

Report

## Development of the System of Radiological Protection and Medical Exposure: Basic Information and Trends

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The International Commission on Radiological Protection (ICRP) is a community of more than 250 globally-recognised experts in radiological protection science, policy, and practice from more than 30 countries, and is also a charity. The objective of the system of radiological protection is to provide an appropriate level of protection for people and the environment against the harmful effects of radiation exposure without unduly limiting the individual or societal benefits of activities involving radiation. This article briefly overviews the history of ICRP, the development of the system of radiological protection, and the recent trends of its publications, especially from the viewpoint of medicine.

**Key words:** radiological protection, history, international commission on radiological protection, medicine

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### 1. Discovery of Radiation and Its Harmful Effects

Soon after the discovery of radiation (X-rays) by Röntgen in 1895<sup>1)</sup>, many of the harmful effects of radiation, such as inflammation, burning, and death, were found and reported as listed in Table 1<sup>2)</sup>. However, physicians at the time regarded the use of radiation as potentially beneficial for medical purposes owing to its penetrative characteristics, and some of them proactively attempted for diagnosis and therapy using radiation. Sad to say, it is reported that many radiologists and clinical nurses sacrificed their lives because of undeveloped radiological

protection guidance, insufficient knowledge of the harmful effects of radiation, and poor information sharing<sup>3)</sup>.

Radiation effects have usually been classified into stochastic effects (malignant diseases and heritable effects) and deterministic effects (e.g. burns and epilations). Recently deterministic effects have been called “tissue reactions” since the effects are not necessarily quantitatively pre-determined. Radiation effects, especially acute radiation effects have been studied in depth and are summarized in the International Commission on Radiological Protection (ICRP) Publication 118 (Table 2).

Nowadays, a lot of information on radiation effects and radiological protection is available via the internet. The information on radiological protection in Japanese language is abundant owing to the efforts of Japanese experts and the translation project conducted by the Japan Radioisotope Association for many years, which is

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**Table 1.** Discoveries of radiation and its harmful effects<sup>2)</sup>.

Year	Event	Reference
1895	Discovery of X-rays	Röntgen <sup>1)</sup>
1896, Jan.	Skin inflammation	Grubbe <sup>4)</sup>
Mar.	Eye inflammation	Edison <sup>5)</sup>
Apr.	Epilation without inflammation	Daniel <sup>6)</sup>
Apr.	X-ray burning	Hawks <sup>7)</sup>
Nov.	Experiment on X-ray burning	Edison <sup>8)</sup>
1901	Death without burning	Rollins <sup>9)</sup>
1902	Carcinogenesis and transfer	Frieben <sup>10)</sup>
1911	Induction of leukaemia	von Jagie <i>et al.</i> <sup>11)</sup>
1923	Radium jaw	Blum <sup>12)</sup>
1924	Schneeberger disease	Ludewig and Lorensen <sup>13)</sup>
1926	Leukopenic anemia among dial painters	Reitter and Martland <sup>14)</sup>
1927	Genetic mutations in fruit flies	Muller <sup>15)</sup>
1929	Sarcoma among dial painters	Martland <sup>16)</sup>

**Table 2.** Projected thresholds for acute exposure indicated in ICRP Publication 118<sup>17)</sup>.

Effect	Organ/Tissue	Time to develop effect	Acute exposure (Gy)
Temporary sterility	Testes	3–9 weeks	~0.1
Permanent sterility	Testes	3 weeks	~6
	Ovaries	<1 week	~3
Depression of haematopoiesis	Bone marrow	3–7 days	~0.5
Main phase of skin reddening	Skin (large areas)	1–4 weeks	~3–6
Skin burns	Skin (large areas)	2–3 weeks	5–10
Temporary hair loss	Skin	2–3 weeks	~4
Late atrophy	Skin (large areas)	>1 year	10
Telangiectasia at 5 years	Skin (large areas)	>1 year	10
Cataract (visual impairment)	Eye	>20 years	~0.5
Acute pneumonitis	Lungs	1–3 months	6–7
Renal failure	Kidneys	>1 year	7–8
Fibrosis/necrosis	Bladder	>6 months	15
Cognitive defects	Brain	Several years	1–2
Cognitive defects in infants <18 months	Brain	Several years	0.1–0.2

now an outsourcing business supported by the National Regulation Authority.

A system of radiation protection has been developed through the integration of the understanding of biology, dosimetry, and risk estimates to support the medical and other radiation applications. This article briefly overviews the history of ICRP, development of the system of radiological protection, and the recent trends of its publications, especially from the viewpoint of medicine.

## 2. ICRP

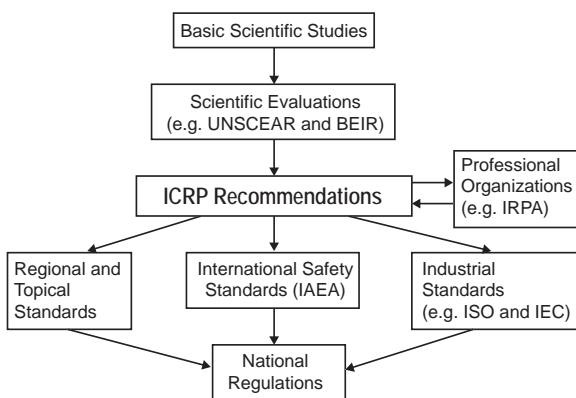
In the Second International Congress of Radiology (ICR) held in Stockholm in 1928, the International X-ray and Radium Protection Committee (IXRPC) was created. Then, after World War II, its name was revised to ICRP<sup>18)</sup>.

ICRP is now a community of more than 250 globally-recognised experts in radiological protection science, policy, and practice from more than 30 countries, and is

also a charity (not-for-profit organisation) registered with the Charity Commission of England and Wales. It is greatly respected as an independent, international organisation that advances the science of radiological protection for the benefit of the public, in particular, by providing **ICRP Recommendations** and guidance on all aspects of protection against ionising radiation (Fig. 1).

ICRP comprises the Main Commission, the Scientific Secretariat, four standing Committees (Committee 1 on Effects, Committee 2 on Doses, Committee 3 on Medicine, and Committee 4 on Application), and a series of Task Groups<sup>19)</sup>. From 2003 to 2017, Committee 5, which treats the protection of the environment was active, but this committee was integrated into Committees 1, 2, and 4 in 2017. ICRP is financially supported by international organization, multilateral regulators and institutions, international and academic societies, and royalties from ICRP publications.

The objective of the system of radiological protection is



**Fig. 1.** Role and relationship of ICRP Recommendations and other international and national organizations for establishing radiological protection regulations<sup>19</sup>. ICRP Recommendations are directly considered for national regulations in some cases.

to contribute to an appropriate level of protection for people and the environment against the harmful effects of radiation exposure without unduly limiting the individual or societal benefits of activities involving radiation (2011 Annual report)<sup>20</sup>. For this purpose, a recent ICRP fundamental publication defined three principles of radiological protection, namely, justification (of practice), optimization (of protection), and dose limitation; however, reaching the polished and well-designed system of protection was a long journey. In the next section, the history of ICRP and the evolution of the system of radiological protection are briefly summarized from the viewpoint of the control of radiation exposure to workers, including medical staff.

### 3. Brief Overview of the Development of the System of Radiological Protection

The first recommendation of radiological protection from ICRP was published in 1928<sup>21</sup>. It suggested preparation of well-conditioned rooms, restrictions on working hours, and the provision of long holidays for X-ray and radium workers (physicians, radiological technologists, and nurses). Thus, medical staff were the target of the first recommendation of radiological protection.

It also noted that: *An X-ray operator should on no account expose himself unnecessarily to a direct beam of X-rays. An operator should place himself as remote as practicable from the X-ray tube.* These are not quantitative limitations, but it is interesting that the spirit of these recommendations is similar to that of optimization, balancing the benefits and harmful effects. Although, there were no dose limits 90 years ago, a dose-limit-like value of approximately 1000 mSv/y was estimated for occupational exposure.

In 1934, a tolerance dose for X-ray exposure of 0.2 r/day (roentgen per day)<sup>22</sup>, which approximately corresponds to 500 mGy/y was recommended. In 1950, after ICR renamed ICRP, the following guidance was given: *In circumstances under which the whole body may be exposed over an indefinite period to X or  $\gamma$  radiation of quantum energy less than 3 MeV, the maximum permissible dose received by the surface of the body shall be 0.5 roentgen in any one week.* This dose corresponds to 0–3 r (rad = 0.01 J/kg = 0.01 Gy) per week (150 mGy/y) measured in free air. The aim of radiological protection at this time was only to avoid the occurrence of deterministic effects<sup>23</sup>.

In 1954, the unit of “rad” started to be used because different types of radiation other than X- and  $\gamma$ -rays were also considered for the system of radiological protection<sup>24</sup>. The unit of rem (roentgen equivalent in man and mammal) was also introduced (eq.1), since the biological effectiveness depends on the type of radiation (neutrons and X- and  $\gamma$ -rays) even when the absorbed dose is equal.

$$\text{REM} = \text{RBE}_{\gamma} D_{\gamma} + \text{RBE}_n D_n \quad (1)$$

Here,  $\text{RBE}_{\gamma}$  and  $\text{RBE}_n$  are relative biological effectiveness factors for X- and  $\gamma$ -rays and for neutrons, and  $D_{\gamma}$  and  $D_n$  are the absorbed doses, respectively. Permissible daily deposition in body, maximum permissible concentration in liquid media for radionuclides were also given in the recommendation<sup>24</sup>.

1958 was the first year of the independent series of ICRP Publications<sup>25</sup>. In this publication, the following guidelines were given: *The maximum permissible total dose for occupational exposure accumulated in the gonads, the blood-forming organs and lenses of the eyes at any age over 18 years shall be governed by the relation*

$$D = 5(N - 18),$$

where  $D$  is tissue dose in rems and  $N$  is age in years. This limit is almost commensurate with the dose limit of 50 mSv/y. Dose criteria were defined for each organs and tissues, respectively:

- (a) *A maximum dose of 8 rems/13 weeks for the skin.*
- (b) *A maximum dose of 20 rems/13 weeks for the hands and forearms, feet and ankles.*
- (c) *A maximum dose of 4 rems/13 weeks for limited exposure of internal organs other than the thyroid, the gonads and the blood-forming organs.*

In 1964 (ICRP Publication 6), ICRU and ICRP decided to use the quality factor (QF) for radiological protection purpose instead of the RBE, since the RBE depends on the endpoint and also varies with the dose rate. Then, in Publication 9 in 1966, the dose equivalent started to be used with the QF<sup>26, 27</sup>. In para (52) it said: *As any exposure may involve some degree of risk, the Commission*

*recommends that any unnecessary exposure be avoided, and that all doses be kept as low as is readily achievable, economic and social considerations being taken into account.* This is almost the same concept as the optimization of protection in the recent fundamental recommendation<sup>28)</sup>.

ICRP Publication 26 was published in 1977, in which the following three well-known principles of radiological protection are written:

- (a) *no practice shall be adopted unless its introduction produces a positive net benefit;*
- (b) *all exposures shall be kept as low as reasonably achievable, economic and social factors being taken into account; and*
- (c) *the dose equivalent to individuals shall not exceed the limits recommended for the appropriate circumstances by the Commission.*

Effective dose was also introduced in the 1977 ICRP Recommendations<sup>28)</sup>. The recommended annual dose-equivalent limit for the uniform irradiation of the whole body was 50 mSv (5 rem) for radiation workers and 5 mSv for the members of the public, while it was lowered to 1 mSv for the members of the public except under special circumstance in Paris statement in 1985<sup>30)</sup>.

In the ICRP 1990 recommendation, the system used the two major process-based approaches of “practice”, which causes exposure to radiation, and “intervention”, which decreases exposure<sup>31)</sup>. No essential changes were made to the three principles or dose limitation for radiation workers and the members of the public in the recent 2007 ICRP recommendation<sup>28)</sup>. The 2007 Recommendation evolved from the previous process-based protection approach using practices and interventions to an approach based on the exposure situation of planned, emergency, and existing exposure situations, considering the categories of exposure (occupational, public, and medical exposure of patients). Although revisiting the entire history of ICRP and recounting the progress of the system of radiological protection would be interesting, an overview paper of ICRP history<sup>18)</sup> provides an informative and detailed summary.

#### 4. Recent Topics of Medical Exposure

It is thought that the recent notable point changes in radiological protection was the Seoul statement in 2011, in which a lower dose limit for the lens of the eye and lower threshold for cardiovascular disease were proposed. The latter was not for radiation control but as a cautionary statement for the medical staff. In addition to the traditional use of radiation in medicine, such as fluoroscopy

for diagnostics, rapid technical revolution and the development of computing technology have produced a number of medical applications of radiation in recent decades, such as computed tomography, single photon emission computed tomography, positron emission tomography, intensity modulated radiation therapy, interventional radiology, brachytherapy, gamma knife, proton and heavy-ion medical accelerators, boron neutron capture therapy, and radiopharmaceuticals. These techniques have been used not only for radiation diagnosis and therapy, but also for studies in biological and medical science.

Radiation workers include medical doctors, clinical nurses, radiological technologists, and medical physicists. Patients include healthy patients (regarding only diagnosis), ill patients, children, adults, and pregnant women. Other people may be exposed to radiation when a patient who intakes a radioactive material (radiopharmaceutical) walks around a hospital or outside. For example, carers may be present in such cases.

The characteristics of medical exposure indicate that the level of dose may vary from low to sufficiently high for harmful effects of radiation to occur in normal tissue or organs, especially in the case of therapy, and an increase in the cancer risk can be expected. Through epidemiological research, ICRP recognizes that *epidemiological methods used for the estimation of cancer risk do not have the power to directly reveal cancer risks in the dose range up to around 100 mSv<sup>28)</sup>*. However, it is considered that avoiding unnecessary risk from exposure is a prudent judgement for public policy. It is obviously important to ensure that more good than harm is expected from medical radiation.

In radiotherapy, while patients may receive a very high dose up to several tens of Gy, the number of such patients is limited, and it is clear that the people who receive the benefit form the radiation exposure are the same as those incurring the risk due to radiation exposure. An overdose will immediately cause a radiation accident in this case. In addition, because the recent development of medical machines has led to the rapid spread of the use of radiation worldwide, it is crucial that ICRP ensures the quality of radiological protection in medicine. Table 3 shows the recent publications of ICRP related to the work of Committee 3.

Although guidelines to prevent radiation accidents and avoid overdoses/underdoses are necessary for the appropriate use of radiation while ensuring the quality of diagnosis/therapy, the number of medical staffs involved in therapeutic program may be the key to solve the issue of complexity. For example, the likelihood of an accident will depend on how many specialized staff can be assigned to establish a therapeutic program. Although there will be some difference between the national

**Table 3.** Recent list of publications of ICRP related to medicine.

Publication 103	The 2007 Recommendations of the International Commission on Radiological Protection
Publication 105	Radiological Protection in Medicine
Publication 106	Radiation Dose to Patients from Radiopharmaceuticals - Addendum 3 to ICRP Publication 53
Publication 112	Preventing Accidental Exposures from New External Beam Radiation Therapy Technologies
Publication 113	Education and Training in Radiological Protection for Diagnostic and Interventional Procedures
Publication 117	Radiological Protection in Fluoroscopically Guided Procedures outside the Imaging Department
Publication 120	Radiological Protection in Cardiology
Publication 121	Radiological Protection in Paediatric Diagnostic and Interventional Radiology
Publication 127	Radiological Protection in Ion Beam Radiotherapy
Publication 128	Radiation Dose to Patients from Radiopharmaceuticals: A Compendium of Current Information Related to Frequently Used Substances
Publication 129	Radiological Protection in Cone Beam Computed Tomography (CBCT)
Publication 135	Diagnostic Reference Levels in Medical Imaging
Publication 139	Occupational Radiological Protection in Interventional Procedures
Publication 140	Radiological Protection in Therapy with Radiopharmaceuticals

regulations and laws, it may be preferable to deploy a specialized staff member for each objective, such as dose assessment and care planning to ensure medical quality and reliability<sup>32</sup>.

OECD/NEA reported that Japan is the country with the largest number of X-ray CT systems per person (107.12 per million population)<sup>33,34</sup>. On the other hand, the diagnostic reference level<sup>35</sup> is routinely reviewed in Japan to compare the average exposure dose patients in a hospital with those in other hospitals. Radiation is now indispensable to maintain the quality of public health; however, unnecessary exposure should be avoided from the viewpoint of radiological protection.

## 5. Summary

ICRP established in 1928, has been developing a system of radiological protection to support medical and industrial uses of radiation that is based on scientific knowledge, experience, and social values. Recent medical applications of radiation have enhanced functionality and complexity enabling wide range of diagnoses and therapies. It will be important for medical staff to have adequate knowledge of radiation effects, dose (the meaning of effective dose), risk, and radiological protection not only to prevent medical accidents, but also for communication with patients to conduct informed consent. In case of emergency exposure situation following a nuclear or radiological accident, medical staff will play an important role in supporting or working with lay people who may be strongly concerned about the effect of radiation.

ICRP provides informative and educative materials for radiological protection in medicine on its website. The dissemination of such information is highly desirable.

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## Conflict of Interest

The authors declare that they have no conflict of interest.

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