



# Status of Domestic and International Recommendations for Protection Design and Evaluation of Medical Linear Accelerator Facilities

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Various types of high-precision radiotherapy, such as intensity-modulated radiation therapy (IMRT), tomotherapy (Tomotherapy), and stereotactic body radiation therapy have been available since 1997. After being covered by insurance in 2015, the number of IMRT cases rapidly increased 18-fold from 2011 to 2018 in Korea. IMRT, which uses a high-beam irradiation monitor unit, requires higher shielding conditions than conventional radiation treatments. However, to date, research on the shielding of facilities using IMRT and the current understanding of its status are insufficient, and detailed safety regulation procedures have not been established. This study investigated the recommended criteria for the shielding evaluation of facilities using medical linear accelerators (LINACs), including 1) the current status of safety management regulations and systems in domestic and international facilities using medical LINACs and 2) the current status of the recommended standards for safety management in domestic and international facilities using medical LINACs. It is necessary to develop and introduce a safety management system for facilities using LINACs for clinical applications that is suitable for the domestic medical environment and corresponds to the safety management systems for LINACs used overseas.

**Keywords:** Intensity-modulated radiation therapy, Shielding, Medical safety, Linear accelerator, Monitor unit

## Introduction

Since 1997, the quality and results of radiation therapy have improved because of the expansion of clinical applications of intensity-modulated radiation therapy (IMRT), stereotactic body radiation therapy, and tomotherapy (Tomotherapy). Accordingly, the number of IMRT cases increased from 1,921 in 2011 to 34,759 in 2018 because IMRT was covered by insurance in 2015 [1]. High-precision radiation therapy, such as IMRT, uses a relatively large amount of beam irradiation (measured in monitor units, MUs) and requires

higher shielding conditions than conventional treatments [2,3]. However, IMRT research and the understanding of its current status in Korea are still insufficient. Therefore, it is necessary to supplement and revise the detailed operation notices for “facility inspection” in Article 85 and “regular inspection” in Article 88 of the Enforcement Decree of the Nuclear Safety Act by considering the results of the development of appropriate shielding evaluation technology for IMRT [4]. Because of the rapid increase in the use of IMRT after coverage by medical insurance in Korea, this study had the goal of promoting safe and efficient use of medical

radiation by investigating and analyzing the status of appropriate domestic and international shielding evaluation recommendation standards for medical linear accelerator (LINAC) facilities.

## Regulations on Safety Management of Medical Linear Accelerator Facilities for Treatment in Foreign Countries

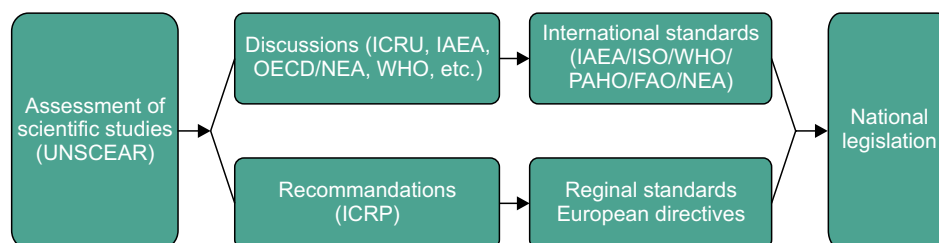
### 1. International law enactment process on radiation protection

Specific legal requirements for radiation protection are based on various recommendations and suggested standards issued internationally by multiple organizations [5]. For example, an evaluation of scientific research is being conducted by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) through discussions with organizations, such as the International Commission on Radiation Units and Measurements (ICRU), the International Atomic Energy Agency (IAEA), the Organization for Economic Cooperation and Development/Nuclear Energy Agency (OECD/NEA), and the World Health Organization (WHO). Based on scientific analyses and international experience, the International Commission on Radiation Protection (ICRP) recommends measures to protect radiation workers, patients, and the general public from radiation. The aforementioned discussions and recommendations are reviewed by standards agencies, such as the IAEA, International Organization for Standardization (ISO), WHO, Pan American Health Organization (PAHO),

Food and Agriculture Organization of the United Nations (FAO), NEA, and regional standard European guidelines. Additionally, international laws on radiation protection are being enacted (Fig. 1).

### 2. Progress of the International Commission on Radiological Protection recommendations

The recommendation of the ICRP was first issued as recommendation 1 in 1959, with the ninth recommendation issued in 1966 after several revisions [6,7]. The ICRP recommends the use of basic standards to enact laws on radiological protection in most countries, similar to the recommended standards for dose limits adopted in most countries. The standard dose limit was first presented in ICRP-26, and after two revisions, the recommended standard was finally presented in ICRP-103 [8-10]. In particular, the dose limit is applied to the equivalent and effective dose considering both external and internal exposure, and the concept of the committed equivalent dose is used to calculate the dose resulting from internal exposure. Compared with ICRP 26, ICRP 60 lowered occupational exposure from 50 mSv per year to 20 mSv per year (based on 5 years), and the public exposure was also lowered from 5 mSv to 1 mSv. Protective measures for pregnant female workers are recommended to protect the fetus or embryo, such that the dose to be received during pregnancy is below the public dose limit (1 mSv).



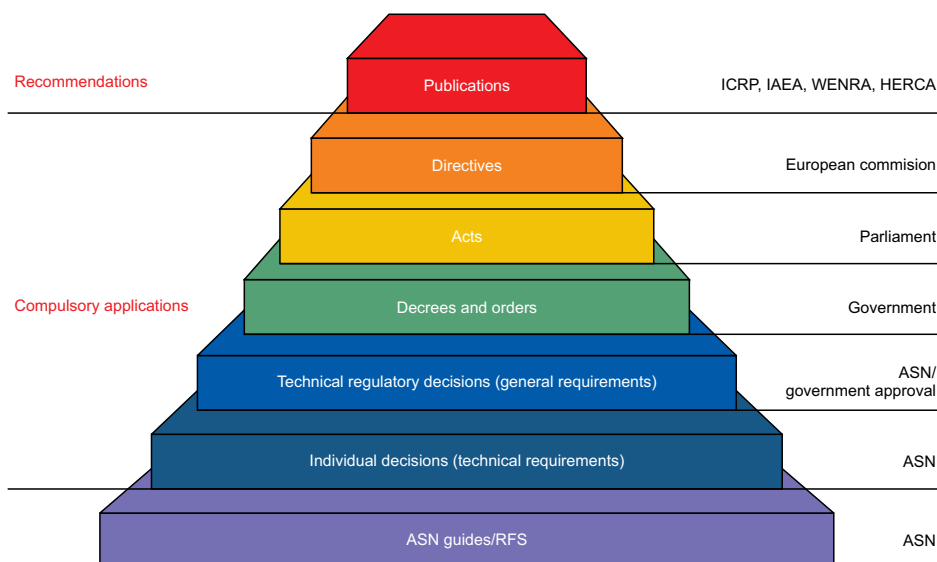
**Fig. 1.** Procedures for enactment of international law on radiation. UNSCEAR, United Nations Scientific Committee on the Effects of Atomic Radiation; ICRU, International Commission on Radiation Units and Measurements; IAEA, International Atomic Energy Agency; OECD/NEA, Organization for Economic Cooperation and Development/Nuclear Energy Agency; WHO, World Health Organization; ICRP, International Commission on Radiation Protection; ISO, International Organization for Standardization; PAHO, Pan American Health Organization; FAO, Food and Agriculture Organization of the United Nations. Data from International Commission on Radiological Protection (Recommendations of the ICRP. ICRP publication 130) [10].

### 3. Legal characteristics of nuclear policy

Although radiation protection-related policies are regulated by laws, various complex regulatory methods are being used, with various laws enacted by competent ministries rather than a single unified law in Korea. Therefore, the Act stipulates only the basic principles of radiation protection, and the specific details are entrusted to subordinate statutes, such as the Enforcement Decree and Enforcement Regulations. Fig. 2 shows the system followed by France, such as laws and regulations, and the standards published and presented in the ICRP, IAEA, and others have the characteristic of being a non-binding proposal

[5]. Directives follow the European Commission, and the legal standards for various countries are established as discussed below. The standards for the United States, Japan, Germany, France, and United Kingdom (UK) were found to vary by state rather than having a unified format. In addition, the recommendations of the International Radioactive Committee are not legally binding; however, these are the standards that are cited by default in most countries.

As shown in Table 1, the US Nuclear Regulatory Commission (NRC), French Nuclear Safety Authority (ASN), and Canadian Nuclear Safety Commission (CNSC) operate as independent agencies, whereas Korea's National Safety and Security Commission (NSSC), the UK's Health and Safety



**Fig. 2.** Radiation regulation levels and recommended standards in France. ICRP, International Commission on Radiation Protection; IAEA, International Atomic Energy Agency; WENRA, Western European Nuclear Regulators Association; HERCA, Heads of the European Radiological Protection Competent Authorities; ASN, Nuclear Safety Authority; RFS, Fundamental Safety Rules. Data from International Commission on Radiological Protection (Recommendations of the ICRP. ICRP publication 130) [10].

**Table 1.** Names and positions of nuclear power agencies by country

Position	Country	Organization
Independent agency	USA	NRC
	France	ASN
	Canada	CNSC
Government agency	Korea	NSSC
	UK	HSE
	China	NNSA
Independent/government agency	Japan	NRA

NRC, Nuclear Regulatory Commission; ASN, Nuclear Safety Authority; CNSC, Canadian Nuclear Safety Commission; NSSC, National Safety and Security Commission; HSE, Health and Safety Executive; NNSA, National Nuclear Safety Administration; NRA, Nuclear Regulation Authority.

Executive (HSE), and China's National Nuclear Safety Administration (NNSA) operate under government agencies. In the case of the Japanese Nuclear Regulation Authority (NRA), as a government/independent agency, related laws and regulations have been enacted. Most nuclear safety regulations in developed countries, such as the United States and France, are overseen by independent organizations, but in major Asian countries, such as Korea, government agencies are in charge of nuclear safety regulations, so their independence and autonomy are inferior to those of advanced countries. As an example, Fig. 2 shows the level of radiation regulation and recommended standards in France.

### Domestic and Foreign Recommendations for Safety Management of Medical Linear Accelerators

The internationally known reports on the shielding design of a medical LINAC are listed in Table 2. The shielding calculation and evaluation criteria presented in each report were analyzed [6-18].

## 1. Domestic

In Korea, the procedure for seeking permission to use a radiation-generating device is listed in subparagraph 5 of Article 64 of the Nuclear Safety Act [4], which stipulates that a radiation safety report must be prepared and kept in accordance with the guidelines for preparing a radiation safety report in the Nuclear Safety and Security Commission Notification No. 2019-21 [19]. Regulations related to radiation exposure in Korea are found in the Enforcement Decree of the Nuclear Safety Act and Article 91 of the Act states that "the exposed dose of radiation workers and frequent entrants shall not exceed the dose limit" [4]. The exposure dose assessment and exposure management are specified under Article 133 of the Act as amended in May 2020 [4]. The dose limits of the Act are presented in Table 3 below. According to Article 13 of the "Standards for Radiation Protection (etc.)" of the Atomic Energy Safety Commission notice, the annual radiation dose should not exceed 20 mSv in a radiation-controlled area with full accuracy, and the radiation dose per week is 1 mSv [20]. The annual radiation dose should not exceed 1 mSv, and the radiation

**Table 2.** Reports on safety management (shielding design) of medical linear accelerator usage facilities for treatment

Year	Organization	ID	Title
1976	NCRP	49	Structural shielding design and evaluation for medical use of X- rays and gamma rays with energies $\leq 10$ MeV
1977	NCRP	51	Radiation protection design guidelines for 0.1-100 MeV particle acceleration facilities
1986	NCRP	79	Neutron contamination from medical electron accelerators
2003	NCRP	144	Radiation protection for particle accelerator facilities
2005	NCRP	151	Structural shielding design and evaluation for megavoltage X- and gamma-ray radiotherapy facilities
2006	IAEA	47	Radiation protection in the design of radiotherapy facilities
2016	ISO	16645	Radiological protection-medical electron accelerators-requirements and recommendations for shielding design and evaluation
2017	IPEM	75-2	Design and shielding of radiotherapy treatment facilities

NCRP, National Council on Radiation Protection and Measurements; IAEA, International Atomic Energy Agency; ISO, International Organization for Standardization; IPEM, Institute of Physics and Engineering in Medicine.

**Table 3.** Dose limits of Nuclear Safety Act in Korea

Item	Effective dose limits (mSv/y)	Equivalent dose limits	
		Lens (mSv/y)	Hands, feet, skin (mSv/y)
Radiation worker	$\leq 50, 100$ mSv/5 y	150	500
Frequent visitor	6	15	50
General public	1	15	50

dose per week should not exceed 0.1 mSv in areas, such as residential areas, adjacent to the boundary of radiation facilities. The standards for usage facilities and distribution facilities are specified in Article 19 of the “Rules on Technical Standards for Radiation Safety Management (etc.)” of the Atomic Energy Safety Commission Announcement, and radiation safety evaluations are conducted in accordance with Article 4 of the “Guidelines for the preparation of radiation safety reports” of the Nuclear Safety and Security Commission announcement [4,21]. The guidelines require the investigation and specification of data on elements constituting the radiation source, radiation workers, general public, and factors affecting the environment to evaluate radiation safety objectively and quantitatively. However, if an objective evaluation method is not established, it is specified that existing cases or data can be used. “Guidelines for the preparation of radiation safety reports” of the Atomic Energy Safety Commission Notice Article 5 provide detailed guidelines for radiation safety reports and specify the guidelines for securing procedures, methods, and results for the evaluation of the expected exposure dose [4].

## 2. National Council on Radiation Protection and Measurements 151

The National Council on Radiation Protection and Measurements (NCRP) is a non-profit corporation recognized by the U.S. Congress that provides recommendations on radiation protection and measurement, publishes guidelines, collects information, and conducts evaluations. The NCRP 151 [15] report recommends that altered or newly introduced facilities to accommodate high-energy accelerators or new treatment techniques should undergo radiation shielding design and safety assessment based on state-of-the-art recommendations. The NCRP 151 report recommends that employees who work in controlled areas and are directly responsible for the use and management of radiation need to receive training in radiation management and perform routine personal dose monitoring. The NCRP 151 report recommends a shielding design goal (P) of 5 mSv per year (or 0.1 mSv per week), which is one-half of the effective dose for controlled areas. In the case of a pregnant radiation worker, the report states that the worker

should not be exposed to a level exceeding 0.5 mSv per year, considering the fetus of the worker. In the NCRP 151 report, public areas are defined as areas accessible to individuals, such as patients and facility visitors (e.g., visitors and delivery services). The exposure of any individual in a public area is limited to an effective dose that does not exceed 1 mSv per year. The NCRP 151 report recommends a weekly shielding design goal (P) of <0.02 mSv per week (<1 mSv per year) for public areas.

## 3. International Atomic Energy Agency 47

The IAEA is an international organization established to promote the peaceful use of nuclear energy. In 1953, 80 UN member states established the IAEA site in response to President Dwight D. Eisenhower’s speech “Atoms for Peace” at the United Nations General Assembly in 1953. In 1957, IAEA was adopted at the International Conference of the United Nations Headquarters and established as an independent and specialized organization of the United Nations. The IAEA defines radiological protection standards through consultation and cooperation with other organizations, such as the International Labor Organization, and regulates the application of these standards. The International Basic Safety Standards (BSS) for the safety of ionizing radiation and radiation sources are supported by various safety guidelines and safety reports that address occupational exposures from natural radiation sources. This standard provides a system and necessary guidance to protect workers from exposure to radon and naturally occurring radioactive materials. The IAEA 47 report [16] under the section of “Radiation Protection in the Design of Radiation Therapy Facilities” describes the Safety Series No. 115 (BSS), which describes in detail the requirements for the design and shielding of radiation therapy facilities. In the case of radiation-controlled areas, the IAEA recommends a dose limit of 20 mSv per year, not exceeding 50 mSv per year, and an average of 20 mSv per year. In the case of the IAEA, there is no legal standard for shielding design criteria. However, as shown in Table 4, the shielding design standards presented in the UK are 6 mSv per year for radiation-controlled areas and 0.3 mSv per year for public areas.

**Table 4.** Shielding design goal for safety management of facilities using LINACs for treatment

Report	Controlled areas	Public areas
NCRP 49	0.1 rem/wk	0.01 rem/wk
NCRP 51	100 mrem/wk, 2.5 mrem/h	10 mrem/wk, 0.25 mrem/h
NCRP 151	5 mSv/y, 0.1 mSv/wk	1 mSv/y, 0.02 mSv/wk
IAEA 47	6 mSv/y, 0.12 mSv/wk	0.3 mSv/y, 0.006 $\mu$ Sv/wk
IPEM 75-2	20 mSv/y (IRR 1999)	0.3 mSv/y (IRR 1999)
Korea	20 mSv/y, 1 mSv/w	1 mSv/y, 0.1 mSv/wk

LINAC, linear accelerator; NCRP, National Council on Radiation Protection and Measurements; IAEA, International Atomic Energy Agency; IPEM, Institute of Physics and Engineering in Medicine; IRR, Ionizing Radiation Regulations.

**Table 5.** External exposure dose limits specified by international organizations

Item	Organization		
	ICRP	NCRP	IRR 1999
Radiation-controlled areas			
External exposure dose limit			
Year	5 year average: 20 mSv	50 mSv	20 mSv
Accumulated dose	5 year average: 20 mSv, yearly maximum: 50 mSv	10 mSv $\times$ age	5 year average: 100 mSv, yearly maximum: 50 mSv
Dose-equivalent annual limit (skin and other organs)			
Lens	150 mSv	150 mSv	150 (20) mSv
Skin	500 mSv	500 mSv	500 mSv
Hands, feet	500 mSv	500 mSv	500 mSv
General public areas			
Effective annual dose limit			
Continuous, frequent exposure	1 mSv	1 mSv	1 mSv
Non-frequent exposure	-	5 mSv	5 mSv
Annual dose limit (skin and other organs)			
Lens	15 mSv	15 mSv	15 mSv
Skin	50 mSv	50 mSv	50 mSv
Hands, feet	-	50 mSv	50 mSv

ICRP, International Commission on Radiation Protection; NCRP, National Council on Radiation Protection and Measurements; IRR, Ionizing Radiation Regulations; -, not available.

#### 4. European Atomic Energy Community

The European Atomic Energy Community (EURATOM) was established to promote safety and efficiency in radiation-related research and work, focusing on research on nuclear power and radiation protection. EURATOM has 28 member states in Europe, including France, Germany, the United Kingdom, Belgium, and the Netherlands. Based on the BSS for radiation protection, the EURATOM provides BSS for protecting the public and workers' health, as found in "Council Directive 96/29/EURATOM (1996)" [22]. The EURATOM Directive (96/29) is based on the ICRP's Ionizing Radiation Regulations (IRR 1999), and the EURATOM

Directive (13/59) is based on IRR 2017. The EURATOM Directive was derived from the ICRP report, which outlines standards for radiation protection and practices in EU member countries. The Institute of Physics and Engineering in Medicine (IPEM) 75-2 [18] was published in July 2017 as a radiation safety report based on the latest European BSS (EC 2013). Table 5 presents some commonly used regulatory limits recommended by the ICRP, NCRP, IAEA, and the UK's IRR-approved codes of practice.

## 5. International Organization for Standardization 16645

The International Electrotechnical Commission (IEC) 60601 report concerns the design and construction of accelerators to ensure equipment operation safety, and the IAEA 47 report provides recommendations on accelerators, safety devices, protection design, calculation, and radiation control and monitoring. The ISO 16645 applies to LINACs with 4–30-MV X-ray energies, including specific equipment, such as medical electron LINACs, robotic arms, helical IMRT devices, and electron beam-based intraoperative radiation therapy devices. The radiation protection requirements and recommendations presented on page 6 of the IEC 60601 report cover aspects related to regulatory, shielding design objectives and other design criteria, the manufacturer's role, and the interaction between experts and stakeholders related to radiation protection and radiation around LINACs. In relation to a shielding design goal, ISO 16645 defined the "equivalent dose used in the design calculation and evaluation of barriers constructed for the protection of workers or the public," and the shielding design goal was stipulated as an effective dose limit. However, ISO 16645 does not present prescribed values separately. It is recommended not to exceed the standard in controlled and public areas based on the effective dose limit prescribed by the IAEA and ICRP.

### Discussion

This study investigated and compared the classifications of radiation-controlled areas, public areas, and external exposure dose limits for each area in the ICRP, NCRP, UK-IRR99, and domestic nuclear-related laws and regulations. In controlled areas, the external exposure dose limit is <20 mSv per year according to the ICRP domestic standards for a 5-year average, and <50 mSv per year according to the NCRP. In public places, the external exposure dose limit is stipulated to be <1 mSv per year by the ICRP, NCRP, and domestic standards. For the shielding design goal, NCRP 151, IAEA 47, IPEM 75-2, and ISO 16645 were reviewed and found to be more conservative than the general external exposure dose limit. As NCRP reports 49–51 and 151 were

published, the shielding design goals tended to increase in both public and management areas. Regarding the allowable dose for the shielding design in controlled areas, NCRP recommends <5 mSv per year, IAEA and ISO recommend <6 mSv per year, and IPEM recommends <20 mSv per year. In Korea, the permissible target dose for setting shielding design goals has not yet been specifically stated and recommended. The IAEA, ISO, and IPEM recommend <0.3 mSv per year, and NCRP recommends <1 mSv per year for the shielding design goal for public areas. This study found that the external exposure dose limit and shielding design objectives were established conservatively in the NCRP 151 and IAEA 47 reports relative to those of the IPEM 75-2 in the UK and the domestic nuclear law using the same values for a controlled area. Table 4 shows the shielding design goals for the safety management of facilities using medical LINACs.

IMRT is a therapeutic technique that generates a group of pencil beams with a small beam area using a multi-leaf collimator or a mechanical shutter to deliver intense doses to a tumor and relatively small doses to normal organs adjacent to the tumor. Compared with three-dimensional conformal radiation therapy (3D-CRT), IMRT or volumetric modulated arc therapy (VMAT) requires a relatively greater beam generation (more MUs) to deliver the same dose to the patient. Therefore, because the doses irradiated to the patient were the same, the amount of primary radiation and scattering radiation between 3D-CRT and IMRT do not differ significantly. However, because the amount of leakage radiation emitted from the accelerator head increases significantly, the IMRT factor ( $IF$ ) should be considered as an increase in the irradiation rate for IMRT treatment relative to that of conventional 3D-CRT. In NCRP 151, the average MU value of IMRT is defined as the ratio of the absorbed dose ( $D_{pre}$ ) prescribed for patient treatment in each IMRT treatment plan to the radiation dose during IMRT treatment. The  $IF$  is defined as the ratio of the MU of 3DCRT ( $MU_{3DCRT}$ ) to the MU of IMRT ( $MU_{IMRT}$ ). The  $IF$  is determined as the MU ratio between 3D-CRT and IMRT conditions for a field size of 10 cm×10 cm, a source-to-axial distance of 100 cm, and a depth of 10 cm to deliver the same absorbed dose. The NCRP 151 recommends using an  $IF$  in the range of 2–10.

$$IMRT \text{ factor } (IF) = \frac{MU_{IMRT}}{MU_{3DCRT}} = \frac{\sum_i \frac{MU_i}{(D_{pre})_i}}{MU_{3DCRT}}$$

IAEA 47, IPEM 75-2, and ISO 16645 recommend that the *IF* be calculated in the same way or similar to that used in NCRP 151. In addition, it should be noted that IPEM 75-2 provides more details for the *IF*s. This results in a 2.5-fold increase for step and shoot IMRT and a 5-fold increase for dynamic IMRT. IPEM 75-2 also recommends the use of a conservative value of “3” for VMAT.

## Conclusions

In this study, recommendations related to shielding design based on an overseas report of the Nuclear Safety Act and on shielding design and evaluation guidelines were investigated. In addition, the international regulations and systems related to nuclear laws and medical radiation facilities, such as those in the United States, UK, Japan, and France, were compared with domestic systems. Because the usage of IMRT is rapidly increasing, it is necessary to promote awareness and develop evaluation techniques for the introduction and assessment of appropriate IMRT factors. For safe and efficient management of radiation treatment facilities, it is necessary to establish recommendations and regulations for the safety management (shielding calculation) of facilities using medical LINACs in domestic situations. It is expected that the results of this analysis of the relevant organizations and related reports will be useful for the development of recommendations for the safety management of facilities using LINACs in Korea.

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## Conflicts of Interest

The authors have nothing to disclose.

## Availability of Data and Materials

All relevant data are within the paper and its Supporting Information files.

## Author Contributions

Conceptualization: Dong Wook Kim and Sang Hyoun Choi. Data curation: Jae-ik Shin and Na Hye Kwon. Formal analysis: Jae-ik Shin and Dong Wook Kim. Funding acquisition: Dong Oh Shin and So Hyun Ahn. Investigation: Dong Wook Kim and So Hyun Ahn. Methodology: Dong Wook Kim and Sang Hyoun Choi. Project administration: Dong Wook Kim and Sang Hyoun Choi. Resources: Dong Oh Shin and So Hyun Ahn. Software: Jae-ik Shin and Na Hye Kwon. Supervision: Dong Wook Kim and SYC. Validation: Dong Wook Kim and Dong Oh Shin. Visualization: Jae-ik Shin and Na Hye Kwon. Writing—original draft: Dong Wook Kim and Sang Hyoun Choi. Writing—review & editing: Dong Wook Kim, Dong Oh Shin, and So Hyun Ahn.

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