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General Principles of Radiation Protection in Fields of Diagnostic Medical Exposure

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After the rapid development of medical equipment including CT or PET-CT, radiation doses from medical exposure are now the largest source of man-made radiation exposure. General principles of radiation protection from the hazard of ionizing radiation are summarized as three key words; justification, optimization, and dose limit. Because medical exposure of radiation has unique considerations, diagnostic reference level is generally used as a reference value, instead of dose limits. In Korea, medical radiation exposure has increased rapidly. For medical radiation exposure control, Korea has two separate control systems. Regulation is essential to control medical radiation exposure. Physicians and radiologists must be aware of the radiation risks and benefits associated with medical exposure, and understand and implement the principles of radiation protection for patients. The education of the referring physicians and radiologists is also important.

Keywords: Medical Exposure; Radiation Protection; Justification; Optimization; Diagnostic Reference Level

INTRODUCTION

Since its discovery of X-ray by Wilhelm Conrad Roentgen, medical radiation is widely used and it is inevitable use for diagnosis and treatment of patients. Due to the Japanese nuclear accidents on March 2011, the whole world trembled in fear of radiation. This had a side effect of increasing awareness of medical radiation exposure and increase of interest in radiation protection in Korea.

International commission of radiation protection (ICRP) suggested general principles of radiation protection as three key words; justification, optimization and dose limit. Because medical exposure of patients has unique considerations, it is not appropriate to apply dose limits or dose constraints. Dose limits are not at all relevant, since ionizing radiation, used at the appropriate level of dose for the particular medical purpose, is an essential tool that will cause better than harm. Therefore medical radiation does not have dose limits, and generally used diagnostic reference level (DRL) as a reference value (1).

To decrease radiation exposure risks, any medical radiation exposure must be justified and the examinations which use ionizing radiation must be optimized. Justification means that the examination must be medically indicated and useful. Optimization means that the imaging should be performed using doses that are as low as reasonably achievable (ALARA), consistent with the diagnostic task.

PRINCIPLES AND STANDARDS

General principles of radiation protection based on ICRP recommendation 103 (2)

International Commission on Radiological Protection (ICRP) proposed a system of radiation protection with its three principles of justification, optimization and individual dose limitation in publication 26. In publication 60, ICRP revised its recommendations and extended its philosophy to a system of radiological protection while keeping the fundamental principles of protection. ICRP published report 103, as a revised general recommendation for a system of radiation protection in 2007. This new recommendations provide guidance on the fundamental principles on which appropriate radiological protection can be based.

The principles of radiological protection

In ICRP's previous Recommendations, they gave principles of protection as fundamental for the system of protection, and have now formulated a single set of principles that apply to planned, emergency, and existing exposure situations. In these Recommendations, they also clarified how the fundamental principles apply to radiation sources and to the individual, as well as how the source-related principles apply to all controllable situations.

Two principles are source-related and apply in all exposure situations

① The principle of justification: Any decision that alters the

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radiation exposure situation should do more good than harm.

This means that, by introducing a new radiation source, by reducing existing exposure, or by reducing the risk of potential exposure, one should achieve sufficient individual or societal benefit to offset the detriment it causes.

② The principle of optimization of protection: the likelihood of incurring exposures, the number of people exposed, and the magnitude of their individual doses should all be kept as low as reasonably achievable, taking into account economic and societal factors.

This means that the level of protection should be the best under the prevailing circumstances, maximizing the margin of benefit over harm. In order to avoid severely inequitable outcomes of this optimization procedure, there should be restrictions on the doses or risks to individuals from a particular source (dose or risk constraints and reference levels).

One principle is individual-related and applies in planned exposure situations.

③ The principle of application of dose limits: The total dose to any individual from regulated sources in planned exposure situations other than medical exposure of patients should not exceed the appropriate limits recommended by the Commission.

The concepts of dose constraint and reference level are used in conjunction with the optimization of protection to restrict individual doses. A level of individual dose, either as a dose constraint or a reference level, always needs to be defined. The initial intention would be to not exceed, or to remain at, these levels, and the ambition is to reduce all doses to levels that are as low as reasonably achievable, economic and societal factors being taken into account. Diagnostic reference levels are already being used in medical diagnosis (i.e., planned exposure situations) to indicate whether, in routine conditions, the levels of patient dose or administered activity from a specified imaging procedure are unusually high or low for that procedure. If so, a local review should be initiated to determine whether protection has been adequately optimized or whether corrective action is required.

Categories of exposure

The Commission distinguishes between three categories of exposures: occupational exposures, public exposures, and medical exposures of patients.

Occupational exposure

Occupational exposure is defined as all radiation exposure of workers incurred as a result of their work. ICRP limits its use of 'occupational exposures' to radiation exposures incurred at work as a result of situations that can reasonably be regarded as being the responsibility of the operating management. The employer has the main responsibility for the protection of workers.

Public exposure

Public exposure encompasses all exposures of the public other than occupational exposures and medical exposures of patients. It is incurred as a result of a range of radiation sources. The component of public exposure due to natural sources is by far the largest, but this provides no justification for reducing the attention paid to smaller, but more readily controllable, exposures to man-made sources. Exposures of the embryo and fetus of pregnant workers are considered and regulated as public exposures.

Medical exposure of patients

Radiation exposures of patients occur in diagnostic, interventional, and therapeutic procedures. There are several features of radiological practices in medicine that require an approach that differs from the radiological protection in other planned exposure situations. The exposure is intentional and for the direct benefit of the patient. The application of these Recommendations to the medical uses of radiation therefore requires separate guidance.

Principles of radiation protection in medical fields from the ICRP Recommendation 105 (1)

Unique characteristics of radiological protection in medicine

Several features of radiation exposure in medicine for patients require an approach to radiological protection that is somewhat different from that for other types of radiation exposure. The exposure of patients is deliberate. Except in radiation therapy, it is not the aim to deliver radiation dose, but rather to use the radiation to provide diagnostic information or to conduct an interventional procedure. Medical uses of radiation for patients are voluntary in nature, combined with the expectation of direct individual health benefit to the patient. The voluntary decision is made with varying degrees of informed consent that includes not only the expected benefit but also the potential risks. The amount of information provided in order to obtain informed consent varies based on the exposure level (e.g. whether diagnostic, interventional, or therapeutic) and the possible emergent medical circumstances that may be attributable to radiation exposure.

The exception to the concept of a voluntary exposure leading to a direct individual medical benefit is the use of radiation in biomedical research. In these circumstances, the voluntary exposure usually accrues to a societal benefit rather than an individual benefit. Informed consent is always needed.

Screening is performed with the aim of identifying a disease process that has not become manifest clinically. Current screening practices using ionizing radiation appear to be valid and are recommended for certain populations. Patients undergoing screening should be fully informed of the potential benefits and risks, including the radiation risks. Each application of ionizing radiation for screening of asymptomatic individuals should be evaluated and justified with regard to its clinical merit.

Application of principles of radiation protection in medical fields

Because medical exposure of patients has unique considerations, it addresses the proper application of the fundamental principles (justification, optimization of protection and application of dose limits) of radiation protection. With regard to medical exposure of patients, it is not appropriate to apply dose limits, because such limits would often do more harm than good. Often, there are concurrent chronic, severe, or even life-threatening medical conditions that are more critical than the radiation exposure. The emphasis is then on justification of the medical procedures and on the optimization of radiological protection. In diagnostic and interventional procedures, justification of procedures (for a defined purpose and for an individual patient), and management of the patient dose commensurate with the medical task, are the appropriate mechanisms to avoid unnecessary or unproductive radiation exposure. Equipment features that facilitate patient dose management, and diagnostic reference levels derived at the appropriate national, regional, or local level, are likely to be the most effective approaches. In radiation therapy, the avoidance of accidents is a predominant issue. With regard to comforters and carers, and volunteers in biomedical research, dose constraints are appropriate.

Justification

Justification in radiological protection of patients is different from justification of other radiation applications, in that generally the very same person enjoys the benefits and suffers the risks associated with a procedure. (There may be other considerations: attendant occupational exposures could be correlated with patient doses or sometimes there can be a trade-off; screening programs may benefit the population rather than every screened person. But usually, risks and benefits accrue to the same person). And, a very important aspect in daily medical practice: the fact that a method or procedure can be regarded as justified as such does not necessarily mean that its application to the particular patient being considered is justified.

There are three levels of justification of a radiological practice in medicine.

① At the first and most general level, the proper use of radiation in medicine is accepted as doing more good than harm to society.

② At the second level, a specified procedure with a specified objective is defined and justified. The aim of the second level of justification is to judge whether the radiological procedure will improve the diagnosis or treatment, or will provide necessary information about the exposed individuals.

③ At the third level, the application of the procedure to an individual patient should be justified. Hence all individual medical exposures should be justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved.

Optimization

Optimization of protection for patients is also unique. In optimization of protection of the patient in diagnostic procedures, again the same person gets the benefit and suffers the risk, and again individual restrictions on patient dose could be counterproductive to the medical purpose of the procedure. The optimization of radiological protection for patients in medicine is usually applied at two levels: (1) the design, appropriate selection, and construction of equipment and installations; and (2) the day-to-day methods of working. The basic aim of this optimization of protection is to adjust the protection measures for a source of radiation in such a way that the net benefit is maximized. The optimization of protection in medical exposures does not necessarily mean the reduction of doses to the patient. The optimization of radiological protection means keeping the doses 'as low as reasonably achievable, economic and societal factors being taken into account,' and is best described as management of the radiation dose to the patient to be commensurate with the medical purpose.

Diagnostic reference levels

The diagnostic reference level (DRL) applies to medical exposure, as a form of investigation level. DRLs are supplements to professional judgment and do not provide a dividing line between 'good' and 'bad' medicine. They contribute to good radiological practice in medicine. The numerical values of DRLs are advisory; however, implementation of the DRL concept may be required by an authorized body. It is inappropriate to use the numerical values for DRLs as regulatory limits or for commercial purposes. The values should be reviewed at intervals that represent a compromise between the necessary stability and the long-term changes in the observed dose distributions. The selected values could be specific to a country or region.

A DRL can be used to improve a regional, national, or local distribution of observed results for a general medical imaging task, by reducing the frequency of unjustified high or low values. Also it promotes attainment of a narrower and optimal range of values that represent good practice for specific imaging protocols.

The guiding principles for setting a DRL are: ① the regional, national, or local objective is clearly defined, including the degree of specification of clinical and technical conditions for the medical imaging task; ② the selected value of the DRL is based on relevant regional, national, or local data; ③ the quantity used for the DRL can be obtained in a practical way; ④ the quantity

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used for the DRL is a suitable measure of the relative change in patient tissue doses and, therefore, of the relative change in patient risk for the given medical imaging task; ⑤ the manner in which the DRL is to be applied in practice is clearly illustrated.

CURRENT STATUS OF MEDICAL RADIATION EXPOSURE

Increasing use of medical radiation

After the rapid adoption of multi-detector CT, radiation doses from CT are now the single largest source of diagnostic radiation exposure to patients. The significant change in ionizing radiation exposure was due to an increase in medical exposure and other causes did not increase significantly (3,4). The National Council on Radiation Protection and Measurements reported the changes of ionizing radiation exposure of the population of the United States. The expected average radiation exposure in the US was 3.6 mSv in the 1980s, but increased to 6.2 mSv in 2006. Medical exposure accounted for approximately 72% increase in ionizing radiation exposure between 1980s and 2006, that is, medical exposure went from 15% of all exposure in the 1980s to 48% of all exposure in 2006. Specifically, CT was the most important contributor, at 49% of all medical exposure. Nuclear medicine contributes 26% of all medical exposure. Exposure resulting from radiation therapy was not included in the results (4).

In Korea, Kim investigated the number of diagnostic radiation procedures based on the statistics of National Insurance. Total number of images has increased by 37% between 2007 and 2011.The fraction was 78% for conventional radiography, 11% for dental radiography, 7% for mammography, 3% for CT, 1% for fluoroscopy procedures, and 0.2% for angiography. They estimated effective doses for CT and conventional radiography based on the survey data in Korea. Although some limitation, estimated collective dose of Korean population from medical diagnostic examinations was 68,000 man·Sv. The estimated collective dose has increased by 50% since 2007. Annual effective dose per person was 1.4 mSv, which was contributed by 0.79 mSv for CT, 0.44 mSv for conventional radiography, 0.09 mSv for fluoroscopy, 0.05 mSv for angiography, 0.02 mSv for mammography, and 0.004 mSv for dental examinations (5).

Medical radiation control system in Korea

Regulation is essential to control medical radiation exposure. For medical radiation exposure control, Korea has two separate control system. First, diagnostic radiation control falls under the Medical Services Act which is carried by the Ministry of Health and Welfare. On the other hand, therapeutic radiation and nuclear medicine control falls under the Nuclear Safety Act which is carried by the Nuclear Safety and Security Commission. There are two components to the rules under the medical service act; one is for safety control of diagnostic X-ray generating equipment; management of equipment and radiation protection facilities, regulated by Korean center for disease control, the other is for installation and operation of special medical equipment quality assurance system on CT, MRI and mammography. These cover the management of equipment, occupational exposure, and radiation protection facilities, but the current regulation is not focused on patient safety. Many national and international organizations have made a significant effort to regulate and monitor medical radiation exposure using guidelines, accreditation, or even laws. This could be achieved by continuous interest from health professionals and organizations.

CONCLUSIONS

Physicians and radiologists must be aware of the radiation risks and benefits associated with medical exposure, and understand and implement the principles of radiation protection for patients. The education of the referring physician and radiologist are also important.

DISCLOSURE

The author has no potential conflicts of interest to disclose.

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