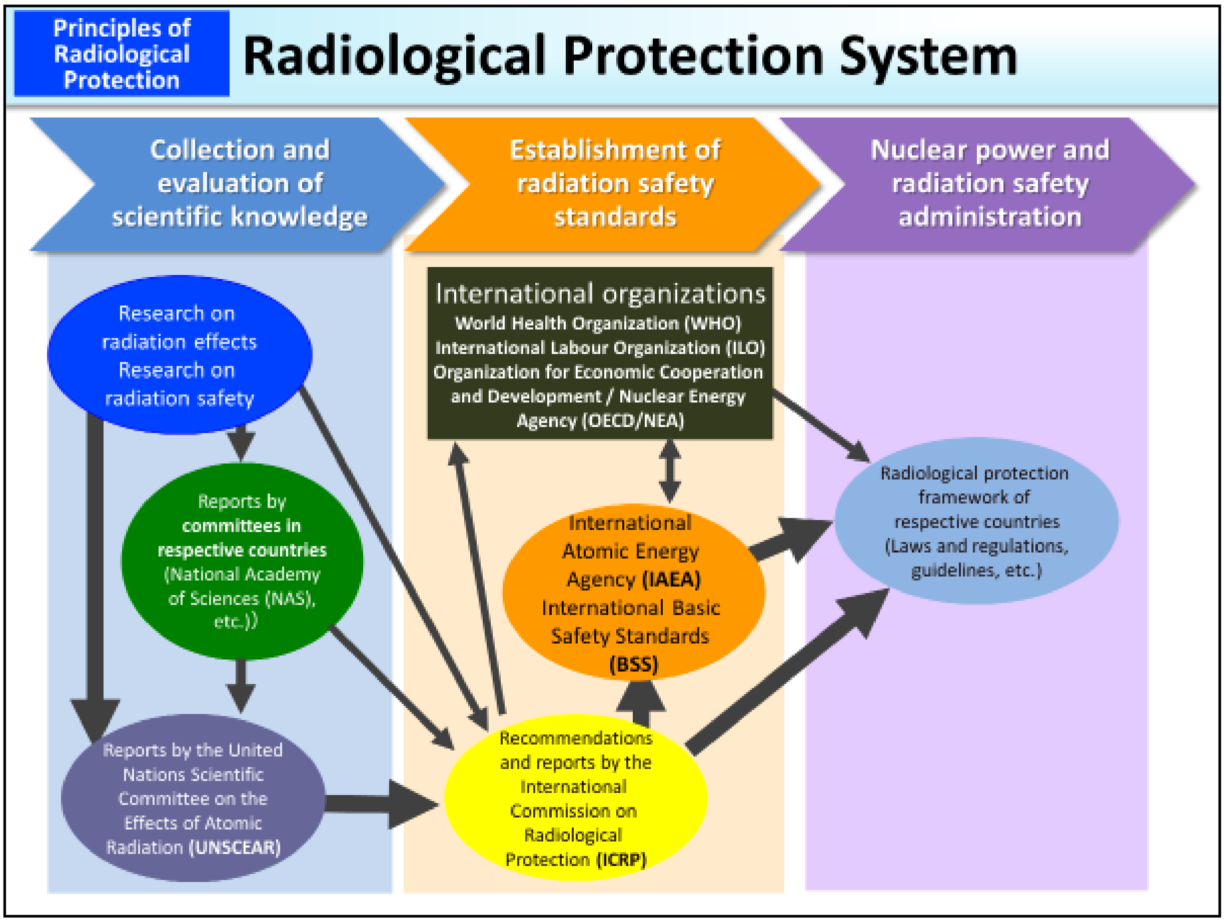

Every year, a large number of reports on research concerning radiation sources and effects are publicized by researchers worldwide.

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) comprehensively evaluates wide-ranging research outcomes, compiles scientific consensus obtained internationally from a politically neutral standpoint, and periodically releases its positions in the form of a report.

The International Commission on Radiological Protection (ICRP), which is an independent private international academic organization, makes recommendations concerning radiological protection frameworks from a professional perspective, while referring to reports, etc. by the UNSCEAR. In consideration of ICRP Recommendations and the International Basic Safety Standards established by the International Atomic Energy Agency (IAEA) based on an international consensus, the government of Japan has also formulated laws, regulations and guidelines, etc. concerning radiological protection.

Included in this reference material on March 31, 2013
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Principles of Radiological Protection

International Commission on Radiological Protection (ICRP)

International Commission on Radiological Protection (ICRP)

The Commission aims to make recommendations concerning basic frameworks for radiological protection and protection standards. The Commission consists of the Main Commission and four standing Committees (radiation effects, doses from radiation exposures, protection in medicine, and application of the Commission's recommendations).

(Reference) Dose limits excerpted from ICRP Recommendations

	1977 Recommendations	1990 Recommendations	2007 Recommendations
Dose limits (occupational exposure)	50 mSv/year	100 mSv/5 years and 50 mSv/year	100 mSv/5 years and 50 mSv/year
Dose limits (public exposure)	5 mSv/year	1 mSv/year	1 mSv/year

mSv: millisieverts

The International X-ray and Radium Protection Committee was established in 1928 for the purpose of protecting healthcare workers from radiation hazards. In 1950, the Committee was reorganized into the International Commission on Radiological Protection (ICRP), which was assigned a significant role as an international organization that makes recommendations concerning basic frameworks for radiological protection and protection standards. In recent years, the Commission made recommendations in 1977, 1990 and 2007 (p.161 of Vol. 1, “Aims of the Recommendations”). When the ICRP releases its recommendations, many countries review their laws and regulations on radiological protection accordingly (p.171 of Vol. 1, “ICRP Recommendations and Responses of the Japanese Government”).

ICRP Recommendations are based on wide-ranging scientific knowledge, such as that obtained through epidemiological studies on atomic bomb survivors, and its radiological protection system has been maintained since 1990 on the basis of its position that comprehensive estimation of deterministic effects (tissue reactions) and stochastic risks is basically unchanged.

Included in this reference material on March 31, 2013
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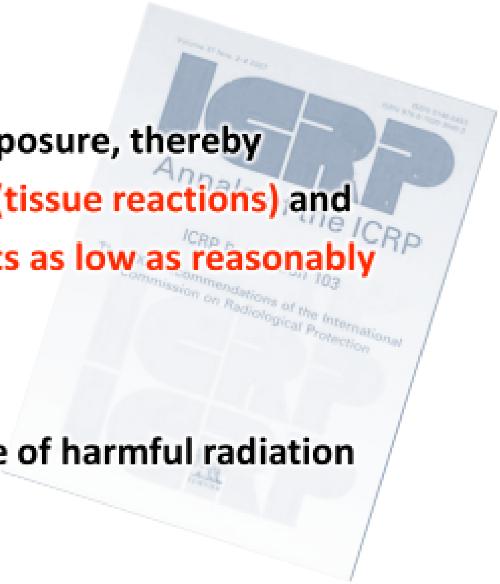
Principles of Radiological Protection

Aims of the Recommendations

Aims of the Recommendations (2007 Recommendations of the International Commission on Radiological Protection (ICRP))



1) To protect human health

- Manage and control radiation exposure, thereby preventing deterministic effects (tissue reactions) and reducing risks of stochastic effects as low as reasonably achievable

2) To protect the environment

- Prevent or reduce the occurrence of harmful radiation effects

Source: Prepared based on the ICRP Publication 103, "The 2007 Recommendations of the International Commission on Radiological Protection" (ICRP, 2007)

The ICRP makes recommendations with the aim of contributing to an appropriate level of protection of human beings and the environment against the detrimental effects of ionizing radiation exposure without unduly limiting preferable human beings' efforts and behavior associated with the use of radiation.

The 2007 Recommendations state that in order to achieve this, scientific knowledge on radiation exposure and its health effects is an indispensable prerequisite, but due consideration needs to be given to social and economic aspects of radiological protection in the same manner as in other risk management-related sectors.

The major aim of the ICRP Recommendations has been the protection of human health, but the aim to protect the environment was newly added in the 2007 Recommendations.

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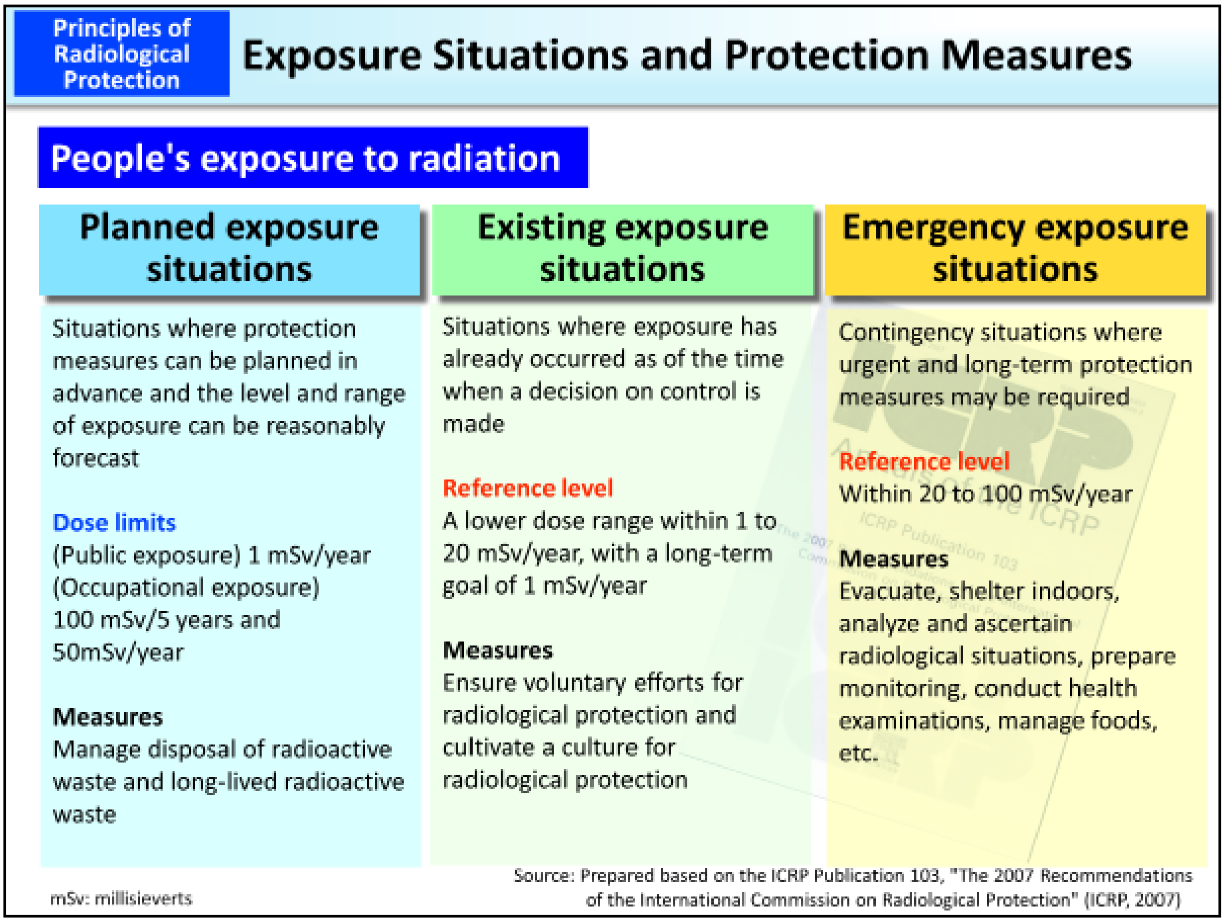

The International Commission on Radiological Protection (ICRP) categorizes exposure situations into normal times that allow planned control (planned exposure situations), emergencies such as an accident or nuclear terrorism (emergency exposure situations), and the recovery and reconstruction period after an accident (existing exposure situations) and sets up protection standards for each of them.

In normal times, protection measures should aim to prevent any exposure that may cause physical disorders and to reduce risks of developing cancer in the future as low as possible. Therefore, the dose limit for public exposure is set at 1 mSv per year, requiring proper management of places where radiation or radioactive materials are handled to ensure that annual public exposure doses do not exceed this level. For workers who handle radiation, the dose limit is set at 100 mSv per five years.

On the other hand, in an emergency such as a nuclear accident (emergency exposure situations), as physical disorders that would never be seen in normal times may develop, priority should be placed on measures to prevent serious physical disorders rather than on measures to be taken in normal times (to reduce risks of developing cancer in the future). Therefore, a reference level of 20 to 100 mSv/year is set for the public instead of applying dose limits and efforts to reduce exposure doses are required. For people who are engaged in emergency measures or rescue activities, a level of 1,000 or 500 mSv may sometimes be adopted as a rough indication depending on the circumstances.

Then, in the recovery and reconstruction period (existing exposure situations), a reference level is to be set within the range of 1 to 20 mSv/year, which is lower than the reference level in an emergency but higher than the dose limits applicable in normal times.
(Related to p.171 of Vol. 1, “ICRP Recommendations and Responses of the Japanese Government”)

Included in this reference material on March 31, 2013
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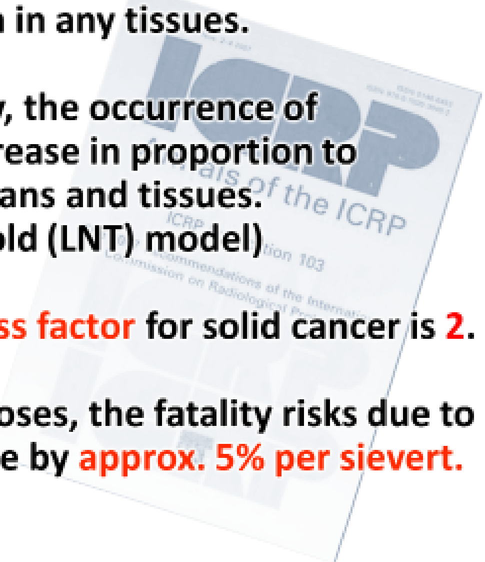
Principles of Radiological Protection

Biological Aspect

Health effects of radiation have deterministic effects (tissue reactions) and stochastic effects.

- **Absorbed doses up to approx. 100 mGy are not judged to cause any clinically significant dysfunction in any tissues.**
- **In the range below approx. 100 mSv, the occurrence of stochastic effects is assumed to increase in proportion to increases in equivalent doses in organs and tissues. (Adoption of the linear non-threshold (LNT) model)**
- **The dose and dose-rate effectiveness factor for solid cancer is 2.**
- **Assuming a linear reaction at low doses, the fatality risks due to cancer and heritable effects increase by approx. 5% per sievert.**



Source: Prepared based on the ICRP Publication 103, "The 2007 Recommendations of the International Commission on Radiological Protection" (ICRP, 2007)

One of the aims of the ICRP Recommendations is to provide considerations and assumptions for building a radiological protection system, thereby preventing the occurrence of deterministic effects (tissue reactions). The ICRP recommends the introduction of protection measures in cases where annual doses have increased close to 100 mGy (≒100 mSv), which is the minimum threshold.

The probability of stochastic effects is very low in the case of annual doses below approx. 100 mSv, and the linear non-threshold (LNT) model, which is based on the assumption that the occurrence of stochastic effects increases in proportion to increases in radiation doses exceeding background doses, is considered to be practical for the management of radiological protection at low doses and low dose rates, and also preferable from the viewpoint of the precautionary principle.

While the ICRP uses, as the grounds for its recommendations, the data for atomic bomb survivors, which is the data concerning a single exposure, what should be controlled is mostly a long-term gradual exposure. Therefore, the ICRP makes adjustments to offset mitigated effects due to low doses and low dose rates. Various values have been reported as a result of animal testing and experiments using human cells to induce chromosomal abnormalities or mutations, but the dose and dose-rate effectiveness factor for radiological protection has been defined as 2 (p.116 of Vol. 1, "Cancer-promoting Effects of Low-dose Exposures"). In other words, if the total exposure dose is the same, long-term low-dose exposure would cause half the effects as those caused by exposure at one time.

As a result of the abovementioned adjustments, risks of fatal cancer are considered to increase by approx. 5% per sievert at low doses and low dose rates.

(Related to p.86 of Vol. 1, "Deterministic Effects (Tissue Reactions) and Stochastic Effects")

Included in this reference material on March 31, 2013
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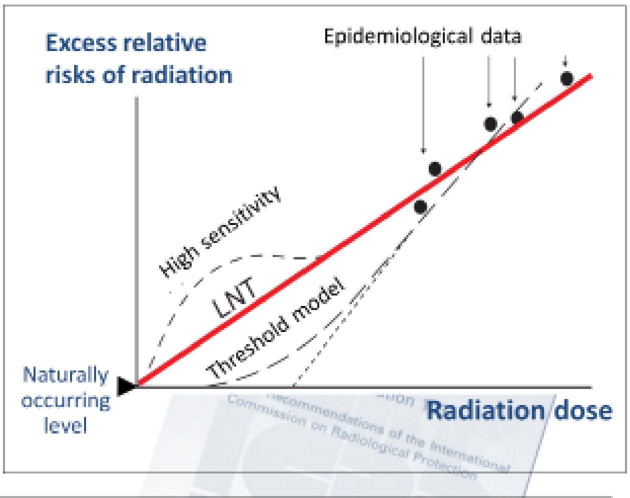
Principles of Radiological Protection

Disputes over the LNT Model

◎Affirmative positions:
National Academy of Sciences (2006)
There is no specific safety dose for radiation exposure.

◎Critical positions:
Académie de Médecine; Académie de Science (2005)
Exposure to radiation below a certain dose does not actually cause cancer, leukemia, etc. and therefore, the LNT model represents overestimation not suited to the reality.



⇒The International Commission on Radiological Protection (ICRP) adopts the linear non-threshold (LNT) model as a simple and reasonable assumption for the purpose of radiological protection.

Disputes over the appropriateness of adopting the linear non-threshold (LNT) model for the evaluation of risks of stochastic effects for radiation below 100 mSv have not been settled scientifically. For example, in 2006, the National Academy of Sciences (NAS) publicized its position that the LNT model is scientifically appropriate, stating that there is epidemiological evidence to prove that radiation below 100 mSv also increases cancer risks. In 2017 onward, papers have been published such as one showing the dose-effect relation in a low-dose region of 100 mGy or lower[1,2] and one stating that it is impossible to rule out threshold models.[1]

On the other hand, the Académie de Médecine and the Académie de Science jointly publicized their position in 2005, stating that exposure to radiation below a certain dose does not actually cause cancer, leukemia, etc. and therefore that the LNT model represents overestimation not suited to the reality. As the grounds for their position, they cited such facts as that increases in cancer risks are not observed in data for residents in high natural radiation areas in India and China and that defensive biological reactions against low-dose radiation have been found one after another.

The ICRP Recommendations are intended to achieve a practical aim of radiological protection, i.e., the provision of a simpler and more reasonable assumption for the management of risks of low-dose exposure, by adopting the LNT model and defining the dose and dose-rate effectiveness factor as 2. On the other hand, the Recommendations also state that it is judged inappropriate for public health planning to estimate hypothetical incidences of cancer or hereditary diseases among a large number of people due to long-term exposure to very low doses of radiation in consideration of the uncertainties concerning low-dose exposure.
(Related to p.86 of Vol. 1, “Deterministic Effects (Tissue Reactions) and Stochastic Effects”)

1. Lubin et al.: J. Clin. Endocrinol Metab. 102(7): 2575–2583, 2017.
2. Lene H. S. Veiga et al.: Radiat. Res. 185(5): 473–484, 2016.
Source
- The National Academy of Sciences, “Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII Phase 2”, 2006.
- Aurengo, A. et al., “Dose–effect relationships and estimation of the carcinogenic effects of low doses of ionizing radiation”, Académie des Sciences - Académie nationale de Médecine, 2005.
- ICRP Publication 103, “The 2007 Recommendations of the International Commission on Radiological Protection” (ICRP, 2007)

Included in this reference material on March 31, 2013
Updated on March 31, 2022

Principles of Radiological Protection

Three Fundamental Principles of Radiological Protection

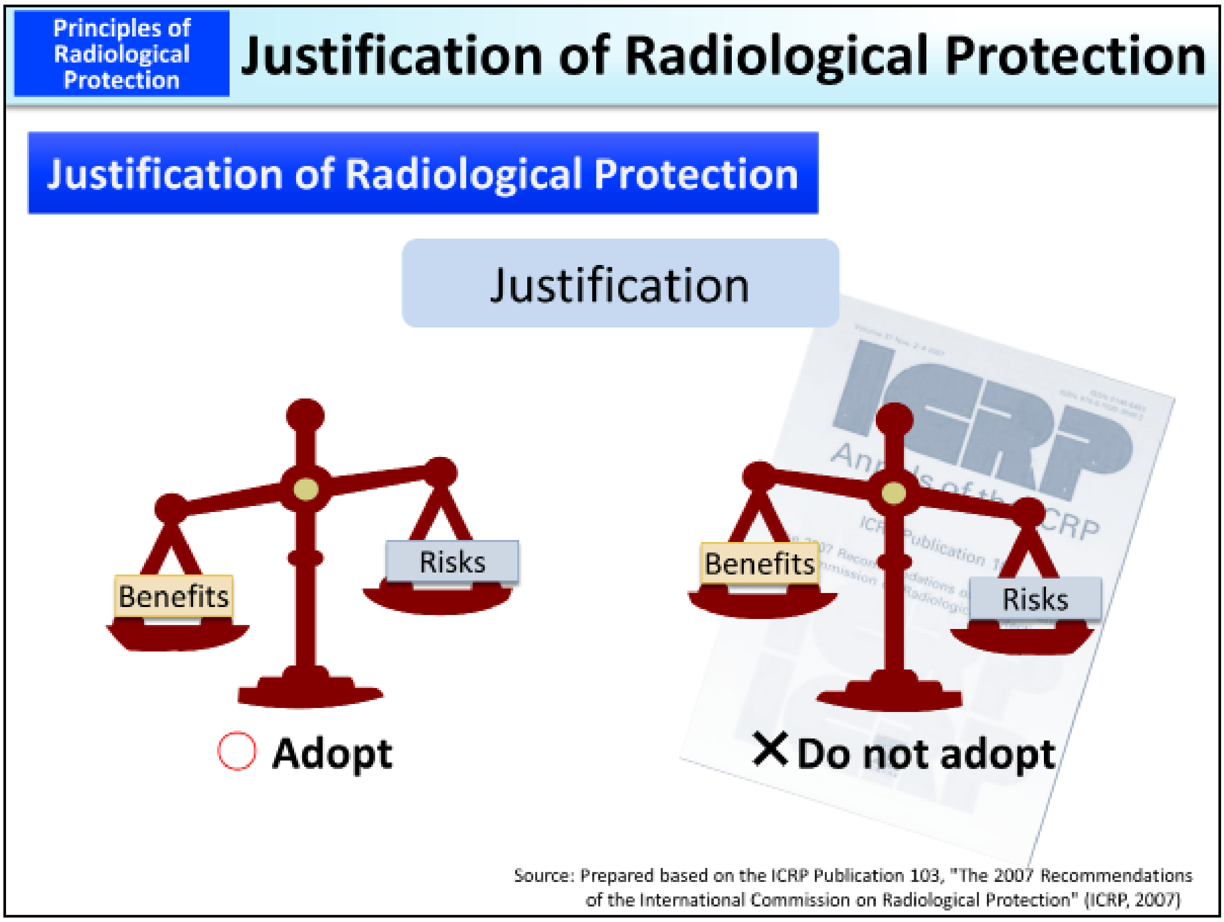
ICRP's three fundamental principles of radiological protection

- **Justification**
- **Optimization**
- **Application of dose limits**

Source: ICRP Publication 103, "The 2007 Recommendations of the International Commission on Radiological Protection" (ICRP, 2007)

In cases of cancer and heritable effects, effects appear stochastically. At present, the linear non-threshold (LNT) model is adopted in radiological protection even for low doses (p.164 of Vol. 1, "Disputes over the LNT Model"), due to which the safety and the danger cannot be clearly divided. Therefore, the protection level is considered based on the idea that risks cannot be completely eliminated and on an assumption that such risks can be tolerated. This is the very basis of the principles of radiological protection, placing emphasis on the "justification," "optimization" and "application of dose limits" (p.166 of Vol. 1, "Justification of Radiological Protection," p.167 of Vol. 1, "Optimization of Radiological Protection," and p.169 of Vol. 1, "Application of Dose Limits").

Included in this reference material on March 31, 2013
Updated on March 31, 2015

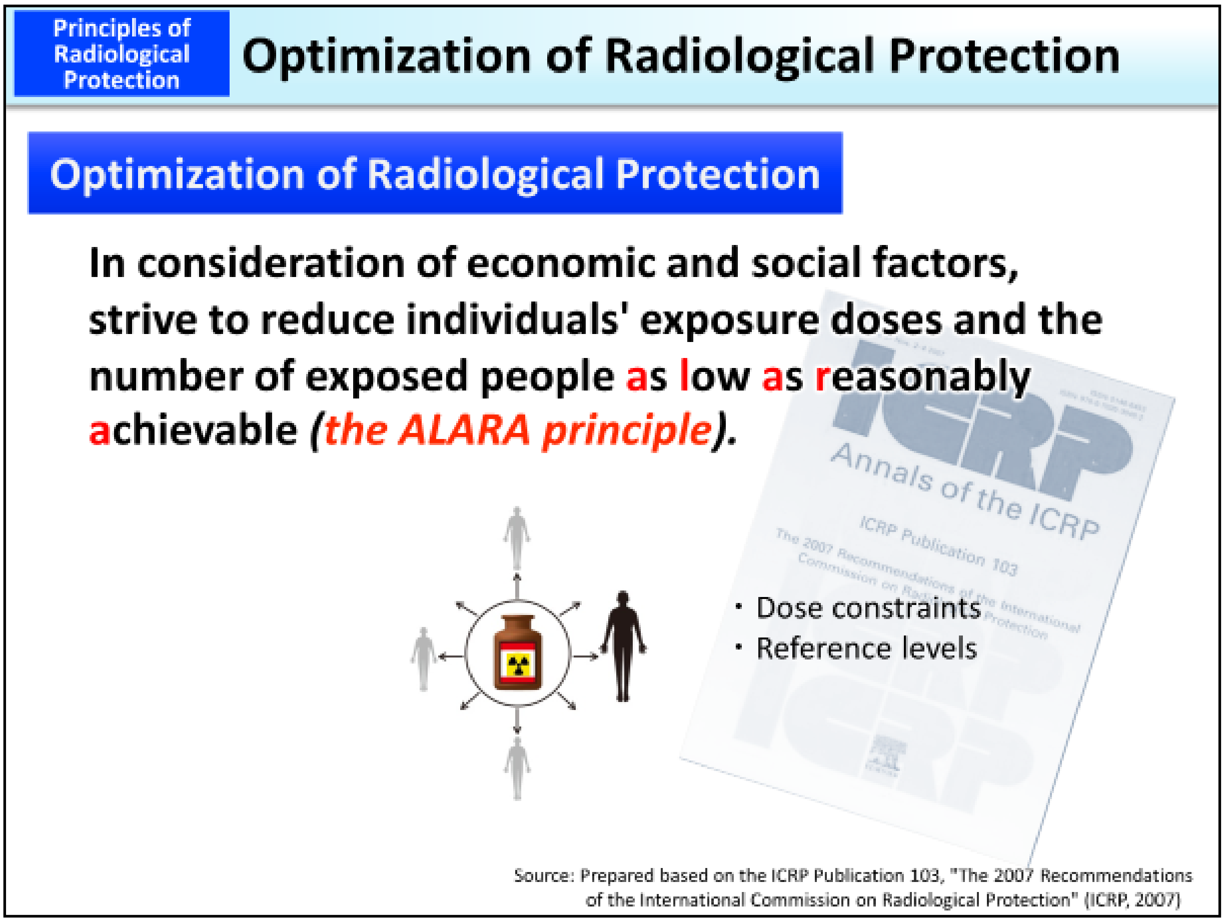


The first principle is the justification of radiological protection. This is the fundamental principle that an act of using radiation is permitted only when the benefits or merits outweigh the radiation risks.

This principle is applied not only to acts of using radiation but also to all activities that bring about changes in exposure situations. In other words, this is also applied to emergency exposure situations and existing exposure situations, as well as to planned exposure situations. For example, justification is required even in the case of considering decontamination of contaminated areas.

(Related to p.98 of Vol. 1, “Risks of Health Effects of Radiation”)

Included in this reference material on March 31, 2013
Updated on March 31, 2015



The second principle is the optimization of radiological protection. When merits of an act of using radiation outweigh radiation risks, it is decided to use radiation by taking measures to reduce exposure doses as low as reasonably achievable. This is called the ALARA principle. The optimization of radiological protection means to strive to reduce exposure doses as low as possible, while taking into consideration social and economic balances, and does not necessarily mean to minimize exposure doses.

In order to promote the optimization of radiological protection, dose constraints and reference levels are utilized. Reference levels are adopted as indicators to limit individuals' doses from specific radiation sources in decontamination work, for example.

Included in this reference material on March 31, 2013
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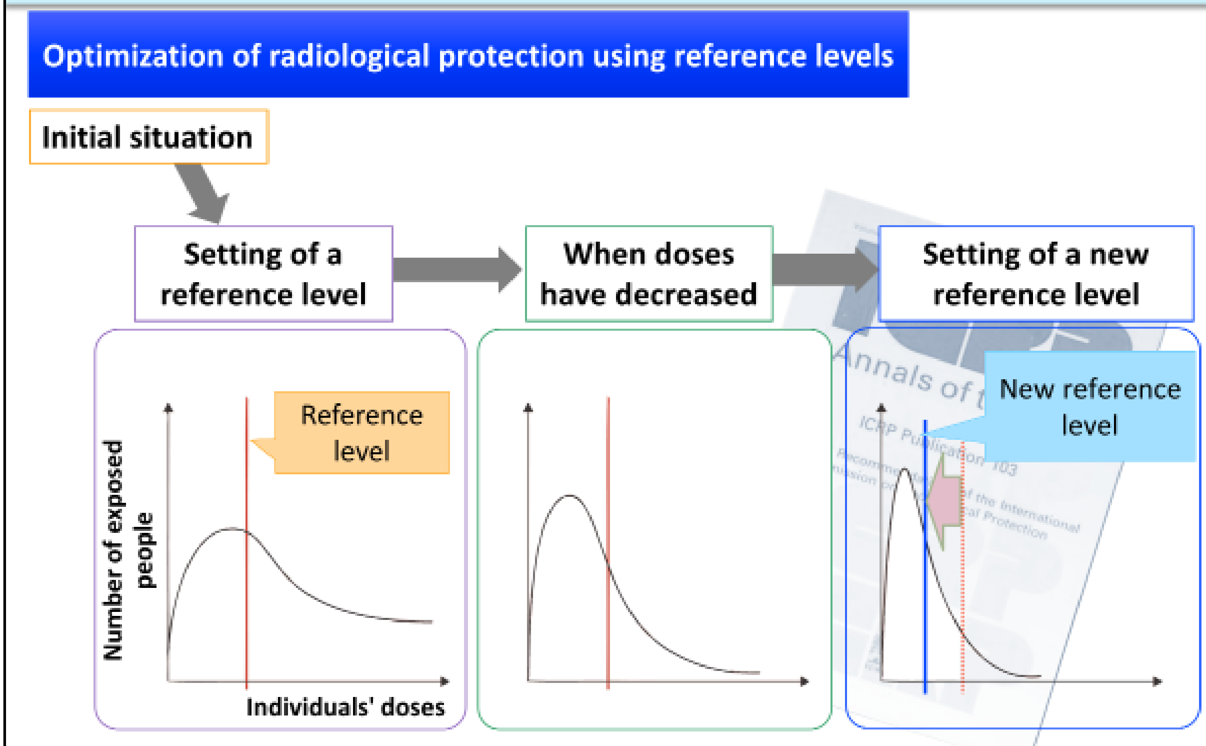
Principles of Radiological Protection

Reduction of Exposure Doses Using Reference Levels



Source: Prepared based on the ICRP Publication 103, "The 2007 Recommendations of the International Commission on Radiological Protection" (ICRP, 2007)

The concept of reference levels as suggested in the 2007 Recommendations of the ICRP has been adopted in promoting measures to reasonably reduce exposure doses due to nuclear power plant accidents, etc. In an emergency such as an accident or nuclear terrorism (emergency exposure situations), the focus is placed on measures to prevent serious physical disorders. Therefore, dose limits (limits for exposure to all regulated radiation sources under planned exposure situations) are not applied. Instead, a reference level is set within the range of annual doses of 20 to 100 mSv for the public and protection activities are carried out so as to limit individuals' doses below that level. Physical disorders that would never be seen in normal times may develop in an emergency. Accordingly, measures to prevent such physical disorders are prioritized over measures to be taken in normal times (to reduce risks of developing cancer in the future). Thereafter, in the recovery and reconstruction period (existing exposure situations), a reference level is set within the range of annual doses of 1 to 20 mSv for the public, and efforts for the optimization of radiological protection are commenced.

Reference levels aim to ensure that no one receives an unduly high dose in a circumstance where exposure doses among individuals are not even. When considering protection measures for the entirety, if there are people who are likely to receive doses exceeding the predetermined reference level, countermeasures for those people are preferentially taken. If dose disparity within a group diminishes as a result of such intensive countermeasures, and there is almost no one who receives a high dose exceeding the reference level, a new lower reference level is set as necessary to further reduce exposure doses as a whole. In this manner, exposure dose reduction can be achieved efficiently by setting appropriate reference levels depending on the circumstances.

Included in this reference material on March 31, 2013
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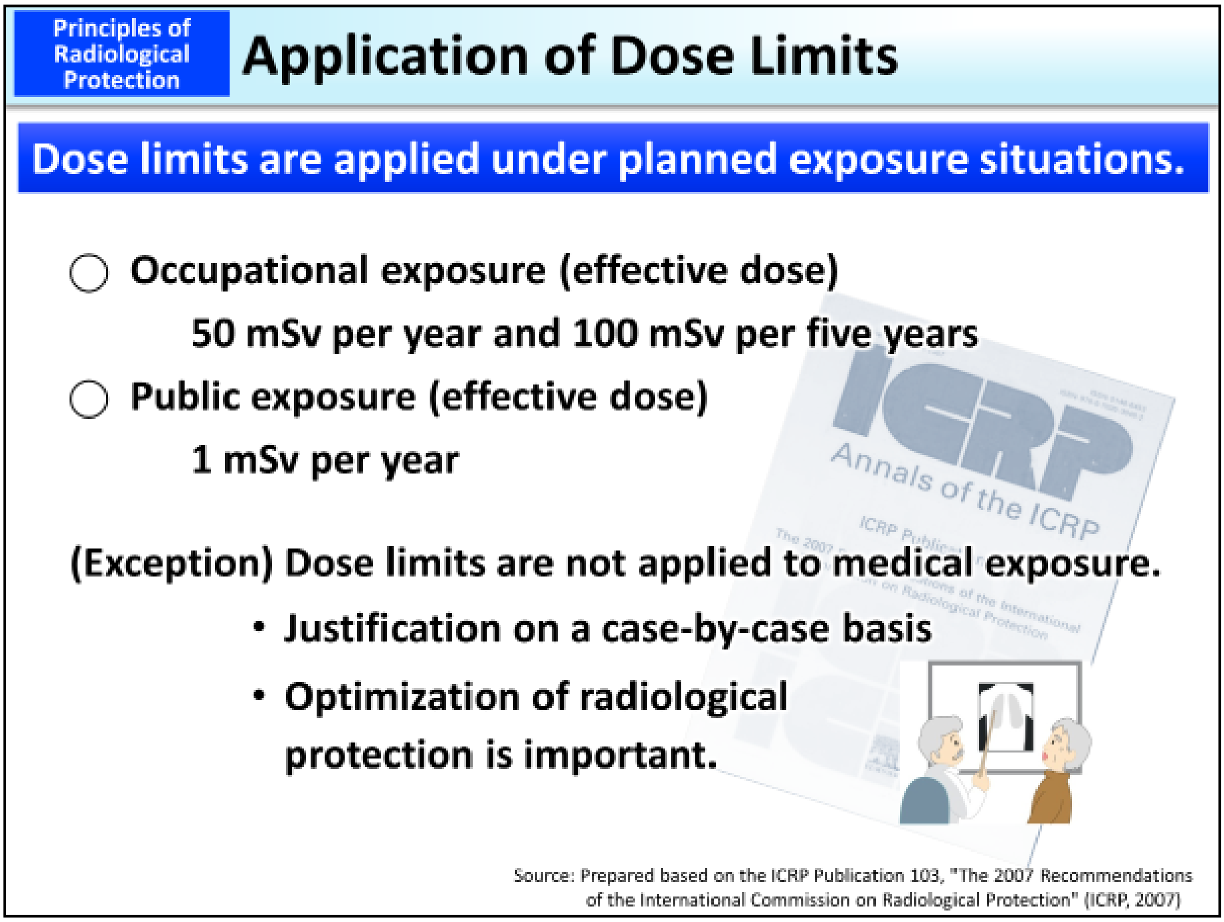

The third principle of radiological protection is the application of dose limits. The 2007 Recommendations of the ICRP specify the effective dose limit for occupational exposure (excluding radiation work in an emergency) as 100 mSv per five years and 50 mSv for the specific one year.

The effective dose limit for public exposure is specified as 1 mSv per year.

Dose limits are the standard limits below which the total exposure to all radiation sources under management is to be controlled. The goal is not to merely keep the total exposure below those dose limits but continued efforts are required to reduce exposure doses through further optimizing radiological protection. In this sense, dose limits do not stand for permissible exposure doses, nor do they represent the threshold to divide the safety and the danger.

Regarding medical exposure in treatment or health checkups, dose limits are not applied. This is because the application of dose limits to medical exposure may hinder patients from receiving necessary inspections or treatment and is sometimes detrimental to them. Accordingly, the justification is to be made from three viewpoints (the fact that radiation use in medicine is more beneficial than harmful to patients; application of specific methods to patients exhibiting specific symptoms; and application of methods customized for respective patients), and doses are to be optimized by applying diagnostic reference levels, etc.

Included in this reference material on March 31, 2013
Updated on March 31, 2016