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Invited Review

Radiological protection of patients

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General Comments about Radiological Protection of Patients

The benefits of ionizing radiation in the diagnosis and treatment of cancer, as well as other conditions such as cardiac ablation, are well established. However determination, monitoring, and evaluation of patient doses is not an easy task. Furthermore, radiation doses for individual patients may vary greatly from one radiological procedure to another.

Attention is needed to reduce unnecessary radiation exposure to patients from ALL types of radiation producing machines and equipment. The patient risk from radiation injury - stochastic and/or deterministic - must be weighted against the benefits of a proper medical examination or treatment as well as the risk of depriving the patient from the necessary medical care. Arbitrary reduction of radiological patient doses without regard to *final outcome* is detrimental to proper medical care provided to the patient. Sacrificing image quality in order to reduce patient dose is potentially harmful to the patient as well. We believe most individuals prefer to bear the risk of radiation if it means finding a life-threatening lesion, instead of missing it.

Furthermore, the role of radiation exposure incurred from screening procedures such as mammography, needs to be properly considered and differentiated from medically indicated procedures. A known radiation induced risk needs to be balanced against diagnostic efficacy of a screening procedure. In these cases, regulations on standards and guidelines for determination, monitoring, and evaluation of patient doses may be appropriate. Trends in mammography quality before and after the implementation of the US Mammography Quality Standards Act (MQSA) of 1992 have recently been evaluated and published by Orhan Suleiman, *et al.* (1999). In this report, the technical data collected in the US have been compared with the corresponding data in Canada.

However, even here, it has been recognized that we cannot assume that one dose limit fits all. It is advisable to consider individual patient specifics if it means the difference between detection and miss.

Scientific Guidelines and Professional Standards

Universal standards and guidelines for determining, monitoring, and evaluating medical exposure of patients have long been the objectives of many scientific and professional organizations, international regulatory bodies, and government agencies. Efforts directed at attaining these objectives have occupied the time and effort of medical physicists worldwide. The evaluation of this apparent conflict between the two sides of the radiation "sword" - benefit and harm - is the joint responsibility of qualified medical physicists and authorized physicians.

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A *qualified* medical physicist has been defined by several organizations (AAPM 2001 and European Commission 1997) as an individual who is competent to practice independently and legally authorized to practice in one or more of the subfields in medical physics. Similarly, an *authorized* physician has been defined by a number of professional organizations (ACR 2000, European Commission 1996, European Commission 1997) as a licensed physician with documented training in and understanding of physics in one or more of the subfields of radiation physics. Certification / licensing / national registry by a professional organization [(a,b,c,)] (EFOMP 1995) in the appropriate subfields(s), as well as continuing education in handling radiation-producing equipment is essential. A qualified medical physicist and an authorized physician have the expertise necessary to determine, monitor, and evaluate this tradeoff between the patient dose reduction and patient's *final outcome.* They have the expertise to establish protocols for radiation procedures and evaluate radiation outcomes. Moreover, medical physicists are charged with educating hospital staff (such as nurses and radiation technologists) in the proper handling of radiation producing equipment and radioactive materials to avoid harmful practices. Experience shows that substantial (nearly 40%) dose reduction in radiological procedures is possible by training of the physicians and staff (Rehani 1995, Archer 2000).

Standards for the performance of radiation procedures in radiotherapy, nuclear medicine, radiology as well as interventional radiology have been developed by scientific and professional organizations [(d)] (AAPM 2001, ACR 2000). The objective of these standards, which are reviewed and revised on a periodic basis, is to improve the quality of radiation services to patients using ever-increasing complex technology. These scientific standards are not *rules* to be regulated but a *code of practice* to ensure high-quality radiological care of patients. An existing standard may be modified for an individual patient and available resources. The standards should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding the propriety of any specific procedure or course of conduct is the responsibility of an authorized physician in consultation with qualified medical physicist in light of all the circumstances presented for the individual patient and / or situation.

To protect patients from unnecessary radiation, we need to understand the complexities of as well as the limitations in the assumptions that are made in determining, monitoring, and evaluating the patient doses in therapeutic and diagnostic procedures. The role and responsibilities of medical physicists in containment of radiation dose to the patients are described briefly below.

Radiological Protection of Patients in Radiation Therapy

In *radiation therapy,* the first responsibility of a medical physicist and a radiation oncology physician is to the patient: they have to assure the best possible radiation treatment given the state of current technology, skills of the staff, and the resources available in the radiation oncology department. A radiation therapy physicist brings a unique perspective - that of a scientist trained in physics, including

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radiological and clinical physics - to the clinical team in a radiation oncology program to assure accurate delivery of all aspects of a treatment prescription. In *radiation therapy*, the radiation protection of the patient is achieved by delivering an accurately prescribed dose (within 5%) to the organ/tissue of interest while minimizing the dose to the surrounding uninvolved organs/tissues. Because of potential serious patient injury in radiation therapy, the radiation treatment beams have to be planned by qualified medical physicists who give consideration to individual patient specifics. Because of the ever-increasing complexity in treatment planning computer systems as well as treatment delivery equipment, skills and training of qualified medical physicists need to be updated on an ongoing basis. With proper education and training of the physicists, accidental overexposure of large number of patients, such as the one that occurred in Costa Rica in 1996, could have been avoided.

Radiation therapy physicists are involved in measuring and calibrating radiation doses from radiation producing equipment such as Cobalt machines, linear accelerators, simulators, CT-Sims, as well as brachytherapy sources and equipment such as low-, medium-, and high-dose rate (LDR, MDR, and HDR) and intravascular devices. Following the guidelines and protocols provided by scientific organizations medical physicists measure head and collimator leakage, MLC (multi-leaf collimators) leakage / interleaf leakage for these increasingly complex equipment to ensure patient protection from unnecessary radiation. Physicists also perform characterization of radiation treatment beams by measuring and determining various treatment parameters such as beam quality/ energy, depth dose characteristics of radiation beams, field size/shape dependence of radiation beams, characteristics of beam modifiers (such as physical wedges, universal wedges, and dynamic wedges), and intensity modulation of radiation beams in IMRT (Intensity Modulated Radiation Therapy).

In *radiation therapy*, medical physicists are also involved in providing radiation oncology physicians with optimal treatment plans using treatment planning computers with complex calculation algorithms that have inherent limitations in estimating patient doses under all possible conditions or configurations. The limitations in the existing dose calculation algorithms need to be understood and tested. Assurance of the accuracy of treatment parameters (so-called Quality Assurance) in radiotherapy, including correct transfer of parameters between the simulator, treatment plan and the treatment machine, and periodic reviews of each patient's chart are the responsibility of medical physicists. As part of quality assurance, medical physicists often have the output of the radiation treatment beam(s) checked independently either by another qualified medical physicist or by utilizing TLD mailing services [e, f].

Medical physicists are also involved in the *in vivo* dose measurements of radiation patients using devices such as films, diodes, TLD (thermoluminescent dosimeters). Use of these devices requires special knowledge and expertise. Acceptance testing, commissioning of any radiation producing equipment and use of any measuring devices in radiation therapy requires also careful application and attention of medical physicists. The role and responsibilities of medical physicist in radiation therapy have been described in details by scientific organizations in many publications (AAPM 1985, Beletti 1996).

Radiological Protection of Patients in Nuclear Medicine

In *nuclear medicine,* qualified medical physicists are involved in testing, upon installation, all imaging equipment used in nuclear medicine.

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They also monitor the performance of the equipment on a periodical basis to ensure that everything is functioning within the manufacturer's stated specifications and acceptable performance standards. In diagnostic nuclear medicine – intended for planar as well as tomographic imaging - the goal is to produce the diagnostic images of the highest possible quality consistent with the clinical use of the equipment and to obtain the intended information from the examination. In general, the level of the radiation dose to the patients undergoing nuclear medicine examinations is very low. Therefore, the level of patient protection required in diagnostic nuclear medicine should be on a par with the level of radiation doses.

Furthermore, in nuclear medicine procedures with therapeutic intent, the medical physicist is responsible for preparing a table of organ doses for all the procedures that involve administration of radiopharmaceuticals to patients. The table is specific to the dosage schedule used at the facility. Keeping in a mind that models - Monte Carlo or otherwise – used for organ calculations assume standard weight, height, size, shape of a standard man, woman, and child. Thus separate tables for patient size and gender are needed. Due to the complexities involved in calculating patient / organ doses in therapeutic nuclear medicine; the radiation protection of patients should be the responsibility of a qualified medical physicist.

Radiological Protection of Patients in Diagnostic and Interventional Radiology

In *diagnostic* and *interventional radiology,* qualified medical physicists are involved in the process of optimizing the radiation used for imaging. This involves several specific actions. The first is to insure that the quality of images is adequate for the specific clinical objective. This is achieved through consultation on the selection of appropriate imaging equipment, evaluation of equipment performance in the context of quality assurance programs, and the education of medical and technical staff on the appropriate imaging procedures and protocols. The primary objective is to insure that an examination produces the necessary diagnostic information without the application of unnecessary radiation to the patient. A physicist determines the amount of radiation used for the different types of examinations. These data are used to insure that sufficient exposure levels are used to produce the required diagnostic information and that appropriate patient dose limiting techniques are being applied. A related function of medical physicists in diagnostic and interventional radiology is to insure that medical and technical staffs are utilizing appropriate practices to control the levels of radiation to which they are exposed. The medical physicist is a major source of information and consultation resource to the clinical staff on the reduction of the risk associated with inadequate image quality and incorrect, an often life treating, diagnoses. Through this process the medical physicist guides the use of radiation so that it is optimized to produce the necessary diagnostic information without unnecessary human exposure. The role and responsibilities of clinical medical physicist in diagnostic radiology have been described in details by scientific organizations in many publications (AAPM 1994, EFOMP 1999).

In *diagnostic radiology*, physicists are responsible for monitoring and evaluating the patient exposures and comparing them with the published surveys for similar examinations and calculation of specific organ doses for diagnostic procedures and/or for specific patient. The entrance skin dose (ESD) is still by far the simplest indicator of patient's injury. The ESD can be measured directly with TLD or ionization chamber. It can also be estimated from the dose-area product (DAP). These quantities are used to determine the radiation risk. The ESD and DAP can be used for comparison purposes with published values such as Reference Values (RV) [AAPM Task Group Report in progress]. The US adopted RVs are similar to the Diagnostic Reference Levels (DRL) recommended by the European Commission's Medical Exposure Directive (European Commission 1997). The

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RVs and DRLs are not and should not be regarded as regulatory limits. They provide upper level guidelines of patient exposure that should initiate facility investigation when the exposure is exceeded. The RVs and DRLs are established based on the judgement of medical physicists and imaging physicians for standard imaging protocols. These protocols are based on some standard conditions (such as phantom size and group of patients) with consideration to adequate image quality. However, we must realize that RVs and DRLs will vary depending on the available technology, and may not exist for all procedures that are currently performed in radiology. Moreover, we must recognize that the ESD is strongly dependent on the patient's thickness and beam quality. Thus any arbitrarily reduction in the ESD can result in an increased noise (or loss in contrast) and therefore loss in image quality. There are times, however, that patient dose can be reduced without a substantial loss in image quality. The medical physicist is the best-suited individual to monitor patient doses and to reduce them (if possible) without substantially compromising efficacy of diagnostic procedures. Medical physicists are also in charge of patient safety - including radiation, mechanical, and electrical safety. They assist physicians in the evaluation of quantitative studies, such as the measurement of cardiac ejection fraction. In addition they are responsible for initial and continuing education of the physician and imaging staff to ensure efficient and proper use of radiation producing equipment.

In *interventional radiology*, an increasing number of invasive procedures, mostly with therapeutic intent, involve the use of medical devices under fluoroscopic guidance. These procedures, typically involving extended fluoroscopic time, are performed by a variety of medical specialists who may not have proper training in the use of radiation. As the number of interventional procedures has increased in the recent past, medical physicists have become concerned about patient's radiation exposure in these procedures. Fluoroscopic devices can deliver radiation at a very high rate of 5 cGy per min. The physicians need to become aware of the potentially serious radiation-induced skin injury caused by long periods of fluoroscopy employed in these procedures. Also, in recent years, with the increased use of mobile CT (Computed Tomography) in surgical procedures, the doses to the patients have increased considerably. Patients are often unaware that they are exposed to radiation and thus are uninformed of the ill effects of radiation in their procedures.

Examples of interventional procedures, that typically require extended fluoro exposure time, include, but are not limited to, angioplasty (coronary and other vessels), cardiac ablation, vascular embolization, stent placement, endoscopic cholangiopancreatography, biliary drainage, and urinary or biliary stone removal. Although, angioplasty often takes about 45 minutes, on some occasions the procedure may last several hours. The types of injuries to the skin and adjacent tissues, which may result from long exposure to fluoro have been reported in literature (Shope 1996, Wagner *et al.* 1994).

The absorbed dose rate in the skin from a direct beam of a fluoro is typically between 2 to 5 cGy/min, but may be as high as 50 cGy/min, depending on the size of the patient and the mode in which the fluoro is operated. In addition, many fluoro-guided procedures involve image recording (fluorography) using films or digital means to record images permanently. The recording modes usually involve much higher dose rates than those used in fluoroscopy. Contributions from fluorography must also be included in assessing the total absorbed dose to the skin.

Radiation injuries, with onset of months or years after the interventional procedures, cannot be diagnosed easily. When symptoms of injury occur, most interventional physicians may not be in direct contact with the patients. Therefore, many of them are unaware of the potential radiation injuries to their patients. In addition to skin injuries, there is an increased risk of late effects, such as radiation-induced cancers in other tissues and organs. The potential for such late effects should be considered in the risk/benefit analysis, especially in pediatric and

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young adult patients, or in procedures involving exposure to radiosensitive tissues such as breast. For these reasons, in 1994, the US Food and Drug Administration (US FDA 1994) issued a public health advisory warning physicians about the potential risks of fluoro irradiation. The agency recommended that institutions:

(1) Adopt standard procedures and protocols for each fluroscopic procedure,
(2) Determine radiation dose for each fluoroscope,
(3) Evaluate treatment plans to gauge the risk of radiation injury,
(4) Change treatment plans to reduce that risk,
(5) Record in each patient's file the information needed to calculate the absorbed dose of radiation to the skin and other organs.

But it should be noted that the FDA has no authority to force physicians or institutions to honor these recommendations. It is worth noting that the interventional procedures could also result in an increased occupational exposure to physicians and staff, which is of concern to medical physicists.

Summary Statements

A major concern of medical physicists in any subfields of radiation medicine - radiology, interventional radiology, nuclear medicine, and radiotherapy - is to protect patients from unwarranted radiation. To achieve this, European Commissions Medical Exposure Directive [97/43/EURATOM (MED), 1997] requires services of *qualified* medical physicist at *all* radiation facilities. Such policy should be adopted by *all* regulators and government agencies. It is also advisable to establish a comprehensive Standard Operating Procedures Manuals for each specific radiation procedure in any radiation facility. The protocols should be consistent with the scientific and professional standards, which are established by national and international organizations.

The Standard Operating Procedure Manual should address all aspects of the radiation procedures including, but not limited to, patient selection, normal conduct of the procedure, action levels in response to the complications, calibration procedures for all radiation producing equipment and radioactive sources, quality assurance checks of the equipment and dose measuring devices, dose calculation protocol, *in-vivo* dose measurement, monitoring, evaluation, and documentation of patient dose(s), safety programs, emergency procedures, patient education, and staff continuing education. Since each radiation facility is unique, the Standard Operating Procedure Manual must be individualized based on the resources and goals of the program. However, the basic principles of monitoring and evaluation of the patient doses as well as of the outcomes must be addressed on an ongoing, formalized, systematic, and comprehensive manner. The Manual should also include sample quality assessment and improvement plans that lend themselves to a multi-disciplinary problem solving approach that is consistent with the continuing quality improvement philosophy obtaining at a radiation facility.

In conclusion, I would like to endorse any effort that promotes safe use of radiation while minimizing the unnecessary dose to the patients and radiation workers. In particular I would like to encourage proper education and training of medical physicists. I would also like to discourage any arbitrary imposition of radiation limits by the regulators that would limit the ability of physicians and medical physicists to provide optimal therapeutic or diagnostic radiation to the patient.

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