measure like- low kVp scanning, DLP, recommended dose level.

### OBSERVATION AND RESULTS

Total 64 respondents were enrolled. Out of them 18 (28.1%) were female and 46(71.8%) were male (Fig 1)

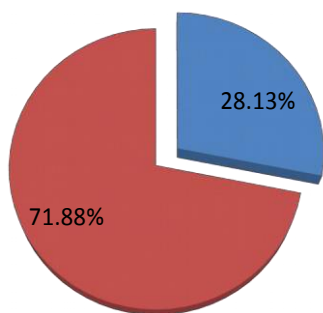


Fig. 1: Gender distribution of subjects.

There was wide distribution of study subjects age wise, most of the respondent were 20-30 years age group and least number are 50-60 years age group.

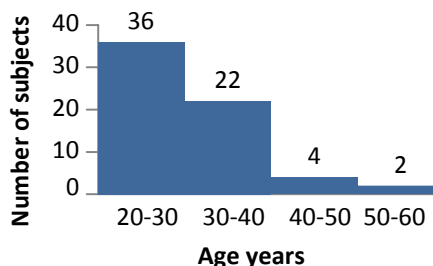


Fig.2. Age distribution of subjects

There was a wide variation of subjects according to qualification: majority of participants were graduate among them 6% had completed their masters degree, but more than one third population were working without proper education as recommended by governing authority.

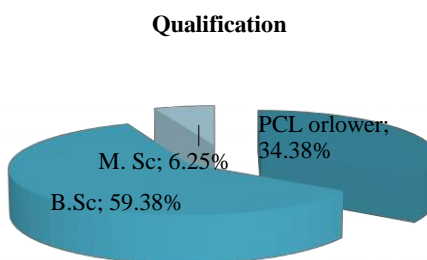


Fig.3. Qualification distribution of subjects.

There was variation in Experience among subjects were found with most of population having experience less than 5 year found

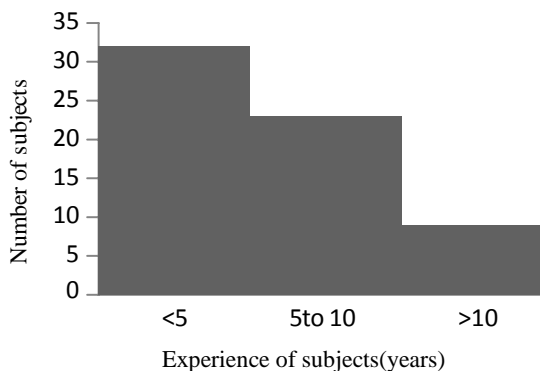


Fig. 5: Experience of subjects.

Different patient radiation dose protection parameters were evaluated by questionnaire. Regarding equipment model all answered correctly, but regarding dose modulation in their scanner about 54% answered incorrectly, about 54% of them had knowledge relating to the advantage of low kVp but more than 96% radiographer were found not observing dose displayed in scanner. Almost 68.7% of them had idea of recommended dose for organ but most of them lacked idea regarding recommended dose value and DRL value for particular investigation as shown.

Table no.1. Response regarding Different protective technique of enrolled subjects.

Parameters	Proper	Partial	Improper
About model and scanner	64		
Dose modulation	29	-	35
Advantage of low kVp	35	21	8
Monitoring of dose index	2	40	22
Idea of recommended dose	20	-	44
Recommended dose for Organ	44	-	20
Idea of DRL	16	-	48
Effective dose in CT	14		50
<b>Daily water phantom test</b>	4	-	60
How often monitor CTDI displayed in scanner	2	40	22
Parameters	Proper	Partial	Improper

Subject were question for their practices regarding abdominal scan with following option, most of respondent answered they do regularly for all patient and only 13 percentage answered they do with limited clinical indication.

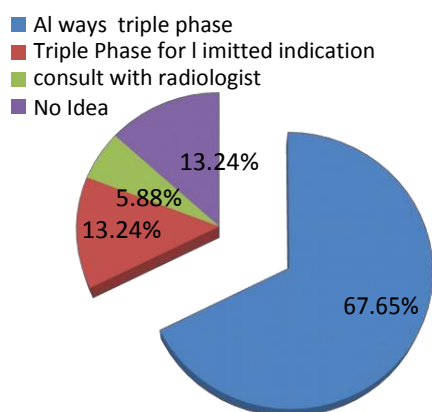


Fig.6: Response regarding multiphase abdomen scan

Regarding dose optimization practices of the participant questions related to dose adjustment with body habitus and limiting scan coverage range were asked. Most of the participants modified them only according to their convenience.

Table no.2. Response of respondent regarding their practices

Questions	Always	Limitedly (sometime)	Never
How often you adjust scanning parameter	7.8%	53.1%	39%
How often you modify start and end location	3.1%	75%	21.8%

## DISCUSSION

Dose reduction in CT scan means careful optimization of scanning parameter which is performed by CT technologist. They should know common tips and tricks for proper scanning so that dose received by patient are as low as reasonably achievable and a good image quality is achieved with minimum dose. The dose received by patient can be reduced by designing of instrument in such a way so that instrument can automatically reduce dose based on patient attenuation characteristics. Most importantly dose reduction is solely based on technologist performance practices. We evaluated the technologist performance practices in tertiary care center where most qualified staff were present. After the survey we found out that educational status of one third CT radiographer was lower than recommended by Nepal Health Professional Council.

Regarding knowledge of equipment we found most responses of participant were correct, but regarding quality assurance test almost all responses were “no” or “rare”. Knowledge of Computed Tomography Dose Index (CTDI), DLP and effective dose calculation in CT scan were evaluated in this study and about 53 % of respondent had knowledge about these parameters but most of the respondent lacked knowledge of diagnostic reference level (DRL) and recommended dose limit for different organ. On the another question only 21 % population have idea of calculation of effective dose in CT scan suggesting lack of knowledge related to it. Patient size is critical value for protocol optimization, so protocol should be tailored by adjusting patient parameter to patient size. The report from our survey showed that almost 90% of respondent did not modify scanning parameter which are not according to the finding of Costello JE et.al. where they suggested tailoring scanning parameter with patient condition.[10]A study conducted by Goldman et al mentioned protocol on basis of patient weight at Massachusetts General Hospital where weight specific protocol were utilized.[11]

For the evaluation of technique of limiting anatomic coverage to specific organ which is helpful for minimizing radiation dose by limiting scan length in multi-Phase examination, we found that most of radiographers were utilizing same length for all phase which were not according to “Guideline to radiation protection”. Altering protocols to minimize the anatomy radiated should be done in consultation with the other radiologists at one's institution because they may have different opinions regarding the “critical” anatomy. Depending on the particular indication, discussion with the referring clinicians may also be necessary to ensure that the relevant clinical issues and limitations of the modified protocol are addressed. [12]

With a reduction of the tube voltage from 120 kV to 80 kV at abdominal CT, the radiation dose is reduced by 32%

to 42%. [13] Similarly we found significant populations have idea of low kVp scanning but about 7% respondent modify the parameter based on patient size which contradicts the finding of research conducted by Hollingsworth C et. al in pediatric patients in which size-based scanning is practiced by more pediatric radiologists. [14]

While performing multiple phases during abdominal scanning additional dose is added. The finding of present survey indicates that large number of the respondent perform triple phase contrast scanning for all abdominal scan which is comparable study conducted by Guite KM et al. where more than 50% of patients were exposed to at least one unindicated phase, [15]. In another study conducted by Chan MG et al taking delayed phase scan is unnecessary because about 95.8% case were of no benefit [11]. Similarly study conducted by Goldman et al mentioned that due to cumulative effects of radiation dose to patients with liver disease dose should be minimized because of frequent repeated examination in such group. [12] Furthermore another study conducted by Guite KM et al [15] also suggested no clinical benefit of delayed scan.

## CONCLUSION

In this questionnaire survey we found out that most of the radiographers were unaware of proper practices regarding patient radiation dose reduction. Most of them used multiphase scanning technique for abdominal scanning routinely without adjusting exposure parameter. In addition we also found that they did not change the anatomical coverage during scan. For patient protection, technologist should be aware of the radiation dose data and diagnostic reference level for individual scan so that dose received should be as low as reasonably achievable. Overall we found some corrective measure should be initiated to change the practice pattern of technologist. Mainly their habit towards tailoring of scanning protocol with anatomical and pathological indication is needed, so that patient dose can be minimized.

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# **PRACTICAL USE OF IONIZING RADIATION AND RADIATION PROTECTION IN MEDICAL ACTIVITIES AT TRAN HUNG DAO GENERAL HOSPITAL**

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## **Abstract**

There are five main categories of applications using ionizing radiation in Tran Hung Dao General Hospital which are medical X-ray, nuclear medicine, radiotherapy, blood irradiation and radiopharmaceutical production. The medical X-ray includes diagnostic, interventional, dental, portable X-ray and mammography. 37 X-ray machines are licensed and utilized in hospital. For nuclear medicine, we use 10 unsealed radioisotope sources for diagnosis and therapeutic treatment. The radioactive source used in the blood irradiator is Cs-137 with an activity of 112 TBq in 2008. Especially, there is a cyclotron which is located in site of hospital. The cyclotron is able to produce radiopharmaceuticals for PET and SPECT. Radiation protection is realized to be crucially necessary for operation of such ionizing radiation devices. A radiation protection committee was established to help hospital to control any activity related to ionizing radiation. Radiation protection consideration extensively includes shielding design of room where radiation-emitted device is located, issue of rule and procedure for operation of specify device or source, education on radiation protection for staffs, QC and all other relevant aspects. As a result, there is no situation which leads to harmless for medical staffs and unintended exposure for patients.

## 1. INTRODUCTION

The use of ionising radiation is now pervasive and routine in almost branches and specialties of medicine. The inherent properties of ionising radiation provide many benefits but also may cause potential harm. In the practice of medicine, there must be a judgement made concerning the benefit to risk ratio. This requires not only knowledge of medicine but also of the radiation risks. Especially, there are all kind of radiation applications in medicine which are developed in Tran Hung Dao General Hospital in Hanoi, Vietnam. Tran Hung Dao Hospital was established in 1951. The hospital is a high specialized multi-field medical facility in Hanoi and is considered one of the largest in Vietnam. There are five main categories of applications using ionizing radiation in Tran Hung Dao General Hospital which are medical X-ray, nuclear medicine, radiotherapy, blood irradiation and radiopharmaceutical production. There are 21 diagnostic X-ray meachines, 8 CT scanners, 2 intervention X-ray machines, 4 dental X-ray, 01 bone densitometer and one mammography. Some of them are outstanding techique, such as Toshiba Aquilion One CT scanner with 320-row detector and Optima 580 CT scanner with a efficient virtual simulation tool for radiotherapy planning system.



Figure 1.1. Toshiba Aquilion One CT scanner



Figure 1.2. Optima 580 CT scanner

Nuclear medicine is one of biggest application of radiation in medical activity at Tran Hung Dao General Hospital. There are 4 SPECT and 01 PET/CT which are already used for medical imaging. Recently, 01 SPECT/CT and 01 PET/CT have installed and have been done acceptance test and operation education. 10 unsealed radiopharmaceuticals are used for nuclear medicine at the hospital. Especially, I-131 radioisotope is used for thyroid cancer therapy with 10 isolation rooms for treatment.



Figure 1.3. PET/CT facility.

Interventional cardiologists, radiologists, orthopaedic and vascular surgeons and others, who actually operate medical x-ray equipment or use radiation sources, should possess more information on proper technique and dose management than is contained here. However, this text may provide a useful starting point.

The most common ionising radiations used in medicine are X, gamma, beta rays and electrons. Ionising radiation is only one part of the electromagnetic spectrum. There are numerous other radiations (e.g. visible light, infrared waves, high frequency and radiofrequency electromagnetic waves) that do not possess the ability to ionize atoms of the absorbing matter. The present text deals only with the use of ionising radiation in medicine

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## 2. RADIATION ACTIVITIES IN TRAN HUNG DAO GENERAL HOSPITAL

Exposure to radiation can, however, harm the health of both patients and medical staff. With human exposure to ionising radiation in medicine exceeding that of any other man-made source, it is important to have safety standards in place.

The most effective way to reduce patient risk in radiological examinations is through appropriate test performance and through the optimization of radiological protection for the patient. These are primarily the responsibility of the radiologist, the nuclear medicine clinician and the health physicist.

As a matter of policy, certain procedures should be phased out, as better alternatives become available. For example, the use of fluoroscopy or photofluorography in the screening of tuberculosis in children is no longer indicated (normal radiography is a less harmful alternative for this age group), and more generally, fluoroscopy without electronic image intensification exposes patients to unacceptably high doses of radiation compared to alternatives. Such procedures are currently banned in most developed countries

Radiation dose reduction must therefore be a priority goal particularly for procedures carried out on children, or in pregnancy. In pediatric use, dose reduction is achieved in practice principally through technical factors specific to children. In nuclear medicine, the smaller size of children means that acceptable images can be achieved using smaller administered doses than for adults, whilst in diagnostic radiology, particular care must be exercised in ensuring that radiation is focused as narrowly as possible on the specific area of interest.

Before a diagnostic procedure is performed on a female patient of child-bearing age, it is important to determine whether she may be pregnant, and if so, whether the fetus is in the primary radiation area, and whether the procedure might involve a relatively high dose (e.g. barium enema or pelvic CT scan). Medically-indicated diagnostic studies which are remote from the fetus (e.g. x-rays of the chest or extremities, lung scans) can be safely carried out at any time during pregnancy, provided the equipment is in good working order. Commonly, the benefit of making an informed diagnosis outweighs the potential contra-indications of the radiation risk in such cases.

CT can be a life-saving tool for diagnosing illness and injury in children. Between 5 and 9 million CT examinations are performed on children annually in the United States alone, and use of this procedure is increasing steadily, both due to its utility in common diseases and because of technical innovation.

Yet despite its many clear advantages, CT also poses a major disadvantage in terms of significant radiation exposure. Despite accounting for only 12% of diagnostic radiological procedures in the USA, CT scans deliver around 49% of the US population's collective radiation absorption from medical procedures as a whole

There are countless areas where the power of radiation and nuclear techniques has been harnessed for the benefit of mankind, not only in medicine, but also in industry, agriculture and other fields of science and technology. The benefits to patients in terms of lives saved through improved medical diagnosis and treatment techniques are countless and the well-trained and controlled use of radiation has become a key part of modern medical treatment, especially for certain forms of cancer.

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TABLE 1. EXAMPLE TABLE

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In accordance with good academic practice, reference sources should be cited in the text to support the assertions it contains. IAEA style is to use numbered references in square brackets. There are different formats for sources such as books [1], internal reports [2], personal communication [3], unpublished data [4], single chapters from books [5], journal articles [6], websites and on-line databases [7], papers from a proceedings [8], presentations including slides and handouts [9], and INFCIRCs [10]. Sources ‘in preparation’ or ‘in press’ use these terms in place of the year. Titles are given in their original languages if these use Latin alphabets, or translated into English for languages that do not use Latin alphabets. Please see the reference list below for examples of how to format the sources numbered [1–11]. The text in the reference list is Times New Roman 9 point regular.

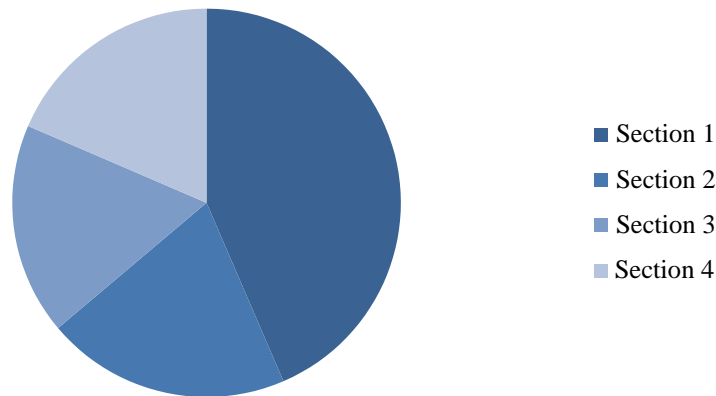


FIG. 1. Chart showing the number of words in each section of this example paper.

## 8. BIBLIOGRAPHY

A bibliography is an optional section. If a source is not cited in the text but may nevertheless be of interest to the reader, it can be included in a bibliography, which follows the reference list. Sources that appear in the reference list should not be included in the bibliography. Please see the example bibliography at the end of this paper. The text in the bibliography is Times New Roman 9 point regular.

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Put the email address after the affiliation of the corresponding author, whether he or she is the first author or not. Please put the name of the authors’ organization(s) in English. Do not give the organization’s street address or postal code. For international organizations, no country is given. Please use the name of the country as it is given in the IAEA Member State list (for example, use ‘Russian Federation’, not ‘Russia’).

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## **ACKNOWLEDGEMENTS**

The heading of the acknowledgements section is Times New Roman 10 point bold capitals, centred. The acknowledgements section is an optional section and can be used to list funding bodies and other sponsors of the research, and to mention people who supported the research but whose contribution was not of a type to merit authorship of the paper.

## **REFERENCES**

- [1] AUTHOR, A., Book Title in Title Case, Series No. if applicable, Publisher, Place of Publication (Year).
- [2] AUTHOR, A., Internal Report Title in Title Case, internal report, Organization, Location, Year.
- [3] LETTER-WRITER, A., Organization, personal communication, Year.
- [4] RESEARCHER, A., Organization, unpublished data.

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- [5] CHAPTER-AUTHOR, A., "Title of chapter in sentence case", Book Title in Title Case, Publisher, Place of Publication (Year).
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- [9] PRESENTER, A., "Title of presentation in sentence case", Paper No., paper presented at Organization seminar on subject, Location, year.
- [10] Title of INFCIRC in Title Case, INFCIRC No., IAEA, Vienna (Year).

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AUTHOR, A., AUTHOR, B., Book Title in Title Case, Series No. if applicable, Publisher, Place of Publication (Year).

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## **DEVELOPMENT OF A RADIATION PROTECTION CULTURE IN TRINIDAD AND TOBAGO**

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### **Abstract**

The paper seeks to evaluate the status of the radiation protection culture in Trinidad and Tobago and propose a way forward for implementation and improvement. Since obtaining IAEA membership in November of 2012, Trinidad and Tobago has made several strides in the implementation and development of a radiation protection culture. The main accomplishments includes the drafting of a National Radiation Emergency Plan, preparation of a finalised draft of legislation “Ionizing radiation Protection and Security Bill”, establishment of a radiation safety committee for public health institutions and participating in various training and education courses by the IAEA to develop and strengthen our regulatory framework. Law is good, but culture is better, therefore the future of safe radiation practices in Trinidad and Tobago depends on the development of a strong radiation protection and safety culture.

### **1. INTRODUCTION**

The Republic of Trinidad and Tobago (T&T) is a twin island, developing nation located in the Caribbean. Unlike its English-speaking neighbours, Trinidad and Tobago’s economy is primarily industrial with focus on petroleum and petrochemicals manufacture. As a result, the use of ionizing radiation in T&T is concentrated in both the industrial and medical sectors. In fact, it is estimated that forty percent (40%) of radioactive sources are used in the medical sector and sixty percent (60%) in the industrial sector [1] with the petrochemical industry being the primary user of radioactive sources particularly for well logging operations and radiographic analysis of pipelines. The need for establishing a radiation protection culture on a national level, and improving radiation protection culture at an organizational level is therefore evident. This paper seeks to analyse the radiation protection culture of the medical sector, however, when discussing the very principles of radiation protection there are no difference between sectors [2] and thus the suggestions, implementation and change can be applied across the board.

### **2. RADIATION PROTECTION CULTURE AND ITS IMPORTANCE**

Radiation Protection focuses on people and behaviour (culture) to prevent harm to the worker and others when hazardous equipment is being operated, it encompasses a blend of science, ethics, values and experience and also utilizes various approaches, including those related to the wider safety culture outlined by the IAEA guidelines and the Nuclear Regulatory Commission, United States of America [2]. Radiation Protection culture is effectively a sub-set of the wider safety culture, and it must integrate with these wider cultural considerations in any workplace. It is particularly important that Radiation Protection culture considerations are not developed per country or per organization since almost all of the thoughts already developed and published on nuclear safety or process safety culture are directly relevant to Radiation Protection culture. Its principles include the use of well-established justification, optimization and dose limitation standards, but also involves the development of competence through training and education.

Embedding Radiation protection at a cultural level within an organization is by far the most effective way of delivering the improved performance and world-class excellence in our institutions. Culture implementation promotes radiation risk awareness, establishes fundamentals of radiation safety and protection according to science and values, promotes shared responsibility for safety and efficiency amongst practitioners, operators,

management and regulators and allows for the maintenance of radiation protection heritage throughout the lifetime of the organization. [2]

The implication of a strong radiation protection culture for the reduction and prevention of radiation incidence and reduction of doses to as low as reasonably achievable (ALARA) is impossible to overemphasize. Safety Culture is at the root of all our behaviour in the workplace and a good safety culture, will manifest itself in the adoption of safe behaviour amongst all workers and the prevention of incidents and hazards to their colleagues. [3]. Achieving this is a challenging task and progress for developing countries depends on the priority of the government and its understanding and conviction of the basic requirements for protection against the risks associated with exposure to ionizing radiation. [4]The pressures of cost and productivity, essential to the survival of a business or the delivery of high quality healthcare, often appear to compete with the desire for high levels of safety. Yet experience shows that far from being in competition, good safety culture and good, cost effective performance and customer care are complementary. The same priorities and patterns of behaviour inherent in a good safety culture also support high quality operations and productivity. [3]

### 3. OUR CURRENT STATUS

According to Rozental, the main reason for the deficiency of sources control and dose limitation are related to the lack of an appropriate legal and regulatory framework [4]. He also states that without proper control of sources and practices, including waste management, there is a likely high percentage of overexposure to hospital patients and industrial radiography workers. [4] This statement proved to be true in Trinidad and Tobago with the famously reported incident of 2010 at a private radiotherapy facility resulting in an overexposure to two hundred and twenty three (223) patients [5].

Following this incident, Trinidad and Tobago has made many advances in the development and implementation of a radiation protection programme. The first significant step was attaining membership with the International Atomic Energy Agency (IAEA) in November 2012 [6]. Through membership with the IAEA, Trinidad and Tobago has been able to strengthen its radiation protection culture by the involvement in many training courses and conferences, see Table 1. These courses are aimed on the development and implementation of a national regulatory body and ionizing radiation protection laws. Through these trainings, a revised source inventory has been produced according to the IAEA's guidelines.

At present, there is no single organization or regulatory framework that completely and comprehensively covers the control or protection of radiation sources. The responsibility is shared between different government ministries and state agencies governed by various international conventions, individual legislation and regulations e.g. Ministry of National Security, Ministry of Health, Ministry of Foreign and CARICOM Affairs, Ministry of Agriculture, Land and Fisheries, Occupational Safety and Health Agency, Customs and Excise Division, Office of Disaster Preparedness and Management, Environmental Management Authority, Institute of Marine Affairs, Solid Waste Management Company Ltd and T&T Bureau of Standards. However, through trainings and direct assistance from the IAEA, the creation of our national radiation safety regulatory framework has progressed.

Currently, the Ionizing Radiation Protection and Security Bill, 2016 is in its final draft and is presently under comprehensive review by the Pre-Legislative Review Committee of the Ministry of the Attorney General and Legal Affairs [1]. Subsequently the bill will be submitted to the Legislation Review Committee and then to the Parliament of Trinidad and Tobago. The Bill aims to provide for the safe, secure and peaceful uses of ionizing radiation, for the establishment of a National Ionizing Radiation and Security Authority.

Additionally, there exist the Ionizing Radiation (Protection of Employees) Regulations, 2013 and the Ionizing Radiation (Medical Exposure) Regulations, 2013. These two draft Regulations were prepared in 2008 by the Ministry of Health Technical Working group and were based on the IAEA Basic Safety Standards of 2007. These two draft Regulations require review and updating to ensure consistency with the present Ionizing Radiation Protection and Security Bill, 2016 and conformity with the IAEA's present relevant Safety Standards.

Trinidad and Tobago also developed a draft National Radiation Emergency Plan in November 2012 [7]. This plan seeks to establish an organized and integrated capability for a timely, coordinated and effective response by national agencies and first response organizations to radiation emergencies. It provides operational guidance for identified stakeholders to: regain control of the situation; prevent or mitigate consequences at the scene; render first aid; manage the treatment of radiation injuries; and prevent, to the extent practicable, the occurrence of radiation health effects in workers and the public. The Ministry of Health is currently the authority

responsible for coordinating the technical expertise in the detection and assessment of the risk of radiation injury and the Office of Disaster Preparedness and Management (ODPM) will coordinate the efforts of all stakeholder agencies towards preserving life and restoring normalcy.

Within the public health sector, there exists a radiation safety committee consisting of all the radiation protection experts for the different health authorities categorized by geographical location. This committee meets periodically to discuss successes and challenges in radiation protection and safety at the various institutions across Trinidad and Tobago. To date, cultural issues such as poor attendance to radiation protection trainings and late return of dosimeters are among the top complaints and several suggestions have been raised to address these challenges.

The manifestation of a good radiation protection culture is heavily dependent on the experts present in the organization. The Medical Physics (MP) profession plays an active role in the diagnostic and therapeutic applications of medical ionizing radiation. In addition to the clinical uses of ionizing radiation, Medical Physicists (MPs) provide the core foundation for a functioning radiation protection and safety programme in the workplace. In Trinidad and Tobago, the number of MPs in the public health sector are limited to four, which are based in oncology at the National Radiotherapy Centre (NRC), the sole public institute offering radiotherapy services. The ratio of MPs to the number healthcare facilities utilising ionizing radiation generating devices and radioactive sources is therefore extremely unbalanced [8]. A direct result of this uneven ratio stems from the overall understanding of radiation. Radiation is still widely considered a “mystical phenomenon” for many healthcare workers and by extension, the wider general public. The University of the West, Indies, St. Augustine Campus received directive by the Ministry of Health in 2013 to create a programme to develop more professionals in the field of radiation protection. The Masters of Science programme in Biomedical Physics was launched in September of 2016 and the first group is due to finish in the year 2018. Through this programme the university aims to produce competent individuals in the field of Medical Physics, thereby aiming to increase the amount of experts present in the nation.

Professional bodies have a direct role to play in promoting the development of a strong radiation protection culture. They must take a lead in ensuring that Radiation Protection practitioners are aware of the importance of cultural issues, and should help to equip them adequately for this task [3]. In Trinidad and Tobago there are three professional bodies which can support radiation protection culture implementation and growth: the Trinidad and Tobago Organization of Medical Physicists (TTOMP), the Radiological Society of Trinidad and Tobago and the Society of Radiographers Trinidad and Tobago (SORADTT). The TTOMP was registered as a non-governmental organization (NGO) in April 2015 and serves to provide a voice for all medical physicists on the island and serves as an avenue for bringing awareness to members of the general public. Additionally, it acts as a link to other international organizations such as the International Organization for Medical Physics (IOMP), of which we are a member, and is a benchmark for ensuring consistency and optimization of science in both the medical and industrial settings. [9]. The TTOMP’s main aim is awareness, and focuses on enhancing student membership and outreach programmes and educational talks in efforts to expand the familiarity of medical physics and its applications in Trinidad and Tobago and thereby improve our radiation protection culture.

TABLE 1. Trinidad and Tobago’s participation: IAEA Technical Corporation Activities

Name of Activity	Location	Date
Developing and Strengthening National Legal Frameworks for Nuclear Applications	Belize	April 2017
RLA9082: School of Drafting Regulations	Vienna	January 2017
Developing and Strengthening National Legal Frameworks for Nuclear Applications	Belize	April 2017
Meetings to discuss/draft National Legislation	Vienna	2015-2016
Sub-regional workshop on Safeguards for States in the Caribbean Region	Panama	June 2015
Sub-regional workshop for Caribbean Countries on Civil Liability for Nuclear Damage	Panama	June 2015
Regional Training Course on the Regulatory Authority Information System	Trinidad and Tobago	January 2017

I <sup>st</sup> Coordination Meeting on the IAEA TC Project RLA9081: Strengthening Cradle-to-Grave Control of Radioactive Sources	Jamaica	April 2016
Regional Training course on Practical Aspects for setting up and validating National Inventories of sealed radioactive sources	Bahamas	Sept 2016
Regional Meeting on the Implementation of the International Basic Safety Standards in Medical Practice	Chile	March 2015
National Workshop on the Authorization and Inspection of the Facilities and Activities relating to radiation sources in the Framework of the regulatory infrastructure development project	Tunisia	February 2015

#### 4. THE WAY FORWARD

The fundamental driver and leadership for a strong safety culture must come from the very top of the organisation. Management at all levels must believe in the process of cultural change and be prepared to lead. [3] It is therefore important for the professional bodies such as the TTOMP, SORADTT and the Radiological Society to educate and sensitize the management of all relevant organizations in order to begin effecting change in our radiation protection culture.

Another key player in developing and embedding a strong workplace radiation protection culture is the Radiation Protection Adviser or Radiation Protection Expert and the Radiation Protection Officer. However, this is a role that is not well understood in many areas. Amongst radiation protection specialists it is clear that the role is intended to assist the employer to optimise radiological protection and to maintain compliance with the law. The Radiation Protection Officer is usually a front line supervisor who monitors and strives to maintain the radiological safety of teams working with radiation. In Trinidad and Tobago these posts need to be made available and distinct from the posts of medical physicist in the public and private arenas. These persons will therefore be able to devote time to meeting within their organization and can together form a protection body in order to initiate change in our radiation safety culture. This however, can only be done through first sensitization of the managers and top leaders in the country, for without the understanding of why these positions are important, they will not be created. The implementation of the Ionizing Radiation Protection and Security law can also mandate the instating of certain professionals in an institute where ionizing radiation is generated or radioactive sources are used.

Some of the key features of a strong safety culture are personal responsibility for safety, leadership commitment with safety, decisions are made reflecting safety first, safety undergoes constant examination, open reporting of problems, errors are made without blame and safety undergoes constant examination. These and other features of radiation safety and protection cultures must be the benchmark by which we compare and analyse each institution utilising ionizing radiation.

Trinidad and Tobago currently has laws for occupational safety and health and in addition policies for occupational safety and health management. Since radiation protection and safety falls under the umbrella of occupational safety, in the future these laws and policies can be amended to include radiation protection and safety in the workplace, thus making them more comprehensive. [10] [11][12]

Law is good, but culture is better. Laws are the foundation for improvement but without culture, growth will be stagnant. Therefore our way forward should be beyond the implementation of law and to the behaviours, trainings and principles needed for the establishment of a good radiation protection culture. It must be noted that radiation protection and safety must always be reviewed as dose constraints, ethical considerations and other principles can change.

#### 5. ACKNOWLEDGEMENTS

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## PERCEPTION AND AWARENESS REGARDING RADIATION AMONGST MEDICAL TRAINEES IN A TERTIARY CARE CENTRE SETTING IN THE HILLY STATE OF UTTARAKHAND IN INDIA

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### Abstract

Introduction: Every potential healthcare worker must have basic information about radiation. Aim : Assessing perception and awareness of radiation amongst nursing trainees. Providing systematic information. Assessment of change in the same. Material and Methods: In a sub group of nursing trainees in a tertiary care medical centre, pre-test evaluation of all participants was done by getting a simple questionnaire with total of 15 questions based on perception (4) and knowledge (11) of radiation. Intervention in the form of a short interactive workshop was conducted followed by post-test evaluation. The pre and post test were compared and results assessed baseline and changes. Results: Total of 183 students, all females (mean=19.43 years) participated in the study. We observed a Pre-test, post-test scores and overall improvement in perception and knowledge of 56.14%,76.62 and 20.48% respectively. Fear of cancer and infertility were commonly associated with radiation exposure. The participants showed no difference in preference for working in radiation areas after intervention. Conclusions: Improvement in perception and knowledge after imparting systematic knowledge to students in this sub-group of students in the State of Uttarakhand.

Key Words: Radiation, Perception, Knowledge, Uttarakhand, India.

### 1. INTRODUCTION

Radiation is a necessary part of our planet ecosystem, it has existed all along [1]. Use of radiation in medicine was incepted since 1890s [2]. Currently, radiation in medicine plays a prominent role in medicine where many of the diagnostic, interventional and therapeutic procedures exist where we use radiation to diagnose, monitor and treat a variety of diseases. Although justification and appropriateness is directly concerned with amount of doses in medical imaging/therapy, currently it is not clear that low dose radiation is associated with cancer. However, risks of low dose radiation have societal and psychological importance in accordance with biological effect of radiation [3]. Children are more susceptible to radiation. Stochastic effect of radiation and its cancer risk is most feared and least understood because it has no minimal threshold doses and adverse outcomes take at least 1-2 decades to manifest [4-6]. The review of the published scientific literature marks the knowledge and perception of radiation is limited. Various studies have been performed among medical professionals. Notably there are very limited studies among nursing students. Nursing profession is very important because they prepare, monitor and provide all channels of care of patients undergoing different radiation modalities. It is very necessary to know about radiation, on the other hand perception of radiation in work place may have impact on their working preferences [7]. This study aims to assess basic awareness, perception and knowledge about radiation among nursing students in a tertiary care setting.

### 2. METHODS

This project was carried out after review and acceptance by the approval of the Institutional research cell in integration with the ethical committee. This prospective cross-sectional study was conducted in tertiary care Institute. Following a literature review, a 15 question questionnaire was prepared. 11 questions were based on knowledge and 4 were based on perception of radiation. Demographic information of nursing students included age, gender, occupation and education level. The questionnaire was administered to nursing students before and after a short interactive training programme on basics of radiation in medicine. The completed questionnaires

were assessed by one assigned researcher and score were noted on the basis of radiation knowledge and perception in a total score ranging from 0-20. Questionnaire survey data were collected before and after the training and were analysed using paired t test. All the statistical analyses were performed using statistical package for social science (SPSS) 20.0.

**2.1. Demographics of Nursing Students**

Population	Gender	Age(Min-Max)	Education	Occupation	Experience
AIIMS Rishikesh(n=183)	Female	18-25	Pursuing undergraduate	Student	None

**3. RESULTS**

A total of 183 responses were received from 240 responders (76.25 response rate). The final score findings showed that the range of the total scores obtained by the nursing students before and after the training were 6.5-16(mean score 11.23, SD=1.75) and 9-18.5(mean score 15.33, SD=1.8) marks respectively. It was found that there was a significant increase in terms of overall scores by the respondents after attending the training programme(p<0.0005).

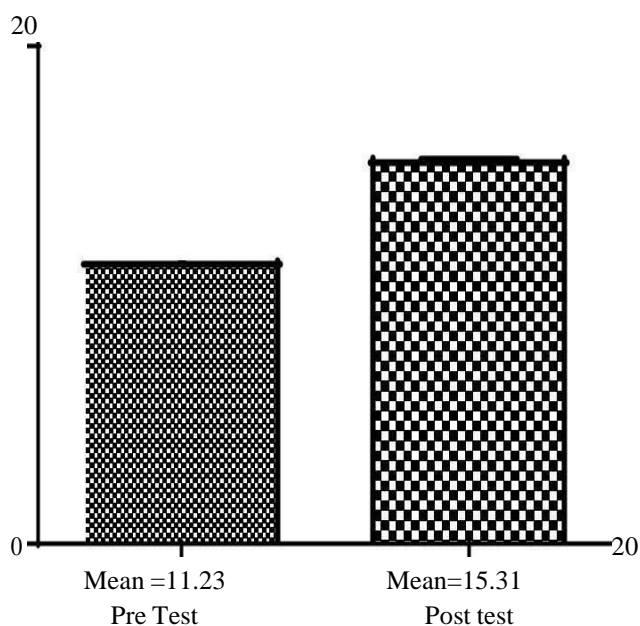


Figure 1: Graphical representation of Pre and Post test during training programme evaluation, A significant increase in knowledge and perception are showing in above graph.

**4. DISCUSSION**

Our project results refers to overall lack of knowledge about on radiation in prelims session. After training session, significant improvement was found in knowledge and perception about radiation. To the best of our knowledge no research has been performed specially among nursing students. In the literature, it is suggested that nurses can reduce the risks of radiation by applying the established principles of ALARA, three basic principles of radiation protection (Time, distance & shielding) as well as wearing of protective clothing and dosimeters in their routine working environment. In our study a clear result obtained that most respondent have

fear of radiation and they have a psychological answer that radiation causes cancer. This study reflects that the most serious perceived fear of radiation is cancer and infertility among this subgroup. Nearly 90 percent respondent in prelims marked the answer radiation causes cancer. Also they are confused about work safety in radiation areas. If given a choice most preferred not to work in radiation areas on prelim questionnaires and this response improved after the session. In this pilot project study there are limitations like single tertiary care study, small sample size and limited questionnaire. We plan to conduct a similar study on a larger scale. We hope that, through adequate measure like discussion, education, training and training we would be able to improve on the perception and awareness in more sectors of healthcare.

## 5. CONCLUSIONS

Nursing workers are expected to assess, guide, prepare and monitor the patients during and after various procedures including radiation based imaging/therapy. Their knowledge on this aspect must be improved at the level of training. In our study we observed improvement in this aspect after a one point intervention in the form of an interactive training programme. Larger studies and interventions would be required in order to improve awareness and perception on this aspect.

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## **RADIATION SAFETY TRAINING IN MEDICINE IN THE MIDDLE EAST**

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### **ABSTRACT**

The use of radiation in Medicine has been on the rise in many countries. A lot of diagnostic and therapeutic procedures may expose patients and staff to high radiation dose which can be reduced to low levels to ensure the safety and protection against the harmful effects of radiation exposures. The objective of this presentation is to ensure the following:

1. Implementing an effective radiation safety strategy
2. Examining the role of the hospitals in creating a radiation safety program
3. Enforcing radiation safety practice for patients, staff, physicians and visitors.
4. Providing regular radiation safety education to concerned staff
5. Identifying opportunities to improve radiation safety performance

By adhering to the principles and doctrines of radiation safety set forth by international organizations, the safety culture among radiation workers will be enhanced and the productivity as well as performance of the protocols will be optimized. The Middle East Organizations of Medical Physics (MEFOMP) has done tremendous efforts in delivering the radiation safety culture within its territories.

## **1. INTRODUCTION**

Many MEFOMP countries follow the standard Radiation Safety Training which is adopted from the IAEA with some modifications according to the local nuclear regulatory authority guidelines. This program includes notice to workers of the organization's existence and workers' responsibility to help keep dose equivalents ALARA, a review of summaries of the types and amounts of by-product material used, occupational doses, changes in radiation safety procedures and safety measures, and continuing education and training for all personnel who work with or in the vicinity of Radiation by-product materials or equipment.

The needs of the Radiation Safety Program are:

- 1) To maintain radiation exposures at a level as low as reasonably achievable (ALARA);
- 2) To contain radioactive materials in areas in which their presence is intended and to limit the inadvertent release to, and consequent contamination of, unrestricted areas; and
- 3) To ensure compliance with all applicable regulations.

## **2. PURPOSE**

Under the Radiation Protection Regulations of most of the MEFOMP local Standards, every licensee is required to implement a Radiation Safety Program that meets specified requirements. This entry Program below specifies the Radiation Safety measures implemented by most Hospitals, Radiation Facilities, laboratories and work areas governed by nuclear substance and radiation producing devices in MEFOMP Countries.

This Radiation Safety Program will be submitted as a part of the application for the local National Licences Compliance. This Radiation Safety Program incorporates best practices, in addition to legal requirements. Therefore, compliance with the program will also serve to protect the Institutions (Licensee) and individuals from civil liabilities, which may arise from exposure to members of the public.

## **3. OBJECTIVES:**

The overall objectives of the Radiation Safety Program are:

1. Prevent deterministic effects (radiation injuries).
2. Minimize the probability of stochastic effects for workers by requiring that doses be maintained as low as reasonably achievable (ALARA).
3. Protect the public and environment by ensuring that releases of radioactive material are maintained ALARA.
4. Achieve compliance with the local National Radiation Safety Standards and Regulations.

#### 4. SCOPE

This entry applies to all activities involving the acquisition, use, storage, transfer, shipping, production, disposal and abandonment of nuclear substances and radiation devices in institution laboratories and work areas.

This program applies to all persons working with or in proximity to nuclear substances and radiation devices under any institution licences, including but not limited to: Radiology and Radiotherapy staff, Medical Physicists, Biomedical Engineering, Nursing, OR staff, Surgery, Nuclear Medicine, CathLab...

#### 5. APPROACH

This training course will provide basic information related to Radiation Physics in order to train staff on issues related to patient protection against radiation and to use Standard and International Radiation Safety Applications in Radiology.

The approach will be based on Knowledge, Regulations, and Clinical Practice, all are set forth to enable participants to understand, comply, and apply the principals of Radiation Protection effectively. This Training is tailored to be a comprehensive approach that applies to all users of radiation in different levels to ensure an excellent and efficient acquisition of the radiation knowledge.

#### 6. RADIATION SAFETY COURSE OUTLINE

<b>Time</b>	<b>Lecture</b>
<b>08:00-08:30am</b>	<b>Registration</b>
08:30- 09:00am	Why radiation protection in radiology is so important today?
09:00- 09:20am	What radiation quantities you should know?
09:20 - 09:50am	Biological Effects of Ionizing Radiation
<b>09:50-10:10 am</b>	<b>Break</b>
10:10 -10:50 am	Patient versus staff radiation risks in radiology
10:50-11:30 am	How to protect yourself in radiography and CT room
11:30 -12:10 am	How to protect patient and staff in interventional procedures
12:10 -12:20pm	Discussions
<b>12:20 - 13:20 pm</b>	<b>Lunch Break</b>
13:20 -13:50 pm	Radiation and pregnancy
13:50-14:50 pm	<b>Practical Exercises</b>
14:50 - 15:10 pm	<i>Assessment Questionnaires</i>
15:10- 16:00 pm	<b>Evaluation &amp; Discussion</b>

## **7. CERTIFICATION:**

The attendees of this training course will set for an exam at the end of taking this course and upon passing the exam, they will be granted a certificate of completion and 8 CME from the MEFOMP Training and Education committee body after approval of the program.

## **8. REFERENCES**

[https://rpop.iaea.org/RPOP/RPoP/Content/AdditionalResources/Training/1\\_TrainingMaterial/](https://rpop.iaea.org/RPOP/RPoP/Content/AdditionalResources/Training/1_TrainingMaterial/)



# **POSITION OF MEDICAL PHYSICIST IN TUNISIA AND IN AFRICA:**

## **THE NEED FOR A NEW WAY OF THINKING**

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### **Summary**

Tunisia has currently 9 radiotherapy centers, 12 nuclear medicine departments and a great number of equipments dedicated to diagnostic radiology and interventional radiology, distributed between public and private sectors. As being a user country of new medical technologies dedicated to diagnosis and treatment, Tunisia has taken a lot of delays in the field of training, recognition of diploma and profession and recruitment of qualified staff in medical physics. Some thirty medical physicists were allocated to radiotherapy department. In other areas, one notes an increased lack of these specialists namely in diagnostic radiology, interventional radiology, nuclear medicine, and radiation protection. Tunisia has competent and well qualified medical staff using the same technology as that of the developed countries, and the expectations of the population in terms of quality care are growing. However, the need of medical physicist that accompany these new techniques are growing. The situation is not better in the majority of other African countries. Speaking about the number of medical physicists (MP) employed in the field of imaging radiology, Egypt occupies the first position with approximately 50 MP for 95 million inhabitants, followed by South Africa , 10 MP for 55 million inhabitants and then Algeria, 10 MP for 45 million inhabitants. Nigeria occupies the fourth position with less than 10 MP for a population of 182 million inhabitants. Thus a rapid reflection on the increased lack of these health professionals is needed to relaunch the training, recognize the diploma and the profession of a medical profession as a health profession.

Key words: medical physicist, diagnostic radiology, nuclear medicine, radiation protection

### **1. INTRODUCTION:**

The increased lack of medical physicists is very worrying in our country [1] and in the vast majority of African countries [2] [3]. The non recognition of diploma intensified this shortage and made the need for medical physicists urgent because of the increased complexity of diagnosis and treatment equipment . In its part, the AIEA has tried to draw the attention of the countries members about the worrying shortage of medical physicist's effectives in Africa, mainly in the field of diagnostic radiology, interventional radiology, nuclear medicine, and in radioprotection, and it highlighted the diversity of these effectives per inhabitant in some countries which are in question [4]. This bitter observation does not go hand in hand with the big investment of the AIEA, which always in its part provides technique assistance to countries members to establish training in medical physics.

This situation of medical physicist's shortage becomes worrying mainly because the heavy technical equipments dedicated to radio diagnosis and treatment become integrated more and more into their medical physics conception. This situation persists so long as stakeholders, such as the Federation of African Medical Physics Organisations (FAMPO) and the International Organization for Medical Physics (IOMP) do not play their full role by better collaboration with national authorities and the support of national societies.

### **2. TRAINING OF MEDICAL PHYSICISTS: CURRENT SITUATION IN TUNISIA AND IN AFRICA**

Since 2007, a university curriculum for the training of medical physicists has been found by two institutions, the Faculty of Medicine of Tunis and the Higher Institute of Medical Technologies of Tunis and this is done through providing a master research in "Biophysics, Radio physics and Imaging radiology". Thirty students with a license degree in physics or an equivalent degree are selected each year numerously 10 students for each specialty. The period of studies is four semesters, or two years, distributed between the two organizing

institutions of this master. The two first semesters, is considered as the first year of study which it constitutes the core curriculum for the three specialties. The third semester is reserved for the End-of-studies project. However, this training remains truncated and is not supplemented by a clinical training program, because of the non-recognition of this diploma by the guardianship authorities and the lack of qualified physicists.

These professionals of medical physics answered by their competence to the clinical needs essentially in radiotherapy, and the majorities are recruited in Radiotherapy Centers of private clinics (table1). About the public sector, recruitment is aimed at filling the gaps within the radiotherapy departments. Thus, the number of created jobs is much lower than the number of students who are graduated and has consequently stopped training. Radio physics branch has been, therefore, stopped by 2014 after providing about 40 graduates who were trained mainly in radiotherapy and the majority of whom were recruited by the privatesector.

TABLE 1. Physical infrastructure in Radiotherapy

Equipments	Tunis		Sousse		Sfax		Total
	Public	Private	Public	Private	Public	Private	
Centers	1	4	1	1	1	1	9
Medical Physicist	6	5	5	3	3	2	24
Cobalt Units	2	2 x 1	1	1	1	2	9
Accelerator (Varian iX)	3	2 x 2	1	2	1	2	13
Contac therapy RT 150 kV	1	0	1	0	0	0	2
Simulator Scan	1	0	1	1	1	1	5
Curiethron LDR	2	0	1	0	1	0	4
TPS	1	2 x 1	1	1	1	1	7
HDR (24 channels) Ir192	1	0	0	0	0	0	1

In other fields, one notes an increased lack of these specialists in medical physics, notably in radio diagnostic, interventional radiology (table 2), nuclear medicine (table 3 and 4) and radio protection and this in the two sectors private and public ones.

TABLE 2. Physical infrastructure in Radiology. Each hospital, clinic and imaging center has its own department of radiology

Private	Public		Radiologist
Private imaging centers	373	Teaching hospital	24
Privat cliniques	93	Regional hospital	32
Total			499

TABLE 3. Physical infrastructure in nuclear medicine

Equipments	Tunis		Sousse		Sfax		Total
	Public	Private	Public	Private	Public	Private	
Centers	2	6	1	1	1	1	12
Gamma Camera	3	5	1	1	1	1	12
SPECT/CT	1	0	1	0	1	0	3
PET/CT	1*	1+1*	1*	0	1*	0	5
CYCLOTRON **	1	0	0	0	0	0	1

TABLE 4. Nuclear medicine staff

Equipments	Tunis		Sousse		Sfax		Total
	Public	Private	Public	Private	Public	Private	
Physicians	16	6	10	1	7	1	41
Medical Physicist	0	0	0	0	0	0	0
Radiopharmacist	0	0	1	0	0	0	1
Technologist	13	7	8	2	8	2	40
Total	29	13	19	3	15	3	82

Tunisia is not distinguished from other African countries by this increased lack of medical physicists. Indeed, it is important to recall that in its investigation, the AIEA stressed the shortage of medical physicists (MP) in Africa, in the field of the imaging radiology and highlighted the diversity of these effectives per inhabitant in some countries in question[4]. Egypt occupies the first position for about 50 MP by 95 million inhabitants, followed by South Africa, 10 MP by 55 million inhabitants and Algeria, 10 MP by for 45 million inhabitants. Nigeria occupies the fourth position with less than 10MP for a population of 182 million inhabitants. For the other African countries the shortage of professionals in medical physics is almost total. Furthermore, of the 9 countries with a training cycle in medical physics, three countries, Egypt, South Africa and morocco offer clinical training. This lack of clinical competence means that the training of medical physicists is incomplete and does not enable them to fully carry out their activities independently.

### **3. PRINCIPLES CAUSING SHORTAGES IN MEDICAL PHYSICISTS**

Tunisia, like many other African countries, has very competent and well-qualified medical staff using the same technology as developed countries and the growing expectations of the population regarding quality of care mean that the delay in the training of medical physicists is not related to the level of health in the country. Several arguments could be offered to explain this contradictory situation. The following points are made by way of example: 1) Radiologists and nuclear physicians, by virtue of their demands and their increasing activities, remain fixed on the medical side without worrying about a possible investment beforehand, the contribution of medical physics to their specialty. 2) Confusion over the role and responsibilities of the medical physicist in a hospital environment led to the belief that a good maintenance contract could encompass the tasks and workloads of the medical physicist and ultimately play its role, has resulted in inadequate quantification in terms of human resources needs. 3) The proximity of "physician-medical physicist", as well as the radiation protection of patients, remains a culture that is acquired over the years. The absence of this culture in the majority of our African countries continues to confuse the role and responsibilities of medical physicists in hospitals. 4) The medical physicist is required to highlight his competences in the field of medical physics and to value them to make himself indispensable to the eyes of all the medical staff, mainly doctors and thereby gain their confidence. Unfortunately, it faces a difficult task due to lack of equipment, human resources and infrastructure. All these different points and of course others make that there is no strong signal sent by the users of the ionizing radiation for medical purposes to incite the guards such as the Ministries of health and higher education to renovate of this university education.

### **4. REFLECTIONS AND RECOMMENDATIONS**

The recognition of the profession of radio physicist as a health profession contributes to the quality and safety of care by better defining its role and responsibilities [5]. Moreover, Article 79 of the European Directive 2013/59/Euratom [6] requires that " Member States shall ensure that arrangements are in place for the recognition of radiation protection experts and medical physics experts". Articles 82 and 83 of that directive specify all the tasks assigned to them. In the French regulations, the areas of intervention of the medical physicist are defined by the decree of 19 November 2004 [7] and the rules relating to the exercise of his profession are specified in Ordinance No. 201748 of 19 January 2017 [8].

This bitter observation of the lack of medical physicists in Africa appears to contradict the AIEA's enormous investment by publishing practical guides, manuals and atlases of quality assurance and quality control, setting up a program academic and clinical training, establishment of platforms, support for national, regional and specific cooperation projects such as RAF projects, support for the training of personnel and the sending of experts and specialists. The AIEA has always provided technical assistance to member countries to establish training in medical physics and to strengthen national capacities through the harmonization of practical procedures in dosimetry, quality assurance, audits, clinical training and continuing training.

At a time when everyone agrees that medicine is increasingly dependent on well-trained medical physicists working in a complex clinical environment, where physical, medical and technological knowledge is constantly evolving [9] [10] Africa is experiencing a shortage of medical physicists aggravated by the lack of recognition of the diploma and profession. This situation is likely to last if national and international institutions do not deploy all their energy and strength to cope with the uncomfortable situation that is plaguing the continent. The Federation of African Medical Physics Organisations (FAMPO) is called upon to play its full role by direct actions of supervision and support of national societies. These societies are in turn called upon to undertake awareness-raising actions by the supervisory authorities and to be more persuasive and effective in the various scientific manifestations of learned societies of radiology and nuclear medicine in order to make them aware of the roles and responsibilities of the medical physicist. The International Organization for Medical Physics (IOMP) is in turn called upon to collaborate with national bodies, encourage the exchange of scientific and professional information, and provide advice on the teaching, training and accreditation of programs [3]. It is

also invited to become more involved so that the "International Day of Medical Physics" initiative is celebrated in the different African countries and that the media and hospitals pay more attention to it. It is therefore urgent to structure this teaching and complement it with clinical training programs in accordance with the IAEA guidelines and recommendations [11] and to enhance it by recognizing the diploma.

## 5. CONCLUSION

As part of a multidisciplinary team, the medical physicist brings his expertise to all questions relating to radiation physics in medical applications within his / her field of intervention, thus ensuring the radiation protection of the patient, workers and the public.

The approach taken by African countries to overcome the increased lack of medical physicists is still insufficient and timid in the light of our growing needs for these health professionals, which contribute positively to the advancement of the diagnostic and therapeutic fields of medicine.

Tunisia's delay in training, recruitment and recognition of the medical physicist's diploma is not commensurate with the health status of the country. A rapid reflection on the needs of medical physicists should be carried out in collaboration with the tutors to relaunch the training and consolidate it, knowing that the modernization of our health system can only be done by recognizing the profession of medical physicist as a profession of health.

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# ***IMPLEMENTATION OF INDONESIAN REGULATION OF INTEGRATION RADIATION PROTECTION AND RADIATION SAFETY PROGRAM INTO MANAGEMENT SYSTEM IN MEDICAL ORGANIZATION***

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## **Abstract**

The paper will review and integrated two Indonesian regulation that is regulation of Radiation protection and radiation safety for Radiation Source and regulation of Management System for Nuclear Facilities and Activities. Integration will be identified especially for a medical facility. It's also in line with IAEA recommendation on GSR part 3 Radiation protection and radiation safety of Radiation Source on requirement 5 that the principal parties shall ensure that protection and safety are effectively integrated into the overall management system. In Indonesia, the obligation of implementation radiation protection and radiation safety in a medical organization is a mandatory requirement of Article 14 of Government Regulation (GR) no. 29 of 2008 on the Licensing Radiation Facilities and Radioactive Source. For now, radiation protection and radiation safety program and management system of the medical organization is implemented in two different programs and each program is like not connected each other. Because of that condition, Indonesia amendment GR no. 29 of 2008 were part of the amendment in this regulation is Article 14 that in line with IAEA recommendation on GSR part 3 and integration two regulation will be foster the safety culture.

## 1. INTRODUCTION

As specified in International Conference on Radiation Protection in Medicine in Bonn, Germany, in December 2012 in the action no.8 Strengthen radiation safety culture in health care, One effort that can be done is with implementation of Radiation protection and radiation safety for medical purposes integrated into management system. The obligation to implementation radiation protection and radiation safety in medical organization is mandatory requirement of article 14 of Government Regulation (GR) no. 29 of 2008 on the Licensing Ionizing Radiation Source and Radioactive Material. The implementation of that government regulation is licensing holder should establish radiation protection and radiation safety programs for medical processes both for diagnostics and therapy. More detail requirement for establishing radiation protection and radiation safety is regulated in BAPETEN Chairman Regulation (BCR) no. 4 of 2014 on the Radiation protection and radiation safety for Radiation Source. In addition to the two regulations Indonesia also establishing BCR no. 4 of 2010 on the Management System for Nuclear Facilities and Activities. Since that all organization that utilizing radiation source should follow that regulation, for establishing and implementation of management system. For now, that two regulation is implementing in different program, and each program is like not connected each other's. As if Radiation protection and radiation safety Program is only radiation protection officer responsibility, it's becomes separate from implementation of management system in the organization.

Because of that condition some problems appears which is no control and concern from top management to implementation of radiation protection and radiation safety program, no control to quality process on radiation sources uses and no performance assessment regularly by top management. Integration of radiation protection and radiation safety requirement in the system management requirement in medical field should be started from top management commitment to demonstrate that radiation protection and radiation safety at highest level within organization, quality control x-ray diagnostic equipment and radiotherapy, personnel competence, limitation, optimization and justification process as well as assessment should be included in the management system medical organization.

## 2. METHODE

- The method of this study is review and identify Indonesian regulation BAPETEN Chairman Regulation (BCR) no. 4 of 2014 on the Radiation protection and radiation safety for Radiation Source and BCR no. 4 of 2010 on the Management System and identify every requirement in the BCR no. 4 of 2014 into BCR no. 4 of 2010.
- The Integration that two regulation, it use for implementation Indonesian regulation GR 29 of 2008 revision article 14.

### 3. RESULT

#### 3.1 RADIATION PROTECTION AND RADIATION SAFETY (BCR NO. 4 OF 2014)

This regulation provides guides for establishing and implementing radiation protection and radiation safety program. Requirement such as limitation, optimization and justification for radiation protection. Before conduct an integration of radiation protection and radiation safety requirement for facilities and activities in medical facility into management system, the first step is identify radiation protection and radiation safety requirement base on ensure BCR 4 of 2014 for medical facility.

Scope of BCR 4 of 2014 is person who responsible to radiation protection and radiation safety and requirement of radiation protection and radiation safety on Radiation Source. This table below give a requirement for radiation protection and radiation safety requirement especially implemented in medical facility base on BCR 4 of 2014..

TABLE I. RADIATION PROTECTION AND RADIATION SAFETY REQUIREMENT

REQUIREMENT	DESCRIPTION
Prime Responsibility in medical facility	Top Management should establish radiation protection and radiation safety organizer that consists of Person who in charge in all radiation facilities and activities in medical organization, Radiation Protection Officer and Medical Practitioner
Radiation Protection Requirement	<p><i>Justification</i> Medical exposure for patients shall be carried out by consultation between medical practitioner and referring medical practitioner.</p> <p><i>Limitation</i> Radiation exposure shall carried out by follow dose limits, monitoring radiation program should be establishing by organization for worker, public and environmental.</p> <p><i>Optimization</i></p> <ul style="list-style-type: none"> <li>- Set dose constraint for worker and publics</li> <li>- Set diagnostic reference levels</li> <li>- Quality Assurance clinical and technical</li> </ul>
Safety on Radiation Source	<ul style="list-style-type: none"> <li>- Radiological assessment covering planned exposure situations and emergency exposure situation</li> <li>- Safety assessment radiation sources</li> </ul>

All requirement in the table should be set and approved by top management as a program of radiation protection and radiation safety in medical facility both for diagnostic or therapeutic facilities.

Top management could be a licensing holder in medical organization so they should establishing organizer of radiation protection and radiation safety for implementation of radiation protection and radiation safety program. But organizer of radiation protection and radiation safety in the implementation such a another organization in whole medical organization. When performance assessment doing or all management system assessment carry out by management, the organizer radiation protection and radiation safety performance is not cover in that assessment. It is because, the organizer of radiation protection and radiation safety is not covered on business process in management system medical organization.

#### 3.2 MANAGEMENT SYSTEM FOR FACILITIES AND ACTIVITIES (BCR 4 OF 2010)

All requirement in Indonesian regulation about Management system for facilities and activities is fully adopted from IAEA Safety Guide GS-R-3 Management System Facilities and Activities. In this review the requirement of management system divided into 5 major requirementie:

1. General Requirement coverings safety culture, graded approach and documentation of system management.
2. Management Responsibility coverings management commitment, satisfaction of Interested parties, organizational policies, planning and responsibility and ahotity for management system.
3. Resources Management coverings provision of resources, human resources and Infrastructure and the working environment.
4. Process Implementation coverings developing process, process management and generic management system process of radiation and protection programs as part of business process in medical facility.
5. Measurement, assessment and Improvementcoverings:
  - Monitoring and measurement for all process implementation
  - Self assessment
  - Independent assessment
  - Management review
  - Non-conformances and corrective and preventive action
  - Improvement

Each major requirement has detail requirement to be implemented on medical facility. Radiation protection and radiation safety requirement should be integrated into detail requiement of system management. Interaction between organization and implementation of radiation protection and radiation safety will lead to the stronge safety culture in the organization.

### 3.3 INTEGRATED RADIATION PROTECTION AND RADIATION SAFETY (BCR NO. 4 OF 2014) INTO RADIATION PROTECTION AND RADIATION SAFETY PROGRAM (BCR 4 OF 2010)

This integration useful for registrant or licensee on medical facility for controlling implementation of radiation protection and radiation safety under management system organization. Implementation radiation protection and radiation safety should be sustaining and continuously improving in line with improving effectiveness of management system. This is essential in order to foster and sustain a strong safety culture in an organization. Table below give an integration radiation protection and radiation safety program into organization management system especially for medical radiation source uses.

TABLE II. INTEGRATED RADIATION PROTECTION AND RADIATION SAFETY REQUIREMENT INTO MANAGEMENT SYSTEM REQUIREMENT

<b>Management System Requirement</b>	<b>Integration Radiation Protection and Radiation Safety Requirement into Management System</b>
General Requirement	<ul style="list-style-type: none"> <li>- Radiation protection and radiation safety requirement should be understood and implemented by individuals in the organization, from senior managers downwards, and shall foster a strong safety culture. Organizer of radiation protection and radiation safety should be part of organizationstructure.</li> <li>- Documentation of system management should be covers documentation of process implementation of radiation protection and radiation safety from process setting up unit for diagnostic radiology or nuclear medicine process, QA for X-ray unit or radiopharmacy, patients data, medical practitioner data, therapy or diagnostic process documentation from pre therapy/diagnostic process, during therapy/diagnostic process until post discharge patients process.</li> <li>- All information shall be record, maintain and controlled under system management organization.</li> </ul>
Management Responsibility	<ul style="list-style-type: none"> <li>- Medical management organization shall be responsible for establishing, applying, sustaining and continuously improving a radiation protection and radiation safety requirement on management system process to ensure safety of patients, worker</li> </ul>

	<p>and publics.</p> <ul style="list-style-type: none"> <li>- Organizer of radiation protection and radiation safety should set the mechanism of interaction between management with interested parties including supplier of diagnostic equipment, nuclear medicine and regulatory body related with safety and radiation protection fulfilment.</li> </ul>
Resources Management	<ul style="list-style-type: none"> <li>- Human resources related to the implementation of radiation protection and radiation safety such as radiation protection officer, medical practitioner, Medical Doctor, Expert or Medical physicists or Radiologist, Radiographers etc should be provide by management.</li> <li>- infrastructure should be met safety standard including radiation protection equipment such as surveymeter, radiation contamination etc., the working environment, knowledge and information, and suppliers, as well as material and financial resources.</li> </ul>
Process Implementation	<ul style="list-style-type: none"> <li>- Process business in the diagnostic radiological and nuclear medicine process should be including the fulfilment of radiation protection radiation safety requirement.</li> </ul> <p>For diagnostic radiological, the process that should be controlled from medical radiological equipment and software, and, for nuclear medicine, appropriate radiopharmaceuticals and techniques and parameters to deliver a medical exposure of the patient that is the minimum necessary to fulfil the clinical purpose of the radiological procedure. For therapeutic radiological procedures, the radiological medical practitioner, in cooperation with the medical physicist and the medical radiation technologist, should control process for justification, limitation and optimization exposure for each patient. For therapeutic radiological procedures in which radiopharmaceuticals are administered, the process should be controlled for ensuring that for each patient the appropriate radiopharmaceutical with the appropriate activity is selected and administered. All process should be documented and record of all process should be maintained.</p>
Measurement, assessment and Improvement	<p>The effectiveness of the management system of medical facility/organization should be measured, assessed and improved especially for radiological reviews. Radiological review performed periodically. The radiological review shall include an investigation and critical review of the current practical application of the radiation protection principles of justification and optimization for the radiological procedures that are performed in the medical radiation facility.</p>

### 3.4 CONCLUSION

Integration radiation protection and radiation safety programs into system management made involvement of management for ensuring implementation of radiation protection requirements and safety requirements in the use of radiation sources for both diagnostic and therapeutic could be done well. Dose limit, dose constraints and diagnostic reference level can be assuredly met if the radiation protection and protection program becomes part of the implementation of the management system. All performance of each of the elements of radiation protection and safety radiation program can be assessed by management. Because this issue is very essential, Indonesia amendment GR no.29 of 2008 Licensing Ionizing Radiation Source and Radioactive Material Specially in article 14 in line with with IAEA recommendation on GSR part 3 Radiation protection and radiation safety of Radiation Source on requirement 5.

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# **RADIATION SAFETY CONCERNS ARISING FROM ELECTRICAL SAFETY ISSUES OBSERVED WITH X-RAY EQUIPMENT DURING ROUTINE MEDICAL PHYSICS INSPECTIONS**

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## **Abstract**

The Department of Medical Physics and Clinical Engineering provides a regional diagnostic physics imaging support service to hospitals and public health facilities utilising ionising radiation in the west / northwest of Ireland. Radiation protection of staff, patients and public comes under the remit of this department. A series of deficiencies in equipment / environmental electrical safety and operational controls have been observed during recent medical physics surveys of existing facilities. These include damaged X-ray exposure cables and switches, the inappropriate extension of an exposure cable and the unacceptable reattachment of a controller cover. All of the issues outlined had the potential to cause serious radiation incidents. The findings of the biennial surveys highlight the importance of ongoing vigilance during routine quality assurance assessments to ensure protection of staff and patients is not compromised. The regular maintenance and repair of equipment by appropriately qualified personnel is an absolute requirement. Additional training of staff to emphasise the risks of using defective or poorly repaired equipment from an electrical and radiation safety perspective is warranted. The findings also confirm the importance of regular on-site inspection of all radiology equipment by suitably qualified medical physicists.

## **1. INTRODUCTION**

The Department of Medical Physics and Clinical Engineering (Dept. of MPCE) provides a regional medical physics support service for the acute hospitals of the Saolta University Health Care Group and for the Health Service Executive (HSE) public dental clinics in the west and northwest of Ireland [1]. Radiation protection of staff, patients and public comes under the remit of this department. In Ireland, all new X-ray equipment must be commissioned by a medical physicist before it can be used clinically [2]. The commissioning process occurs post installation and is the final step to ensure that the equipment performs as expected and within the tolerances specified in the relevant guidance documents [3][4][5]. A review of the electrical safety aspects of the installation and the correct functioning of all controls is also carried out. Routine quality assurance (QA) assessments are carried out on dental X-ray equipment every two years thereafter[5].

The importance of the independent commissioning of X-ray equipment was highlighted by a very serious incident that occurred in a dental practice in the west of Ireland in the 1980s where no such preclinical performance testing had been carried out. A new dental intra-oral X-ray machine was installed but due to the incorrect wiring of the exposure switch, the timer circuit was circumvented. Consequently, the unit generated X-rays continuously on connection to the mains power supply and imparted a significant radiation exposure to the dental surgeon who was in close proximity to the machine. A nurse present in the clinic received a much lower exposure due to her distance from the unit. In addition, a young patient undergoing examination on the dental chair was almost injured by the eventual explosive failure of the X-ray tube head due to the continuous generation of X-rays [6]. A similar phenomenon was observed for an older dental intra-oral unit that also produced X-rays on connection to the mains power supply. It transpired that due to the age of the equipment and the associated stress and strain on an internal power cable over a prolonged period of time, the very thin cable

insulation degraded sufficiently to cause a short circuit. This replicated the action of pressing the exposure switch [7]. A series of deficiencies in equipment electrical safety and operational controls observed during recent medical physics surveys of dental X-ray equipment shall be presented in this paper. All defects had the potential to cause an electrical or radiation safety incident and relate to equipment over fifteen years old.

## 2. METHODOLOGY

The integrity of exposure cables, control buttons and electrical cables is evaluated during commissioning and routine QA assessments of X-ray devices. It was during routine QA assessments that a series of cable and controller related defects were observed. Faults that had the potential to initiate an electrical or radiation incident resulted in the immediate removal of the equipment from service. The senior manager was informed of the potential hazards involved and advised to arrange a repair or replacement of the equipment. A follow up physics QA assessment was required before the reintroduction of repaired equipment into clinical service.

In the case of replacement equipment, it was necessary to obtain the appropriate licensing amendments from the Office of Radiological Protection of the Environmental Protection Agency (ORP-EPA). This allowed for the decommissioning of the existing equipment and the acceptance into custody / installation of a new X-ray unit [8]. The medical physicist (MP) then commissioned the new X-ray unit and with the approval of the radiation protection adviser (RPA), the unit could then be licenced for use and introduced into clinical service.

## 3. RESULTS

### 3.1 Intra-oral exposure cable

The X-ray exposure cable (Fig. 1) had significant damage to the external insulation along its entire length. The cable damage could result in a potential failure mode of an electrical short, either directly or indirectly via fluid ingress, resulting in an unintended and/or uncontrolled X-ray exposure. The X-ray unit was removed from clinical use immediately. This equipment is over 20 years old and remains out of clinical use pending a decision on whether to repair the cable or replace the complete X-ray unit.



*FIG. 1. Damaged intra-oral X-ray exposure cable*

### 3.2 Intra-oral exposure switch

The physical external damage to the exposure switch on an intra-oral X-ray unit (Fig. 2) and the audible evidence of a freely moving component inside the switch resulted in this unit being removed from clinical service pending replacement of the switch. A potential failure mode due to the ingress of fluid during routine cleaning and disinfection could result in a switch malfunction. A further failure mode involved the potential of the loose internal component activating the exposure circuit. A replacement exposure switch with integrated cable was fitted. A follow up physics QA inspection was carried out prior to reintroduction into clinical service.



*FIG. 2. Front and side view of damaged X-ray exposure switch*

### 3.3 Extended exposure cable

An extra-long exposure cable for a dental intra-oral X-ray had undergone an obvious extension which had been concealed with insulation tape (Fig. 3). It transpired that the modification was carried out to enable staff to retreat outside the two-metre controlled area during X-ray exposure [5][9]. A modification of this nature does not meet accepted medical equipment management standards and would be contrary to manufacturer standards for use and maintenance. Potential failure modes involving ingress of fluids, foreign bodies or total failure were considered, all of which could have resulted in unpredictable and / or undesirable effects. The unit was removed from clinical use immediately pending replacement with a continuous cable of sufficient length. On installation of the new cable and integrated exposure switch, a physics QA assessment was carried out and the X-ray unit was deemed acceptable for clinical use.



FIG. 3. Extended intra-oral X-ray exposure cable

### 3.4 X-ray controller repair

The dislodged faceplate of the controller module of an intra-oral X-ray unit had been fixed into position with standard “cable ties” (Fig. 4). Selection of the appropriate program and exposure times was by use of membrane type buttons on the faceplate. This approach to correct the dislodged faceplate could have resulted in a misalignment between the faceplate and the internal active buttons with consequent potential for the inappropriate selection of exposure parameters. It was also noted that the strain release collar between the controller and the exposure hand switch cable had become unseated with the internal cables exposed (Fig. 5) which could have resulted in an electrical / radiation incident. The unit was taken out of clinical use pending appropriate repair and replacement of the components. Due to the age of the equipment, it was deemed no longer economically viable to repair and considered financially prudent to decommission it and replace with a new model. A new X-ray unit was acquired, commissioned and introduced into clinical service.



FIG. 4. Faceplate attached with cable ties



FIG. 5. Damaged strain release collar

## 4. DISCUSSION

The condition of equipment encountered highlights that the deficiencies in equipment management as encountered by Cooney et. al still exist in the dental X-ray equipment sector [7]. All of the equipment was past the recommended twelve-year lifespan and perhaps would have been already replaced had economic circumstances permitted [10]. The lack of regular contracted preventative maintenance has been identified as a

contributing factor. In line with international best practice for medical equipment maintenance, it is HSE policy that all medical devices / equipment are maintained in a safe and reliable condition and are properly serviced and repaired [11]. In the case of electrical and radiation safety related issues, economic factors should not and cannot be used as justification for the continued clinical use of unsafe X-ray equipment. Staff have a duty of care to themselves, their colleagues and patients not to use any equipment that may be potentially unsafe [12]. Where budgetary constraints inhibit the repair of defective equipment, the equipment shall be removed from service until such time as repair or replacement is possible. Under no circumstance should ad-hoc or rudimentary repairs be carried out by non-qualified personnel.

Under current legislation and licensing procedures, all dental practices utilising X-ray equipment must hold a licence and renew it every four years [8]. With the impending transposition of the new European Union basic safety standards (EU BSS) into Irish law in February 2018, a graded approach to regulatory control has been proposed. This may result in a less stringent approach to dental licence holders due to the lower perceived risk associated with the use of this type of X-ray equipment [13]. In light of the findings presented in this paper, the authors caution against any relaxation of existing regulatory regimes across the dental sector.

A more robust and risk based approach to dental X-ray equipment management is required to enhance patient and staff safety and to comply with accepted best practice for all medical devices [11]. A proposed work flow for the effective management of issues encountered during medical physics QA assessments is outlined in Fig. 6 to ensure appropriate follow up and that final closure is obtained.

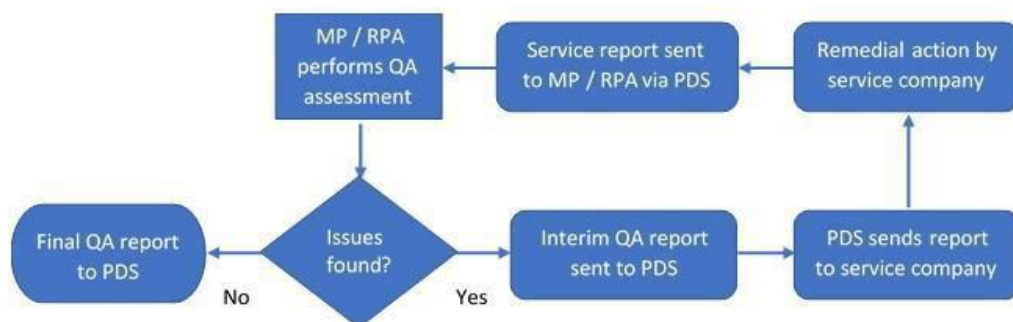


FIG. 6. Workflow for management of dental X-ray issues. Medical Physicist (MP), Radiation Protection Adviser (RPA), Principal Dental Surgeon (PDS)

## 5. CONCLUSION

The issues outlined highlight the importance of increased vigilance and awareness of the potential electrical and radiation hazards associated with the use of damaged or poorly repaired X-ray equipment. An electrical fault of any piece of medical equipment can have serious implications. For X-ray equipment, any such unexpected behaviour has the potential to cause an unintended exposure to ionising radiation, an overexposure or a physical injury to patients, staff or members of the public, similar to the events that occurred previously [6].

It is essential that comparable incidents do not occur again and it is imperative that staff are made aware of the risks, take responsibility for routine operator inspection of the equipment they use and remove from service any X-ray unit with obvious electrical or mechanical faults. Electrical safety awareness and training shall be incorporated into all future radiation protection courses carried out by the Dept. of MPCE. A more effective approach to X-ray equipment management is warranted to prevent avoidable incidents. The findings of this paper highlight the need for routine dental X-ray equipment preventative maintenance to be carried out by reputable and competent service engineers. In addition, regular on-site medical physics QA assessments must be performed to ensure that the potential risks of electrical and radiation hazards are minimised.

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## **CURRENT EPIDEMIOLOGIC TRENDS FURTHER HEIGHTEN THE NEED FOR GREATER IMPLEMENTATION OF RADIATION PROTECTION**

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### **Abstract**

Non-communicable diseases (NCDs) cause nearly 70% of deaths worldwide, almost 3/4 occurring in low and middle-income countries due to inequities in disease prevention and treatment. The WHO reports that four NCDs account for over 80% of such deaths - cardiovascular diseases, cancer, chronic respiratory diseases, and diabetes complications. [1] Management of these dominant NCDs frequently entails diagnostic imaging and/or image-guided (interventional) procedures, as embedded within evidence-based guidelines. Based on NCDs trends and progressive delivery of Universal Health Coverage, medical radiation procedures and hence exposures will significantly increase. Therefore, the in-facility use of radiation protection guidance tools is a priority for stakeholders. The paper reports: epidemiologic trends; several UN meetings; some WHO targets and World Health Assembly resolutions; and a few examples of in-country programs where radiation protection has been integrated into an NGO's initiatives of increased access, quality, and appropriate use. Overall, high-level work has been accomplished towards medical exposure justification and optimization, but low-resource grassroots healthcare has yet to reap full benefits of the Bonn Call for Action. Compared to system-based regulations, end-user-initiated and collaborative networks constitute a more sustainable and effective strategy to improve awareness, safety culture and the use of guidance tools in facilities.

### **1. BACKGROUND**

On 22 May 2017 at the 70<sup>th</sup> World Health Assembly, in her final address as WHO Director General, Dr. Margaret Chan articulated that during her tenure, "The trend that most profoundly reshaped the mind-set of public health was the rise of chronic noncommunicable diseases" and "...the strongest call for action comes from high-level political commitment." In 2011 such commitment took form as the U.N. General Assembly Political Declaration on Noncommunicable Diseases. Dr. Chan proceeded to state that the World Health Report was the "most influential publication" of her era in office. The document had led directly to incorporation of Universal Health Coverage (UHC) within the U.N. Sustainable Development Goals, and had highlighted the extent to which NCDs constitute a major 21<sup>st</sup> century country development challenge. [2] To be clear, while *noncommunicable* diseases will constitute a dominant epidemiological reason for increasing medical radiation exposures in decades to come, the concurrent fight to prevent, manage, and/or eradicate morbidity and mortality attributable to communicable diseases, as well as other ailments and conditions, shall continue. However, within this paper, NCDs are the public health priority considered hereafter.

### **2. THE METRICS OF THE NCDs AGENDA**

In 2015, the WHO Director General's office defined the methodology of reporting to the U.N. General Assembly on progress towards national commitments outlined in the aforementioned 2011 U.N. Political Declaration on NCDs, as well as in a 2014 U.N. Outcome Document on NCDs. The resultant WHO Noncommunicable Diseases Progress

Monitor 2015 comprises basic profiles of Member States, assessing ten overarching major progress indicators from 2011-2015 [1], not inclusive of medical imaging or radiotherapy.

A coinciding WHO Global Monitoring Framework on NCDs was established to track implementation of the “NCDs Global Action Plan to report on attainment of 9 global targets for NCDs by 2025 against a baseline in 2010” whereby governments [2]:

- (a) set national NCD targets for 2025 based on national circumstances
- (b) develop multisectoral national NCD plans to reduce exposure to risk factors and enable health systems to respond in order to reach these national targets in 2025 and
- (c) measure results, taking into account the Global Action Plan.

Herein medical uses of radiation could fall under global targets 1 and 9 (below, Table 1 and Fig. 1) but have yet to figure within this formal NCDs agenda dialogue, or within subset outcome and progress indicators to be revisited at the 3<sup>rd</sup> High-level U.N. Meeting on NCDs in 2018. “Member States will negotiate in early 2018 setting out the objective of the meeting, the level of participation, and its duration.” [3]

TABLE 1. WHO: 9 GLOBAL TARGETS FOR NCDs BY 2025 COMPARED TO A 2010 BASELINE [2]

<b>Target 1:</b> A 25% relative reduction in the overall mortality from cardiovascular diseases, cancer, diabetes, or chronic respiratory diseases.
<b>Target 2:</b> At least 10% relative reduction in the harmful use of alcohol, as appropriate, within the national context.
<b>Target 3:</b> A 10% relative reduction in prevalence of insufficient physical activity.
<b>Target 4:</b> A 30% relative reduction in mean population intake of salt/sodium.
<b>Target 5:</b> A 30% relative reduction in prevalence of current tobacco use in persons aged 15+ years.
<b>Target 6:</b> A 25% relative reduction in the prevalence of raised blood pressure or contain the prevalence of raised blood pressure, according to national circumstances.
<b>Target 7:</b> Halt the rise in diabetes and obesity.
<b>Target 8:</b> At least 50% of eligible people receive drug therapy and counselling (including glycaemic control) to prevent heart attacks and strokes.
<b>Target 9:</b> An 80% availability of the affordable basic technologies and essential medicines, including generics, required to treat major NCDs in both public and private facilities.



FIG. 1. Global mechanism for the NCDs agenda, adapted from WHO Noncommunicable Diseases website [3]

Thus, epidemiologic trends and reactionary U.N. agency contexts set the new international scene to consider as this Bonn follow-up meeting convenes to contemplate betterment of international radiation protection



implementation. Governments of low-resource Member States, where burdens of morbidity and mortality of NCDs are already increasing most rapidly [4], seek greater guidance regarding how to achieve accessible, equitable, high-quality, appropriate, sustainable, and *safe* UHC. Medical exposures do figure prominently within evidence-based clinical guidelines, algorithms, and best practices for the management and control of many NCDs, most notably in oncology. Medical exposures will therefore likely continue to increase strikingly, and greater implementation of (e.g.) referral guidelines and CDS (Clinical Decision Support) to insure appropriateness will continue to be of paramount importance, as will optimization. However, medical uses of radiation have yet to be integrated explicitly within major NCDs progress monitoring and UHC frameworks.

This conference may consider how best to align radiation protection synergistically with the burgeoning NCDs agenda. Specifically, how can this conference’s outcomes touch even the neediest of NCD patients and the individual practitioners serving them, those who remain largely untouched by high-level documents and calls to action?

### 3. EPIDEMIOLOGIC CONSIDERATIONS AND IMAGING

NCDs, also known as chronic diseases, are the culprits of 70% of annual global mortality, killing 40 million people per year. 15 million of these perish between ages 30-69, and more than 80% of such “premature deaths” take place in low- and middle-income nations. Furthermore, 80% of these “premature deaths” are caused by four disease groups. “Cardiovascular diseases account for most NCD deaths, or 17.7 million people annually, followed by cancers (8.8 million), respiratory diseases (3.9 million), and diabetes (1.6 million).” [5]

Beyond the scope of the paper is an itemization of myriad evidence-based clinical guidelines which inform regarding medical radiation exposures for the prevention, control, and management of the four aforementioned disease categories. This includes but certainly is not limited to interventional imaging for (e.g.) establishing patency of coronary or cerebral arteries, image-guided aspirations or biopsies or tumor ablations, image-guided placements of central venous catheters for administration of chemotherapy or other medications, and image-guided placement and/or serial management of dialysis catheters in the commonplace setting of diabetic nephropathy. Also beyond the paper’s scope is a description of nuclear imaging modalities such as positron emission tomography (PET) for cancer staging and management, or bone scans to assess osteomyelitis as a complication of diabetes.

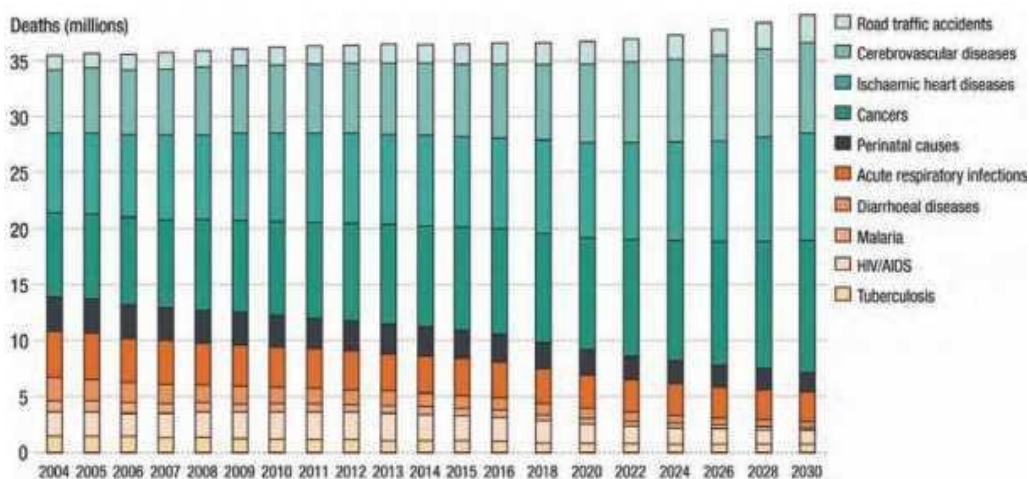


FIG. 2. Projections of mortality and burden of disease 2004-2030, from WHO Health Statistics and information systems, [14]

#### 4. THE WHO, WHA RESOLUTIONS, AND MEDICAL EXPOSURES

The World Health Organization has estimated that medical imaging is inadequately available to more than half of the world's population. [6] Concerning NCDs, concrete management data for cancer were spelled out by *Lancet Oncology* commissions for surgery and radiotherapy. [4] [7] These prove the socioeconomic benefits of countries' investments in oncologic surgery and radiotherapy, including frameworks for implementation per defined population density/per capita. The commissions presented their work as part of a World Health Assembly (WHA) technical briefing and WHA side events over serial years (2014-16). Resultant dialogue guided by ministries of health led to the proposal and unanimous adoption in 2017 of the WHA 70.12 resolution on Cancer Prevention and Control in the Context of an Integrated Approach, "acknowledging that, in 2012, cancer was the second leading cause of death in the world with 8.2 million cancer-related deaths, the majority of which occurred in low- and middle-income countries... with the annual number of new cancer cases projected to increase from 14.1 million in 2012 to 21.6 million by 2030." [8]

Currently, medical imaging serves a complementary role to multiple WHA resolutions; for example, WHA68.15 Surgical Care, WHA67.19 Palliative Care, WHA60.29 Health Technologies, and WHA67.23 Health Technology Assessment. To date, optimal medical imaging infrastructure per unit population has yet to be defined so as to best serve populations, commensurate with epidemiology. For example, data exist on the number of CT scanners in a country, in the absence of epidemiologic recommendations regarding how many CT scanners ideally should be in a country's public health system. The pre-existing *Lancet Oncology* models for cancer surgery and radiotherapy could be followed. [4] [7] Similar data and recommendations will one day be generated for medical imaging, and defined stepwise medical radiation management implementation should be included from the starting line.

#### 5. RP AND IN-COUNTRY IMPLEMENTATION: PERSPECTIVE OF A NON-STATE ACTOR

RAD-AID International is one of several radiology-related non-state actors officially affiliated with the WHO; as such, the organization seeks to collaborate with the WHO and other non-state actors as a team working towards public health targets delineated by the U.N. and WHO. RAD-AID's model places emphasis on in-country human capacity development and training within the fields of diagnostic imaging, interventional imaging, and radiotherapy. Across all of its partner locations, a key educational goal is to optimize the use of medical radiation exposures in patient care via multidisciplinary teams including medical physicists, radiologists, radiographers, nurses, and other health professionals. One challenge is the lack of formal education for the role of medical physicists in some low- and middle-income countries; this presents a dilemma where finding an appropriate stakeholder to take institutional ownership of dose optimization and quality assurance can prove difficult. If stakeholders agree about the goal, but have no support or resources for implementation, then the sustainability of radiation protection programs can be endangered. When incorporating radiation protection into global health programs, key factors for successful integration include relevant content, effective communication, stakeholder ownership, available resources, human capacity development via training and formal education, and government support.

In the RAD-AID Cancer Imaging and Treatment Initiative, which has sites in China, Kenya, and Tanzania, medical physicists "play a vital role in the multidisciplinary team of radiotherapy. Additionally, some RAD -AID partner locations, such as Tanzania, show an emergence of functional imaging techniques, so all scopes of medical physics are critical for success in outreach initiatives. In a stepwise approach supporting in-country human capacity building, the participation of medical physicists in RAD-AID International contributes to the mission of sustainable impact in radiology—including medical imaging and radiotherapy." [7][9] In another location, at the Lao Friends Hospital for Children (LFHC), the imaging professional on-site has been educated in a train-the-trainer fashion by volunteers to use medical exposures appropriate to the pediatric population, to implement radiation protection measures—such as shielding and collimation, and to teach his or her own colleagues about the importance of these processes. By integrating education on radiation protection from the outset to a key stakeholder, LFHC has always had a culture of dose optimization. As a closing example, RAD-AID works with the Guyanese Ministry of Health and the University of Guyana to provide education regarding the optimal use of computed tomography. Multidisciplinary teams of RAD-AID volunteers work with colleagues in Guyana on implementation of quality assurance processes from installation, protocol development for dose optimization, contrast safety, and communicating with clinicians regarding appropriateness guidelines for ordering. Having input from the Ministry of Health has been critical for setting a foundation of radiation protection at this location. [7][9][13]

#### 6. DISCUSSION REGARDING THE WAY FORWARD

Tangible improvement in radiation quality and safety in the community will only occur when facilities and practitioners apply the recommendations and tools. The following (Fig. 3 below) illustrates the need for continuation of efforts at various levels by different stakeholders. [9] While significant progress has taken place in the first 4 steps in recent years, more work is required for the last on-the-ground, front lines step. Most conferences and consultations to date have primarily addressed steps 2 and 3. Potential tools for the way forward may include RP surveys from the grassroots level through the top levels. Perhaps RP networks amongst users rather than regulatory authorities could be considered: self-help local and regional networks and chapters within each country. Not every country and certainly not every practitioner realize that RP support exists outside of their country. Maybe a next step could mirror the models of *Lancet Oncology* Commissions for surgery and radiotherapy? Or perhaps a simplified national template is warranted, following a proven model such as that for airline safety, with the U.N. agencies wielding their power to convene and providing a background coordination mechanism?



*Fig. 3 Translating research findings to improve practice. Research provides the scientific basis to improve knowledge in radiation risks; compare utilization, exposures, and trends; underpin advocacy messages, recommendations, and guidance tools; and guide interventions to reduce risks and improve practice [9]*

## 7. CONCLUSIONS

Strengthening of stakeholder collaboration has resulted in significant worldwide, system-wide improvement in radiation protection in medicine following the Malaga and Bonn conferences. Some examples include the adoption of the International Action Plan for the Radiological Protection of Patients, International Action Plan for Occupational Radiation Protection, Bonn Call for Action, and revised International Basic Safety Standards. As well, Council Directive 2013/59/Euratom was issued [10]; making basic safety standards for radiation protection legally binding throughout the European Union and initiating the process of country by country transposition. Landmark documents coupled with many fruitful meetings, workshops, initiatives, and the growth of multiple regional and national radiation protection campaigns (e.g. Image Gently and Image Wisely, EuroSafe, Canada Safe Imaging, AFROSAFE, Arab Safe, LatinSafe, Japan Safe) signify tremendous multinational collaborative momentum since Bonn. However, further system-wide and facility-based actions shall prove vital and complementary towards tangible continued improvement in patient care and radiation safety. Due to significant discrepancies in resources and practice settings, tailored solutions are preferred to meet local needs. Translating the BSS and Bonn Call for Action into broad implementation, to impact the most resource-constrained workplaces, remains elusive.

Opportunities exist to strengthen the use of recommendations and guidance tools in radiology facilities. Compared to authority-imposed regulations, end-user-initiated and mutually supported collaborative networks are more sustainable and effective strategies to improve radiation safety awareness, culture, and integration of recommendations into daily practice. Local, national and regional coordination between these end-user based

networks would ensure bi-directional communication: a timely awareness of evolving trends and more effective end-user advocacy for assistance from international organizations.

In conclusion, need for implementation of radiation protection will skyrocket concurrent with an anticipated rise in medical exposures in coming decades, to match population growth and a changing epidemiological landscape; particularly the scourge of NCDs which disproportionately affects low- and middle-income countries. Practitioner acceptance and use of collaboratively developed radiation safety recommendations and guidance tools rank among the top priorities for radiation protection now and in the next decade. Proposed is to map the way forward regarding how outcomes of this conference could touch even the neediest of patients, practitioners, and facilities; and how best to align radiation protection with the burgeoning public health priority, the NCDs agenda, which aims to address 70% of global mortality.

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# USING A PATIENT RADIATION PROTECTION MANUAL AS A FRAMEWORK FOR HEALTHCARE AUDIT

## A PRACTICAL EXAMPLE OF ACHIEVING CHANGE

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### ABSTRACT

A *Patient Radiation Protection Manual*<sup>1</sup>, developed by the author, was issued by the Irish Health Service Executive (HSE) to all clinical radiological facilities in Ireland, in 2013. This manual is a guidance document, specifically designed to promote a practical focus on patient radiation safety. It consists of seven sections detailing different elements of radiation safety and each section outlines key performance indicators (KPIs). The KPIs were successfully adopted by healthcare auditors from the HSE in the development of audit tools which were used to measure compliance with radiation safety legislation and best practice guidelines.

### INTRODUCTION

In order to ensure best practice and safe outcomes for both patients and staff, it is imperative that all those who work with medical ionising radiation have the appropriate education, information and training on radiation safety<sup>2</sup>. In recent years, as new technologies have developed, the use of ionising radiation in diagnostic and therapeutic procedures has increased considerably. And now, as latent effects of radiation dose to patients and staff become more apparent, the application of the three A's – Awareness, Appropriateness, Audit - is critical to promote good radiation safety practices<sup>3</sup>.

In 2013, the Irish Health Service Executive (HSE) introduced the *Patient Radiation Protection Manual* nationally as a guidance document for all staff working with medical ionising radiation. The manual has a specific focus on the practical aspects of patient radiation safety, with the aims of providing the necessary information regarding roles and responsibilities of clinical staff and promoting an awareness of radiation safety for patients. The manual acts as a central repository for information related to radiation safety legislation and consists of seven sections detailing different elements of radiation safety. Each section outlines key performance indicators (KPIs) for that particular area of practice.

The KPIs were successfully adopted by healthcare auditors from the HSE in the development of audit tools which were used to measure compliance with radiation safety legislation and best practice guidelines.

This paper outlines the purpose of the *Patient Radiation Protection Manual*, how it is presented and details the healthcare audits that were undertaken, based on the KPIs within the manual.

#### **PURPOSE, SCOPE AND OBJECTIVES OF THE *PATIENT RADIATION PROTECTION MANUAL***

The *Patient Radiation Protection Manual* is a guidance document to support the practical application of the safe and optimal use of medical ionising radiation in radiological locations, and to assist staff in developing local policies and procedures specific to their area of practice. By using this manual, it is expected that staff will have an increased understanding of their legislative and regulatory responsibilities in promoting radiation safety.

The objectives of the manual are as follows:

- To promote an understanding of the legislative requirements of staff in relation to patient safety and medical ionising radiation.
- To provide guidance on specific areas of practice, and roles and responsibilities of staff, in relation to patient radiation safety.
- To support the training and education of staff who work with medical ionising radiation.
- To assist locations in demonstrating compliance with regulatory requirements, national healthcare standards, accreditation and potential future licensing requirements.

#### **THE *PATIENT RADIATION PROTECTION MANUAL* FRAMEWORK**

The manual was developed using the *National Standards for Safer Better Healthcare*<sup>4</sup> as a template. These standards identify eight themes for patient safety which are outlined in *Figure 1*.

**Figure 1: Themes from the National Standards for Safer Better Healthcare**





The *Patient Radiation Protection Manual* is designed to incorporate the eight themes outlined above and is divided into seven sections. Each section focuses on a particular aspect of patient radiation safety and highlights the relevant themes associated with that area. *Figure 2* lists the seven sections of the manual.

**Figure 2: Sections of the Patient Radiation Protection Manual**

SECTIONS IN THE PATIENT RADIATION PROTECTION MANUAL	
1.	GOVERNANCE AND WORKFORCE
2.	RADIOLOGY EQUIPMENT
3.	INCIDENT REPORTING AND LEARNING
4.	PATIENT PREGNANCY PROTOCOLS
5.	CLINICAL AUDIT
6.	DIAGNOSTIC REFERENCE LEVELS

Clinical audit is a statutory requirement under Irish legislation for all radiological locations that administer medical ionising radiation to patients. To support this obligation, each section of the manual lists a suite of KPIs associated with that area of practice. These KPIs are measurable indicators that demonstrate progress towards a specific target and are listed at the start of each section. Each section of the manual, together with the associated KPIs and corresponding theme from the *National Standards for Safer Better Healthcare*, are described in *Figure 3*.

**Figure 3: Manual section, associated KPIs and corresponding theme from the *National Standards of Safer Better Healthcare***

Section of the Patient Radiation Protection Manual	Key Performance Indicators	Theme for the <i>National Standards of Safer Better Healthcare</i>
Governance and Workforce	<ul style="list-style-type: none"> <li>• Membership and terms of reference of the Radiation Safety Committee are available.</li> <li>• Minutes of meetings and records of attendance are available and up to date.</li> <li>• Records of actions taken following recommendations.</li> <li>• Induction and training dates for all staff working with medical ionising radiation are available and up to date.</li> </ul>	<p>Theme 5 – Leadership and Governance</p> <p>Theme 6 - Workforce</p>
Radiology Equipment and Reports	<ul style="list-style-type: none"> <li>• Licence from the Office of Radiation Protection and Environmental Protection is available and in date.</li> <li>• Equipment service records are available and up to date.</li> <li>• Evidence of a Quality Assurance programme.</li> </ul>	Theme 3 – Self Care and Support
Incident Reporting and Learning	<ul style="list-style-type: none"> <li>• Incidents are appropriately reported, investigated and acted upon.</li> <li>• Evidence of improvements as a result of incident investigations.</li> <li>• Evidence of staff awareness of incident reporting procedures.</li> <li>• Evidence of an annual review of all patient radiation safety incidents and near miss events.</li> </ul>	Theme 3 – Self Care and Support
Patient Pregnancy Protocols	<ul style="list-style-type: none"> <li>• Record kept of pregnancy status for female patients of childbearing age.</li> <li>• Documentary evidence of decision to proceed with imaging a pregnant patient.</li> <li>• Record of incidences where foetus inadvertently received a radiation dose and actions taken.</li> </ul>	<p>Theme 2 – Effective Care and Support</p> <p>Theme 3 – Safe Care and Support</p>
Patient Protocols	<ul style="list-style-type: none"> <li>• Evidence of patient protocols for specific procedures.</li> <li>• Evidence of patient identification policy.</li> <li>• Evidence of consent policy.</li> <li>• Evidence of use of referral criteria.</li> </ul>	<p>Theme 2 – Effective Care and Support</p> <p>Theme 3 – Safe Care and Support</p>
Clinical Audit	<ul style="list-style-type: none"> <li>• Evidence of local clinical audit.</li> <li>• Evidence of improvement plans as a result of audit recommendations.</li> <li>• Terms of reference of radiological clinical audit group.</li> </ul>	Theme 2 – Effective Care and Support
Diagnostic Reference Levels	<ul style="list-style-type: none"> <li>• Evidence that local diagnostic reference levels have been set and are reviewed annually.</li> <li>• Evidence of actions taken to improve diagnostic reference levels.</li> </ul>	Theme 2 – Effective Care and Support

## HEALTHCARE AUDIT

The HSE, as regulator of radiation protection in Ireland, sought assurance that radiological locations were operating in accordance with legislative requirements and were, at all times, promoting best practice in relation to patient radiation safety.

A number of audits were commissioned between November 2014 and July 2017 with the aim of determining compliance. These audits were undertaken by members of the healthcare audit team from the Quality Assurance and Verification Division within the HSE. The auditors were external to the radiological service and having no previous experience in the field, required a context expert to accompany them. The author, as the context expert and author of the *Patient Radiation Protection Manual*, helped with developing the audit tool, the interpretation of data and generating the final report.

These audits were retrospective in nature and involved a systematic review of documentary evidence from a specified period of time. Semi-structured interviews were conducted by the authors with relevant staff on site and analysis of local policies and procedures, risk management frameworks and local walk-a-rounds were undertaken. A wide spectrum of radiological locations were audited, including large academic teaching hospitals, step down radiological facilities and private locations. The audits did not include dental facilities that operate radiological equipment.

The incorporation of the *Patient Radiation Protection Manual* into local work practices was well established, having been issued in 2013 to all locations. The KPIs described in the manual formed the basis of the audit tools for each audit and made searching for evidence more focused and efficient.

Five sections of the manual were reviewed, with 23 audits conducted in total. The audit titles are listed below, together with the link to each summary report:

- *Audit of patient pregnancy protocols and diagnostic reference levels as outlined in the Medical Exposure Radiation Unit's (MERU) Patient Radiation Protection Manual*
- *Audit of incident reporting and learning as outlined in section 3 of the Medical Exposure Radiation Unit's (MERU) Patient Radiation Protection Manual*
- *Audit of incident reporting and learning in radiotherapy as outlined in section 3 of the Medical Exposure Radiation Unit's (MERU) Patient Radiation Protection Manual*
- *Audit of the justification process in diagnostic radiology.*

These audits demonstrated various levels of compliance with legislative requirements and best practice in relation to patient radiation safety. They highlighted areas of good practice which could be shared nationally and identified areas for improvement, both locally and nationally, which required attention. The recommendations made formed the basis of

quality improvement plans, both nationally and locally, which encouraged best outcomes for patients and staff.

## CONCLUSION

The *Patient Radiation Protection Manual*, as a benchmark for best practice, provided KPIs which could be used to measure compliance across a variety of locations. Without these KPIs, the audits would not have been as successful or effective in identifying and promoting good practice.

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## **WAYS OF IMPLEMENTATION OF SCIENTIFIC AND EDUCATIONAL ISSUES OF PATIENT'S AND PERSONNEL'S RADIATION PROTECTION IN GEORGIA IN THE LIGHT OF BONN CALL FOR ACTION**

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### **Abstract**

An evaluation of the results of the study of modern post-graduate program of the continuous medical education program "Radiation Protection and Safety" for medical workers were carried out. The study included 200 radiologists from Tbilisi and different regions of Georgia, among them 35% of dentists, 40% of conventional radiology, 15% of CT and 10% of specialists in nuclear medicine. The level of knowledge and skills was checked in the field of Physical principles of medical imaging, Basic radiobiology and radiation risk, Principles of radiation protection, including the competence of "justification" of radiological procedures and National Radiation safety infrastructure. The results of the tests showed the necessity for improvement of the educational curriculum at the level of a bachelor in medical profile universities. The changes required are: the inclusion of a basic radiobiological course in the curriculum of the faculty of medicine and expansion of the medical imaging methods. In addition, in the residency courses we consider to be appropriate to introduce "risk management" elements.

### **1. INTRODUCTION**

In January 2013, on the Conference of the National Academy of Sciences of Georgia "Medical radiation protection issues, the challenges, opportunities, development perspectives", the scientific and educational issues of implementation of the new International Basic Standards in nuclear and radiation safety were introduced. The resolutions of the conference in the form of Recommendations were sent to the relevant government agencies.

On the basis of the above mentioned resolutions in the Laboratory of Problem of Radiation Safety of Beritashvili Center of Experimental Biomedicine the following priority directions for research was developed:

1. Experimental and clinical trials for the development of complex (cyto-genetic, and physiosological) criteria and elaboration of the test-methods of individual radiosensitivity[1].

2. Preparation of methodological basis of assessment of radiation dose and risk in the medical exposition for Georgian population.
3. Preparation of educational programs on radiobiology and radiation protection, corresponding to the new International and European standards for undergraduate Bachelor's, and Master's level in Medical Universities and post graduated training courses for medical professionals[2].

To support this process, Tbilisi State Medical University (TSMU) in collaboration with Georgian National Association of Radiology and Beritashvili Centre of Experimental Biomedicine initiated several activities: postgraduate continuing medical education program “Radiation protection” for medical professionals; syllabus “Medical and biological physics” as a basic course in medical physics for the faculty of medicine (first-year students), syllabus of elective course “Radiobiology and radiogenic health risk” as an elective course in the faculty of medicine (fifth-year students), school-seminar programs for medical students from different regions of Georgia (1–2 year students) and conferences with participation of leading International experts and Georgian specialists, program “Biomedical engineering educational initiative in Eastern neighboring area” (Tempus project) and ongoing preparatory work on Master degree Program in Medical Physics.

The present article describes the analysis of the results of the work which was performed for the purpose of the assessment of learning outcomes of the continuous Medical Education program “Radiation protection and safety in Medical Radiology” for Medical Professionals and determining the ways for its further development.

## MATERIALS AND METHODS

The study included 200 radiologists from Tbilisi and various regions of Georgia, including 35% of dentists, 40% of conventional radiology, 15% of CT and 10% of specialists in nuclear medicine. The questionnaire (block of 500 multiple choice questions), (40 questions per listener) was compiled on the Basis of “Guidelines on Radiation Protection Education and Training of Medical Professionals in the European Union” [3], which included five main topics:

- a) Radiation Hazard – the health effects and mechanisms of low and high dose of radiation.
- b) Medical Imaging Physics – characteristics of different types of radiation and mechanisms of their interaction with matter, physical principles of medical imaging, the image quality, techniques constructive elements characteristics, the factors influencing the image quality and its indicators.
- c) Radiation Protection - basic principles, methods and ways of radiation protection, elements of operational radiation protection.
- d) Radiation Risk Management - health risk assessment, ‘benefit–risk balance assessment and competence of justification, understanding of quality assurance program.
- e) Elements of National Infrastructure for Radiation Safety.

For testing the “Appropriateness Criteria” of American College of Radiology was used.

Basic knowledge and skills was assessed by the number of correct answers, according 5-point scale system. The block of 40 multiple choice questions included 8 questions from each above mentioned 5 topics (6 questions of basic knowledge - 0.1 point each, and 2 questions revealing skills (quantitative evaluation skills) - 1.2 points each). Listeners were tested before and after training courses with the same tests questionnaire.

The results were processed by parametric and nonparametric statistics methods (Wilkinson, Kruskal-Wallis H Test, factorial ANOVA).

## RESULTS

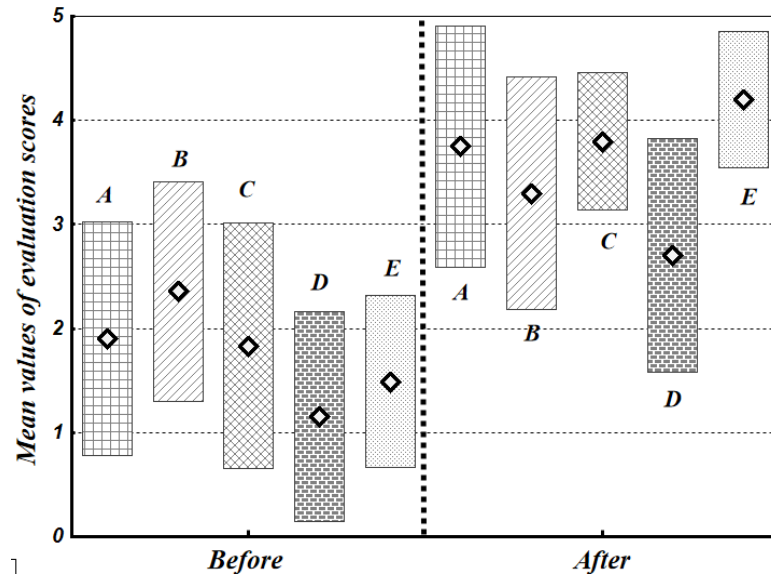


FIG 1. Results of the assessment of medical specialists in the Continuous Medical Education Program "Radiation Protection and Safety in Medical Radiology" (before and after training course). A - Radiation Hazard; B - Medical Imaging Physics; C - Radiation Protection; D - Radiation Risk Management; E - Radiation Safety. Boxes represent 95 % confidence interval of scores

The results of the study represent statistically significant difference between pre- and post-testing results for each group of listeners (Fig 1). Different direction and different level of initial knowledge, skills and competencies was revealed. This differences were also reflected in the high variability of the initial level of knowledge.

Above mentioned clearly indicates the necessity of further improvement of educational programs in Medical Radiology. First of all, it concerns the sphere of medical imaging physics and radiation risk management. It is obvious that the realization of this problem is less likely to be performed within the training courses.

## DISCUSSION

The education of medical professionals that complies with the modern requirements of radioprotection and safety is a systemic problem and requires a system solution. Taking into the account the academic curricula in the Higher Medical Schools of Georgia it will be advisable to make the following changes:

- Basic course of Medical Physics for Medical Universities must be strengthened by the module of Medical Visualization Physics (3d year);
- It is expedient to development of integrated module in Radiobiology and Radiogenic and Health Risk for Bachelor's programs in Medical Radiology, Radiation Oncology and Radiation Hygiene courses.
- Radiation Risk Management (justification) module should be included in residency course of Medical Radiology.

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**STUDY OF CYTOPATHOLOGICAL ACTINIC EFFECTS IN PATIENTS  
SUBMITTED TO RADIOTHERAPY OF CANCER OF THE UTERINE CERVIX  
AT THE NATIONAL INSTITUTE OF CANCER / INCA, RIO DE JANEIRO,  
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**ABSTRACT**

The aim of the present study was to evaluate the evolution of the cervical-vaginal smear cell changes in cervical cancer patients who underwent radiotherapy. This is a cohort study, with a descriptive analytical approach of the cytopathological exams (Papanicolaou smears) performed at Hospital do Câncer II - RJ / INCA, of patients who underwent radiotherapy for cervical cancer. In the years 2009 and 2010, 875 patients underwent radiation therapy for cervical cancer at the Hospital do Câncer II / INCA, however 407 patients were included in the study because they had two or more cytopathological exams after radiotherapy. The total number of smears performed was 2168, with an average of 5 smears per patient (ranging from 2 to 11 smears), until the first semester of 2017. More than half of the cytopathological examinations (1327) presented cytopathic actinic (radiotherapeutic) effects. Follow-up by means of cytopathological analysis of tumor persistence or post-radiotherapy recurrence has shown a satisfactory result with regard to the number of negative cases (1725), however, it is always a great challenge for the professional, even experienced, to differentiate the radiotherapy effects of neoplastic cell atypia.

**Keywords:** Radiotherapy, Actinic Effects, Cytopathology, Cervical Cancer.

## 1. INTRODUCTION

In the world, cervical cancer represents the fourth most common type of cancer among women, except for cases of non-melanoma skin. It is responsible for approximately 265.000 deaths per year [8]. In Brazil, it is considered a public health problem, in 2016, 16.340 new cases were registered, with an estimated risk of 15.85 cases per 100.000 women. The most common treatments for cervical cancer are surgery and radiation therapy. The type of treatment will depend on disease staging, tumor size and personal factors, such as age and desire to maintain fertility [7].

Very often patients with malignant uterine cervix tumors are referred to radiotherapy when the disease is in advanced stages and this fact determines high rates of relapse [6,7].

Radiation therapy consists of the use of ionizing radiation to destroy tumor cells; it is divided into Teletherapy (external) and Brachytherapy (internal). Teletherapy is performed by administering radiation from a source placed away from the patient [18]. The distances most used today are 80 cm for the ancient linear accelerators and the cobalt equipment or 100 cm for the modern linear accelerators. Cobalt therapy equipment is falling into disuse. Linear accelerators can be presented in two main versions: with or without electron beams [12,13]. Each patient can be treated with one or more radiation fields. The sum of the contribution of each field will produce a scheduled dose distribution in a Planning System [12].

When the source of radiation is placed inside the patient or very close to the patient's skin, the treatment is called brachytherapy. The dose rate which the treatment is given defines the type of brachytherapy: low rate (LDR), medium rate (MDR) or high dose rate (HDR). Few radioisotopes are currently used for this purpose. The most used is the Iridium-192, followed by Iodine-125, Cesium-137 and Cobalt-60 [12].

Radiation treatment causes actinic morphological changes, not only in neoplastic epithelial cells, but also in normal cells. These changes induced by radiation often hamper the differential diagnosis of residual lesions, resulting in great difficulties in differentiating neoplastic cells from those with actinic (radiotherapeutic) effects [14,15].

There are intracellular mechanisms capable, in many cases, of leading the cell back to its initial state. However, if the injury is very serious, or the repair mechanisms are compromised or overwhelmed by excessive radiation, the cell will transform [2].

Therefore, the objective of the present study was to evaluate the evolution of cervical-vaginal smear cell changes in patients with uterine cervix cancer who underwent radiotherapy.

## 2. METHODOLOGY

This is a cohort study, with a descriptive analytical approach of the cytopathological exams (Papanicolaou smears) performed at Hospital do Câncer II (HC2) - RJ / National Cancer Institute (INCA), of patients who underwent radiation therapy for cervical cancer. The work was approved by the INCA Ethics Committee (CAAE: 57701616.6.0000.5274).

Patients with uterine cervix cancer submitted to radiotherapy in the period between January 2009 and December 2010 were included, and patients without reference to radiotherapy, without information on the clinical staging of the lesions, patients who did not perform at least two Cytological exams after radiotherapy and that did not have at least two smears with satisfactory cellularity for analysis were excluded from the study.

Patients were identified through the HC2 / INCA Hospital Registry of Cancer (RHC). The clinical-epidemiological data were cataloged through the medical records available in the HC2 / INCA files. A reevaluation of cytopathological smears was performed to evaluate the evolution of actinic cytopathic effects. This information was complemented by the cytopathological report of the smears available in the archives of the Division of Pathology (DIPAT) - INCA. The data were collected in instruments developed for this purpose.

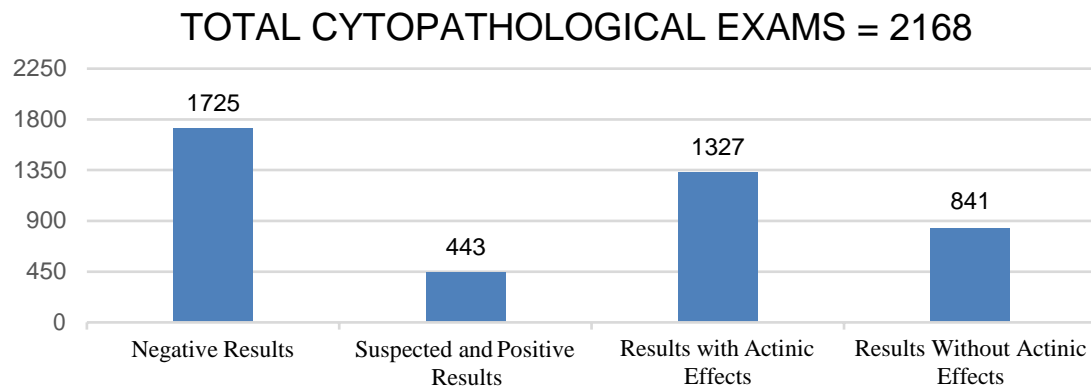
## 3. RESULTS

In the 2009-2010 period 875 patients underwent radiation therapy for cervical cancer at the Hospital do Câncer II / INCA. However, only 407 patients reached the inclusion criteria of two or more cytopathological exams (Papanicolaou smears) after radiotherapy to enter the study.

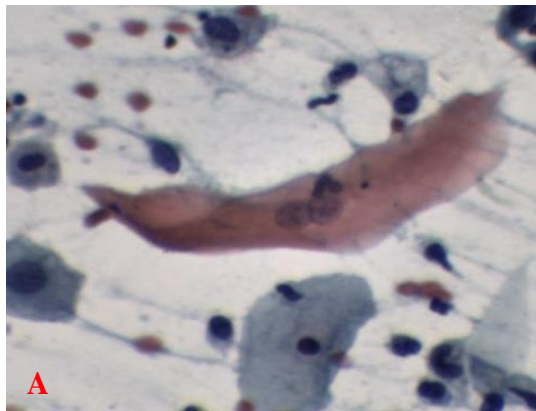
The mean age of the patients included was 51.4 years (ranging from 24-87 years). The total number of smears performed was 2168, with a mean of 5 smears per patient (ranging from 2 to 11 smears), until the first semester of 2017, where 79.6% (n = 1725) of cytopathological results were negative for neoplasia.

More than half of the cytopathological exams, 61.2% (n = 1327), presented cytopathic actinic / radiotherapeutic effects. (**Graph 1**)

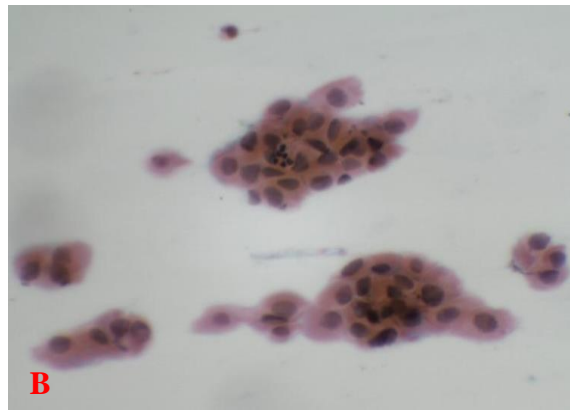
**GRAPHIC 1.** Cytopathologic exams performed after radiotherapy in patients with cervical cancer



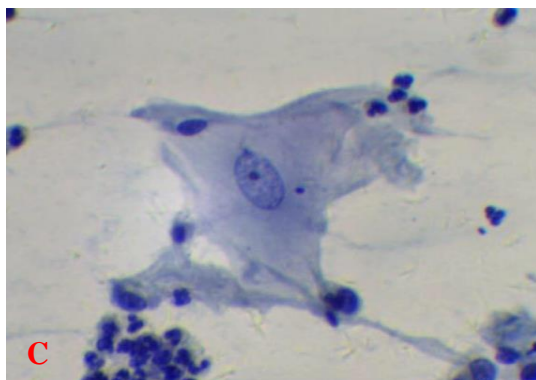
The most frequent actinic effects observed were: binucleation (**Fig.1A**), dyskeratosis (**Fig.1B**), prominent nucleoli (**Fig.1C**), intracytoplasmic vacuoles (**Fig.1D**), as well as amphophilia, macrocytosis, nuclear activation, Cellular atrophy, pleomorphism, multinucleation, and nuclear picnosis. Another finding found in most smears was the intense exsudate leukocyte and necrotic and hemorrhagic areas.



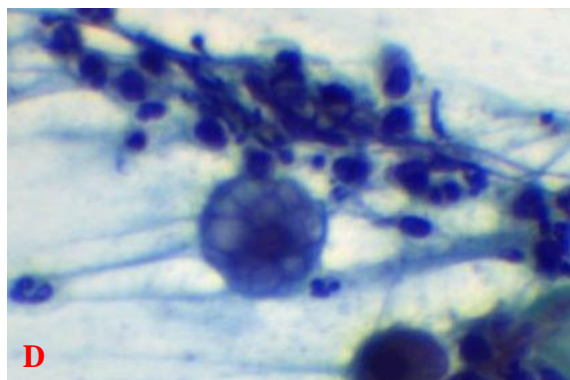
**A.** Binucleated epithelial cell  
(optical microscopy increased - 40x)



**B.** Dyskeratosis cell clusters  
(optical microscopy increased - 40x)



**C.** Epithelial cell with prominent nucleolus  
(optical microscopy increased 40x)



**D.** Cell with intracytoplasmic vacuoles (optical microscopy increased 40x)

**FIGURE. 1.** Epithelial cells showing actinic effects (study cases: patients undergoing radiation therapy for cervical cancer).

#### 4. DISCUSSION AND CONCLUSION

There are many factors that determine the biological response to radiation exposure that include variables associated with the radiation source and the system being irradiated. Among them are radiation dose, type and energy, radiation rate and conditions under which the dose is administered [11].

According to Murad and August (1995), almost all cells undergo radiation-induced changes. The cellular alterations, even presenting a pattern already described in the literature, can evidence a wide and complex series of morphological modifications, with the appearance of bizarre cytological formations difficult to interpret [10].

To date, it has not been possible to establish a protocol that can accurately differentiate the morphological characteristics between benign cells with actinic effects of recurrent malignant cells on post-radiotherapy smears. [14,15].

In our results, we observed through cytopathologic analysis of tumor persistence or post-radiotherapy recurrence, a satisfactory result with regard to the number of negative cases (79.6%), but more than half of the cases had actinic effects (61.2%).

It is always a great challenge for the professional, even experienced, to differentiate the radiotherapy effects from neoplastic cell atypia. Further studies on the subject are important to contribute to the quality of the diagnostic evaluation for the follow-up of post-radiotherapy patients.

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# **PILOT PROJECT FOR IMPLEMENTATION OF THE NATIONAL COMMISSION FOR RADIOPROTECTION AND DOSIMETRY OF THE CONTER**

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## **ABSTRACT**

The aim of this work is to present the pilot project for implementation of the National Commission for Radioprotection and Dosimetry (CNRD) of the Brazilian National Council of Technicians and Technologists in Radiology (CONTER). The commission was created as an effort to develop a radioprotection culture for professionals in radiographic techniques.

Keywords: radioprotection, CONTER, CNRD.

## **1. INTRODUCTION**

The use of ionizing radiation in the fields of medicine, industry and research is of great importance to mankind. However, undue exposure poses a health risk. In Brazil, CNEN and Portaria 453/98 establish three basic principles of radioprotection: (i) justification, which states that any activity involving radiation must be justified, in addition to producing a positive benefit for society; (ii) optimization, which states that all exposures should be kept as low as reasonably practicable and (iii) dose limitation, which determines that individual doses of workers and individuals from the public should not exceed the annual limits established by CNEN [1] and Portaria 453/98 [2].

The need for radioprotection is based on the problems that appear to the professional users of sources that emit ionizing radiations. Therefore, the objective of this work is to present the pilot project of the National Council of Technicians and Technologists in Radiology (CONTER), which created the National Radioprotection and Dosimetry Commission (CNRD), in order to develop a radioprotection culture for radiographic techniques.

## **2. METHODOLOGY**

The project is based on a proposal to develop and implement a system to discuss topics relevant to the professional practice of the class, generating documents that guide and create a culture of radioprotection, serving as a model for CONTER. The decisions of the CNRD are independent and transparent and are not influenced by the CONTER Board.

## **3. RESULTS**

CNRD works in the evaluation, research and technical surveys inherent to the radiological protection, presenting work fronts to evaluate problems, such as: (i) excessive use of radiological examinations; (ii) repetition of examinations for technical errors; (iii) control of absorbed doses; (iv) misuse of dosimeters and radiation protection equipment.

CNRD was created in march 2016 and all work developed so far serves as a reference to CONTER for issues and issues that conflict with other professionals or bodies. The effort to disseminate the correct use of radiation through the use of social networks and booklets has promoted the creation of a culture of radiation protection among the workers and users of the services that use ionizing radiations.

## **4. DISCUSSION AND CONCLUSION**

The work of the National Commission on Radioprotection and Dosimetry by the National Council of Technicians and Technologists in Radiology serves as a reference to CONTER for issues that conflict with other professionals or bodies and the effort to disseminate the correct use of radiation has promoted the creation of a culture of radiation protection among workers and users of services that employ ionizing radiation.

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# **HOW RESEARCH CAN IMPACT RADIATION SAFETY CULTURE IN SOUTH AFRICAN CATHETERISATION LABORATORIES**

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## **Abstract:**

Ionizing radiation is an integral part of modern medicine. The modality offers tremendous benefits for diagnosis, treatment and prognosis of patients. But radiation increases risk of harm for patient and staff. Occupationally related radiation induced cataracts occur in some interventionalists, and this risk should be mitigated. This can be achieved by cultivating a culture of radiation protection (CRP). Several activities can enhance a CRP amongst interventionalists including: formalising radiation safety education and training curricula for radiation workers, implementation of radiation protection policies, encouraging support for such policies and implementation of national regulations. Currently active research project studying the prevalence of cataracts among South African (SA) interventionalists, and investigating their radiation safety practices, demonstrates how research may, in itself, modify the CRP. The article considers the impact that the research process itself may have on a CRP. Such projects having inclusive involvement of members of the relevant professions are seldom carried out in SA. Opportunities were created to influence debate on radiation safety and to encourage a positive CRP in SA. It is proposed that an effective and potentially long-lasting intervention for enhancement of a CRP may be to do research which involves active participation of the radiation worker community.

## INTRODUCTION

Imaging modalities using ionising radiation form the basis of many diagnostic, prognostic and therapeutic procedures in modern medicine. [1] These modalities offer great benefit, but are accompanied by potential health risks for patients and operators. These risks may include, amongst others: skin effects, carcinomas, and cataracts. The lenses have been shown to be prone to developing opacifications which may develop into complete cataracts. [2] This has important health implications for radiation healthcare workers (HCWs).

Safety in catheterisation laboratories can be secured in the following ways: engagement of clinicians to consider alternate modalities in imaging patients, application of the ALARA principle when imaging, vigilance in monitoring patient doses during patient procedures, and consistent use of personal protective equipment (PPE). [3] Management of medical radiation facilities should be engaging and proactive in facilitating a safe radiation work environment. [3] This can be expedited by ensuring that procurement processes are in place to ensure that equipment is purchased, serviced, and that appropriate and adequate PPE is available.

These measures are what determine and shape the culture of radiation protection (CRP) in an organisation. [4,5] The heads of department of radiation units are crucial to fostering a CRP. It is however also the responsibility of everyone in a department to be aware of radiation safety issues and to promote and sustain this culture. Imperative to developing and maintaining a CRP is to include it in the formal training and continued medical educational activities of interventionalists and other radiation HCWs. [4,6]

The aim of the study is to describe key findings and how the research activities of the project contributed to raising awareness about radiation safety in catheterisation laboratories in SA, and therefore how the research process itself impacts radiation safety culture.

## METHODS

This is an observational case study (hereafter called the study) describing the activities related to a national interdisciplinary project using multiple methods to describe the prevalence of cataracts in South African (SA) interventionalists and to understand their radiation safety practices, being carried out in interventional radiology and cardiac catheterisation laboratories country wide, details of which are described elsewhere. [7] Details of the contacts made, the events organized, and the outputs delivered and planned, are described. The number of contacts is given in context of the total numbers of professionals within the disciplines involved during the activities of the PhD. Multiple methods were used to determine the prevalence of cataracts in SA as it had not been described before (quantitative). The researchers also wanted to understand the current radiation safety culture in SA (qualitative). Professionals from the following disciplines were invited to participate in the project to help understand the multiple layers of the research question: public health, occupational health, medical physics and ophthalmology.

The project population included adult cardiologists, paediatric cardiologists and radiologists that perform interventional fluoroscopy see Table 1. A control group of doctors unexposed to radiation was also included.

TABLE 1: Show the population used in the study from different disciplines as well as their respective numbers

	nterventional Radiologists	Adult cardiologists	Paediatric cardiologists	Unexposed group
Approximate number in SA	50	<u>229</u>	<u>41</u>	<u>N/A -</u>
Completed survey	47	42	33	101
Had ophthalmological screening	22	39	29	60
Participated in interviews	29	16	9	N/A -

The quantitative component comprised a survey and ophthalmological screening for cataracts. The qualitative component consisted of in-depth interviews and group interviews using a semi-structured interview schedule.

The data were mainly collected at conferences, scientific workshops and CME meetings see Table 2. At some of these meetings the opportunity arose to introduce the reason for the project and mention about the concerns of radiation safety in the cath. lab. While it cannot be quantified, the impact the researchers' presence had at these meetings is anecdotally believed to have raised awareness about radiation safety in the radiation workplace environment.

TABLE 2: Shows the conferences attended and the approximate number of people that attended

Conference/ meeting	Approximate number of attendees
Interventional radiology workshop (2015)	40 interventional radiologists
Paediatric interventional cardiology workshop (2015)	30 paediatric cardiologists
SA Heart (Nat. cardiology congress) (2015)	200 cardiologists
SA Radiological Society Conference (2015)	400 radiologists
Family Medicine workshop (2015)	30 family medicine doctors
SA Heart (Nat. cardiology congress) (2016)	200 cardiologists
Radiology congress (2016)	100 radiologists
Family medicine workshop (2017)	30 family medicine doctors
Forensic medicine congress (2017)	60 doctors

## RESULTS AND DISCUSSION

The personal contact and involvement of the groups being studied included professionals who were asked various focused questions on their attitudes, training and practices with regards radiation protection. Although this group reached a smaller more limited segment of the target population, the involved and deliberate participation of these participants was more focused and interactive than those filling in the survey or having their eyes examined. All Heads of Department were approached and made aware of the project and invited to participate. The Colleges of Medicine of South Africa (CMSA) and the Medical Research Council of SA (SAMRC) are aware of the project and the SAMRC is acknowledged as the funder of the bursary.

There were 248 participants in the project, 223 completed the questionnaire and 175 participants underwent eye screening. There were 47 (21%) radiologists, 42 (18%) cardiologists, 33 (14%) paediatric cardiologists and 101 (45%) unexposed doctors. Cataracts were present in 23 (13%) of participants. 13 (56%) of the cataracts found were in interventionalists.

The qualitative findings showed that radiologists tended to be better trained in radiation safety than cardiologists. [6] Radiologists tended to be more aware than cardiologists of what constituted a CRP. Both radiologists and cardiologist agreed that building and sustaining a culture of radiation protection was needed. Formalised training was an important consideration in establishing a CRP.

Participants reflected during the interviews that they felt that the research had made a difference to their attitudes and behaviour in the radiation working environment. One cardiologist reported, "It [radiation safety] is something we've never discussed or even brought up in a meeting until you can along actually." While the other cardiologist said: "I am actually worried now. It made me realise how and ...we didn't think about this things" implying the research process had sensitised them to issues on radiation safety.

There was poor compliance in using dosimeters. Only 59 (59%) of participants indicated they consistently used dosimeters. The qualitative data reflected that participants were not vigilant in using dosimeters because they did not receive consistent and regular feedback on their exposure, they were not held accountable for wearing it and they frequently forgot to take it into the cath. lab.

## TRANSLATION AND DISSEMINATION OF RESEARCH FINDINGS

The findings from this project were presented at several forums and it is believed that this may have had an impact in raising awareness about ionising radiation safety in the catheterisation laboratory. These presentations are summarised in Table 3. The work emanating from this project has been published in two peer review journals [6,7] and three other publications are either awaiting submission, or have been submitted for review.

TABLE 3: National and international congresses where the findings of the project was presented

Scientific meeting or Conference	Work presented
Paediatric interventional workshop (Cape Town, 2015)	Talk on radiation safety
SA Heart (2016)	Preliminary findings on paediatric cardiologists
Human Resources for the South African Health System (Pretoria, 2016)	Radiation safety training and education in South Africa: an unseen calamity.
Mixed Methods International Research Association Conference (Pretoria, 2017)	Using multiple methods to understand radiation safety practices in South African interventionalists.
South African Association of Physicists in Medicine and Biology (Durban,2017)	Dosimetry utilisation and practices among South African internationalists.
World Federation of Public Health Associations (Melbourne, 2017)	Radiation Safety Practices Among South African Interventionalists: Reflections on Accessing a 'Hard-to-Reach' Population.

## LIMITATIONS

The observed research activities probably made an impact, but it cannot be assumed that all research in the field will have similar effects. Secondly, it is biased in that the observer of the research project is involved and has a conflict of interest and thus influences interpretation of what was observed.

The observed project also had limitations as it did not measure actual doses and estimates are based on self-reported workload which may under- or over-estimate the workload dose. Future studies looking at empirical dose measurements to the eye are needed. The project did not explore how a culture of radiation protection could be initiated and established in SA and future studies may wish to explore this aspect. The project did not investigate the role management plays in establishing a CRP and future studies could look at this aspect. Future studies could explore issues around patient safety.

## DISCUSSION

Radiation safety in the catheterisation laboratory in South Africa is not well described. The project has help to bridge this gap. It has created awareness about radiation safety by engaging with the Radiological Society of South Africa, The Cardiology Society of South Africa (SA Heart), the Paediatric Cardiology Society of South Africa and the Medical Research Council of South Africa. Participants expressed the opinion that they were more informed and aware of radiation risk and effects following their participation. This is seen as evidence that the process of doing the research project in itself made an impact on the culture of radiation protection amongst interventional radiologists.

## CONCLUSION AND RECOMMENDATIONS

Observational case studies involve studying an individual or small group. There have been very few studies considering how the research process itself brings about change and education of the studied group. [8] These may assist in understanding activities or special cases, but they cannot be used to establish causality and cannot make predictions. A single research project is described here where the overarching aim was to positively influence the culture of radiation protection in SA. The findings around attitudes toward aspects of radiation protection, lens changes and risks in the studied population, and current training and education of interventionalists all contributed to increasing awareness in the studied group. The impact of this research on cultural behaviour is difficult to quantify, but a follow up project could be carried out in two years or more from now to determine if attitudes and perceptions of the target populations have changed. Researchers and some participants felt that although influencing the culture of radiation protection in SA was not the stated aim of this project, it has, as a result of its many and diverse activities and high level of exposure, contributed to raising awareness about radiation protection amongst interventionalists and thus hopefully contributed to an improved radiation safety culture in SA. A stated aim was to motivate changes in the curriculum of interventionalists in training as this will greatly encourage a change in behaviour and facilitate a CRP. Our appeal is that more research of this nature should be encouraged and carried out as an instrument of change in our discipline.

The project described in this study addresses several areas relevant to the IAEA International Conference on Radiation Protection in Medicine (11-15 December 2017): the Bonn Call to Action (2012) by identifying gaps in radiation protection in South Africa and implemented measures to address these gaps (section C.1), radiation safety issues surrounding interventionalists performing fluoroscopic procedures (section C.3 and C.5), understanding the culture of radiation protection in the SA context and facilitated debate on the topic by medical professionals using ionising radiation (section C.10 and C.11). Talks were presented on radiation safety in the cath. lab to paediatric interventional cardiologists (About 75% of SA paediatric interventional cardiologists were present at this talk). As a final attempt to disseminate the findings of this project, a national colloquium on radiation safety is planned for 5-6 December 2017, targeting the Presidents of the Cardiology, Radiology, Orthopaedic and Urology South African Colleges of Medicine (section C.14), and the research project has stimulated ideas for future projects, such as eye dosimetry of SA interventionalists (section C.15). All this is evidence that this research project has made an impact on radiation protection culture and others like it may also achieve this goal. It is thus recommended that research itself can make an impact and researchers should bear this in mind when developing their protocols to make the most of this aspect of research project implementation.

## ACKNOWLEDGMENTS

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## **STRENGTHENING RADIATION SAFETY CULTURE IN HEALTHCARE FACILITY USING WEB BASED INSPECTION (BALIS INFARA)**

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### **Abstract**

The current developments related to awareness of the radiation safety in healthcare facility are contained in joint statement of the Bonn Call for Action. Under the joint statement it is convinced that one measure to strengthen radiation protection on patients and overall health of workers requires the strengthening of radiation safety culture. The regulatory body's measures to strengthen the radiation safety culture of health facilities in Indonesia are faced one of them with the challenge that the quantity of health facilities in Indonesia is relatively very vast and wide scattered throughout Indonesia, while the number of human resources in the regulatory body is limited, furthermore requiring an effective method in order to strengthening the radiation safety culture. One of the measures of the regulatory body to strengthening of radiation safety culture is through a web-based participation inspection (Balis Infara), whereby by this inspection the basic concepts of strong safety culture attributes will be established through the active participation of licensee and foster closer cooperation between regulatory bodies and health facilities in strengthening safety culture

### **1. INTRODUCTION**

As an Indonesian nuclear regulatory bodies (hereinafter referred to as BAPETEN) have a task and function to conduct of inspection, establish regulation and issuing of license in order to regulatory controlling of radiation utilization, which one of the goal is improving the awareness of radiation safety in order to cultivate a safety culture as has been mandated in Law Number 10 Year 1997 on Nuclear Energy[1], whereas the current international awareness in realizing radiation safety in the healthcare facility is contained in a joint statement by Bonn Call for Action which is the specific outcome of "International Conference on Radiation Protection in Medicine: Setting the Scene for the Next Decade" in Bonn, Germany, in December 2012. All States who attended agreed that one measure to strengthen radiation protection of the patient and the health of radiation workers requires the strengthening of radiation safety culture in healthcare facility, which must be supported by all stakeholders, both health facilities and regulatory bodies[2].

The safety culture basically is the nature and attitude in organizations and individuals emphasizes the importance of safety. Therefore, the safety culture requires all obligations relating to safety must be carried out properly, thoroughly, and responsibly[1]. Comprehensive partnerships between all stakeholders are essential, so they are needed to foster closer cooperation of all stakeholders including between regulatory bodies and healthcare facilities in order to strengthen safety culture.

One of the measures to strengthen the safety culture in the controlling of radiation in the healthcare facilities undertaken by BAPETEN through the conducting of inspection is still faced with a various challenge. The one of the challenge is that the users or licensee of healthcare facility have a relatively vast quantity and are scattered throughout of Indonesia while the number of human resources in the regulatory body is limited, therefore it is requiring a breakthrough of methods and tools in order to improve the effectiveness of inspections to realize the strengthening of radiation safety culture in healthcare facilities.

### **2. METHODS**

A paper is a using description methodology in order to describe measure of BAPETEN during conducting of inspection for strengthening safety culture in a healthcare facilities based on the challenge that the

quantity of healthcare facilities in Indonesia is relatively vast and wide scattered throughout Indonesia, while the number of human resources in the regulatory body is limited.

## 2.1. Current safety culture awareness

The International Atomic Energy Agency (IAEA) held the “International Conference on Radiation Protection in Medicine: Setting the Scene for the Next Decade” in Bonn, Germany, in December 2012, in order to the identification of responsibilities and a proposal for priorities for stakeholders regarding radiation protection in medicine for the next decade. This specific outcome of its conference is the Bonn Call for Action that highlights ten main actions, and related sub-actions, that were identified as being essential for the strengthening of radiation protection in medicine over the next decade. The actions are not listed in order of importance. Action by all stakeholders is encouraged, comprises of:

- Action 1: Enhance the implementation of the principle of justification
- Action 2: Enhance the implementation of the principle of optimization of protection and safety
- Action 3: Strengthen manufacturers’ role in contributing to the overall safety regime
- Action 4: Strengthen radiation protection education and training of health professionals
- Action 5: Shape and promote a strategic research agenda for radiation protection in medicine
- Action 6: Increase availability of improved global information on medical exposures and occupational exposures in medicine
- Action 7: Improve prevention of medical radiation incidents and accidents
- **Action 8: Strengthen radiation safety culture in health care**
- Action 9: Foster an improved radiation benefit-risk-dialogue
- Action 10: Strengthen the implementation of safety requirements globally[2].

One of the main actions is **Strengthen radiation safety cultures in healthcare, with related sub-actions are** consecutively comprises of:

- **Establish** patient safety as a strategic priority in medical uses of ionizing radiation, and recognize leadership as a critical element of strengthening radiation safety culture,
- Foster closer co-operation between radiation regulatory authorities, health authorities and professional societies,
- Foster closer co-operation on radiation protection between different disciplines of medical radiation applications as well as between different areas of radiation protection overall, including professional societies and patient associations,
- Learn about best practices for instilling a safety culture from other areas, such as the nuclear power industry and the aviation industry,
- Support integration of radiation protection aspects in health technology assessment; Work towards recognition of medical physics as an independent profession in health care, with radiation protection responsibilities, and
- Enhance information exchange among peers on radiation protection and safety-related issues, utilizing advances in information technology.

Its main actions and related sub-actions strongly indicate that within the framework of strengthening the safety culture requires close cooperation between the regulatory body and the healthcare facility as well as encouraging the importance of using information technology to bridge the exchange of information between the regulatory body and the healthcare facility

## 2.2. BAPETEN's perspective on safety culture during inspection

Awareness of the importance of radiation safety culture has been formally legalized since the enactment of Law No. 10 of 1997 on Nuclear Energy. For more detailed arrangements regulated in many of the implementing regulations in the form of government regulations. In addition, international practices are also widely adopted for reference in the establishing of a regulation related to safety culture. Based on Government Regulation Number 33 Year 2007 on The Safety of Ionizing Radiation and Security of Radioactive Source, safety culture is defined as a blend of the nature of organizational and individual attitudes within an organization that gives attention and priority to Radiation Safety issues [3]. Its mean that national policy and strategy for safety already expressed a long term commitment to safety and also promoting of leadership and management for safety, including safety culture. The implementation of the inspection BAPETEN should be able to ensure that aspects of safety culture should be a major consideration aspect although it’s conducting with grading approach. It is in line with international practise which emphasize that Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a



graded approach[4]. During inspection it will be ensure that licensee has had a measure to realize a safety culture through [5]:

- (1) making standard operating procedures and policies that put Radiation Protection and Safety at the highest priority;
- (2) identify and improve the factors that affect Radiation Protection and Safety according to the level of potential hazards;
- (3) clearly identifying the responsibilities of each personnel for radiation protection and safety;
- (4) establishing clear authority of each personnel in every implementation of Radiation Protection and Safety;
- (5) establishing good communication networks at all levels of the organization, to generate an appropriate flow of information on Radiation Protection and Safety, and
- (6) Establishing adequate qualifications and training for each personnel.

From this inspection result it can be expressed that the safety culture status of a facility can be seen from some characteristics of its safety culture. Strong safety culture can be identified through some of the following characteristics and attributes that consisting of:

- (1) Safety is a clearly recognized value
  - The high priority given to safety is shown in documentation, communications and decision making
  - Safety is a primary consideration in the allocation of resources
  - The strategic business importance of safety is reflected in the business plan
  - Individuals are convinced that safety and production go hand in hand
  - A proactive and long term approach to safety issues is shown in decision making
  - Safety conscious behavior is socially accepted and supported (both formally and informally)
- (2) Leadership for safety is clear
  - Senior management is clearly committed to safety
  - Commitment to safety is evident at all levels of management
  - There is visible leadership showing the involvement of management in safety related activities
  - Leadership skills are systematically developed:
  - Management ensures that there are sufficient competent individuals
  - Management seeks the active involvement of individuals in improving safety
  - Safety implications are considered in change management processes
  - Management shows a continual effort to strive for openness and good communication throughout the organization
  - Relationships between managers and individuals are built on trust
- (3) Accountability for safety is clear
  - An appropriate relationship with the regulatory body exists that ensures that the accountability for safety remains with the licensee
  - Roles and responsibilities are clearly defined and understood
  - There is a high level of compliance with regulations and procedures
  - Management delegates responsibility with appropriate authority to enable clear accountabilities to be established
  - ‘Ownership’ for safety is evident at all organizational levels and for all personnel
- (4) Safety is integrated into all activities
  - Trust permeates the organization
  - Consideration of all types of safety, including industrial safety and environmental safety, and of security is evident.
  - The quality of documentation and procedures is good
  - The quality of processes, from planning to implementation and review, is good
  - Individuals have the necessary knowledge and understanding of the work processes
  - Factors affecting work motivation and job satisfaction are considered
  - Good working conditions exist with regard to time pressures, workload and stress
  - There is cross-functional and interdisciplinary cooperation and teamwork
  - Housekeeping and material conditions reflect commitment to excellence:
- (5) Safety is learning driven
  - A questioning attitude prevails at all organizational levels
  - Open reporting of deviations and errors is encouraged:
  - Internal and external assessments, including self-assessments, are used:
  - Organizational experience and operating experience (both internal and external to the installation) are used

- Learning is facilitated through the ability to recognize and diagnose deviations, to formulate and implement solutions and to monitor the effects of corrective actions
- Safety performance indicators are tracked, trended and evaluated, and acted upon
- There is systematic development of individual competences[6].

### 2.3. Web based participation inspection using Balis Infara

In order to improve the effectiveness of monitoring the utilization of radiation in Indonesia and to respond to the challenges and demands in improving the efficiency, effectiveness and transparency of business processes and working mechanisms, BAPETEN launched an application for inspection radiation facility and radioactive material that is called BAPETEN Licensing and Inspection System Online (Balis Infara) [7]. The Balis Infara works in a web-based real-time online in an internet network, and built using open source software to facilitate public involvement of the monitoring process through an integrated inspection with the Licensing System, and the Radiation Worker Dose Evaluation System. The Balis Infara also provide as a reporting media of safety condition, and also including among others the transport of radiation sources, current information on radiation sources, radiation worker information, and safety and security facility performance .

With the Balis Infara it will be shift the paradigm of inspection, from the conventional inspection model to participatory inspection model, where the involvement of the users plays an important role in determining the effectiveness of inspection. The Balis Infara also encourages users to be able to independently inspect in the same parameters and criteria as the BAPETEN inspectors. The involvement of the users strongly factor to improving a safety culture in the utilization of radiation.

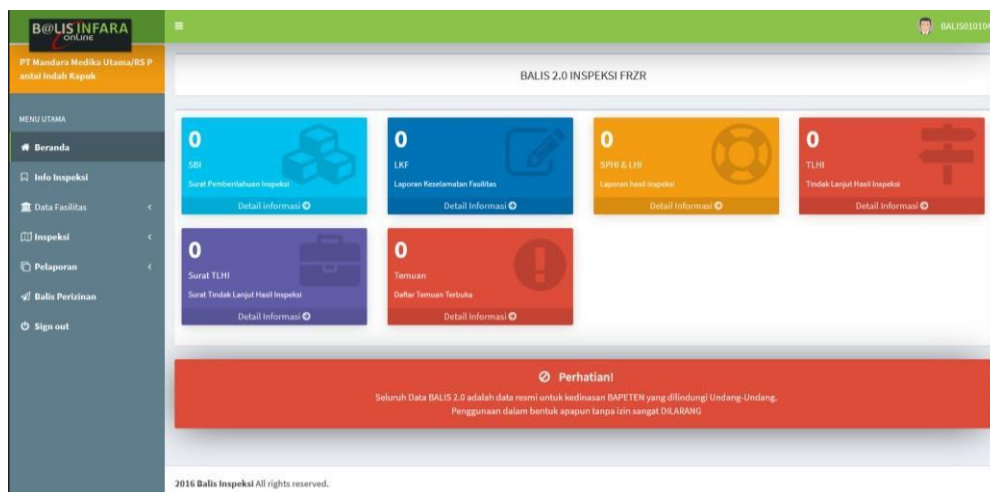


FIG.1. Front end or user display of Balis Infara.

The main features of the Balis Infara for the user or licensee consist of inspection information, radiation facility data, reporting, and data validation. Based on inspection information feature, licensee able to monitor the schedule of inspection, result of inspection, and follow-up action regarding result of inspection. Reporting feature is encouraging users to report on the safety and security status of facilities, location and source movements, as well as changes in workers and equipment. Radiation data facility feature is design to provide a data regarding radiation safety facility such as permit, radiation worker, equipment, radiation source and also other document related to safety. The last feature is data validation, this feature is designed to encourage licensee involvement in updating data and validate related to current status of radiation sources and workers

## 3. RESULT AND DISCUSSIONS

Indonesia is a country with an area of 1,904,569 km<sup>2</sup> and has 17.504 islands, and as of June 9, 2017, Indonesia have 2,661 healthcare facilities [7], that distributed throughout Indonesia. The relatively large quantity of healthcare facilities required an effective policy and strategy for its regulatory controlling not only to cope the safety issue but also safety culture issue. The policies and strategies used in conducting inspections are carried out by applying a risk-based approach, where facilities that have high risk levels will receive high

priority over low-risk facilities. This approach is also in line with international practice requiring regulatory bodies to take a risk-based approach to conducting inspections.

In addition, the policies and strategies used for inspection are also to encourage participation and partnership through a participatory inspection system using Balis Infara, where there will be two-way communication between the licensee and the regulatory body during the inspection activity. Balis Infara also encourages the awareness and involvement of the licensee responsible for radiation safety. Balis Infara will be able to strengthen the safety culture, because it will encourage the realization of the characteristics of a strong safety culture which indicated by some its attribute.



FIG.2. Characteristics of a strong safety culture.

Balis Infara will encourage the realization of the first characteristic that is “safety is the value that is clearly recognized”, because through the participation of the licensee in sending the Facility Safety Report to the Balis Infara shows that attributes of the first characteristics that is “Safety conscious behavior is socially accepted and supported” have been followed and met.

Furthermore, the second characteristic that is “Leadership for safety is clear” it will be reflected if the licensee actively in completing the radiation worker data entry in the Balis Infara. If all radiation worker data is properly filled in the Balis Infara, it will be indicates that the licensee ensure the adequacy and competence of the staff, thereby its reflect that the attribute of the first characteristics that is “management make sure that there are sufficient and competent staff” has been followed and met.

As an effort to meet the third characteristic that is “Accountability for safety is clear” will be meeting when the licensee is actively in completing the data entry in Balis Infara. The licensee will automatically comply with all radiation safety requirements because the Balis Infara has been designed so that all data contents have represented the radiation safety regulation. This will show that the third attribute of safety culture that is “There is a high level of compliance with regulations and procedures” has been followed and met.

Through the Balis Infara will encourage the fourth characteristic that is Safety is integrated into all activities will be meet, because from the Balis Infara will be used as a tool to calculate the Index of Safety and Security, where for good healthcare facilities will be awarded by BAPETEN Safety and Security Awards (BSSA). By obtaining the BSSA is expected to be the motivation for licensee to improve and maintain the safety level of the facility into a good category. It is shows that the fourth attribute of safety culture that is Factors affecting work motivation and job satisfaction are considered can be realized.

Finally, The Balis Infara will also encourage the fifth characteristic of safety that is Safety is learning driven to be fulfilled, because in the Balis Infara will be used by the licensee as a tool to conduct self-assessment, since the assessment indicator that will be performed by the inspector is the same as the existing in the Balis Infara, so the licensee can independently assess the radiation safety performance of their healthcare facility. It is a show that the fifth attribute of safety culture that is Internal and external assessments, including self-assessments, are used has been realized and met.

#### 4. CONCLUSIONS

Based on the results and discussion it can be concluded as follows:

- (a). Balis Infara is one of the breakthrough measures by utilizing information technology conducted by BAPETEN to cultivate closer cooperation between regulatory body and healthcare facilities in promoting and strengthening safety culture.
- (b). Balis Infara changes the paradigm of inspection, from a conventional inspection model to a participatory inspection model, in which the involvement of the licensee plays an important role in determining the effectiveness of the inspection.
- (c). Balis Infara can significantly encourage the fulfillment of strong safety culture characteristics.

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**REWARDS AND CHALLENGES IN PROMOTING  
RADIATION TREATMENT ERROR REPORTING  
CULTURE-A SINGLE INSTITUTION EXPERIENCE**

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### **Abstract**

Reporting of unwanted/unexpected events that may impact the treatment of patients undergoing radiotherapy in our center started in 2004. Over the past twelve years, the reporting norms have evolved. Reported events (2004-2016) were reviewed and their impacts were analyzed. The patterns of reporting have been investigated to identify activities undertaken in promoting patients' safety. Two hundred eight incidents were reported in the department for the past 12 years namely: radiation events (85%), near misses (9%), and non-radiation events (6%). There has been significant increase in reporting over the last 5 years (83%) compared to the first 7 years. From 2004-2009, all reports were related to radiation events (mostly correctible 80-90%) and made by medical physicists (80%). In 2010, the department acquired new equipment, hence, training of new staff, as well as retraining of the incumbent staff was conducted. Subsequently, lectures on patient safety, professionalism and treatment error reporting were done. Developing a reporting culture needs reinforcement of trust in the system. Good communication between hierarchical and interdisciplinary structures is one of the keys to improve patient safety. Continuous professional development is recommended in order to reinforce the humanresource.

## 1. INTRODUCTION

To provide quality radiation oncology service and patient care, a better understanding of error reporting culture in radiotherapy facilities is vital in every step of the treatment process. Obstacles in reporting must be identified to provide awareness into potential areas for improvement. The practice of reporting unwanted or unexpected events that have the potential to impact the treatment of patients undergoing radiation therapy at the Department of Radiotherapy-Jose R. Reyes Memorial Medical Center, Manila, Philippines started in 2004.

Over the past twelve years, the types, magnitude, quality of reports and the reporting norms in the department have evolved. The general objective of this paper is to improve on the incident learning system of a small radiotherapy department with limited resources. Specifically, we aim to identify the various factors that influence the development of reporting culture in the department, and to come up with analyses and recommendations to further improve the said reporting system.

## 2. METHODS

A multidisciplinary team of medical physicists (MPs), radiation oncologists/residents (ROs) and radiotherapy technologists (RTTs) reviewed the documented reported events over the past 12 years. These were then classified into: 1.) radiation events (whether they are correctible or non-correctible), 2.) Near-misses (or potential events), or 3.) Non-radiation events [1].

The impacts of these events were subsequently analyzed. The pattern of events reported and the reporting team member/s were likewise analyzed to identify related activities undertaken in the department ultimately promoting patients' safety.

## 3. RESULTS

In this twelve-year retrospective analysis, only 208 incidents were reported in the Department of Radiotherapy: 85% were radiation events (involving both patients and staff), 9% were near misses, and 6% were non-radiation events (Fig. 1 and Fig. 2). Of the radiation-related events, 83% were correctible and 17% were non-correctible. The latter half of the analyses resulted to a significant increase in reporting, 83% of the events were reported in the last 5 years vs 17% in the first 7 years of the reporting period.

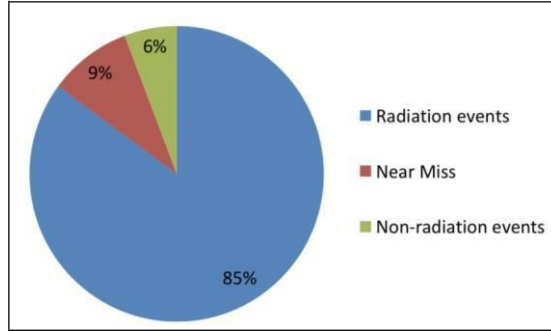


Fig. 1. Types of incidents reported (2004-2016)

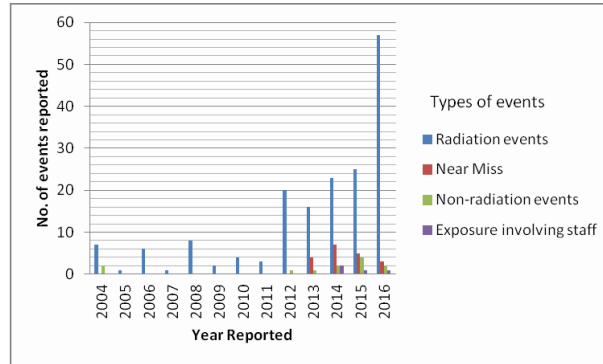


Fig. 2. Types of reported events

The medical physicists (MPs) were the most active members of the team with 42% of the events reported by this group. The radiation oncologists/residents (ROs) and the radiotherapy technologists (RTTs) on the other hand both reported 28% each of the events while the remaining 2% by the rest of the staff. It is interesting to see that the RTTs and the ROs have taken active participation in reporting, achieving 10% more events than the MPs in the last 3 year-period.

#### 4. DISCUSSIONS

From 2004-2009, all reports were radiation-related events. Most of these were correctible events (80-90%) and were relayed by MPs (80% as shown in Fig. 3).

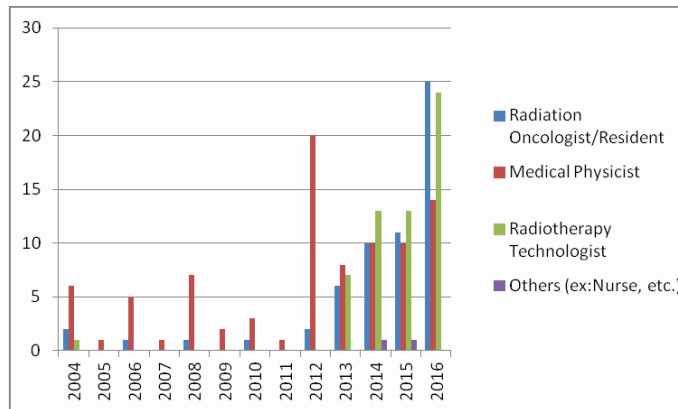


Fig. 3. Reporters of events categorized based on respective profession/discipline

In 2010, the Department of Radiotherapy acquired a new linear accelerator with a dedicated CT Simulator through the partnership with a private institution. With the advent of this new technology, the MPs conducted a training of

new ROs and RTTs, as well as retraining of the incumbent staff on radiation safety placing emphasis on patient safety and reporting of events. Thereafter, lectures on power distance index [2], undergoing audit by the national Quality Assurance Team in Radiation Oncology (QUATRO) [3], performance testing and audit by the regulatory and participating on safety assessment [4] were undertaken.

The department has also adopted a patient safety-first dogma, and a blame-free policy to encourage team members to report errors. From 2010 to 2016, the number of events reported has increased (approximately 7x higher in the year 2016 compared to 2004). Most of these were of the less severe types and majority was reported by the radiation technologists.

Another possible factor in this trend was the simplification of treatment event reporting system. This was achieved thru 1.) adopting a common taxonomy [5] and 2.) providing each with numerical codes for direct causes, contributing factors and radiotherapy stage [6] where the event specifically occurred.

## 5. CONCLUSIONS

Developing a reporting culture needs reinforcement of trust in the system to eliminate any fear of retribution. Good communication between hierarchical and interdisciplinary structures is a key component to improve patient safety – the prime objective of reporting events.

Continuous professional development through trainings and workshops (both local and international) is recommended in order to reinforce the human resource aspect and minimize common causes of errors. And lastly, improved and active participation to Safety in Radiation Oncology (SAFRON) [7] is strongly encouraged to establish an institutional incident learning system.

## ACKNOWLEDGEMENTS

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## **RADIATION PROTECTION AND SAFETY AT PORTUGUESE INSTITUTE OF ONCOLOGY OF COIMBRA – 15 YEARS OF EXPERIENCE**

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### **Abstract**

Portuguese Institute of Oncology of Coimbra is a 240-bed hospital, which provides oncological services to the population of the central region of Portugal since 1962 and has all the conventional radiation practices that a cancer center uses to have - radiotherapy, brachytherapy, nuclear medicine and radiology (except interventional and pediatric procedures). This work aims to show how the creation of the Medical Physics Department as a health care delivery support department in 2003 and the adoption of a policy by the Administration Board on duties and responsibilities in the Radiation Protection (RP) and Safety area based on 1 full time physicist as RP Officer + 4 part-time physicists as RP Supervisors in the main areas of ionizing radiation + the integration of the RPO on the Risk Management Committee of the hospital contributed for the rooting of a safety culture. Some of the additional cornerstones are the internal incident reporting system, firstly based on the European ROSIS but which integrates all aspects of risk management now, and the accreditation within the CHKS healthcare program standards. Future improvements have to be done in more regular “on-job” education a training RPS courses, auditing the application of the RPS procedures and team work.

### 1. INTRODUCTION

Portugal has 10.5 million inhabitants and the regulatory authority in the radiation protection and safety (RP) area is fragmented in several entities so there are few national technical guidelines for hospital end-users and no harmonization of the radiation practices in hospitals. Moreover there is no structured and effective education and training program in place for the qualification of medical physicists. Portuguese Institute of Oncology of Coimbra (IPOC) is a cancer centre with a little more than a half century of existence that covers 2.5 million inhabitants of the centre of the country. Radiation practices are performed for diagnostic purposes in Nuclear Medicine (NM) Department and Radiology (RL) Department (inside and outside department), for therapy purposes in Radiotherapy (RT) Department (external beam radiotherapy (EBRT) and brachytherapy (BT)) and NM Department and for other purposes. This work aims to show how the appointment of a medical physicist (MP) at full time for the RP area in 2002 and the creation in 2003 of both the Medical Physics Department as a health care delivery support department and the Risk Management Committee (RMC) contributed for the rooting of a safety culture at the hospital level.

### 2. THE STARTING POINT

Until 2002, medical physicists were present only in Radiotherapy Department and the RP program already existed covering aspects like individual dosimetry of exposed workers and emergency plans for treatment units (2 linacs and a cobalt-60 machine). Also the Quality Manual already existed with the written normative and operational procedures on quality control of equipments and basic and clinical dosimetry aspects. NM practices began in 2002 for the diagnostic and therapeutic practices in ambulatory regimen and in 2003 in internment regime with two therapy rooms. Radiology department began many years ago but with no support of medical physics nor radiation protection program in place. Another important fact is the transposition of the Directive 97/43/Euratom that occurs in Portugal only in 2002 with the publication of the main diploma of Decree-Law 180/2002. In 2003 IPOC adopted an organization and functioning model for RP based on 1 RP Officer (RPO) and 4 RP Supervisors (RPS) in the main areas where the radiation risk is greater – EBRT, BT, NM and RL recognising that no one better than the MP working in a clinical area to know the specificity of the

radiation practice in this area. Also the Risk Management Committee was created with 6 main areas of risk prevention – fire, clinical emergency, wastes, occupational health, hygiene and safety at work and radiation represented by the RPO. Finally, the RPO integrated the Quality Group created at IPOC at that time in order to undertake the hospital accreditation from CHKS healthcare standards. In 2005, with the approved policy on the organization structure, responsibilities and duties in RP, the Administration board of the hospital delegated to the Medical Physics Department the task of defining and implementing a RP program taking into account the legal requirements and the international recommendations on the matter.

### 3. RADIATION PRACTICES IN NUMBERS AT IPOC

Currently, 1600 patients per year are treated with 2 linacs, a tomotherapy unit, a high dose rate (**HDR**) BT unit with  $^{192}\text{Ir}$  source and BT prostate  $^{125}\text{I}$  seeds implants. Around 140 patients per year are treated with radionuclides in NM and 86% are for radioiodine therapy of differentiated thyroid cancer. 2360 NM diagnostic examinations are performed with a dual ECAM gama camera. Diagnostic examinations are also performed in RL Department with 1000 fluoroCT exam/y and other 4000 exam/y in 2 CT units; 2000 plain radiography/y, 700 fluoroscopy exams/y and 10000 chest exam/y in a radio&fluoroscopy unit and a radiography unit; 9000 exam/y and 25600 exposures/y in a mammography unit; 500 exams/y in a orthopantomography unit and 2 mobile radiography units are used outside RL Department. Interventional and pediatric procedures are not yet performed at IPOC. Other radiation practices include the irradiation of blood products with a free-standing irradiator incorporating a  $^{137}\text{Cs}$  source and around 4200 RadioImmunoAssay (**RIA**) tests performed with radioactive unsealed sources of  $^{125}\text{I}$  (less than 10MBq/year).

### 4. MAIN CHANGES OCCURRED IN BRACHYTHERAPY AND RADIOTHERAPY

In brachytherapy, a radiation protection program has been implemented in 2003 with the licensing of the HDR facility covering structural shielding assessment of the bunker and emergency plan establishment, and in 2004, with the licensing of the prostate implant with seeds of  $^{125}\text{I}$  covering local rules to be followed during the procedure, information on RP for the patient at home and waste management. In 2007, procedures on the management and control of sealed sources have been revised to take into account the new national legal requirements. IPOC became an active department of the ESTRO Radiation Oncology Safety Information System (**ROSIS**) project in 2004 but stopped to input the reports in the database in 2005 because of the time consuming for English translation. However an internal database has been maintained based on the ROSIS methodology and used between 2005 and 2012. In 2014 the system was revised concerning the terminology, classification, taxonomy and categorization of the events and in 2015 the harmonization of the internal incident reporting at the hospital level occurs with a new platform of incident reporting system named Health event & risk management (**HER+**) [1]. This provided an ideal opportunity for integrating all aspects of risk management. All the radiotherapy treatment units have their own emergency plans and it's mandatory for the workers to train the emergency procedure once a year. Every 3 years a course is given for radiation oncologists students in the basic physics of radiotherapy and the basic of radiation protection and safety. Also, every time a new radiotherapy practice is implemented, a seminar is given covering RP matters when applicable. Nowadays, every time a new treatment machine is bought, the MP Department is part of the jury which allows to demand important aspects that have implications in RP like an education and training program for every relevant health professional group, adequate conditions in the contract for the preventive and corrective maintenance of the equipment, acquisition of new equipment for quality control (**QC**) and radiation monitoring, safe removal and disposal of higher energy Linacs, safety conditions with adequate radiation shielding of the bunker.

### 5. MAIN CHANGES OCCURRED IN NUCLEAR MEDICINE

The RP program in NM department is very extensive and covers multiple aspects to assure the safety of installations and unsealed sources, radiation protection of workers, patients and the general public. A Quality Manual includes the normative and operational procedures and the register forms applied to quality control of equipments and to RP measures applied to NM Department. RP topics include the management of radioactive sources from receipt to return to the manufacturer or treatment as a radioactive waste; local rules describing the

procedures to be followed in each controlled area; radiation monitoring in the work areas with high radiation risk of contamination; education and training in RP for new health professionals who don't have education and training in RP in their professional curriculum (nurses and operational assistants); functioning of the therapy rooms (preparation of the room and patients, liquid and solid wastes activity quantification and management); RP measures for the patient and family at home and for workers when the patient is transferred outside the NM Department. In 2014, the MP Department has been integrated by the Administration Board via the Risk Management Commission at the beginning of the project for the planning of the new building that will incorporate the future NM and RL Departments. MP were the strong leaders of this project for defining the functional plan for both radiation departments working with the respective heads of department in 2014, for revising the plants with the architecture company in 2015 and for supervising and reviewing the radiation shielding calculations made by the private company contracted by the architects in 2016.

## 6. MAIN CHANGES OCCURRED IN RADIOLOGY

The licensing of nine radiation imaging units began in 2004 in the RL Department and a RP program has been implemented with the main topics being the classification of radiation working areas, local rules for the work performed in controlled areas and individual radiation monitoring. Undertaking the first accreditation of the hospital by CHKS Standards that has been awarded in 2005, new procedures have been written and training given to the staff of RL Department like, for instance, guidelines on how to protect the foetus during the medical exposure of a pregnant woman. Also to comply to the CHKS standard criteria, patient doses began to be investigated in the scope of a Master degree project not only to assess the compliance with European diagnostic reference levels but also to be able to give dose information to patient or referral doctor upon request in a comprehensible way for the most frequent examinations of mammography, CT and simple radiography procedures [2]. In the scope of a big project of remodelling of the RT Department in 2005 including a CT unit for RT planning, the MP Department acquired 100,000 Euros of equipment to be used for QC of diagnostic equipment and the program of QC of equipments began to be implemented in 2009 in the RL Department for mamography, CT and radio&fluoroscopy units. Optimization of the clinical image quality in mammography versus patient dose began to be investigated with a PhD project in 2009 [3]. This was an important step because it allowed MP to work together with radiographers to improve the image quality by a better positioning of the breast (participation in the task 4 of the IAEA RER9093 project in 2010) and with radiologists to define the clinical image criteria that are relevant for establishing the diagnostic in mammography. We currently move to patient dose audit to better understand the outliers and optimize the exposure protocols used in CT. The participation of both MP and the head of the RL Department to the Scientific Visit organised by IAEA in 2016 at Duke University Medical Centre in USA strengthened the idea that the step forward is better sharing the work done by MP within the RL Department and move from the work done (CQ of equipments and patient dose assessment) to the optimization of the imaging process reinforcing the multi professional team work.

## 7. MAIN CHANGES OCCURRED FOR OTHER RADIATION PRACTICES

An irradiator of blood products incorporating a source of  $^{137}\text{Cs}$  is used since 1996 in the Imunohemotherapy Department but the licensing and the implementation of the RP program began only in 2007. Main aspects of the RP program are the supervision of the annual maintenance of the irradiator including dose map calibration, a control of the radiation exposure levels near the irradiator and wipe test measurements twice a year, an emergency plan for fire prevention covering the radiation safety aspects and a procedure to be used in case of operational failure of the machine. Also RIA techniques using  $^{125}\text{I}$  are performed a long time ago in the Clinical Pathology Department but the radiological practice has been licensing only in 2008 and the main aspects of the RP program cover local rules for working with unsealed sources and radioactive waste arrangements to guarantee the radiation safety of the practice.

## 8. ADVANTAGES AT THE HOSPITAL LEVEL OF AN INTEGRATED MANAGEMENT OF RADIATION PROTECTION AND SAFETY WITH OTHER RISK FACTORS

Currently the individual dose monitoring program covers more than 150 professionals working in ten different departments. Whenever a new collaborator began to work with radiation, an on-job radiation risk assessment is performed for the occupational exposure and an individual dosimeter together with the integration manual in RP at IPOC are delivered. Also basic notions on RP have been contemplated in the IPOC manual on basics in hygiene health and safety that is given to each new collaborator coming working at IPOC. Emergency plans against fire are specific for each department and the question of RP is contemplated if applicable. Although Decree-Law 222/2008 allows pregnant and breastfeeding workers to work with radiation since dose limits for embryo/foetus/newborn or breast fed child are not exceeded, the labour code published by Law in 2009 prohibits those women to work with radiation and the prohibition has been adopted by the IPOC Administration Board and contemplated in the IPOC manual for pregnant and breastfeeding workers written by the Occupational Health Department. The normative procedure applied to radiation wastes management at IPOC has been written in 2016 after the publication of the new legal national requirements and the corresponding licence has been obtained from the Regulatory Commission for the Safety of Nuclear Installations (COMRSIN). Also the IPOC manual for the integrated management of hospital wastes has been revised in compliance with these procedures. Recently an incident related to the radiation exposure of a nurse exceeding the investigation level of 2 mSv per month in consequence of a radioiodine therapy for thyroid cancer of an elderly ill patient has been reported in the platform HER+ and an internal audit has been conducted by the relevant areas of the Risk Management Committee (radiation + clinical emergency + occupational health and safety). The report conclusions pointed out nine corrective actions and lessons learned from this incident and the main ones are 1) the everyday multi-professional planning of the RP measures applied for each individual treatment for patients of high radiation risk (patients who are not self-sufficient and who does not have the capacity to cooperate and fulfil with RP rules); 2) an emergency plan to prevent clinical emergencies with radioactive inpatient taking into account IPOC procedures on clinical emergency and post-mortem service provision; 3) a more regular on-job education and training in RP for nurses and operational assistants through e-learning material.

#### 9. ADVANTAGES AT THE NATIONAL LEVEL OF AN INTEGRATED VISION IN RADIATION PROTECTION AND SAFETY APPLIED AT HOSPITAL LEVEL

The organizational model adopted at IPOC for RP based on 1 RPO + 4 RPS inspired Portuguese authorities when preparing in 2007 the legislation framework for the professional qualifications, duties and responsibilities in RP in the medical sector. The know-how acquired at IPOC in patient dose assessment for diagnostic procedures made it task leader for the assessment of the typical effective patient dose for the TOP20 X-ray examinations in the Portuguese participation in Dose Data Med 2 European project [4]. IPOC was the first hospital to be licensed by COMRSIN for the secure radiation waste management and has been invited at the Portuguese congress of RP in 2016 to present the perspective of the medical sector concerning the new legal requirements and the improvements necessary to the existing legal framework [5]. Finally after completing the IAEA RER9140 course in Lithuania in 2016, IPOC alerted the General Direction of Health about the non compliance with the IAEA Basic Safety Standards co-signed by ILO of the Portuguese labour code in respect to the prohibition for pregnant and breastfeeding workers to work with radiation.

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# AUSTRALIAN INITIATIVES IN RADIATION PROTECTION OF THE PATIENT AND MEDICAL OCCUPATIONAL RADIATION SAFETY TRAINING

## *The Australian Radiation Protection and Nuclear Safety Agency's Radiation Protection of the Patient (RPOP) and Radiation Protection of Medical Personnel (RPOMP) projects*

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### **Abstract**

Australia, like many countries, has identified areas where its medical radiation safety training could be improved. With stakeholder engagement and collaboration, the Australian Radiation Protection and Nuclear Safety Agency developed and implemented two distinct tools to address issues in educating and training General Practitioners in patient radiation safety and for education and training related to occupational radiation safety for medical facility personnel. Using online and blended learning and a modular approach, these projects complement and strengthen existing approaches and offer targeted, tailorable learning solutions in medical radiation safety, with the potential for further development and extension into other areas.

### **1. INTRODUCTION**

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) is the Australian Government's primary authority on radiation protection and nuclear safety. ARPANSA regulates Commonwealth entities using radiation with the objective of protecting people and the environment from the harmful effects of radiation. ARPANSA undertakes research, provides services, and promotes national uniformity and the implementation of international best practice across all Australian jurisdictions. ARPANSA has implemented a number of programs and projects following the Bonn Call for Action. Two of them are of particular significance as they provide different approaches to addressing medical radiation safety.

#### **1.1. RPOP**

ARPANSA, together with the Australian Commission on Safety and Quality in Health Care (ACSQHC) were tasked by the Australian government with improving knowledge and practise around Computed Tomography use and radiation exposure to patients. With a significant percentage of General Practitioners either unaware that CT utilised ionising radiation, or of the relative magnitude of radiation produced, and estimates in the order of 20 to 40 per cent of imaging procedures considered to be unjustified, ARPANSA gave priority to the development of material to assist in this area.

#### **1.2. RPOMP**

For the Radiation Protection of Medical Personnel (RPOMP) project, ARPANSA recognised that there were gaps in the availability and quality of occupational radiation safety training material, as well as with the availability and willingness of suitably qualified and interested parties to deliver it. These issues applied across the breadth of the healthcare system, from major hospitals all the way down to local medical imaging clinics. A 'one size fits all' approach was not considered appropriate, so the RPOMP project embraced a tailorable, modularised approach that catered for 'just-in-time' and blended learning.

## 2. METHODS

### 2.1. RPOP

Australia's General Practitioner (GP) Colleges between them represent and include among their membership the majority of GPs in the country. ARPANSA has expertise in radiation safety, but has little clinical expertise. Recognising both these points, ARPANSA partnered with the Royal Australian College of General Practitioners (RACGP) and the Australian College of Rural and Remote Medicine (ACRRM) to develop and promote the RPOP training content and supporting materials. This included qualitative research in the form of interviews and focus groups, as well as sending out the final draft of the module to more than 43,000 GP's for comment, receiving around 450 detailed responses. Targeting of an online GP Facebook group yielded additional feedback. In addition to ARPANSA's online version, the Colleges also developed clinical case-study versions, all of which are eligible for Continuing Professional Development credits. A supporting handout to facilitate doctor/patient discussions was developed and this, along with the website information, was forwarded in hard copy to all known GP practices.

### 2.2. RPOMP

With the RPOP project, the main target audience was well defined and best accessed through the GP colleges. With the RPOMP project, the scope was much broader, with all staff in medical facilities utilising ionising radiation requiring some training, but with those directly involved requiring more. This necessitated a much broader stakeholder engagement process, involving medical facilities' key staff groups ranging from administrators and cleaners to nurses, physicians and other specialists. In addition, there are different types of facilities, public and private, large and small etc. Another key set of stakeholders are the state and territory regulators. In Australia, ARPANSA regulates Commonwealth entities (e.g. Defence, the ANSTO research reactor) and promotes national uniformity, however most medical facilities are regulated by the states. Much of the content for the RPOMP modules came from resources already in use by some of the medical facilities.

## 3. RESULTS

### 3.1. RPOP

The RPOP project for referrers (GPs) resulted in a linear online module without any login requirements, i.e. anyone can complete it at any time. Feedback has been positive and with GPs generally having excellent memories, it is expected that the module only needs to be done once. The module and its supporting material remain available for reference [1-3]. The ARPANSA RPOP module is relatively simple, following a linear construction with built in self-assessment. The supporting material has proven to be quite successful with ongoing requests for printed hard copies, despite it being available online.

### 3.2. RPOMP

The RPOMP project is more complex, being tailorable by profession, activity (e.g. working in CT, nuclear medicine etc.), location and degree of involvement with ionising radiation. The outputs are also tailorable, with an online version always available, and also the provision for exporting as a PowerPoint presentation or to a SCORM compliant eLearning package.

Fig. 1 (following) gives an indication of the relative complexity of the two programs. Fig. 2 provides an early version RPOMP screen shot indicating the customisation available.

## RPOP *cf* RPOMP: Structure

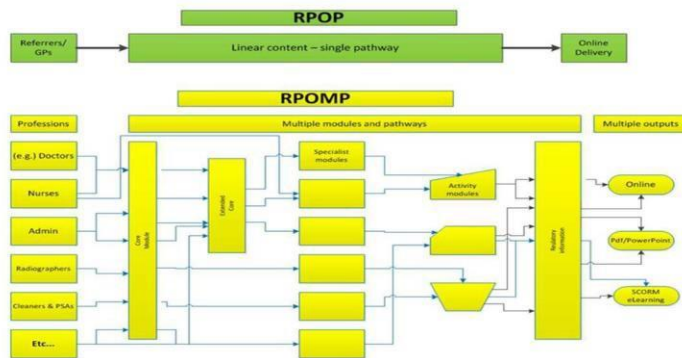


FIG. 1. Flowchart giving an indication of the inputs, outputs and relative complexity of RPOP and RPOMP

The screenshot shows the 'Radiation Protection of Medical Personnel' (RPOMP) interface. It features a questionnaire with five questions and corresponding selection options:

- What is your occupation?** A dropdown menu with '5-Doctors' selected.
- Where is your workplace?** A grid of Australian states and territories: NSW, VIC (highlighted), QLD, WA, TAS, SA, NT, ACT.
- Do you work in an area where ionising radiation is utilised?** Radio buttons for 'Yes' and 'No'.
- Please select any additional activities you may require.** A grid of activity categories: Nuclear Medicine, X-ray/CT, Interventional, Radiotherapy (highlighted), Brachytherapy.
- How would you like to view this course?** Radio buttons for 'Online', 'PDF', and 'eLearning'.

FIG. 2. Early version RPOMP screenshot showing choices and navigation

## 4. DISCUSSION

### 4.1. RPOP

RPOP is considered to have been a success so far, with a review proposed to increase its penetration and effectiveness. Careful stakeholder evaluation and engagement resulted in making the information available to referrers at a number of stages and in different ways. Lessons learnt and information and contacts gained helped to inform the RPOMP project. Future work will focus on embedding the module further into formal GP education and training, as well as reviewing its effectiveness and in turn, applying lessons learnt from RPOMP.

## 4.2. RPOMP

The RPOMP project applies contemporary adult learning principles. Its tailorable format provides acknowledgement that different information is required based on need, and the ability to provide multiple outputs caters for ‘just-in-time’ delivery as well as for blended learning approaches. The modular approach means that occupations and activities originally out of scope may be added with less effort and expense than conventional approaches. ARPANSA intends to expand the training into other areas, for example dental and chiropractic facilities and will likely soon extend it into non-medical areas. The further application of adult learning principles and gamification to assure that those with existing relevant knowledge are rewarded (or at least not penalised by having to undertake unnecessary training), is envisaged. ARPANSA would also welcome the opportunity to partner and share resources with other member states, keeping in mind that these resources have been produced as free services for radiation protection.

## 5. CONCLUSION

ARPANSA’s RPOP and RPOMP modules are intended to provide baseline radiation protection education and training in their respective areas. They will continue to be developed in collaboration with stakeholders. RPOMP in particular applies contemporary adult learning principles and with its tailorable, modularised approach with multiple inputs and outputs is expected to provide a model or platform on which other radiation protection education and training can be built.

## ACKNOWLEDGEMENTS

The RPOP Module was developed with the input of key stakeholders, many of them directly represented by a Project Reference Group (PRG) organised by the Australian Commission on Safety and Quality in Health Care (ACSQHC). Input was received from the Royal Australian College of General Practitioners (RACGP), the Australian College of Rural and Remote Medicine (ACRRM), the Royal Australian and New Zealand College of Radiologists (RANZCR), WA Health - WA Diagnostic Imaging Pathways (WA DIP), the Australian Society of Medical Imaging and Radiation Therapy (ASMIRT), the Australian Diagnostic Imaging Association (ADIA), and NPS MedicineWise (NPS).

Feedback was also received from a number of State Radiation Advisory Councils, as well as from hospitals (with major contributions from Alfred Health), universities and others. Of particular note are the efforts of the RACGP and ACRRM in forwarding the RPOP Module drafts to their members, with their feedback enabling fine tuning of the Module. Also, the pioneering work of the WA DIP is acknowledged.

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**CONTINUOUS PROFESSIONAL EDUCATION  
FOR THE RADIATION PROTECTION IN MEDICINE  
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**Abstract**

Last year the N.N. Alexandrov National Cancer Centre of Belarus in Minsk (Belarus) received a license for educational activities on postgraduate training in the field of oncology and medical physics. The center has developed a number of training courses on oncology, in particular on radiation safety in radiation therapy. The program of the course is discussed in the paper.

**1. INTRODUCTION**

In 2016, the N.N. Alexandrov National Cancer Centre of Belarus in Minsk (Belarus) received a license for educational activities on postgraduate training in the field of oncology and medical physics from the Ministry of Education of the Republic of Belarus. The center has developed a number of training courses on oncology, in particular on radiation safety in radiation therapy. The course participants can be not only Belarusian specialists, but also from other countries. The courses will be conducted in Russian. Course duration is 40 hours.

**2. METHODS**

Within the framework of the training course, the following issues are considered with reference to radiation safety in medicine: basic dosimetric values; background radiation; radiation background from artificial sources; radiation safety standards; the concept of the normalization of radiation exposure; the price of risk in the radiation safety; modern practices of the personal dose normalization; main categories of irradiated persons; protection using time, quantity and distance; radiation protection types; organization of work with IRS; closed sources of radiation and devices, that are generating radiation operation; work with open sources of radiation (radioactive substances); methods of individual radiation protection and hygiene; measures for radiation protection and ensuring radiation safety; limiting radiation exposure of population in the conditions of a radiation accident; the tasks of the radiation safety service [1].

Practical classes are held, where students receive the necessary practical skills for the competent provision of radiation safety in their departments and in healthcare organizations. In particular, the main attention is paid to the following issues: characteristics of the gamma-emitting radionuclide; the main condition for designing radiation protection; engineering methods for calculating protection against primary gamma radiation; calculation of the required thickness of the material for the radiation protection; calculation of protection against scattered gamma radiation; protective materials from radiation; protection against bremsstrahlung of beta particles; transmission of radiation through heterogeneities; labyrinth as one of the methods of protection; protection from radioactive substances formed in the air under the action of bremsstrahlung; protection from harmful substances formed in the air under the influence of ionizing radiation [2, 3].

### 3. CONCLUSIONS

We invite medical physicists to participate in the proposed training course on radiation safety in Minsk. Details and conditions for participation in the seminars can be found on the website of our center.

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# NAVIGATING DIFFERING CULTURAL AND ETHICAL FRAMEWORKS DURING ORGANIZATIONAL CHANGE

## A challenge for radiation protection experts

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### Abstract

Organizational change is a common feature of healthcare provision today. Approaches such as New Public Management (NPM), sometimes referred to as corporatisation, have taken hold in many countries. Whilst the aims may be laudable there can be unintended consequences creating problems for Radiation Protection Experts (RPEs). Empowering senior management executives is a key theme of NPM. If this goes hand in hand with disempowering RPEs there is a risk that radiation protection (RP) can suffer. The system of radiological protection is built on three pillars: science; ethical and social values; and experience. A current ICRP consultation identifies the ethical foundations underpinning the system. Malone and Zolzer describe the ethical basis of RP in diagnostic radiology, adding prudence and honesty to traditional medical ethics. IRPA emphasize that RP professionals within an organization must take the central role in supporting management to drive and embed RP culture throughout the organization. Problems can however arise from the unfamiliarity of many managers with fundamental RP concepts such as justification, optimization and uncertainty of radiation risks. Recognition by management of the role of RPEs is crucial. This requires good communication channels, facilitating engagement between RPEs and senior management to strengthen radiation safety culture in healthcare.

### 1. INTRODUCTION

The Bonn Call-for-Action [1] identifies the need to strengthen safety culture in medicine. Amongst the many definitions of culture, Matsumoto has defined it as: *The set of attitudes, values, beliefs, and behaviours shared by a group of people, but different for each individual, communicated from one generation to the next* [2]. Culture can vary widely between different groups of people. Tensions can arise when different groups of people interact, particularly when there is unfamiliarity with fundamental tenets held by one group or another. Cultural awareness is important to avoid or resolve conflict which may ensue.

The global system of radiological protection has been developed over many years, notably by ICRP [3]. The system relies on the expertise of RPEs, who undertake key roles developing, interpreting and implementing radiation safety systems at international, regional, national and local levels. IRPA has identified knowledge, skills and competences required by an RPE, noting that competences of an RPE include substantial elements of radiation safety management [4]. RPEs have been instrumental in creating the systems designed to ensure the safe use of radiation in medicine, and continue to play a leading role in managing radiation safety in healthcare.

There are many different models for the provision of healthcare, with governments worldwide attempting to reconcile increasing demands for healthcare with a general insufficiency of resources to meet all demands. In a number of countries practices traditionally more associated with the private sector have been introduced into the public sector, including healthcare services. This movement is sometimes known as New Public Management (NPM). Its features include decentralization, increased managerialism and, anecdotally, creation of many new general management positions [5-7].

Individuals appointed to such posts do not for the most part have substantial scientific training, and may be uncomfortable with fundamental scientific concepts such as uncertainty which are central to the practice of radiation safety. Few general managers will have a good initial understanding of radiation dosimetry and risks, nor concepts of justification, optimization and dose limitation, even those with a clinical background in areas such as nursing, physiotherapy and medicine. The dual roles of healthcare professionals with both clinical and managerial responsibilities in their areas of expertise are sometimes acknowledged by the term 'hybrid manager', but the extent of RPE radiation safety roles and responsibilities may not be fully recognized by general managers. This can lead to managerial ambiguity and confusion.

Such problems can come to the fore at times of organizational change, particularly if those appointed to newly-created non-clinical manager posts are not well informed about existing systems of radiation protection

within their organization and beyond. This paper explores differing cultural and ethical influences which may co-exist. It relates to the topic of : *How are we strengthening radiation safety culture in healthcare?*

## 2. METHODS

A mixed methods approach is reported, comprising observation, literature review and qualitative research. The work has been given impetus by a single case study in which an RPE and Medical Physics Expert (MPE) encountered surprising resistance from middle managers when seeking to improve justification and optimization. The managers concerned, who had recently been appointed to newly-created positions after organizational change, were unfamiliar with basic radiation safety concepts and unwilling to accept the advice of the hospital's RPE, who raised concerns which were subsequently corroborated by regulators. Communication channels between the RPE and senior management had been substantially weakened by organizational changes, despite repeated efforts by the RPE to engage with the increasingly multi-layered management structure. Essentially the RPE's professional expert advice was over-ridden by middle managers, who provided misleading information to senior managers in misguided pursuit of a 'good news only' culture and to cut costs. Medical exposures were not optimized and the hospital subsequently incurred reputational damage.

Whilst the literature review is in no sense a systematic review, it is heartening to find readily-accessible publications from ICRP, IRPA and other authorities in the radiation protection field which address related issues. Articles in the literature casting light on NPM are further sources of reference.

## 3. RESULTS

European Basic Safety Standards (BSS) [8] define an RPE as a recognized individual or group having the necessary knowledge, training and experience to give radiation protection advice to ensure effective protection from dangers arising from exposure to ionising radiation (Article 4). They direct member states to require undertakings to seek advice from an RPE on relevant issues (Article 34) and matters relating to compliance with applicable legal requirements (Article 82). They require that medical exposures be justified (Article 55) and optimized (Article 56). They identify MPE responsibilities, which include taking responsibility for dosimetry of medical exposures (Article 83). IAEA Basic Safety Standards [9] require formal recognition of qualified experts (2.21), and that they be consulted as necessary in the proper observance of these Standards (2.46).

IAEA RS-G-1.5 [10] notes that *there may be a dual management system in hospitals* (clinical and administrative). It also notes that *qualified experts* (and others) *have roles and responsibilities for the application of the relevant radiation protection regulations and rules in their particular fields of activity*.

The term 'Radiation Protection Expert' is included in the ILO International Standard Classification of Occupations (ISCO-08) [11]. IRPA Guidance on certification of an RPE lists the following competences: *Manage complex technical or professional activities or projects, taking responsibility for decision-making in unpredictable work or study contexts; take responsibility for managing professional development of individuals and groups* [4]. These competences underline managerial aspects of an RPE's role.

Many publications describe New Public Management, a term which has been described as an attempt to make the public sector more businesslike using ideas and management models borrowed from the private sector. Its core themes include command and control, targets, a strong focus on financial control, new forms of corporate governance, performance monitoring, use of protocols to ameliorate professional behaviour, handing power from individuals to management and concentrating power to the strategic core of organizations [12-13]. The NPM approach in healthcare has always been controversial, and its effectiveness questioned [14-17].

Iles and Sutherland have studied organizational change in healthcare [18], drawing on the work of Ackerman comparing developmental change with transformational change [19]. Developmental change (Fig 1) is incremental change that enhances or corrects existing aspects, often focusing on improvement of a skill or process. By contrast transformational change (Fig 2) is radical, requiring a shift in assumptions made by the organisation and its members. Transformation can result in an organisation that differs significantly in terms of structure, processes, culture and strategy. In practice organization change is chaotic, often involving shifting goals, discontinuous activities, surprising events and unexpected combinations of changes and outcomes [20-21]. The time period during which various phases of transformational change take place is not easily controlled.

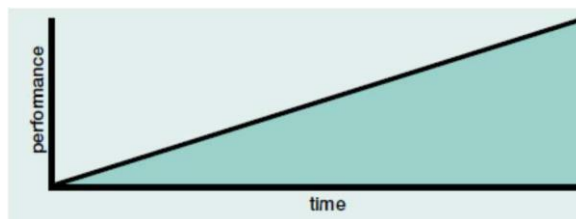


FIG. 1. Developmental change: Improvement on existing situation

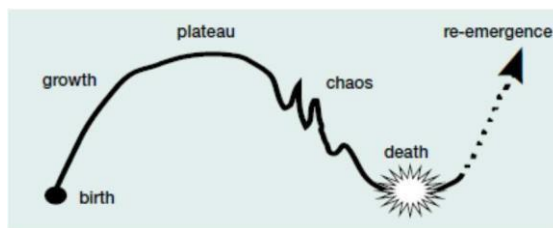


FIG. 2. Transformational change: Emergence of a new state, unknown until it takes shape

In line with the Bonn Call-for-Action to strengthen radiation safety in health care [1], Berwick has written *In the end culture will trump rules, strategies and control standards every single time, and achieving a vastly safer NHS will depend far more on major cultural change than on a new regulatory regime* [22]. Hudson refers to the evolutionary model of safety culture: Pathological → Reactive → Calculative → Proactive → Generative [23]. IRPA recognizes the importance of a sound radiation protection culture, noting that RP professionals must take the central role in supporting management to drive and embed radiation protection culture throughout the organization, whilst noting that they have *the most difficult of leadership roles – that of indirect leadership of their non-RP colleagues, who in many cases may be their business leaders or managers* [24]. The IRPA report notes that radiation protection culture improvement is heavily dependent on the support and leadership behaviours of managers at the highest level within an organisation. Chapple et al have proposed a ‘ten point assessment’ framework to assess radiation safety culture in the medical sector, ranging from ‘Engagement of Management’ to ‘Effective communication’ [25].

ICRP have recently undertaken a consultation on a draft report on the ethical foundations of the system of radiological protection, noting that the system is built on three pillars: the science of radiological protection combining knowledge from different disciplines, a set of ethical and social values, and the experience accumulated from the day-to-day practice of radiological protection professionals[26].

#### 4. DISCUSSIONS

The global radiation safety system is a result of developmental change, with steady improvements built on a platform of existing knowledge created and refined by scientific methodology over more than a century. RPEs are central to this system, which is based on science, social and ethical values, and experience. RPEs have a significant role in the management and leadership of radiation safety and it is important that organizations understand and support this management role. There is a risk that organizational change, perhaps associated with NPM/corporatisation, can result in the disempowerment of RPEs, which can have profound adverse consequences for organizations, patients and staff. There is a need for greater awareness of radiation safety culture issues, including the need for organizations who use radiation to ensure effective communication channels to enable RPEs to undertake their roles efficiently, and to provide and create a positive work environment based on mutual respect and shared understanding [24]. If transformational change is undertaken, how it is implemented is crucial.

#### 5. CONCLUSIONS

Recognition by management of the role of RPEs is crucial. This requires good communication channels, facilitating engagement between RPEs and senior management to strengthen radiation safety culture in healthcare.

## ACKNOWLEDGEMENTS

Figs 1 & 2 are reproduced with the kind permission of Val Iles and Kim Sutherland, authors of *Organisational Change: A review for health care managers, professionals and researchers* (2001).

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