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Use of the effective dose in medical examinations

Recommendation by the German Commission on Radiological Protection

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Anwendung der effektiven Dosis bei medizinischen Untersuchungen

Empfehlung der Strahlenschutzkommission

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In the event of any doubts about the meaning, the German original as published shall prevail.

Contents

1 Introduction

The "effective dose" was introduced by the International Commission on Radiological Protection (ICRP) in order to assess a nominal stochastic radiation risk after radiation exposure which is not uniformly distributed throughout the human organism (see [ICRP 77, 91]). After detailed and difficult discussions, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) decided in 1993 to use the effective dose to quantify medical radiation exposure as well [UN 93]. This was seen as an possibility to use the effective dose to compare exposures arising from the use of ionising radiation for medical diagnosis involving various types of equipment and examination methods, and to make an international comparison concerning the use of medical radiation.

Initially, the effective dose concept was not considered as an option for risk assessment in medical diagnosis. However, in recent years these risks have increasingly become a public concern. In contrast to occupational exposure, each patient should expect to benefit directly from ionising radiation used for medical purposes. With occupational exposure, levels should be kept as low as possible, whereas medical diagnosis requires a specific dose in order, for example, to obtain a useful X-ray image. At the same time, efforts are made to keep patient radiation doses in diagnostic procedures to a minimum, without jeopardising the results of the tests. The ICRP suggested in Publication No. 34, 1982 [ICRP 82] that risk coefficients be used to obtain a more accurate estimation of the individual risk from X-ray examinations. In 1996, in Publication No. 73 [ICRP 96], it recommended that the effective dose also be used to quantify doses and risks in the medical field.

An analysis or evaluation of the various medical examination methods using the effective dose should therefore take account of the benefits as well as the possible risks of radiation exposure. This is easy to achieve in individual cases and comparative studies. However, collective effective doses for an entire population can only be used, to a limited extent, for comparative purposes.

The effective dose is, by definition, the sum of the weighted mean equivalent doses in the individual organs and tissues, although the weighting factors for organs and tissues recommended by the ICRP take account of the relative contribution of the organs to the stochastic radiation risk. These weighting factors represent mean values for age groups (0-75) of both sexes, and mean values for a total population. They therefore represent an age distribution which differs considerably from that of patients in diagnostic radiology and nuclear medicine.

The effective dose does not allow any predictions regarding the appearance of deterministic effects, although the latter play no role in the vast majority of diagnostic procedures.

In addition, one should bear in mind that radiation exposure in diagnostic medicine, especially in diagnostic radiology, might be very unevenly distributed throughout the human organism. Frequently, only parts of organs or tissues with varying degrees of radiation-sensitivity are exposed.

Generally, the radiation doses are low and there are no epidemiological data available indicating that such low doses result in a higher radiation risk than that among a non-exposed control group. Risk values for these dose levels can only be extrapolated from high doses and will therefore be subject to additional inaccuracies.

For all these reasons, the effective dose may only be used for evaluation purposes in diagnostic medicine if the following are taken into account [Str 95]:

– inaccuracies in the calculation of the basic data

– age distribution of exposed patients compared to that of the total population

– often limited life expectancy of patients, and

– immediate benefits to the patient.

2 Quantities used in radiological protection and medical use of ionising radiation

The basic quantity used in all dosimetry is the absorbed dose in tissue. Dose quantities such as the equivalent dose or the effective dose are derived from this. In so doing, account is taken of radio-biological and epidemiological findings (see also [Dre 93, 95, DIN 94, NAR 94]). A fundamental assumption for risk assessment in radiological protection (stochastic effects, $D << 1$ Gy) is the proportionality of dose and risk. Accordingly, if there is an unequal dose distribution over an organ, the mean dose value over the total volume of the organ will be used.

In radiological protection, the following points are taken into consideration, depending on the objectives pursued:

a) Justification

In the process of weighing up benefit against risk, the assessment of detriment or damage should be as realistic as possible. It is not sensible to express detriment using a single quantity, as patient-specific social and psychological factors have to be taken into consideration. The justification for using ionising radiation in medicine is based on medical considerations and must take account of individual circumstances. All doses to each organ, as well as the temporal and spatial dose distribution, should be assessed when determining risk or detriment on a case-by-case basis.

b) Optimisation

Dose quantities such as the entrance dose, the dose-area product and the dose on the image receptor are used to gauge exposure, which should be kept as low as reasonably achievable (ALARA principle). This is achieved, inter alia, by introducing guideline or reference values. Weighted organ doses can be useful as risk-proportional indicators in the optimisation process (for example, in comparing diagnostic radiology examination techniques at different voltages, the differing sensitivities of film-screen systems, analogue and digital recording methods, computed tomography and in nuclear medicine).

c) Limit values

Limit values for medical uses of radiation apply to medical staff only. There are no defined limit values for patients. A defined quantity is required with which to measure exposure. The

effective dose, E, introduced by the ICRP [ICRP 77, 91], has the advantage of being linked to a specific risk/detriment and producing a single numerical value. This value is defined by laying down the weighting factor amounts w_T or w_R (see chapter 3).

3 The effective dose and its applicability

The following recommendation concerns the effective dose and its applicability, as well as modifications for medical risk assessment where risk coefficients are used that take account of the age of the exposed patients.

3.1 The effective dose

The term "effective dose" was introduced by the ICRP [ICRP 77, 91] as a practical means of assessing, both internally and externally, the exposure of tissue and organs relevant to the stochastic radiation risk in the case of non-uniform radiation distribution.

The effective dose, E, is the sum of the respective tissue weighting factors, $w_{T,}$ multiplied by the equivalent organ doses, $H_{T,}$ in the relevant organs and tissues:

$$E = \sum_T w_T H_T \qquad w_T = \frac{a_T}{\sum_T a_T} \qquad \sum_T w_T = 1$$

The individual organ equivalent doses H_T are weighted using factors $w_{T,}$ according to their relative contributions to the stochastic effects. a_T designates the nominal organ risk coefficient.

The organ equivalent dose H_T is the product of the mean absorbed dose value D_T (averaged over the volume of a tissue, organ or other body part *T*, or in the case of skin, averaged over the total surface area) and the radiation weighting factor w_R for the respective radiation quality *R*:

$$H_T = w_R \cdot D_T$$

If several radiation qualities are acting at the same time, the organ equivalent dose is the sum of the products of the radiation weighting factor w_R and the mean energy dose $D_{T,R,}$ obtained from the radiation of radiation quality *R*:

$$H_T = \sum_R w_R \cdot D_{T,\,R}$$

According to this definition of the organ equivalent dose (ICRP 60) [ICRP 91], the radiation weighting factor w_R takes account of differences in the biological effectiveness of the various radiation qualities. Numerical values for w_R are laid down in ICRP 60 .

Taking account of the definition $H_{T,}$ the following applies:

$$E = \sum_{T,R} \sum w_T w_R \cdot D_{T,R}$$

The effective dose is not a measurable quantity.

3.2 Detriment

The term "detriment" was introduced to describe the stochastic radiation risk to an individual or group. It comprises a number of components, according to the exposure of the organs or tissues and its effects:

– the probability of death from radiation-induced cancer, including leukaemia (mortality),

– the probability of contracting non-fatal radiation-induced cancer, including leukaemia,

– the probability of hereditary effects,

– the loss of lifetime as a result of radiation-induced cancer, including leukaemia.

3.3 Weighting factors and risk coefficients

The definition of the effective dose is based on tissue weighting factors, the sum of which is set at 1. The tissue weighting factors in ICRP Publication No. 26 [ICRP 77] were updated in ICRP Publication No. 60 [ICRP 91] and should take account of the relative contribution of the organs to the detriment for a hypothetical world population (averaged over 5 nations) on the basis of new epidemiological data from the survivors of the atomic bombs in Hiroshima and Nagasaki. The ICRP explicitly states that the same tissue weighting factors apply to all age groups and both sexes for radiological protection purposes.

The radiation risk is higher in children and young people than in adults, particularly elderly adults. The relationship between age and radiation risk is covered by risk coefficients for specific age groups.

According to ICRP 60 [ICRP 91] the effects observed in Japan from medium or high doses and high dose rates were extrapolated to lower doses by assuming a linear dose-response relationship and applying a dose and dose rate effectiveness factor (DDREF) of 2. Exposures in diagnostic radiology and nuclear medicine are in the lower dose bands. If age at the time of exposure is taken into account, the risk coefficients may also be used in medicine.

The effective dose concept was originally introduced in order to assess the effect of various doses on the individual tissues of occupationally exposed people and the general population, in a way which is likely to correlate well with the total of the stochastic effects. However, applying the "per caput" effective dose to patients fails to take account of some essential facts. For example, X-ray examinations are by no means carried out uniformly across the population. High-dose examinations are more frequently performed on the elderly population, where age and illness lessen the probability of stochastic radiation effects occurring. Additionally, in diagnostic radiology it makes little sense to analyse the radiation risk separately from the risks of the illness and treatment, without also weighing up the benefits of radiological examinations or treatment [Ste 93; Schi 94].

3.4 Benefits of radiological or nuclear medicine examinations or treatment

There are still clear benefits to be derived from using diagnostic radiology and nuclear medicine in numerous medical situations, despite the use of other imaging techniques (ultrasound scanning, magnetic resonance imaging and endoscopy), as the following examples illustrate:

- early detection of changes to the skeleton and joints as well as monitoring the success of therapy using radiography and scintigraphy,

- recognising localisation and spreading of traumatic or tumorous bone processes by monitoring during treatment,

- X-ray examination of the thoracic organs, particularly the lung, for early detection of localised or disseminated diseases, and for monitoring therapy,

- computerized tomography with non-superimposed and high-contrast cross-section images to detect unhealthy changes, especially in the brain, spinal cord, thorax and abdomen, and to monitor therapy,

- improving screening for breast cancer using mammography, and increasing chances of recovery,

- interventional radiology for low-risk treatment as a substitute for high-risk operations.

The effective dose is useful for comparing exposures that arise from similar uses of radiation in medical diagnosis and where there is a similar age and gender distribution amongst the exposed patients. However, when comparing risks from medical exposures with risks from occupational or environmental exposure, the different age distributions among those exposed must be taken into account. This can be achieved by applying age-specific risk coefficients or other corrections.

3.5 Restrictions and specialities concerning the use of the effective dose

The use of the risk concept (for which the effective dose is an expression) is subject to a number of restrictions and specialities which can be illustrated by a few examples from the medical field:

- In interventional radiology very high exposures may occur locally under some circumstances, and the doses to some tissues, particularly the skin, may reach the threshold for deterministic effects. With certain corrections (ignoring high local skin doses) the stochastic radiation risk for these patients may be assessed according to the effective dose principal, taking account of their ages.

- During examinations of the extremities (these make up 1/5 of all X-ray examinations) the effective dose is calculated using doses from extensive organs (red marrow, bones, muscles, skin), which are then averaged over the whole body. The X-rays produce a low value for the effective dose due to the small proportion of these organs exposed to the field.

– For pre-natal exposure, the effective dose to the mother is not the decisive factor, but rather the dose to the embryo or the foetus, which in diagnostic radiology is equivalent to the organ dose to the uterus.

– When determining the organ dose to the bone marrow in children or young people, account must be taken of the fact that the anatomical distribution of red marrow in their skeleton is completely different from that among adults.

– When evaluating nuclear medicine examinations, account must be taken of particular problems relating to radionuclide distribution, which may be altered by illness and associated metabolic changes so that it no longer corresponds to that of the reference person.

4 Risk assessment in diagnostic radiology

The radiation risk depends to a large extent on the age of the person at the time of exposure. This relationship between age and the additional lifetime risk is shown in percent per Sv in ICRP 60 [ICRP 91], Annex C, Diag. C-5 (see Fig. A 1). If the risk of a diagnostic examination has to be assessed, assuming a particular patient-specific effective dose, it is important to distinguish between the individual risk to the patient and the collective risk, which is based on the sum of the individual doses.

4.1 Individual risk

The medical use of ionising radiation is always determined by weighing up individual benefits against risk. The information on age-dependent fatal cancer risk given in ICRP 60 [ICRP 91] may be used to assess the individual radiation risk of a patient of known age (see Fig. A 1).

The fatal cancer risk of a 1-10 year old child is thus estimated at approx. 14.5% per Sv (mean value for both sexes), and that of a 70-year-old at approx. 1% per Sv. As well as the dependency from age and sex, individual dispositions, which vary enormously, may also account for someone developing or surviving cancer. Exposure of young people carries an additional genetic risk, which does not apply to older people.

4.2 Collective risk to patients

On the basis of the relationship between age and radiation risk (see above) and new epidemiological data, the ICRP set out mean radiation risks for stochastic effects for two relevant population groups in its Publication No. 60 [ICRP 91]. These groups are the working population (18 - 65 years) and the general population. The mean detriment for the general population amounts to 7.3% per Sv compared to 5.6% per Sv for the working population. As far as the lifetime risk of death is concerned, mean values of 5% per Sv for the general population and 4% per Sv for the working population are quoted.

It is not sensible to use these non-differentiated risk coefficients for patients. These two population groups (general population and the working population) should therefore be supplemented by a third relevant group, i.e. patients, the age distribution of which differs

considerably from the other two groups (see Fig. 1). In exactly the same way, it would be sensible to introduce age-specific mean risk coefficients for patients, which could, if necessary, be supplemented by other patient-specific factors arising from the illness.

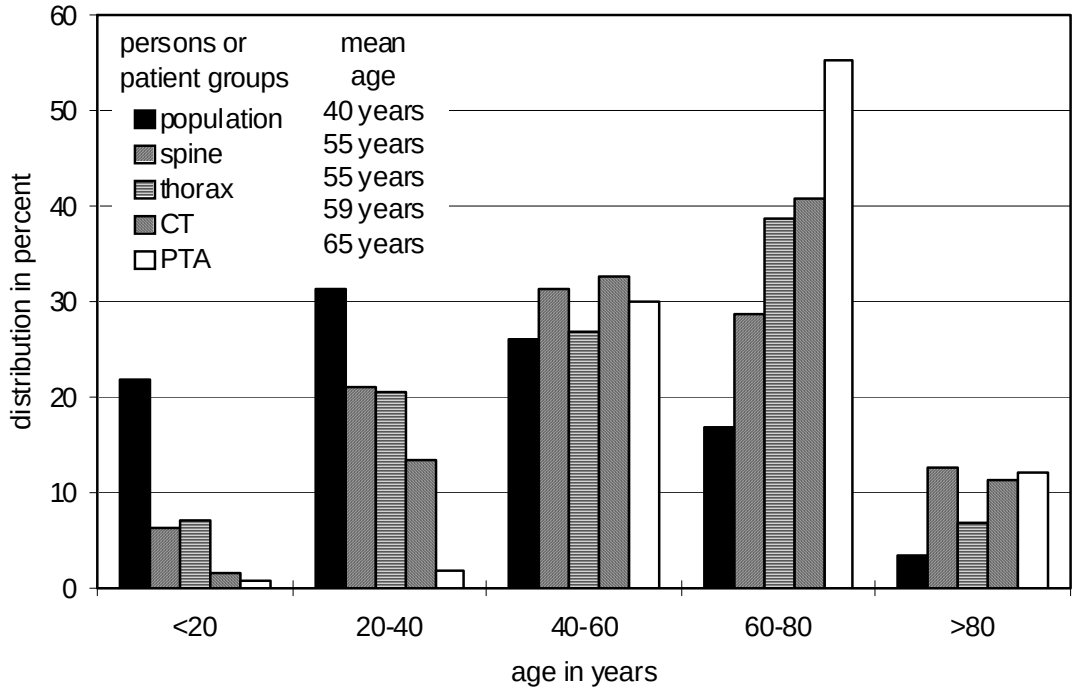

Fig. 1: Age distribution of the various patient groups in radiology departments compared to the age distribution of the German population. (Sources: population: Statistisches Jahrbuch 1992 [Sta 92], Spine and CT: Klinikum Nürnberg Nord 1992/93 [Schm 96], Thorax: Stender [Ste 96], PTA: Deutschland 1990 - 94 [Schm 97a,b])

If the age distribution amongst patients (see Fig. 1), other possible modifying factors, and the relative frequency of various types of radiological examinations are known, it is possible to come up with an estimate for the mean collective risk for patients with the help of the age-specific lifetime risk factor, as defined in ICRP 60 [ICRP 91]. However, one should bear in mind that individual radiation doses in diagnostic radiology or nuclear medicine are usually in a dose range for which risk values cannot be measured but only obtained by extrapolation [Str 95].

Thanks to a representative survey taken in acute hospitals, we have information on the age distribution amongst in-patients in seven high-dose examinations, which together account for approx. 86% of the collective effective dose received from diagnostic radiology procedures. The mean collective risk to in-patients is derived from these data (Fig. A 1, [Vei 95]). There are different risk reduction factors for patients as opposed to the general population, according to the type of examination and the age distribution of the patients concerned. (Cf. Tab. 1).

Tab. 1: Modifying factors for risk coefficients for patient groups in radiology in relation to the risk factor for the general population

	Modifying factors for risk coefficients	
Authors	**[Vei 95]**	**[Wu 96]**
Spine	0.42	0.60
Thorax	-	0.61
Abdomen/pelvis	0.51	-
CT	0.48	0.45
Angiography	0.43	-
Angioplasty	-	0.31

As shown in Annex A, there is an average modifying factor of approx. 0.5 for in-patients compared with to the mean nominal risk to the population, as given in ICRP 60 (5% per Sv). This means that an average additional lifetime fatal cancer risk of 2.5% per Sv or a mean detriment of 3.7% per Sv can be predicted amongst in-patients, where the proportion of elderly people is higher than amongst the general population.

This correction factor is certainly higher than 0.5% for out-patients, as these are on average younger than in-patients. Thus a factor of between 0.6 and 0.7, compared to the value in ICRP 60, would seem realistic for out-patients attending a diagnostic radiology department, as has been calculated in the United Kingdom [Wa 91] and the Netherlands [Be 91]. This would produce a mean risk to patients of 3.3% per Sv for lifetime risk, and 4.8 % per Sv for detriment.

5 Summary and recommendations

The concept of the effective dose

The concept of the effective dose was developed by the International Commission on Radiological Protection (ICRP) as a means of assessing the nominal stochastic radiation risk associated with non-uniform organ dose distribution among occupationally exposed individuals. At a later date, the ICRP devised changes, allowing the effective dose to be used for the general population as well.

Special conditions for medical radiation exposure

Using the effective dose to evaluate the radiation risk in medical examinations is not necessarily possible in all cases, for the following reasons:

The ICRP's risk coefficients, and consequently their tissue weighting factors, represent mean values for the stochastic radiation risk for all age groups. Among other things; it is not sensible to apply these risk coefficients to patients as the age distribution of this group differs considerably from that of a normal population.

The tissue weighting factors apply to a largely uniform irradiation of individual organs and tissues. In contrast to this, in medical examinations, the radiation dose is distributed very unevenly in the organism. Thus, in medical examinations, it frequently happens that only parts of organs of tissues (with very different sensitivity to radiation) are exposed. Further, it should be remembered that stochastic radiation risks in the lower dose range used in medical examinations can only be assessed by means of extrapolation from higher dose range. All these factors make it difficult to calculate an effective dose and to establish a risk value for individual diagnostic examinations.

Applying the concept of the effective dose in medical diagnosis

On the basis of the data set out above, the effective dose is not suitable for assessing the mean collective radiation risk from diagnostic radiology or nuclear medicine examinations for larger populations. When using it in individual examinations, patient-specific factors, such as the age of the patient at the time of exposure, and for some patients, the considerably reduced life expectancy resulting from the illness, must be taken into account. The effective dose is, however, useful for comparing and evaluating different diagnostic techniques and optimising procedures.

The effective dose can be useful for making international comparisons and assessing radiation exposure from diagnostic examinations over the course of several years. The data used to calculate the effective dose and, in particular, to assess a collective risk must be collected and evaluated on a uniform basis.

The ICRP's age-specific risk coefficients for fatal cancer set out in ICRP 60 [ICRP 91] may be used for risk assessment. These risk coefficients range from 14.5% per Sv for a 1-10 year old child to 1% per Sv for 70 year old patients. Consequently, when deciding whether a diagnostic radiology or nuclear medicine examination is indicated, even stricter criteria should be applied for younger patients than for elderly ones.

In calculating mean risk coefficients for patients, there are different modifying factors according to the type of examination and the associated age distribution of the patients compared to the risk coefficients of the total population. On average, the modifying factors amount to approx. 0.5 (for in-patients) or between 0.6 and 0.7 (for out-patients) compared to the risk to the total population.

In diagnostic radiology or nuclear medicine examinations, there is little sense in treating the radiation risk separately from the benefit that the patient derives from such examinations or treatments. In this particular area, it serves no purpose to put forward general risk figures for patients (such as mortality figures based on collective doses) without taking account of the benefit accruing from the examination, the risk arising if no examinations are performed, and the effect of the illness on life expectancy.

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Annex A:
Assessing the mean relative risk for in-patients from diagnostic radiology examinations, taking account of their age distribution

In order to assess the relative risk of certain measures to a population of a given age distribution according to the nominal population risk defined by the ICRP, one needs to know the effective dose differentiated by age group and the relative risk of these age groups in comparison to the mean population risk.

a) Age distribution

The age distribution was taken from a representative survey (INFRATEST) of acute hospitals for seven types of X-ray examination. In accordance with the United Nations report [UN 93] the following age groups were established:

Group I	0 - 15 years
Group II	16 - 40 years
Group III	41 - 64 years and
Group IV	over 65 years.

The age distribution or the distribution of the collective effective doses over these age groups can be seen in Table A 1. From Table A 1 it is also clear that examinations are most frequently carried out on age group IV, or 65 years and above.

b) Effective dose E_k

The effective dose for each type of examination *k* was obtained from the dose-area-product measurements. Surveys from the years 1992 and 1993 [Ber 95] are available on this. Table A 2 shows the mean effective dose values for the various types of examination. The total contribution of the examination types to the effective dose may be calculated from their frequency, which is also given here.

The seven examination types selected account for 86% of the total effective dose received from all diagnostic radiology procedures performed on in-patients in acute hospitals.

c) Age-risk relationship

As observations of Hiroshima and Nagasaki survivors have not yet been completed, the relative risk model is still currently favoured as the method for future predictions. Risk (see Fig. A 1) is age-specific, according to Fig. C-5 in ICRP 60 [ICRP 91]. A mean lifetime risk for the selected age groups (see above) can be seen in this diagram. From this, in turn, we can calculate a relative risk r_i, which may be applied to the general population (Tab. A 3). The sum of the products of the relative risk and the dose quantity d_i per age group

$$R_i = \Sigma r_i d_i$$

produces the relative risk-modifying factor for this examination type for the respective patient group. It can be seen that the mean modifying risk factor for in-patients is between 0.38 (intestinal tract) and approx. 0.5 (abdomen, pelvis, CT), depending on the type of examination. Table A 1 shows modifying factors for the seven examination types. A weighted average for seven examination types produces an overall modifying factor of 0.47 for in-patients.

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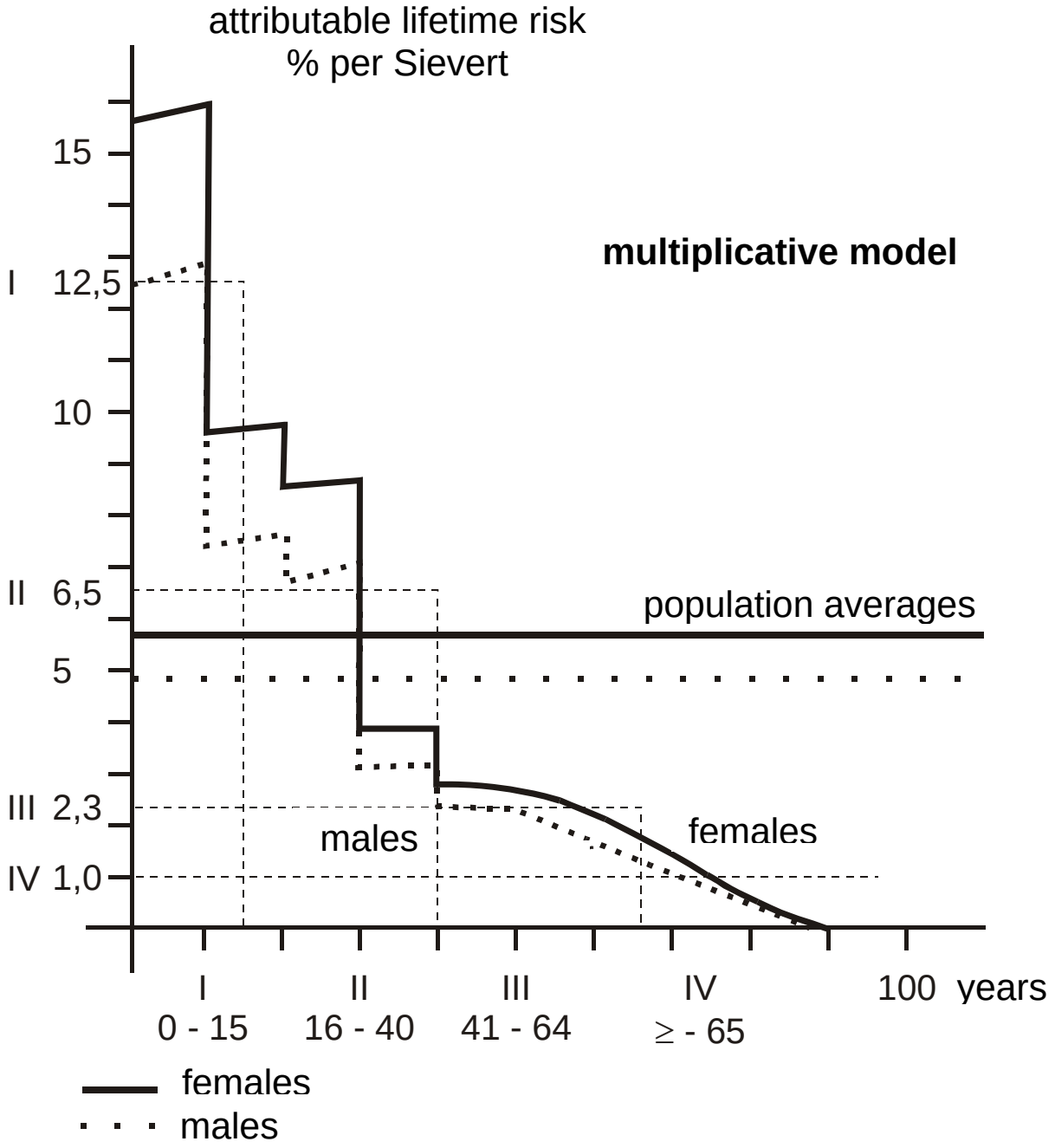

Fig. A 1: Lifetime risk per age group, based on Fig. C-5 in ICRP 60 [ICRP 91]

Tab. A1: Relative collective risk for in-patients in relation to the general population derived form age distribution for this patients (according INFRATEST) over seven examinations with relevant doses (approx. 86% of the collective dose for in-patients)

Age groups and relative radiation risk r related to the average risk of the general population	**Spine**		**Abdomen and pelvis**		**Oesophagus and stomach**		**Intestine**		**Urinary tract**		**Angiography**		**CT**	
(ICRP 60 Annex C)	Fre-quency %	Share of dose d_i^*	Fre-quency %	Share of dose d_i^*	Fre-quency %	Share of dose d_i^*	Fre-quency %	Share of dose d_i^*	Fre-quency %	Share of dose d_i^*	Fre-quency %	Share of dose d_i^*	Fre-quency %	Share of dose d_i^*
I 0 - 15 years $r_I = 2.4$	1.5	0.075	3.3	0.017	6.4	0.033	0	0	2.8	0.14	3.4	0.017	4.8	0.0245
II 16 - 40 years $r_{II} = 1.25$	12.5	0.126	20.2	0.205	16.9	0.175	10.9	0.109	19.1	0.194	8.1	0.083	13.5	0.138
III 41 - 64 years $r_{III} = 0.44$	31.9	0.3215	27.6	0.281	25.8	0.267	31.5	0.315	34.4	0.349	45.9	0.467	34.9	0.358
IV ≥ 65 years $r_{IV} = 0.19$	54.1	0.545	48.9	0.497	50.8	0.525	57.6	0.576	43.7	0.443	42.6	0.433	46.8	0.4795
Total	**100%**	**1**	**100%**	**1**	**99.9%**	**1**	**100%**	**1**	**100%**	**1**	**100%**	**1**	**100%**	**1**
Relative. coll. risk $\sum r\, d_i$ = modifying factor for risk reduction (in-patients)	0.42		0.51		0.51		0.38		0.51		0.43		0.48	

* The share of dose d_i per age group is calculated with assumption that dose D is constant in age group II-IV and D/2 in group I.

Tab. A 2: X-ray examinations of in-patients;
effective dose, frequency and relative contribution to the collective effective dose

Examination type	Effective dose per examination (in mSv)	Frequency x 1000 per year (INFRATEST) *	Contribution in % to the overall effective dose
Thorax	0.30	8 869	
Extremities	0.06	2 580	
Spine	1.20	917	3.0
Pelvis and abdomen	1.05 1.17	405 610	3.1
Hips	0.54	349	
Skull	0.03	983	
Oesophagus + stomach	8.27	144	3.2
Small intestine large intestine	16.38 18.46	15 93	5.3
Gall bladder	7.08	140	
Urinary tract	4.65	580	7.3
Arteriography	18.18	362	17.8
Phlebography	1.64	157	
Mammography	0.50	188	
CT (body area)	11.40	1 506	46.5
Other	3.00	229	
Total			86.3

* Old districts of Germany (67 Million)

Tab. A 3: Relative risk per age group,
derived from Fig. C-5 in ICRP 60 [ICRP 91]

Age groups ([UN 93])		**Lifetime risk** R_i **% per Sv**	**Relative risk** $r_i = R_i/R$
0 - 15	I	12.5	2.40
16 - 40	II	6.5	1.25
41 - 64	III	2.3	0.44
≥ 65	IV	1.0	0.19
R: Mean value for the population (m,f): 5.2% per Sv			