# Radiation Dose and Risk Assessment


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## Abstract


In FDA many disciplines deal with assessing radiation risk, and although the medical benefit usually outweighs the radiation risk, an understanding of radiation dose and its relationship to risk is essential.

In the U.S. annual radiation dose limits exist for members of the general public (1 mSv), occupational workers ( 50mSv) , mammography (3 mGy) and fluoroscopy (10 R/m) equipment, and nuclear medicine research subjects under the authority of a Radioactive Drug Research Committee, RDRC, (50 mSv for adults, and 5 mSv for subjects under the age of 18). Radiation dose limits do not exist for routine medical examinations and other clinical research.

Clinical and research doses range widely, with high doses exceeding the 3 mSv an individual will receive from natural background sources. The increasing complexity of new imaging procedures and emerging technologies has increased the need to better understand the radiation doses patients and subjects receive. A patient undergoing a fused positron emission tomography (PET)/computed tomography (CT) procedure will receive significant doses from both the internal radioactive drug and the external x-ray based CT procedure.

Radiation doses from these various medical procedures will be compared, along with a discussion of radiation terminology. The concept of organ dose will be presented along with the International Council on Radiation Protection (ICRP) term "effective dose", which allows partial body irradiations to be compared with whole body irradiations. Current ICRP, National Council on Radiation Protection (NCRP), Nuclear Regulatory Commission (NRC), and FDA dose standards will be presented.


## Introduction

The safe use of ionizing radiation, a powerful medical tool, has historically been justified because the benefit is greater than the risk. Although it is generally accepted that "…some types of cancer can result from the damage originating in a single cell…", the probability of such an event resulting in a cancer is extremely low.

The radiation protection community has developed a set of regulatory standards to protect society from the harmful effects of radiation. These range from an annual dose limit of 1 mSv (100 mrem) to a member of the general public, 50mSv (5 rem) for an occupational worker, and 500 mSv (50 rem) for emergency action.

Medical use of radiation is not subject to radiation dose limits, and human research conducted under an Investigational New Drug (IND) application is not subject to any specified limits, leaving the ultimate decision with the local Institutional Review Board (IRB). Human research conducted under the authority of a Radioactive Drug Research Committee, RDRC, which is generally recognized as safe, must limit the dose for the whole body and certain organs to 30 or 50 mSv (3 or 5 rem) for adults, and 3 or 5 mSv (300 or 500 mrem) for subjects under the age of 18.

## As Low as Reasonably Achievable (ALARA)

The concept known as ALARA assumes that the user will use the smallest amount of radiation necessary to perform the medically beneficial task. This implies that (1) the user knows how much radiation an individual is receiving, and (2) has a knowledge of the medical benefit associated with the radiation related task.

Comparisons of almost any nature involve an objective and usually quantitative measure. Radiation dose is an important intermediary metric for risk, but it's determination is not simple.

## Entrance Exposure (Air Kerma)

A practical radiation metric is exposure, ionization per unit mass, originally defined as 1 electrostatic unit of charge per cc of air. The value of exposure is that it is a measurable metric. This is important for radiation safety assessment, where the intensity of a radiation source needs to be known by health physicists or first responders. Radiation exposure using the international system of units (SI) is reported as air kerma, and corresponds to the amount of energy absorbed in air. Air kerma, which represents ionization but is also expressed as a unit of dose, is clearly different than the absorbed dose to an organ, although both terms are the same. This can be confusing.

Exposure is converted to absorbed dose in air using traditional units of Roentgen and rad:

I R x 0.869 rad/R = 0.869 rad ~ 1 rad (1 significant figure)

## Radioactivity

The traditional measurable metric for radioactivity is the Curie, originally defined as the amount of radioactivity in 1 gm of radium. This corresponds to $3.7 \times 10^{10}$ disintegrations per second. The SI unit is the Becquerel, which is 1 disintegration per second. One Ci is therefore $3.7 \times 10^{10}$ Bq.

## Radiation Dose – The Physical Unit

The fundamental physical concept is energy absorbed per unit mass, or radiation absorbed dose, the rad. 1 rad = 100 ergs/gm, the SI unit is the Gray, 1 Gy = 1 Joule/kilogram (1 Gray = 100 rads).

## Radiation Dose – The Biological Unit

The Gray (rad) is a physical unit, but 1 Gray (rad) of energy can be deposited within a mass of tissue using different types of radiation, such as photons, electrons, neutrons, and alpha particles. The resulting biological effects may vary. For most nuclear medicine and x-ray examinations the radiation weighting factor is 1, consequently the terms Gray (rad) and Sievert (rem) are used interchangeably. The biological equivalent of dose for a specific tissue or organ is Equivalent Dose, $H_T$, and is equal to the dose in Gray (rads) multiplied by a radiation weighting factor, $w_r$, which accounts for the relative biological effect (RBE) of the different types and energies of radiation. The SI unit for equivalent dose is the Sievert, rem is the traditional unit.

Equivalent Dose $H_T$ = Dose x radiation weighting factor ($w_R$)
**Relates physical quantity to biological end-point**

| Type and energy | $w_R$ (RBE)* |
|---|---|
| Photons - all energies | 1 |
| Electrons - all energies | 1 |
| Neutrons | 5 – 20 |
| Protons, > 2 MeV | 5 |
| Alpha particles | 20 |

* Relative Biological Effectiveness
100 rem = 1 Sievert

## Organ (Tissue) Doses

The single most important metric for risk assessment is the organ dose. Once you know the actual organ dose, you can definitively derive the risk to the patient for the specific associated cancer, e.g. leukemia with bone marrow dose, or thyroid cancer with the thyroid dose. Organ dose tables, derived from Monte Carlo computer calculations, are available which relate the input values of air kerma for x-ray or radioactivity for nuclear medicine, with the output being organ doses.

## The Homogenized Single Figure of Merit for Radiation Dose

In order to relate partial body irradiations to a whole body dose the ICRP, in 1977, introduced the concept of effective dose equivalent to the whole body, $H_{wb}$. It did this by introducing tissue weighting factors, $W_T$, for different tissue. Each individual tissue or organ dose, $H_T$ is multiplied by a unique tissue weighting factor, so that the sum of these is nominally equivalent to radiation risk associated with a uniform whole body dose . $H_{wb}$. This is described by the following expression:

$$\sum_T w_T H_T = H_{wb}$$

In 1991, ICRP Report 60 changed these tissue weighting factors, and replaced the Effective Dose Equivalent, $H_{wb}$., with Effective Dose, *E*.

$$\sum_T w_T H_T = E$$

Effective dose, *E*, allows one to relate partial body irradiations (individual organ or tissue doses, or limited x-ray fields) to a uniform whole body irradiation.

Currently, in the United States, the Nuclear Regulatory Commission regulations are based on the ICRP 26 guidance. The ICRP 26 and ICRP 60 tissue weighting factors are listed below.

### Tissue Weighting Factors

| Organ (Tissue) | ICRP 26 | ICRP 60 |
|---|---|---|
| Gonads | 0.25 | 0.20 |
| Breast | 0.15 | 0.05 |
| Red BC | 0.12 | 0.12 |
| Lung | 0.12 | 0.12 |
| Thyroid | 0.03 | 0.05 |
| Bone Surfaces | 0.03 | 0.01 |
| Remainder | 0.30 | 0.05 |
| Colon, Stomach | | 0.12 |
| Bladder, Liver, Esophagus | | 0.05 |
| Skin | | 0.01 |
| TOTAL | 1.00 | 1.00 |

## Radiation Dose, (E) from a Variety of Sources

| Radiation Source | Effective Dose (E) | Equivalent to # of chest x-rays | Equivalent time from natural background radiation |
|---|---|---|---|
| | | Natural Background | |
| U.S. 1 year | 3 mSv | 150 | 1 year |
| | | Medical Examinations | |
| | | X-ray | |
| Chest x-ray | 0.02 mSv | 1 | 2.4 days |
| Mammo (1 view) | 0.09 mSv | 4.5 | 11 days |
| CT-head | 2 mSv | 100 | 8 months |
| Upper GI fluoro | 3 mSv | 150 | 1 year |
| CT-abdomen | 10 mSv | 500 | 3.3 years |
| | | Nuclear Medicine | |
| Tc-99m-lung perf | 1 mSv | 50 | 4 months |
| Te-99m – bone | 4 mSv | 200 | 1.3 years |
| PET-FDG | 10 mSv | 500 | 3.3 years |
| | | Regulatory Limits | |
| RDRC-adults | 50 mSv | 1500 – 2,500 | 16.7 years |
| RDRC-subjects < 18 | 5 mSv | 150 – 250 | 1.67 years |
| Member Gen Pop | 1 mSv | 50 | 4 months |
| Occupational Limit | 50 mSv | 2,500 | 16.7 years |
| Emergency Worker | 500 mSv | 25,000 | 167 years |

## Medical Benefit versus Risk

If an individual receives an effective dose of 10 mSv (1 rem) from a high dose medical exam, (s)he receives an additional risk of dying from cancer of 0.001 to 0.0001. If the annual mortality rate from cancer is 0.229 without the benefit of the exam, the risk of dying from cancer increases from 0.229 to 0.2291 – 0.230.

If a population of 1,000,000 patients each receive 10 mSv effective dose, their collective life-time risk is 1,000,000 x 0.001 (or 0.0001) which corresponds to 1000 (or 10,000) cancer deaths.

The medical benefits clearly outweigh the radiation risk of most medical examinations. However, the perception of risk changes when estimated for an individual, when the medical benefit of the examination is understood, compared to the risk when addressing large populations.

## In Summary

The benefits of necessary medical examinations are almost always greater than the radiation risk.

Radiation is a carcinogen, consequently ALARA principles must be followed.

Knowledge of the actual radiation dose is essential, and FDA, as a science based regulatory agency needs to understand the underlying concepts of radiation dose and how they relate to risk.

## References


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