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Editorial

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Radiological Protection in Nuclear Medicine with a Focus on LNT Model

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Majority of clinical practices of nuclear medicine (NM) today consists of body imaging, although varieties of non-imaging procedures like thyroidal iodine uptake, measurements of ferrokinetics, red blood cell lifespan, intestinal absorption, etc., as well as in vitro radio-assays were frequently performed in the past [1]. As clinical imaging, NM methods are unique in assessing physiological and biochemical functions of organs and tissues. So, they are called images of functions.

For *in vivo* NM procedures unsealed radioisotopes are administered as radiopharmaceuticals to patients. Patients are exposed to radiation sources within the body (internal exposure). An entire body is exposed more or less to radiation sources distributed within the body. International Commission on Radiological Protection (ICRP) estimates doses to patients from radiopharmaceuticals [2]. On the other hand non-NM clinical imaging using radiation causes external exposures on localized regions of the body.

Since its establishment in 1928 ICRP has played advisory roles and published recommendations on concepts and principles of radiological protection (RP) against ionizing radiation. The recommendations are based not only scientific knowledge but also societal and ethical judgement as well as past experiences in RP and radiological accidents.

United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) publishes scientific annexes in addition to its annual report to UN General Assembly, which provides scientific basis for the system of RP recommended by ICRP.

Adverse health effects of radiation exposures are grouped in two general categories: 1. Deterministic effects (harmful tissue reactions) due to the killing/malfunction of cells following high doses and 2. Stochastic effects *i.e.* cancer and heritable effects involving either cancer development in exposed individuals owing to mutation of somatic cells or heritable disease in their offspring owing to mutation of reproductive cells [3]. The practical system of radiological protection recommended by ICRP is based upon the assumption that at doses below about 100 mGy a given increment in dose will produce a directly proportionate increment in the probability of incurring cancer or heritable effects attributable to radiation. This dose-response model is generally known as 'linear-non-threshold' or LNT. ICRP considers that the adoption of the LNT model provides a prudent basis for the practical purposes of radiological protection, i.e. the management of risks from low-dose radiation exposure [3].

This LNT model has been utilized in radiological protection for over 40 years since stochastic effects were recognized in late 1950's, when the aim of radiological protection became 2 folds therein tissue reactions (deterministic effects) are prevented and also the risks of stochastic effects are minimized to the extent reasonably achievable. Meanwhile LNT has been hotly debated. For instance, Prof. C. Marcus, a member of the Society of Nuclear Medicine and Molecular Imaging (SNMMI), submitted a petition to the U.S. Nuclear Regulatory Commission (NRC) requesting to amend its "Standards for Protection against Radiation" and move the basis of those regulations away from LNT model toward a model taking radiation hormesis under consideration [4]. Two other similar petitions were separately submitted nearly simultaneously in February 2015. Several articles were published in Journal of Nuclear Medicine (JNM) [5,6] which sympathize with these petitions. The petitions apparently aim at avoiding needless concern and fair (radiation phobia) of patients to be exposed to medical radiation, which can lead the patients to deny receiving examinations which cause radiation exposures. NM procedures might be erroneously considered as highly harmful because it causes internal exposures. There are some people who insist that internal exposures are more harmful than external exposures [7], although the theory is strongly criticized for having no scientific evidence [8].

The US Environmental Protection Agency (EPA) recommended NRC to reject the petitions. The attitude of EPA was criticized claiming that it is time to reconsider the use of LNT model [9]. After having reviewed recent epidemiologic studies by science committee, the US National Council on Radiation Protection and Measurements (NCRP) published in April 2018 "Commentary No. 27" [10] in which NCRP concludes that the LNT should continue to be utilized for radiation protection purposes. Prior to the publication, Dr. J. Boice (JB), former chairman of the NCRP wrote a review article on LNT model [11] in which he explains that there are many different models of dose-response curves in low dose domain including linear, sub-linear, threshold, hormesis, and supra-linear response curves. Epidemiology cannot provide an answer because of extreme statistical limitations. BJ concludes "Currently for the practical purposes of radiation protection, the LNT hypothesis reigns supreme as the best of the rest, but new epidemiology and radiobiology might change these conclusions, Stay tuned".

The use of LNT model as the standard of radiological protection was vigorously argued in 2019 at the meetings such as the SNMMI (June in Anaheim, USA), International Congress of Radiation Research (August in Manchester, UK), Japan Radiological Society (October in Nagoya,

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Japan), Japanese Society of Nuclear Medicine (November in Matsuyama Japan), Japan Society of Radiation Oncology (November in Nagoya, Japan). In Japan there is a group of people who insists that LNT model is a fact scientifically proven by recent epidemiological studies. Those people serve as witness in trials supporting plaintiffs who claim compensation from the government for the damage caused by spontaneous relocation at the time of Fukushima nuclear power plant accident in March 2011. The author served as witness in one among the trials supporting defendant explaining that LNT model in low dose exposures is a practical hypothesis to be used for RP and has not been scientifically proven at present, though there are plenty of studies that show LNT is scientifically plausible.

In author's view LNT model should continue to be used for radiological protection purpose because of its prudent attitude and managerial convenience. NM professionals need to be convinced that NM procedures, when it is judged well indicated, provide much larger benefits to the health of patients than potential small harm (increase of risk of cancer which may occur decades later) due to exposures to radiation. Then it should not be too difficult to persuade a patient why he or she must receive the procedure for his or her own health benefits.

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