

# Radiation Protection Standards

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## History of Radiation Protection Standards

Early ignorance of the hazards of radiation resulted in numerous injuries to patients, physicians and scientists and as a result some research scientists took steps to publicize the hazards and set limits on exposures. In 1902, six years after the discovery of x rays, the first dose limit of about 10 rad per day was recommended. This level was set as the lowest value that could readily be measured by fogging of a photographic plate

## Tolerance dose rate

- September 1924 – introduction of the concept of a “tolerance” dose rate for radiation workers, a dose rate that was considered to be one that could be tolerated indefinitely. For purposes of application a safety factor of 10 was applied – one-hundredth of an erythema dose per month

Table 1. Dose Rates for Radiation Workers in the Early Part of the 20th Century

Occupation	Approximate Dose Rate (rad $\text{min}^{-1}$ )
fluoroscopist	0.6 - 4 (hand) 0.005 - 0.05 (body)
x-ray therapy technician	0.006 (body)
radium therapist or technician	0.005 - 0.06 (body)

## U.S. Advisory Committee on X-ray and Radium Protection

- Proposed first formal standard for protecting people from radiation sources.
- Recommended limit on dose rate as 0.1 roentgen per day – in line with the one hundredth of an erythema dose per month.
- Not based on quantitative observation of biological changes but on the absence of observed biological harm.

## Internal Exposures

- 1941 – Limit set for amount of radium that a person could tolerate inside the body
- 1944 – Limit set similarly for plutonium

## New Standards

- Bone marrow dose 300 mrem per week (about 15 rem per year).
- Skin dose 600 mrem per week.

Adopted by ICRP in 1953 and NCRP in 1954.

During the 1950's new data from the atomic bomb survivors, particularly change in sex ratio, resulted in further reductions in standards for external radiation.

## New Standards (II)

1957 – ICRP recommended an annual occupational dose limit of 5 rem per year.

NCRP recommended a lifetime limit of 235 rem for someone who works from age 18 to 65. Also, annual limit to the public of 500 mrem to an individual and 170 mrem per year as the **average** annual dose to a population group

## Cancer Risks

- Atomic bomb survivor data began to provide evidence for increases in leukemia and later in solid cancers in the exposed group. The outcome was the need to estimate the risks of cancer from radiation exposure at low doses (and dose rates). This had to be done by extrapolation from high dose and dose rate studies. Such extrapolations were considered to adhere to a linear non-threshold hypothesis.

## Risk-Based Approaches (I)

- 1977 – ICRP adopted a more formal risk-based approach for setting standards. The approach was based on the premise that the average incremental risk of death from radiation exposure to workers be no larger than that from injuries to workers in “safe” industries –  $1 \times 10^{-4}$  per year.
- Based on cancer mortality, radiation risk was  $1 \times 10^{-4}$  per rem, and so a maximum annual dose limit for a radiation worker was recommended as 5 rem (50mSv) per year (average dose would be less than 10mSv per year)

## Risk-Based Approaches (II)

- 1980s – additional data on cancer mortality from atomic bomb survivors led to increased risk estimates for cancer. The risk coefficient was calculated to be  $4 \times 10^{-4}$  per rem
- This in turn led ICRP to recommend radiation exposure limits of:  
Occupational -10 rem over any 5-year period and 5 rem (50 mSv) in any one year.  
Public – 100 mrem (1mSv) per year averaged over any 5-year period

## Risk-Based Approaches (III)

1991 ICRP (*Publication 60*) The occupational limit was set at 20mSv per year (averaged over defined periods of 5 years). The public limit was set at 1mSv per year

1993 – NCRP published its set of national recommendations:

For cancer, the occupational annual limit was set at no more than 5rem (50mSv) in any one year and a lifetime average of no more than 1.5rem (15 mSv) per year. The public limit for continuous exposures was 100mrem (1mSv) with an annual whole-body limit for infrequent exposure of 5mSv.

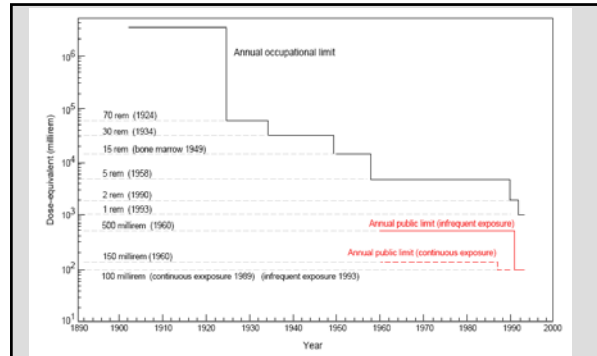
Table 2. Current Standards and Associated Estimates of Risk (NCRP Report Number 116, 1993)

Category	Annual Limit	Recommended Risk Coefficient	Estimated Risk at the Annual Limit
Occupational annual whole-body limit for stochastic effects	5 rem (stochastic)	$4 \times 10^{-4} \text{ rem}^{-1}$ (for fatal cancer)	2 in 1,000 per year
		$8 \times 10^{-5} \text{ rem}^{-1}$ (for severe genetic effects)	4 in 10,000 per year
Occupational lifetime limit	1 rem > age (years)	—	3 in 100 at age 70
Occupational annual limit for deterministic effects	15 rem to lens of eye 50 rem to any other organ or tissue system	—	no risk if limits not exceeded
Public annual whole-body limit for continuous exposure	100 mrem	$5 \times 10^{-4} \text{ rem}^{-1}$ (for fatal cancer)	1 in 10,000 per year
		$1 \times 10^{-4} \text{ rem}^{-1}$ (for severe genetic effects)	1 in 100,000 per year
Public annual whole-body limit for infrequent exposure	500 mrem	$1 \times 10^{-4} \text{ rem}^{-1}$	1 in 10,000 per year
Negligible individual dose (annual whole-body dose per source or practice)	1 mrem	—	no discernible effects (5 in 10,000,000)

•Table 6. Recommended dose limits in planned exposure situations<sup>1</sup>

Type of limit	Occupational	Public
<b>Effective dose</b>	<b>20 mSv per year,</b> averaged over defined periods of 5 years <sup>4</sup>	<b>1 mSv in a year</b> <sup>5</sup>
<b>Annual equivalent dose in:</b>		
<b>Lens of the eye</b> <sup>6</sup>	<b>150 mSv</b>	<b>15 mSv</b>
<b>Skin</b> <sup>2,3</sup>	<b>500 mSv</b>	<b>50 mSv</b>
<b>Hands and feet</b>	<b>500 mSv</b>	-

ICRP 2007



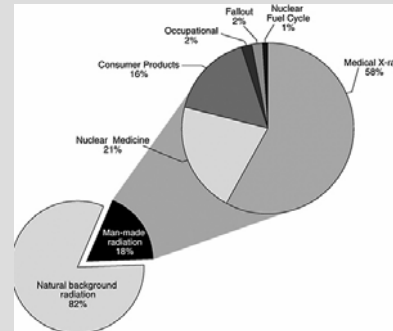
**Radiation Dose Limits over the Past Century** - The 1993 NCRP recommendation for occupational dose limits allows for an average of about 1.5 rem (15 mSv) per year over a working life. The ICRP does not recommend a lifetime dose limit but rather an annual limit of 2 rem (20mSv) per year averaged over any 5-year period.

## What is the Latest on Radiation Protection Standards?

Four new reports address the issue of risk estimates in the context of the current levels and new information.

- Health Risks from Exposure to Low Levels of Ionizing Radiation – BEIR VII Phase 2 (2006)
- ICRP Report 99 – Low-Dose Extrapolation of Radiation-Related Cancer Risk (2005)
- Tubiana M et al. Dose-effect relationships and estimation of the carcinogenic effects of low doses of ionizing radiation, Institut de France Academie des Sciences (2005)
- ICRP 2007 Recommendations and Associated Annex on Biology and Epidemiology

### Background and Man-Made Radiations



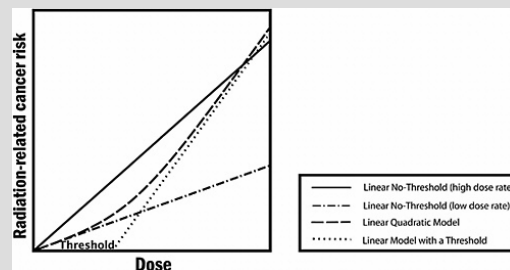
BEIR VII, NAS, 2006

TABLE 7-1 Estimated Range of Effective Doses from Diagnostic Radiation Exposures

Procedure	Type of Examination	Range of Doses
Conventional simple X-rays	Chest films	0.02–10 mGy
	X-rays of bones and skull	
	X-ray of abdomen	
Conventional complex X-rays	GI series	3–10 mGy
	Barium enema	
	Intravenous urogram	
Computed tomography (CT)	Head injuries	5–15 mGy
	Whole-body examinations	
Spiral CT	Head injuries	10–20 mGy
Angiography	Whole-body examinations	10–200 mGy
	Coronary, aortic, peripheral, carotid, abdominal	
	Interventional procedures	
Interventional procedures	Angioplasties with stent placement	10–300 mGy
	Percutaneous dilatations, closures, biopsy procedures	
	Internal emitters	
Internal emitters	Radioisotope studies	3–14 mSv

From BEIR VII

### Linear Nonthreshold Model



From BEIR VII, NAS, 2006

## Dose and Dose-Rate Effectiveness Factor (DDREF)

**DDREF** – A judged factor by which the radiation effect, per unit of dose, caused by a given high or moderate dose of radiation received at high dose rates is reduced when doses are low or are received at low dose rates.

## Radiation Cancer Risk Estimates

The need is to estimate the lifetime risk of cancer resulting from any specified dose of ionizing radiation. The use (within the US) is to apply these estimates to exposure scenarios for groups within the US population. In addition, these risk estimates are used to establish radiation protection standards for the public and for occupationally exposed persons.

## Data Sources

As for previous risk models, BEIR VII placed its reliance on the data for the Japanese atomic bomb survivors. The new information was the DS02 dosimetry and the cancer incidence data. Previously, mortality data were used. Incidence data have the advantage of including nonfatal cancers and of better diagnostic accuracy. Additional data for tumors following occupational and medical exposures were largely used to evaluate whether the conclusions from these studies were compatible with the atomic bomb survivor risk estimates.

## New Risk Estimates (I)

Overall, the magnitude of estimated risks for total cancer mortality or leukemia did not change greatly from estimates in past reports (BEIR V) or from UNSCEAR and ICRP estimates.

## Detriment

The detriment for a tissue T, is defined as

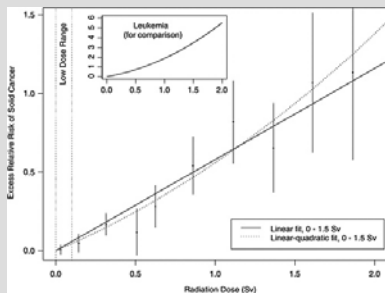
$$D_T = (R_{F,T} + q \cdot R_{NF,T}) I_T$$

Where  $R_T$  is the nominal risk of fatal disease,  $R_{NF}$  is the nominal risk of non-fatal disease,  $q$  is a non-fatal weight (between 0 and 1) reflecting the reduced quality of life associated with living with a serious illness, and  $I$  is the average life lost to the disease relative to normal life expectancy, expressed relative to the average over all cancers. The quality of life factor is a function of the lethality of the disease and a subjective judgement accounting for pain, suffering, and adverse effects of treatment.

## Risk Estimates (II)

For detriment-adjusted cancer incidence, the new estimates (ICRP 2007) are 5.5% per Sv for the whole population (4.1% per Sv for adults). The use of DS02 made only a small change to the estimates (~7%). Again, these are similar to the previous BEIR and ICRP risk estimates that were based on mortality.

These estimates are broadly in line with those obtained from the Cardis et al. (2007) study for low dose rate exposures in radiation workers in the nuclear industry.



Estimated ERR of solid cancers for Japanese atomic bomb survivors. Plotted points are estimated based on solid cancer incidence (averaged over sex and standardized to represent individuals exposed at age 30 who have attained age 60).

From BEIR VII

## Conclusion on Risk Estimates

The difference between the linear and linear-quadratic models in the low-dose ranges is small relative to the error bars. For solid cancer incidence the linear-quadratic model did not offer a significant improvement in fit, and so the linear model was used. For leukemia, the linear-quadratic model was used since it fitted the data significantly better than the linear model.

## Recommendation

- The BEIR VII Committee proposed that “current scientific evidence is consistent with the hypothesis that there is a linear, no threshold dose-response relationship between exposure to ionizing radiation and the development of cancer in humans”.

## Research Needs

Does LNT either underestimate or overestimate the cancer risks at low doses? At present there is insufficient evidence for a role of some specific cellular responses in radiation carcinogenesis.

- There is a continued need to evaluate the relevance of adaptation, low-dose hypersensitivity, bystander effects, hormesis and genomic instability for radiation carcinogenesis.

## DDREF

The BEIR VII Committee took a computational approach to the estimation of DDREF that was based on a Bayesian analysis of combined dose-response data. The Committee considered the following data sets: solid cancer incidence in the LSS cohort of Japanese atomic bomb survivors; cancer and life-shortening in animals; chromosome aberrations in human somatic cells.

## DDREF

The BEIR VII Committee found a believable range of DDREF values for adjusting linear risk estimates from the LSS cohort to be 1.1 – 2.3. A value of 1.5 was selected for solid tumors.

ICRP proposes to continue to recommend a value of 2 while appreciating the need to continue to consider lower values based on new research.

## Genetic Risks

No evidence of radiation-induced germ cell mutations in humans although there is plenty of data for rodents.

The latest approach uses human "spontaneous" mutation data and mouse radiation-induced mutation data (UNSCEAR, 2001 and ICRP, 2007).

The probability coefficients for heritable disease up to the second generation are  $0.2 \times 10^{-2}$  per Sv for the whole population and  $0.1 \times 10^{-2}$  per Sv for adult workers. Exposures are continuous low dose-rate for 2 generations.

## Conclusions

- **The prevailing view from BEIR VII and ICRP (2007) is that the low dose dose-response for solid tumors is linear with no threshold – even when based on incidence**
- **The DDREF is chosen as 1.5 by BEIR VII and remains as 2 for ICRP**
- **There is a need to continue to evaluate the impact of new cellular data on the radiation carcinogenesis process at low exposure levels**
- **There is currently insufficient data to be able to estimate risks for non-cancer endpoints**

## Principles of Radiological Protection

- ICRP has formulated a set of principles that apply to planned, emergency and existing exposure situations. The Commission has 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.

## Principles of Radiation Protection

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

- **The principle of justification:** Any decision that alters the radiation exposure situation should do more good than harm.
- **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.

## Dose Limits

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

- **The principle of application of dose limits:** The total dose to any individual from regulated sources in planned exposure situations should not exceed the appropriate limits recommended by the Commission. Dose limits do not apply to medical exposure of patients.

**Regulatory dose limits are determined by the regulatory authority, taking account of international recommendations, and apply to workers and to members of the public in planned exposure situations. Dose limits do not apply to public exposures in emergency situations, or to public exposures in existing exposure situations**