PERGAMON

ICRP Supporting Guidance 2

Annals of the ICRP

Editorial

THE 2001–2005 COMMISSION

The 2001–2005 Main Commission at its first meeting, in The Hague, the Netherlands, September 2001. Front row from left: Dr. A.J. González, The Hon G.J. Dicus, Dr. J.D. Boice Jr, Prof. R.H. Clarke (Chairman), Dr. A. Sugier, Prof. Z.-Q. Pan. Back row from left: Dr. R. Cox, Prof. F.A. Mettler, Mr. B. Winkler, Dr. L.-E. Holm, Prof. Y. Sasaki, Prof. R. Alexakhin, Prof. C. Streffer. The Scientific Secretary, Dr. J. Valentin, is not present in this photo.

The Commission is an unusual body, with little formal constitutional status. Yet it enjoys significant influence, much due to the professional and personal contributions from its renowned members. According to its constitution, every four years between three and five of the 13 persons on the Main Commission (12 members and a chairman) must be replaced. This ensures renewal and influx of ideas, and at the same time a desirable degree of stability is maintained.

A new four-year period began, and a new Commission came into being, at the beginning of July 2001. There are five new members: Rudolf Alexakhin, Greta Dicus, Abel González, Yasuhito Sasaki, and Annie Sugier. Christian Streffer is also a relative newcomer, having recently inherited the Committee 2 chairmanship.

Members old and new of the Commission will face the challenging task of guiding the preparation of the Commission's Recommendations at the Start of the 21st Century. The

members represent expertise in biology and medicine, physics, epidemiology, and public health, and bring a wealth of professional experience in radiation science and radiological protection to the discussions. They come from different countries and cultures; their discussions are remarkably open, friendly, and candid.

This is an exciting time, with the development of the next ICRP Recommendations, and the Commission is committed to continuing the present very helpful dialogue with the international radiological protection community. The members of the current Commission will enjoy a demanding and intellectually rewarding term of office.

Jack Valentin

PREFACE

The present document is not a numbered ICRP *Publication*. Before the advent of the *Annals of the ICRP* in 1977, some such un-numbered technical guidance reports were published. Within the format of the *Annals of the ICRP*, one such un-numbered report appeared in 1992 (*Annals of the ICRP* Volume 22, Issue 1), and that report, while not numbered as such, is regarded as ICRP *Supporting Guidance 1*. The present document is therefore designated 'ICRP *Supporting Guidance 2*'.

Over the years, the International Commission on Radiological Protection (ICRP), referred to below as 'the Commission', has issued many reports providing advice on radiological protection and safety in medicine. Its *Publication 73* is a general overview of this area. These reports summarise the general principles of radiation protection and provide advice on the application of those principles to the various uses of ionising radiation in medicine and biomedical research.

Most of these reports are of a general nature, and the Commission wishes to address some specific situations where difficulties have been observed. It is desirable that reports on such problem areas be written in a style which is accessible to those who may be directly concerned in their daily work, and that every effort is taken to ensure wide circulation of such reports.

A first step in this direction was taken at the Commission's meeting in Oxford, United Kingdom, in September 1997. At that time, on the recommendation of ICRP Committee 3, the Commission established several Task Groups to produce reports on topical issues in medical radiation protection. Several such reports have now appeared in print.

In addition, ICRP Committee 3 launched several Working Parties at its 1997 and 1998 meetings. In the Commission's organisational structure, Working Parties are used for various tasks of a more limited scope, for instance to prepare shorter papers providing supplementary guidance elaborating on existing recommendations. Such papers, which do not establish new recommendations, can be approved by an ICRP Committee on its own authority, rather than by the Commission itself.

The present document is the result of the work of two such Working Parties of Committee 3. The first and longer part of the document was prepared by a Working Party on Guidance for General Practitioners on Medical Radiation, established in 1997. The terms of reference of this Working Party were to prepare a report providing brief, non-technical replies to frequently asked questions about possible risks with medical uses of radiation and protection against such risks. The primary target group for the report would be non-specialist medical practitioners.

This Working Party was chaired by J. Liniecki. The (corresponding) other members of the Working Party were the members of ICRP Committee 3 (listed below).

The second part of this document was prepared by a Working Party on Diagnostic Reference Levels, established in 1998. The terms of reference of that Working Party were to prepare a brief report compiling information on how this concept has been interpreted and used by various regional, national, and local bodies, and

including additional advice on flexible, reasonable, and practical implementation of such Diagnostic Reference Levels.

This Working Party was chaired by M. Rosenstein. The (corresponding) other members of the Working Party were the members of ICRP Committee 3 (listed below).

Numerous helpful comments on both of the reports in the present document were received from interested parties through the Commission's customary public consultation via the Internet.

The membership of Committee 3 during the period of preparation of this report was:

1997–2001

F.A. Mettler, Jr. (Chairman)
L.K. Harding (Secretary)
H. Nakamura
M.M. Rehani
Y. Sasaki
W.Y. Ussov
J.-M. Cosset
J. Liniecki (Vice-Chairman)
P. Ortiz-Lopez
H. Ringertz
C. Sharp
M.J. Guiberteau
S. Mattsson
L.V. Pinillos-Ashton
M. Rosenstein
W. Yin

2001–2005

F.A. Mettler, Jr. (Chairman)
M.J. Guiberteau
M. Hiraoka
P. Ortiz-Lopez
H. Ringertz
E. Vañó
J.-M. Cosset
I.A. Gusev
J. Liniecki (Vice-Chairman)
L.V. Pinillos-Ashton
M. Rosenstein
W. Yin
C. Cousins
L.K. Harding (Secretary)
S. Mattsson
M.M. Rehani
C. Sharp

The two reports in this document aim to serve the purposes described above. In order to be as useful as possible for those purposes, their style differs in a few respects from the usual style of the Commission's publications in the *Annals of the ICRP*.

The reports were approved for publication by ICRP Committee 3 in September 2001.

PERGAMON

ICRP Supporting Guidance 2

Annals of the ICRP

Radiation and your patient: A guide for medical practitioners

ICRP Supporting Guidance 2
Approved by ICRP Committee 3 in September 2001

Abstract-This didactic text is devoted to the protection of patients against unnecessary exposure to ionising radiation. It is organised in a questions-and-answers format.

There are obvious benefits to health from medical uses of radiation, in x-ray diagnostics, interventional radiology, nuclear medicine, and radiotherapy. However, there are well-established risks from high doses of radiation (radiotherapy, interventional radiology), particularly if improperly applied, and possible deleterious effects from small radiation doses (such as those used in diagnostics). Appropriate use of large doses in radiotherapy prevents serious harm, but even low doses carry a risk that cannot be eliminated entirely. Diagnostic use of radiation requires therefore such methodology that would secure high diagnostic gains while minimising the possible harm.

For assessment of the risk, a quantitative measure of exposure is a necessary prerequisite. Therefore, dosimetric quantities are explained and defined (absorbed dose, effective dose). Basic facts are presented on mechanisms of action of ionising radiations on living matter. Undesired deleterious effects in man are categorised into two categories. The first one comprises sequelae resulting from massive cell killing (the so-called deterministic effects), requiring a high dose for their manifestation (exceeding the threshold dose). The second category includes those effects originating from mutational changes in the cellular DNA. These may eventually lead to development of radiation-induced cancer and to hereditary changes, transmitted to descendants of exposed individuals after irradiation of their gonads.

Data on the magnitude of threshold doses for cell killing effects are presented. On the basis of experimental, clinical, and epidemiological evidence, assessment is also given of the probability with which cancers and hereditary mutations may be induced by doses of various magnitudes, most likely without a threshold dose (below which no effect would obtain).

The text provides ample information on opportunities to minimise doses, and therefore the risk from diagnostic uses of radiation. This objective may be reached by avoiding unnecessary (unjustified) examinations, and by optimising the procedures applied both from the standpoint of diagnostic quality and in terms of reduction of the excessive doses to patients.

Optimisation of patient protection in radiotherapy must depend on maintaining sufficiently high doses to irradiated tumours, securing a high cure rate, while protecting the healthy tissues to the largest extent possible. Problems related to special protection of the embryo and

fetus in the course of diagnostic and therapeutic uses of radiation are presented and practical solutions are recommended.

This issue of the *Annals of the ICRP* also includes a brief report concerning Diagnostic Reference Levels in medical imaging: Review and additional advice.

Keywords: Radiological protection; Radiation risk; Radiology; Radiotherapy; Educational

RADIATION AND YOUR PATIENT

1. What is the purpose of this document?

(1) In the past 100 years, diagnostic radiology, nuclear medicine, and radiation therapy have evolved from the original crude practices to advanced techniques that form an essential tool for all branches and specialties of medicine. The inherent properties of ionising radiation provide many benefits but also may cause potential harm.

(2) In the practice of medicine, a judgement must be made concerning the benefit/risk ratio. When radiation is used for medical purposes, this requires knowledge not only of medicine but also of the radiation risks. This document is designed to provide basic information on radiation mechanisms, the dose from various medical radiation sources, the magnitude and type of risk, as well as answers to frequently asked questions (e.g. radiation and pregnancy). As a matter of making the document easily readable, the text is in a question and answer format.

(3) Interventional cardiologists, radiologists, orthopaedic and vascular surgeons, and others who actually operate medical x-ray equipment or use radiation sources, should possess more information on proper technique and dose management than is contained here. However, this text may provide a useful starting point.

(4) The most common types of ionising radiation used in medicine are x-rays, gamma rays, beta rays, and electrons. Ionising radiation is only one part of the electromagnetic spectrum. There are numerous other radiations (e.g., visible light, infrared waves, high frequency and radiofrequency electromagnetic waves) that do not posses the ability to ionise atoms of the absorbing matter. The present text deals only with the use of ionising radiation in medicine.

2. Is the use of ionising radiation in medicine beneficial to human health?

(5) Yes. Benefit to patients from medical uses of radiation has been established beyond doubt.

(6) *Modern diagnostic radiology* assures faster, more precise diagnosis and enables monitoring of a large proportion of diseases. It has been estimated that in about one half of all cases, radiological procedures (plain film radiography, fluoroscopy, computed tomography) have a substantial impact on the speed of diagnosis and in a large fraction of cases they are of decisive importance. Furthermore, several screening procedures (such as mammography) have been developed which are beneficial for specific populations at relatively high risk of some diseases. In addition, a number of interventional radiological procedures (e.g. angioplasty), introduced in the last 10–20 years, contribute significantly to the effectiveness of treatment of very serious and life threatening diseases of the cardiovascular system, central nervous system, and other organ systems. These procedures are also cost-effective.

(7) *Nuclear medicine* uses radioactive substances, called radiopharmaceuticals, in the diagnosis and treatment of a range of diseases. These substances are especially developed to be taken up predominantly by one organ or one type of cell in the body. Following their introduction into the body for diagnostic purposes, they are followed either by external measurements, yielding images of their distribution (both in space and in time), or by activity measurements in blood, urine, and other media. In all cases the information obtained is of functional character. This information is not obtainable, or obtainable only with less accuracy, by other modalities. Nuclear medicine offers, therefore, unique diagnostic information in oncology (diagnosis and staging), cardiology, endocrinology, neurology, nephrology, urology, and other areas. Most of the methods currently in use are those of choice in the diagnostic process, because they show high sensitivity, specificity, and good reproducibility. Their cost-effectiveness is also high. In addition it should be emphasised that these procedures are non-invasive and present no risk of direct complications to the patient.

(8) One has to remember that whereas electrical generators of ionising radiation (x-ray units, electron accelerators) stop emitting radiation when switched off, radioactive sources do emit radiation, which cannot be modified in the course of radioactive decay. This means that some precautions may have to be taken with such patients given large therapeutic amounts of radionuclides when they are in a hospital and afterwards when they go home – to protect against exposure of staff, relatives, friends, and members of the public.

(9) *Radiation therapy* uses ionising radiation *for treatment*. The incidence of cancer is about 40%, reflecting long life expectancy. Cancer also leads to ~20–30 % cumulative mortality. Current medical practice uses radiotherapy in about half of all newly diagnosed cancer cases. Therapeutic techniques can be highly complex and place very high demands on the accuracy of irradiation. To be effective, they must be approached on an interdisciplinary basis, requiring effective and harmonious cooperation between radiation oncologists, medical physicists, and highly qualified technicians.

(10) However, it should be remembered that radiotherapy of cancer is often accompanied by adverse side effects of the treatment. Some adverse effects are unavoidable and often resolve spontaneously or with treatment. Serious adverse effects may occur and result from the proximity of sensitive normal tissues to the treatment field, or rarely as a consequence of individual radiation sensitivity. They do not undermine the purpose of radiotherapy. Appropriate use of radiotherapy saves millions of lives every year overall. Even if only palliative treatment is possible, the therapy reduces suffering substantially. There are also a few non-malignant diseases whose treatment by radiation is a method of choice.

(11) Radiotherapy using radiopharmaceuticals is generally non-invasive, but limited to several well-established situations where killing hyperfunctioning or malignant cells is important (for example hyperthyroidism, cancer of the thyroid, degenerative and inflammatory diseases of joints, palliative treatment of metastases to the skeleton). In addition, there are many studies showing significant potential for radiolabelled antibodies and receptor-avid peptides to be used in the treatment of several malignancies. However, this mode of treatment is still in its early days.

(12) Ionising radiation is, therefore, one of the basic tools of contemporary medicine, both in diagnosis and in therapy. Today, practice of contemporary advanced medicine without any use of ionising radiation appears unthinkable.

3. Are there risks to the use of ionising radiation in medicine?

(13) There obviously are some risks. The magnitude of risk from radiation is dose-related with higher amounts of radiation being associated with higher risks. The undisputed health benefits of diagnostic x-ray and nuclear medicine diagnostics may be accompanied by a generally small risk (probability) of deleterious effects. This fact has to be taken into account while using ionising radiation sources in diagnosis. Since large amounts of radiation are required in radiation therapy, the risk of radiation-related adverse effects is measurably higher.

(14) The aim of managing radiation exposure is to minimise the putative risk without sacrificing, or unduly limiting, the obvious benefits in the prevention, diagnosis, and also in effective cure of diseases (optimisation). It should be pointed out that when too little radiation is used for diagnosis or therapy, there is also an increase in risk although such risks are not due to adverse radiation effects per se. Too low an amount of radiation in diagnosis will result in an image that does not have enough information to make a diagnosis, and in radiation therapy, not delivering enough radiation will result in increased mortality because the cancer being treated will not be cured.

(15) Experience has provided ample evidence that reasonable selection of the conditions under which ionising radiation is being used in medicine can lead to health benefits substantially outweighing the estimated possible deleterious effects.

4. How do we quantify the amount of radiation?

(16) The frequency or intensity of biological effects is dependent upon the total energy of radiation absorbed (in joules, J) per unit mass (in kg) of sensitive tissues or organs. This quantity is called *absorbed dose* and is expressed in gray (Gy) or milligray (mGy). One Gy equals 1 J per kg.

(17) Some xrays or gamma rays will pass through the body without any interaction, and they will produce no biological effect. On the other hand, that radiation which is absorbed may produce effects. Absorbed doses of radiation can be measured and/or calculated, and they form the basis for evaluation of the probability of radiation-induced effects.

(18) In evaluating biological effects of radiation after partial exposure of the body, absorbed doses must be weighted to take further factors into consideration. These include, e.g., the varying sensitivity to radiation of different tissues and different absorbed doses to different organs. The sum of such weighted organ doses, the *effective dose*, is used to compare risks of partial and whole body irradiation at doses experienced in diagnostic radiology and nuclear medicine. It is expressed in sievert (Sv) or millisievert (mSv). One Sv equals 1 J per kg. Effective dose is not applicable to radiation therapy, where very large absorbed doses affect individual tissues or organs. This is because the same proportionality of risk to dose as in diagnostics cannot be assumed.

5. What do we know about the nature (mechanism) of radiation-induced biological effects?

(19) Cells can be killed by radiation. During cellular division, chromosomal aberrations due to radiation may result in loss of part of the chromosomal DNA, which results in cell death. The probability of chromosomal aberrations is proportional to dose and those cells free of critical damage to DNA retain their dividing potential.

(20) Surviving cells may carry changes in the DNA at a molecular level (mutations). Elementary, primary damage to DNA results from chemical damage by free radicals, originating from radiolysis of water. DNA damage also can result from the direct interaction of ionising particles with the DNA double helix (rarely).

(21) Important changes in DNA occur in the form of breaks in continuity of the DNA chains, although other forms of damage also arise. These breaks may affect one strand of the helix (single strand breaks, SSB) or both strands in the same location (double strand breaks, DSB). SSB occur very frequently in the DNA without irradiation, and are easily and effectively repaired by specific enzyme systems. In contrast, many induced DSB are more complicated and less easily repaired. As a result, a significant proportion of the damage is repaired incorrectly (mis-repair). These mis-repaired breaks can lead to chromosomal aberrations and gene mutations.

(22) Some of the genes mutated in such a way form the first step (initiation) of the very long and complicated process of carcinogenesis, requiring also several subsequent mutations (most likely not induced by radiation) in the affected cells. Similar mutation mechanisms, when affecting germinative cells, may lead to hereditary mutations expressed in descendants of the irradiated persons. Of course, the essential point in considering these possible sequelae of irradiation is the frequency (or probability of occurrence) of undesired effects in persons irradiated with a given dose, or in their descendants.

6. How are effects of radiation classified?

(23) There are two basic categories of the biological effects that may be observed in irradiated persons. These are (1) those due largely to cell killing (*deterministic*); and (2) mutations, which may result in cancer and hereditary effects (*stochastic* or *probabilistic*).

(24) Effects due to cell killing (such as skin necrosis) have a practical threshold dose below which the effect is not evident, but in general when the effect is present its severity increases with the radiation dose. The threshold dose is not an absolute number and varies somewhat by individual. Effects due to mutations (such as cancer) have a probability of occurrence that increases with dose, it is currently judged that there is not a threshold below which the effect will not occur, and finally the severity of the effects is independent of the dose. Thus a cancer caused by a small amount of radiation can be just as malignant as one caused by a high dose.

(25) *Deterministic effects*. These effects are observed after large absorbed doses of radiation and are mainly a consequence of radiation induced cellular death. They occur only if a large proportion of cells in an irradiated tissue have been killed by radiation, and the loss cannot be compensated for by increased cellular proliferation. The ensuing tissue loss is further complicated by inflammatory processes and, if the damage is sufficiently extensive, also by secondary phenomena at the systemic level (e.g. fever, dehydration, bacteraemia etc.).

(26) In addition, possible effects of healing processes, e.g. fibrosis, may contribute to additional damage and loss of function of a tissue or an organ. Clinical examples of such effects are: necrotic changes in skin, necrosis, and fibrotic changes in internal organs, acute radiation sickness after whole body irradiation, cataract, and sterility (see Table 1).

(27) Doses required to produce deterministic changes are usually large (in most cases in excess of 1,000 – 2,000 mGy). Some such changes occur in a small proportion of patients as side effects of radiotherapy. They can also be found after complex interventional investigations (such as vascular stenting) when long fluoroscopy times have been used.

(28) The relationship between the frequency of a given deterministic effect and the absorbed dose has a general form as presented in Fig. 1. It can be seen that the essential feature of this dose–response relationship is the presence of a threshold dose. Below this dose, no effect may be diagnosed, but with increasing dose the intensity of the induced damage increases markedly and in some situations, dramatically.

(29) An example of deterministic damage to the skin is presented in Fig. 2. The damage was caused by prolonged fluoroscopy through the same skin site during coronary angioplasty.

(30) Malformations induced by exposure of the conceptus to radiation in the period of organogenesis (3rd–8th week of pregnancy) are also due to cell killing and are classified as deterministic effects. The same applies to malformations of the forebrain, leading to mental retardation, induced by exposure between the 8th and the 15th week (and to some extent up to the 25th week) after conception.

(31) The threshold doses are, however, substantially lower than those found for deterministic effects after irradiation in extrauterine life: thus, 100–200 mGy form a

Table 1
Deterministic effects after whole-body and localised irradiation by x and gamma rays; approximate absorbed threshold doses for single (short-term) and fractionated or low dose-rate (long-term) exposures. From various sources; see ICRP *Publications* 41, 58, and 85

		Threshold absorbed dose (mGy)	
Organ/tissue	Effect	Short-term exposure (single doses)	Long-term exposures (yearly doses, repeated for many years)
Testicles	Temporal sterility	150	400
	Permanent sterility	3,500 – 6,000	2,000
Ovaries	Sterility	2,500 – 6,000	>200
Ocular lens	Detectable opacities	500 – 2,000	>100
	Visual impairment (cataract)	5,000	>150
Bone marrow	Haemopoiesis impairment	500	>400
Skin	Erythema (dry desquamation)	2,000	–
	Moist desquamation	18,000	–
	Epidermal and deep skin necrosis	25,000	–
	Skin atrophy with complications and telangiectasia	10,000–12,000	1,000
Whole body	Acute radiation sickness (mild)	1,000	–

threshold range for malformations induced between the 3rd and the 8th week, and ~200 mGy for the aforementioned brain damage (8th–25th week).

6.1. Stochastic effects

(32) As mentioned above, irradiated and surviving cells may become modified by induced mutations (somatic or hereditary). These modifications may lead to two clinically significant effects: malignant neoplasms (cancer) and hereditary mutations.

(33) *Cancer*: Ionising radiation is a carcinogen although a relatively weak one. Careful follow-up of over 80,000 atom bomb survivors in Hiroshima and Nagasaki over the last 50 years indicates that there have been 12,000 cancer cases of which

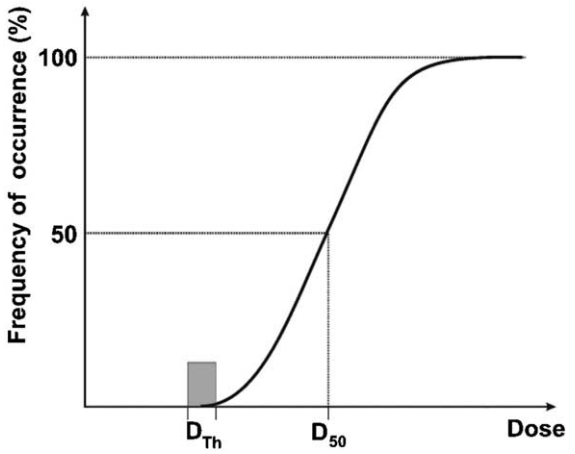

Fig. 1. A general dose–response relationship for radiation induced deterministic (cell killing) effects. D_{Th}-threshold dose

fewer than 700 excess deaths were due to radiation. Expressed another way, only about 6% of the cancer occurring in these survivors is radiation-related.

(34) These observations allow estimation of the probability with which a given dose may lead to diagnosis (incidence) and death (mortality) from various cancers. Among the latter, there are several forms of leukaemia and solid tumours of different organs; mostly carcinomas of the lung, thyroid, breast, skin, and gastrointestinal tract. Radiation-induced cancers do not appear immediately after radiation exposure but require time (a latent period) to become clinically apparent.

(35) Examples of minimum latent periods are: 2 years for other leukaemia than chronic lymphatic (non-CLL leukaemias), about 5 years for thyroid and bone cancer, and 10 years for most other cancers. Mean latent periods are 7 years for non-CLL leukaemias and more than 20 years for most other cancers. It is important to note that some tumours do not appear to be radiation-induced, or only weakly so. These include carcinomas of the prostate, cervix, uterus, lymphomas, and chronic lymphatic leukaemia.

(36) *Hereditary effects*: The risk of hereditary effects of ionising radiation has been estimated on basis of experiments on various animal species, because there are no demonstrated effects in humans (the likely values of probability per unit dose are given later in this document).

(37) From careful analysis of the experimental studies and epidemiological surveys, it may be concluded that dose–response relationships for these two categories of stochastic effects have a distinctly different form from those characterising deterministic sequelae. A general dose–response relationship for cancer is presented in Fig. 3. The principal features of the relationship may be summarised as follows:

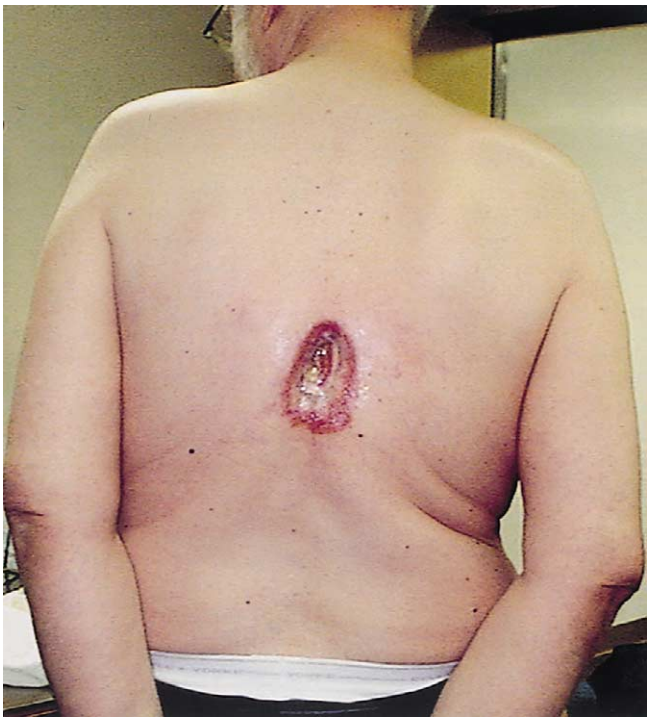

Fig. 2. Photograph of the patient's back 21 months after a coronary angiography and two angioplasty procedures within three days; assessed cumulative dose 15,000 to 20,000 mGy. The patient has consistently refused skin grafting after excision of necrotic tissues. (Photograph courtesy of F. Mettler).

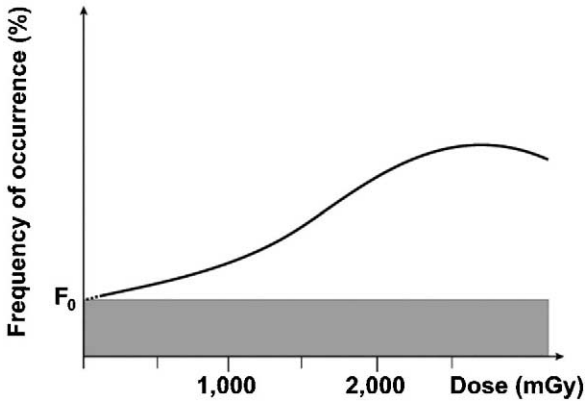

Fig. 3. A general dose–response relationship for radiation–induced stochastic effects (here, cancer incidence after gamma irradiation). Shaded area – control incidence (F_0) in a non-irradiated population. Broken line – extrapolation to the lowest doses for which there is no direct evidence of an associated effect.

a) The induction of cancer by x-rays or gamma rays yields increasing frequency of the effect with increasing dose up to a maximum above which the curve flattens off, with a possible decline at still higher doses.
b) At the lower end of the curve, below $\sim$100–200 mGy, any potential effect cannot be measured easily. This is due to statistical uncertainty because of the large amount of spontaneous cancer and the impact of confounding factors. This uncertainty should not be interpreted as the presence of a dose threshold. It is assumed that at low doses ($<$200 mGy), the probability of the effect (its frequency) is most likely to increase proportionally with the dose.
c) There is always a spontaneous frequency of the effect (mutations, cancer) in non-irradiated populations (F_0 in Fig. 3), which cannot be differentiated qualitatively from that induced by radiation. In fact, mutations or cancers induced by irradiation have the same morphological, biochemical, and clinical, etc., characteristics as the cases occurring in non-irradiated individuals.

7. What is the magnitude of the risk of cancer and hereditary effects?

(38) Analysis of the epidemiological data of irradiated populations has allowed derivation of the approximate risk of radiation-induced cancer. The lifetime value for the average person is roughly a 5% increase in fatal cancer after a whole body dose of 1,000 mSv (which is much higher than what would be found in most medical procedures). A statistically significant increase in cancer has not been detected in populations exposed as adults to doses of less than 50 mSv.

(39) It appears that the risk in fetal life, in children, and in adolescents exceeds somewhat this average level (by a factor of 2 or 3). In persons above the age of 60 it should be lower roughly by a factor of ~ 5 (due to limited life expectancy and therefore less time available for manifestation of a cancer, which is a late appearing effect of the exposure).

(40) The higher dose diagnostic medical procedures (such a computed tomography, CT, scan of the abdomen or pelvis) yield an effective dose of about 10 mSv. If there were a large population in which every person had 1 such scan, the theoretical lifetime risk of radiation-induced fatal cancer would be about 1 in 2,000 (0.05%). This can be compared with the normal spontaneous risk of fatal cancer, which is about 1 in 4 (25%) in industrialised countries.

(41) Individual risk may vary from the average yielded by theoretical calculations. The cumulative radiation dose from diagnostic medical procedures is very small in many individuals. However, in some patients the cumulative doses are relatively high, 50 mSv or more, and the cancer risk should be carefully considered.

(42) Many relatively high dose diagnostic procedures (such as CT) should be clearly justified. When properly justified, the benefit of the examination will far outweigh the risk. Unjustified procedures at any dose level should be avoided. In radiotherapy there is a risk of second cancers but the risk is small compared with the imperative to treat the current malignancy.

(43) Hereditary effects as a consequence of radiation exposure have not been observed in humans. No hereditary effects have been found in studies of the offspring and grandchildren of the atomic bomb survivors. However, as based on animal models and knowledge of human genetics, the risk of hereditary deleterious effects have been estimated to not be greater than 10% of the radiation-induced carcinogenic risk.

8. Are people exposed to ionising radiation from any other sources than medical diagnosis and treatment?

(44) Yes. All living organisms on this planet, including humans, are exposed to radiation from natural sources. An average annual effective dose from this so-called natural background amounts to about 2.5 mSv. This exposure varies substantially geographically (from 1.5 to several tens of mSv in limited geographical areas). Artificial sources – except medicine – add very minute doses to the population at large.

9. What are typical doses from medical diagnostic procedures?

(45) Various diagnostic radiology and nuclear medicine procedures cover a wide dose range depending upon the procedure. Doses can be expressed either as absorbed dose to a single tissue, or as effective dose to the entire body, which facilitates comparison of doses to other radiation sources (such as natural background radiation).

(46) Typical values of effective dose for some procedures are presented in Table 2. The doses are a function of a number of factors such as tissue composition, density, and thickness of the body. For example, it takes less radiation to penetrate the air in the lungs for a chest radiograph than to penetrate the tissues of the abdomen.

(47) One should also be aware that even for a given procedure, there may be a wide variation in the dose given for that same procedure on a specific individual

Table 2
Typical effective doses from diagnostic medical examinations using x-rays or isotope scans in the 1990s, and associated broad levels of risk. Data from the UK National Radiological Protection Board

Diagnostic procedure	Effective doses (mSv) clustering around a value of:	Equivalent period of natural background radiation	Lifetime additional risk of cancer per examination[a]
Chest x-ray examination Teeth x-ray Arms and legs x-ray Hands and feet x-ray	0.01	A few days	Negligible risk
Skull x-ray Head x-ray Neck x-ray	0.1	A few weeks	Minimal risk: 1 in 1,000,000 to 1 in 100,000
Breast x-ray mammography Hip x-ray Spine x-ray Abdomen x-ray Pelvis x-ray CT of head Lung nuclear medicine isotope scan Kidney isotope scan	1	A few months to a year	Very low risk: 1 in 100,000 to 1 in 10,000
Kidneys and bladder x-ray (IVU) Stomach x-ray – barium meal Colon x-ray – barium enema CT of abdomen Bone isotope scan	10	A few years	Low risk: 1 in 10,000 to 1 in 1,000

[a] These very small risk levels are added to the 1 in 3 chance we all have of getting cancer.

when performed at different facilities. This variation may be up to a factor of ten and is often due to differences in the technical factors for the procedure such as film/screen speed, film processing, and voltage. In addition, often there are even wider variations in and among facilities for a given type of procedure, due to less than satisfactory conduct of the procedure in some facilities.

10. Can radiation doses in diagnosis be managed without affecting the diagnostic benefit?

(48) Yes. There are several ways to reduce the risks to very low levels while obtaining very beneficial health effects of radiological procedures, far exceeding the health impact of a possible detriment. In this context, it should also be mentioned that a high ratio of benefit vs. radiological risk depends to a large extent on a good methodology for procedures and high quality in performing them. Therefore, quality assurance and quality control in diagnostic radiology and nuclear medicine also play a fundamental role in the provision of appropriate, sound radiological protection of the patient.

(49) There are several measures that will minimise the risk without sacrificing the valuable information that can be obtained for patients' benefit. Among the possible actions that can be taken, it is *necessary to justify the examination* before referring a patient to the radiologist or nuclear medicine physician.

(50) Repetition should be avoided of investigations made recently at another clinic or hospital. Results of the investigations should be recorded in sufficient detail in patients' documentation, and carried over to another health-care unit. This rule could result in avoidance of a significant fraction of unnecessary examinations.

(51) Failure to provide adequate clinical information at referral may result in an incorrect procedure or technique being chosen by radiologist or nuclear medicine specialist. The result may be a useless test, with the investigation contributing only to patients' exposure.

(52) An investigation may be seen as a useful one if its outcome – positive or negative – influences management of the patient. Another factor that potentially adds to the usefulness of an investigation is if it boosts confidence in a diagnosis.

(53) To fulfil these criteria, indications for any specific investigation, both in the general clinical situation and for a given individual patient, must be made by the referring physician on the basis of medical knowledge. Difficulties may arise in the referral procedure mainly due to the dynamic development of the field of medical imaging. Technical progress in medical radiology and nuclear medicine has been enormous over the last 30 years; in addition two new modalities have entered the field: ultrasound and magnetic resonance imaging.

(54) It is not surprising therefore, that following the technical developments may be difficult both for a general practitioner and even for specialists in many fields of medicine. There are, however, several published guidelines, which may help in making an appropriate referral, using well-founded criteria, based on clinical experience and epidemiology (see p. 27).

(55) The most important circumstances that should be taken into account to avoid inappropriate referrals can be broadly categorised as follows: possibility of obtaining similar information without using ionising radiation, i.e. by means of ultrasound (US) or magnetic resonance imaging (MRI). Their use is indicated where these modalities are available, and when the cost (this applies mostly to MRI), waiting times, and organisational difficulties are not prohibitive. The guidelines mentioned above also provide information when these modalities are preferable as an initial, and sometimes the only, investigation to be performed.

11. Are there situations when diagnostic radiological investigations should be avoided?

(56) Yes. There are well-established views – not always respected – that in some circumstances, radiography or fluoroscopy do not contribute anything to the management of patients. This applies to situations when a disease could not have progressed or resolved since the previous investigation, or the data obtained could not influence the treatment of patients.

(57) Examples of the most common unjustified examinations include: routine chest radiography at admission to a hospital, or before surgery, in the absence of symptoms indicating cardiac or pulmonary involvement (or insufficiency); skull radiography in asymptomatic subjects of accidents; lower sacro-lumbal radiography in stable degenerative condition of the spine in the 5th or later decade of life. There are of course many additional examples.

(58) Screening of asymptomatic patients for presence of a disease may be done only if national health authorities determine that high incidence in a given age bracket, high efficacy of early disease detection, low exposure of screened individuals, and easily available and effective treatment may result in high benefit vs. risk ratio.

(59) Positive examples include radiography for detection of tuberculosis in societies or groups with high prevalence of the disease, mammography for early detection of breast cancer in women after 50 years of age, or screening for gastric carcinoma by specialised contrast fluoroscopy in countries with high incidence of this disease. All factors involved in screening must be periodically reviewed and reassessed. If positive criteria cease to be satisfied, the screening should be discontinued.

(60) Irradiation for legal reasons and for purposes of insurance should be carefully limited or excluded. Generally, irradiation of individuals for legal reasons entails no medical benefit. One common example is that insurance companies may require various x-ray investigations to satisfy the expectation that a person to be insured is in good health. In numerous cases such demands, particularly in asymptomatic individuals, should be treated with caution; they often appear unjustified when medically they are not in the direct interest of the person concerned.

12. Are there special diagnostic procedures that require special justification?

(61) While all medical uses of radiation should be justified, it stands to reason that the higher the dose and risk of a procedure, the more the medical practitioner should consider whether there is a greater benefit to be obtained. There are radiological procedures that deliver doses at the upper end of the scale presented in Table 2.

(62) Among these, a special position is occupied by computed tomography (CT), and particularly its most advanced variants like spiral or multi-slice CT. The usefulness and efficacy of this great technical achievement is beyond doubt in particular clinical situations. However, the ease of obtaining results by this mode and the temptation to monitor frequently the course of a disease or perform screening should be tempered by the fact that repeated examinations may deliver an effective dose in the order of 100 mSv, a dose for which there is direct epidemiological evidence of carcinogenicity.

13. Do children and pregnant women require special consideration in diagnostic procedures?

(63) Yes. Both the fetus and children are thought to be more radiosensitive than adults.

(64) Diagnostic radiology and diagnostic nuclear medicine procedures (even in combination) are extremely unlikely to result in doses that cause malformations or a decrease in intellectual function. The main issue following in-utero or childhood exposure at typical diagnostic levels (a few to a few tens of mGy) is cancer induction.

(65) Before a diagnostic procedure is performed, it should be determined whether a patient is (or may be) pregnant, whether the fetus is in the primary radiation area, and whether the procedure is relatively high dose (e.g. barium enema or pelvic CT scan). Medically indicated diagnostic studies remote from the fetus (e.g. radiographs of the chest or extremities, ventilation/perfusion lung scan) can be safely done at any time of pregnancy if the equipment is in proper working order. Commonly, the risk associated with abstaining from making the diagnosis is greater than the radiation risk.

(66) If an examination is typically at the high end of the diagnostic dose range and the fetus is in or near the radiation beam or source, care should be taken to minimise the dose to the fetus while still making the diagnosis. This can be done by tailoring the examination and examining each radiograph as it is taken until the diagnosis is achieved and then terminating the procedure. In nuclear medicine, many radiopharmaceuticals are excreted by the urinary tract. In these cases, maternal hydration and encouraging voiding will reduce bladder residence time of the radiopharmaceutical and therefore will reduce the fetal dose.

(67) For children, dose reduction in achieved by using technical factors specific for children and not using routine adult factors. In diagnostic radiology care should be taken to minimise the radiation beam to affect only the area of interest. Because children are small, in nuclear medicine the use of a lower administered activity than that which would be used for an adult will still result in acceptable images and reduced dose to the child.

14. What can be done to reduce radiation risk during the performance of a diagnostic procedure?

(68) The most powerful tools for minimising radiation risk are appropriate performance of the test and optimisation of radiological protection of the patient. These are the responsibility of the radiologist or nuclear medicine physician and the medical physicist.

(69) The basic principle of radiological protection of patients in *radiological x-ray investigations and nuclear medicine diagnostics* is that necessary diagnostic information of a clinically satisfactory quality should be obtained at the expense of a dose as low as reasonably achievable, taking into account social and economic factors.

(70) Evidence obtained in numerous countries indicates that the range of entrance doses (i.e. doses measured at surface of the body at the site where x-ray beam is entering the body) for a given type of radiographic examination is very wide. One example is given in Fig. 4.

(71) Sometimes the lowest and highest doses, measured at individual radiological installations, differ by a factor of $\sim$100. As most measured doses tend to group at the lower end of the distribution (cf. Fig. 4) it is clear that the largest doses, above, say, the 70th or 80th percentile of the distribution, cannot be reasonably justified. By establishing so called *diagnostic reference levels* for each of principal investigations at such a percentile, one can identify the places (institutions, x-ray machines) in need of corrective actions, which will easily and substantially reduce the average dose to patients on a country-wide scale.

(72) This goal may be reached by co-operation of radiologists with medical physicists and auditing persons or teams. There are numerous technical factors that, when systematically applied, reduce exposure significantly. The effort to optimise protection requires a good organisation as well as permanent willingness and vigilance to keep the doses as low as reasonably achievable. It is easy to show that the risk, even

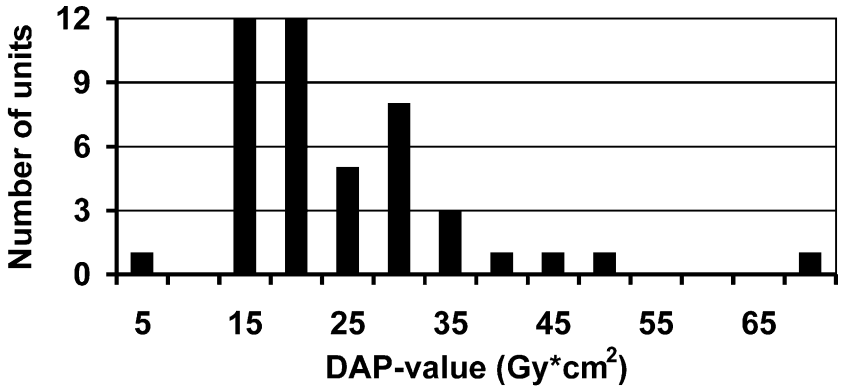

Fig. 4. Distribution of patient dose for intravenous urogram (IVU) examinations at 45 clinics in Sweden. Data from the Swedish Radiation Protection Authority. DAP – dose–area product.

if it is quite small, can still be reduced several-fold compared with the situation prevailing in previous decades.

(73) Among the procedures that should be avoided are: (1) fluoroscopy and photofluorography for screening for tuberculosis in children and adolescents. Instead, only normal radiographs should be made at this age; (2) fluoroscopy without electronic image intensification. In most industrialised countries such a procedure, which gives quite high doses to the patient, is now illegal.

(74) It should be emphasised that *radiological interventional procedures* lead to higher doses to patients than normal diagnostic investigations. However, indications for such procedures result in most cases from a high risk from conventional surgery. Appropriate modern equipment and training of personnel allow the exposure of the patient to be limited to an acceptable level, securing a high benefit/risk ratio.

(75) In *nuclear medicine*, the magnitude of the dose to the patient depends principally on the activity[1] of the administered radiopharmaceutical. The range of activity of the latter, administered for a given purpose, varies among different departments by a small factor. Usually, a factor of three spans the highest and the lowest values. In several countries, there are established reference or recommended levels and usually, exceeding those should be avoided in examination of an individual of standard size.

(76) There are also accepted rules (formulae) for changing the activity as a function of body mass and for reducing the activity given to children relative to that administered to adults. Typical effective doses to patients in diagnostic nuclear medicine are in a similar range as those observed in x-ray diagnostics (see Table 2). Good procedures and adherence to the principles of quality assurance and quality control secure a high benefit–risk ratio for properly justified examinations.

(77) During pregnancy, investigations using radiopharmaceuticals should be treated in a similar way as normal radiographic procedures. Accordingly, they should be performed only if no alternative diagnostic methods are available and if the investigations cannot be delayed until after delivery. To avoid serious damage to the fetal thyroid, *any procedure employing free* ^{131}I *ions – even in small activities – is contraindicated* starting ~10–12 weeks into the pregnancy (when the fetal thyroid becomes functional).

(78) Lactating women may be investigated with radiopharmaceuticals. There are some radiopharmaceuticals that are relatively long-lived and which are excreted in breast milk (such as iodine-131). After administration of such radiopharmaceuticals, breast-feeding must be discontinued to avoid transfer to the child. There are, however, other radionuclides that are short-lived (such as most technetium-99^{m} compounds) that may not require discontinuation of breast-feeding, or discontinuation is needed only for a few hours or a day.

[1] Activity – number of nuclear disintegration per second (dps) in a given sample. Used as a measure of quantity of radioactive substances, here radiopharmaceuticals administered to patients. The unit is the becquerel which is 1 dps. A megabequerel (MBq) is 1 million dps.

15. What can be done to reduce radiation risk during the conduct of radiation therapy?

(79) Radiotherapy based on proper indications is frequently a successful way of prolonging the life of a patient, or of reducing suffering when only palliation is possible, thus improving the patient's quality of life. To achieve this success requires the highest standards of performance (accuracy of delivered dose), both when planning irradiation for an individual patient and in actual delivery of the dose.

(80) Successful eradication of a malignant tumour by radiation therapy requires high absorbed doses to the target (tumour) tissue, and there is a delayed (and usually low) risk of late complication.

(81) Actually, while the generic justification of radiotherapy cannot be questioned in the vast majority of cases, in certain cases there are increasing efforts to decrease the delivered dose and to reduce the irradiated volumes. This mainly concerns some specific types of cancers, such as Hodgkin's disease and for cancers of children, where the almost constant association with chemotherapy may allow the radiation oncologist to reduce dose and irradiated volume and thus to achieve a subsequent reduction in adverse side effects.

(82) However, in a large number of cases, decreasing the dose to the target volume is not possible since it would unacceptably decrease the cure rate. Therefore, the optimisation of radiological protection of radiotherapy patients is based on the principle that the dose to the irradiated target (tumour) must be as high as is necessary for effective treatment, while protecting nearby healthy tissues to the maximum extent possible. Conformal therapy has helped greatly in this regard.

(83) The decision to undertake a radiotherapy course is optimally made through a multidisciplinary team including surgeons and medical and radiation oncologists. This discussion should confirm the justification of the procedure, absence of more beneficial alternative treatments, and commonly the optimal way of combining different techniques (radiotherapy, surgery, and chemotherapy). When such a multidisciplinary approach is not possible, the radiation oncologist making the decision should keep in mind the alternative treatments or combine treatment strategies.

16. Can pregnant women receive radiotherapy?

(84) A malignant tumour in a pregnant woman may require radiotherapy in attempt to save the life of the patient. If a tumour is located in a distant part of the body, the therapy may proceed with individually tailored protection of the abdomen (screening). If the beam needs to be closer to the conceptus but still not irradiating the latter directly, special precautions need to be taken and an expert in dosimetry should make calculations of the dose to the fetus before it is decided to start the therapy.

(85) A dose to the conceptus (3–8 weeks post conception) from *direct irradiation* by the primary beam will reach values exceeding substantially thresholds for malformations of various organs, or of the brain (8 to 25 weeks) with resulting mental retardation in post-uterine life. It may also lead to stunting of fetal growth, even if the treatment took place in the third trimester of pregnancy.

(86) It should also be remembered that irradiation of the fetus in all trimesters of the pregnancy carries an increased risk of cancer in the newborn in the first or second decade of life and at *therapeutic doses*, this risk can be substantial. Therefore, in view of all mentioned factors, termination of pregnancy may be considered. The decision should be based on careful estimation of the risk to the fetus, which in turn requires calculation of the dose to conceptus by a qualified expert. The decision itself should be made by the women to be treated in consultation with their physician, partner, and counsellor.

(87) Particularly difficult problems arise when radiotherapy is performed in a woman with early, undiagnosed pregnancy. The result is sometimes a massive irradiation of the conceptus in a period when malformations are easily induced (at or after 3 weeks post conception). To avoid such unintentional irradiation, it may be necessary to perform pregnancy tests to diagnose, or exclude, pregnancy before undertaking radiotherapy.

(88) Therapy of hyperthyroidism with ^{131}I in a pregnant woman is strictly contraindicated. This is partly due to possibility of external irradiation of the fetus, but mostly due to radioactive iodide crossing the placenta into the fetal circulation with subsequent uptake by its thyroid. The gland may well be destroyed by beta radiation from the ^{131}I taken up. Therefore, other methods of treatment should be employed, if possible, until delivery.

(89) When thyroid cancer with metastases is diagnosed in a pregnant woman, treatment with ^{131}I, if it cannot be delayed until after delivery, is not compatible with continuation of the pregnancy.

17. Can treatment of patients with radiation endanger other people?

(90) Medical radiation can be delivered to the patient from a radiation source outside the patient (e.g., from an x-ray machine for diagnosis or a linear accelerator for radiotherapy). Regardless of how much dose the patients receive, they do not become radioactive or emit radiation. As a result, such patients present absolutely no radiation hazard to family or others.

(91) The other way that medical radiation is given is by placing radioactive materials in the patient. In these cases the patient will emit radiation. For *diagnostic* nuclear medicine studies (such as a bone or thyroid scan), the amount of radioactivity injected is small and such patents present no hazard to their family or to the public. Such patients are discharged immediately after the procedure.

(92) Patients may undergo radiation *therapy* by having radioactivity injected or radioactive sources implanted in the tumour. Such patients may or may not present a hazard to others, depending on the penetration capability of the radiation emitted by the radionuclide. Some are very poorly penetrating (such as iodine-125 prostate implants). Such patients are discharged. Others who receive iridium-192 or caesium implants must remain in the hospital until the sources are removed. In those cases, the radiation is penetrating enough that there will have to be restrictions on visiting the patient.

(93) Patients treated with a high activity of iodine-131 for cancer of the thyroid, or in some cases for hyperthyroidism, or patients with permanent implants of radioactive sources (a special category of brachytherapy), constitute a special case. Once released home from a clinic or hospital, they may present some – however slight – risk to their family members if they do not observe specific rules of behaviour. These patients must be informed to avoid close bodily contact with children, and of other necessary precautions, by specialists responsible for the conduct of their therapy.

18. Suggested sources of further information

The Internet offers many sources of additional information. It is not possible to give an exhaustive list here. A few international sites are listed as starting points for further searches:

European Commission (radiological protection pages) – europa.eu.int/comm./environment/radprot/
International Atomic Energy Agency (medical pages) – www-naweb.iaea.org/nahu
International Commission on Radiological Protection – www.icrp.org
World Health Organization – www.who.int

PERGAMON

ICRP Supporting Guidance 2

Annals of the ICRP

Diagnostic reference levels in medical imaging: Review and additional advice

ICRP Supporting Guidance 2
Approved by ICRP Committee 3 in September 2001

Abstract-Diagnostic reference levels (DRLs) should be used by regional, national and local authorised bodies. The numerical values of DRLs are advisory, however, implementation of the DRL concept may be required by an authorised body.

The concept of DRLs allows flexibility in their selection and implementation.

The present ICRP advice does not specify quantities, numerical values or details of implementation for DRLs. This is the task of the regional, national and local authorised bodies, each of which should meet the needs in its respective area. ICRP considers that any reasonable and practical approach, consistent with the advice, will improve the management of patient doses in medical imaging.

Keywords: DRL; Reference level; Medical imaging; Diagnostic radiology; Radiological protection

MAIN POINTS

- Diagnostic reference levels (DRLs) should be used by regional, national, and local authorised bodies. The numerical values of DRLs are advisory, however, implementation of the DRL concept may be required by an authorised body.
- The concept of DRLs allows flexibility in their selection and implementation.
- The present ICRP advice does not specify quantities, numerical values, or details of implementation for DRLs. This is the task of the regional, national, and local authorised bodies, each of which should meet the needs in its respective area.
- The ICRP rationale for its advice is that any reasonable and practical approach, consistent with the advice, will improve the management of patient doses in medical imaging.

1. INTRODUCTION

(1) The purpose of this document is to provide additional advice to regional, national, and local authorised bodies and the clinical community on the application of diagnostic reference levels as a practical tool in diagnostic radiology and nuclear medicine. Achieving acceptable image quality or adequate diagnostic information, consistent with the medical imaging task, is the overriding clinical objective. Diagnostic reference levels are then used to help manage the radiation dose to patients so that the dose is commensurate with the clinical purpose.

(2) A review was conducted of the various approaches that have been taken by authorised bodies, working in concert with professional medical groups, to establish diagnostic reference levels for medical imaging tasks. While the approaches are not uniform in aim and methodology, it is concluded that there are a variety of ways to implement the concept of diagnostic reference levels, depending on the medical imaging task of interest, the regional, national, or local state of practice, and the regional, national, or local preferences for technical implementation.

(3) The document briefly reviews the existing ICRP guidance, summarises the information on approaches taken to date, and presents additional advice from ICRP Committee 3. The advice given here provides a framework for diagnostic reference levels that is consistent with earlier ICRP guidance, but allows more flexibility in their selection and use. While some illustrative examples are given, the advice does not specify the quantities to be used, the numerical values to be set for the quantities, or the technical details of how regional, national or local authorised bodies should implement diagnostic reference levels.

2. EXISTING ICRP GUIDANCE

(4) *Publication 60* (ICRP, 1991) provided the following recommendation in the section on optimisation of protection in medical exposure in paragraph (S34): '*Consideration should be given to the use of dose constraints, or investigation levels, selected by the appropriate professional or regulatory agency, for application in some common diagnostic procedures. They should be applied with flexibility to allow higher doses where indicated by sound clinical judgment*'.

(5) *Publication 73* (ICRP, 1996) introduced the term 'diagnostic reference level', explained its place in the Commission's broader concept of reference levels, and expanded the *Publication 60* recommendation in (S34) in more detail [paragraphs (99) through (106) of *Publication 73*]. The main points are summarised below:

(a) The term used is 'diagnostic reference level'.
(b) The purpose is advisory. It is a form of investigation level to identify unusually high levels, which calls for local review if consistently exceeded. In principle, there could be a lower level also (i.e., below which there is insufficient radiation dose to achieve a suitable medical image). Diagnostic reference levels are not for regulatory or commercial purposes, not a dose constraint, and not linked to limits or constraints.
(c) The examination types include diagnostic radiology and nuclear medicine (viz., common examinations and broadly defined types of equipment).
(d) Their selection is by professional medical bodies, using a percentile point on the observed distribution for patients, and specific to a country or region.
(e) The quantities should be easily measured, such as absorbed dose in air or tissue-equivalent material at the surface of a simple standard phantom or representative patient for diagnostic radiology, and administered activity for diagnostic nuclear medicine.

3. REVIEW OF REFERENCE LEVELS IN MEDICAL IMAGING

(6) There have been a number of approaches to reference levels used for medical imaging. Typically, reference levels are used as investigation levels (i.e., a quality assurance tool) and they are advisory. But, there are exceptions where the approach uses 'achievable levels' indicative of more optimum conditions, mentions dose constraints, or incorporates a dose limit or suspension level (only for mammography used for screening). To clarify paragraph (5 b), the numerical value of a diagnostic reference level is advisory (i.e., the numerical value is not for regulatory or commercial purposes, not a dose constraint, and not linked to limits or constraints). However, authorised bodies may require implementation of the concept of a diagnostic reference level.

(7) There have been fairly consistent criteria for selecting reference levels, although the criteria used to date differ for diagnostic radiology and nuclear medicine. In diagnostic radiology, reference levels usually have been derived from distributions of dosimetric quantities for patients observed in practice in the relevant region or country. Usually, only upper levels have been selected and lower levels have not been specified. In nuclear medicine, reference levels usually have been derived from pragmatic values of administered activity based on accepted custom and practice. Typically, all reference levels are developed through co-operation between radiation protection authorities and professional groups or specialists (i.e., clinical peer involvement).

(8) There have been different aims for various reference levels. While reference levels apply to a selected medical imaging task, often the clinical and technical conditions are not fully defined, with the degree of definition dependent on the aim. At least three general aims can be identified:

(a) To improve a regional, national, or local distribution observed for a general medical imaging task, by identifying and reducing the number of unjustified high or low values in the distribution;
(b) To promote good practice for a more specific medical imaging task; and
(c) To promote an optimum range of values for a specified medical imaging protocol.

(9) A number of different quantities have been used for reference levels. The quantity selected is dependent on the type of clinical procedure, for example, whether it is an individual radiographic projection, a procedure or examination consisting of multiple projections or field locations, or a diagnostic nuclear medicine procedure (i.e., a specific radiopharmaceutical and clinical purpose). The quantity used is also dependent on the body setting the reference level, and is related to the desired aim, local preference, and the unique irradiation conditions.

(10) The observations given above highlight the array of considerations and approaches to reference levels, whose features are displayed in Table 1 (Approaches to Reference Levels) and Table 2 (Listing of Reference Levels), which is a listing of approaches and values that have been selected by a number of authorised bodies in recent years.[1] Tables 1 and 2 are for background information and are not part of the additional advice from Committee 3 given in paragraphs (12) through (24).

[1] There are continuing efforts to develop and implement diagnostic reference levels throughout the world. A recent IAEA/EC/PAHO/WHO Conference (IAEA, 2001) included a number of papers on these developments in diagnostic radiology and nuclear medicine.

Table 1
Approaches to reference levels

Document	Term Used	Exam Type: Measured Quantity	Selection	Purpose
ICRP 73 (1996) Radiological Protection and Safety in Medicine. ICRP Publication 73. International Commission on Radiological Protection (1996)	**diagnostic reference level**	diagnostic radiology and nuclear medicine (common exams & broadly defined types of equipment); easily measured quantity (for radiology, absorbed dose in air or in tissue-equivalent material at surface of a simple standard phantom or representative patient; for nuclear medicine, administered activity)	professional medical bodies; percentile point on observed distribution for patients; specific to country or region	advisory: form of investigation level, identify unusually high levels; in principle, lower level also; not for regulatory or commercial purposes; not a dose constraint; not linked to limits or constraints
CRCPD (1988) (General, U.S.) Average Patient Exposure Guides. CRCPD Publication 88-5. Conference of Radiation Control Program Directors, Inc. (1988) [see Note 1]	**patient exposure guides**	medical, mammography and dental: ESE in mR; measurements in air, no phantom	derived from inspection of data from US surveys; reflect "state of current practice"	non-regulatory: tied to specific technique factors: patient thickness, SID, grid, film speed, kVp (for dental)
IPSM (1992) (General, U.K.) National Protocol for Patient Dose Measurements in Diagnostic Radiology. Dosimetry Working Party, Institute of Physical Sciences in Medicine (1992)	**reference dose levels**	radiographs: ESD in mGy exams: DAP in Gy cm^2 [average for at least 10 adult patients, avoid extremes in physique (70 ± 10 kg)]	rounded 3rd quartile values from U.K. surveys	p.15: "... could be construed as dose constraints that have been set at the national level"; "achievement of doses below reference levels should not be construed as an indication of satisfactory or optimum performance"
IAEA (1996) (BSS) International Basic Safety Standards Protection against Ionizing Radiation and for the Safety of Radiation Sources. Safety Series No. 115. International Atomic Energy Agency (1996)	**guidance levels**	radiographs: ESD in mGy (for film-screen combinations with relative speed 200; reduce by factor of 2 to 3 for film speed 400–600) computed tomography: MSAD in mGy (on axis of rotation, water phantoms for head and body) mammography: AGD in mGy; 4.5 cm, 50/50; Mo-Mo fluoroscopy: ESD rate in mGy per minute nuclear medicine: A in MBq	derived from wide-scale surveys for typical adults	corrective actions if doses fall substantially below levels with no useful information or medical benefit ... or if doses exceed levels

Note 1: CRCPD (1988) was preceded by earlier U.S. guidance (FR, 1978). CRCPD (1988) superseded an earlier document (CRCPD, 1980) and has since been superseded by a later document (CRCPD, 1992). [FR (1998). Federal Register, Volume 43, No. 22. Radiation Protection Guidance to Federal Agencies for Diagnostic X Rays.] [CRCPD (1980). Patient Exposure Guides for Diagnostic X Ray.] [CRCPD (1992). Average Patient Exposure Guides. CRCPD Publication 92-4.]

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Table 1 (*continued*)

Document	Term Used	Exam Type: Measured Quantity	Selection	Purpose
NRPB (1999) (General, U.K.) Guidelines on Patient Dose to Promote Optimisation of Protection for Diagnostic Medical Exposures. Documents of the NRPB, Vol. 10, No. 1. National Radiological Protection Board (1999) **Also, ARSAC (1998) (Nuclear Medicine, U.K.)** Notes for Guidance on the Clinical Administration of Radiopharmaceuticals and Use of Sealed Radioactive Substances. Administration of Radioactive Substances Advisory Committee (ARSAC), Department of Health (U.K.) (1998)	**suspension level** (screening mammography); **reference doses**; **achievable doses**; and **diagnostic reference levels** (DRL, nuclear machine)	radiographs: ESD; mGy for adult, uGy for pediatric mammography: MGD in mGy for standard breast model dental radiographs: intraoral, PED in mGy; panoramic, DWP in mGy mm fluoroscopic exams: DAP in mGy cm^2 computed tomography: single slices, $CTDI_w$ in mGy; exams, DLP in mGy cm nuclear medicine: 4 in MBq	**reference doses** 3rd quartile distribution of mean values, U.K. survey **achievable doses** values achievable by standard means in widespread use: radiographs, mean value for facilities meeting European recommendations mammography, value based on U.K. survey of good technique **diagnostic reference levels** guidance for practitioners in U.K.	**suspension level** (screening mammography) if exceeded, subject to immediate review of practice **reference doses** investigation levels: threshold for the internal investigation of potentially poor practice within a department; not a formal regulatory tool **achievable doses** supplemental to reference doses; promote optimisation of practice **diagnostic reference levels (nuclear medicine)** pragmatic values based on accepted customs & practice; thresholds above which special justification is required; required by certificate issued by regulatory authority (previously, maximum usual activities, MUA)
EC (1999a) (General) Guidance on Diagnostic Reference Levels (DRLs) for Medical Exposures. Radiation Protection 109. Directorate-General, Environment, Nuclear Safety and Civil Protection. European Commission (1999) **Also, Nordic (1996) (General); SSK (2000) (Nuclear Medicine)** [see Note 2]	**diagnostic reference levels**	radiographs: ESD in mGy fluoroscopic exams: DAP in mGy cm^2 [average for at least 10 adults; avoid extremes in physique (70±3 kg)] mammography: ESD in mGy for a standard phantom nuclear medicine: A in MBq	radiography: 3rd quartile values from European surveys nuclear medicine: administered activity necessary for a good image during a standard procedure	**x-ray examinations:** groups of standard-sized patients or phantoms, broadly defined types of equipment; levels expected not to be exceeded when good and normal practice is applied; when consistently exceeded, review procedures and equipment **nuclear medicine:** ''optimum'' national values; for children, a fraction of adult values

Note 2: [Nordic (1996). Nordic Guidance Levels for Patient Doses in Diagnostic Radiology. Report on Nordic Radiation Protection Co-operation No. 5 (Denmark, Finland, Iceland, Norway and Sweden)] [SSK (2000). Diagnostic Reference Levels in Nuclear Medicine. Recommendation of the Radiation Protection Commission (Session 167) (Germany)]

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Table 1 (*continued*)

Document	Term Used	Exam Type: Measured Quantity	Selection	Purpose
European Commission Documents with Same Approach				
EC (1990) (General) Working Document on Quality Criteria for Diagnostic Radiographic Images. CEC XII/173/90. Commission of European Communities (1990)	**reference dose value** (criteria for radiation dose to the patient)	radiographs: ESD; mGy for adult, uGy for pediatric mammography: 4.5 cm; grid not specified; EC (1990) mammography: ESD in mGy; 50 mm breast = 45 mm PMMA; OD = 1.0; EC (1993) mammography: ESD in mGy; 5 cm, Mo target, Mo/Al filter; EC (1996a) computed tomography: single slices, $CTDI_w$ in mGy; exams, DLP in mGy cm (head phantom, 16-cm diameter; body phantom, 32-cm diameter; PMMA)	3rd quartile values from European surveys	investigation levels (investigate reason for exceeding): tied to diagnostic requirements, image criteria and good radiographic technique
EC (1993) (Mammo) European Guidance for Quality Assurance in Mammography Screening. EUR 14821. European Commission (1993)		adults: use sample of 10 patients near standard size, 60–80 kg; pediatric: use sample of 10 patients, 4–6 years old, 15–25 kg		
EC (1996a) (General) European Guidelines of Quality Criteria for Diagnostic Radiographic Images. Eur 16260 EN. European Commission (June 1996)				
EC (1996b) (Paediatric) European Guidelines on Quality Criteria for diagnostic Images in Paediatrics. EUR 16261 EN. European Commission (July 1996)				
EC (1999b) (CT) European Guidance on Quality Criteria for Computed Tomography. EUR 16262. European Commission (May 1999)				

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Table 1 (*continued*)

Document	Term Used	Exam Type: Measured Quantity	Selection	Purpose
EC (1996c) (Mammo) European Protocol on Dosimetry in Mammography. EUR 16263 EN. European Commission (June 1996)	**limiting value**	mammography: ESAK & AGD in mGy; 45 mm PMMA; OD = 1.0	conversion from EC (1993) value for ESD	p. 49: "dose constraints"; "used to cover different terms like limiting values, reference levels, action levels, etc.
FDA (1997) (Mammo, U.S.) Quality Mammography Standards; Correction; Final Rule. Federal Register, Volume 62, Number 217, 60613–60632. Food and Drug Administration (November 10, 1997) at [www.fda.gov/cdrh/fr/fr1110af.html]	**dose limit**	mammography: AGD in mGy, craniocaudal view; using accepted FDA phantom; for all systems; for technique factors and conditions used clinically for a standard breast (4.2 cm; 50/50)	adapted from American College of Radiology quality control manual	regulatory requirement (shall not exceed): for screening mammography; quality assurance test, perform at least annually; part of extensive equipment quality assurance requirements (provision effective April 1999)
AAPM (1999) (General, U.S.) Reference Values-Applications and Impact in Radiology. American Association of Physicists in Medicine Task Group (November 1999 Draft)	**reference value**	radiographs: ESAK in mGy (ESE in mR) ; measurements in air, no phantom computed tomography: CTDI in mGy, in phantom with backscatter fluoroscopy: ESAK rate in mGy per minute (ESE in mR per minute))	derived from 75th or 80th percentile of U.S. survey data	non-regulatory: to assist medical professionals in evaluating exposure levels; if exceeded, facility investigates reason; reduce, if possible without sacrificing image quality
NRPB (2000) (Paediatric) Reference Doses and Patient Size in Paediatric Radiology. NRPB-R318. National Radiological Protection Board (November 2000)	**reference dose**	radiographs: ESD in uGy complete examinations: DAP in mGy cm^2 pediatric ages: neonate, 1, 5, 10 and 15 years [use of measured values, for individual children, normalised to standard size of nearest pediatric age]	rounded values of third quartile European surveys	provisional reference doses: useful and practical way of promoting optimisation of patient protection; referenced to concepts in ICRP publications and the EC Medical Exposure Directive

List of Symbols and Acronyms:

ESD - entrance surface dose (with backscatter)
ESD rate - entrance surface dose rate (with backscatter)
ESAK - entrance surface air kerma (free-in-air)
PED - patient entrance dose (free-in-air)
ESE - entrance skin exposure (free-in-air)
MSAD - multiple scan average dose
CTDI - computed tomography dose index (U.S.)
$CTDI_w$ - weighted computed tomography dose index (EC)
OD - optical density
DLP - dose length product
DAP - dose area product
DWP - dose width product
AGD - average glandular dose
MGD - mean glandular dose
A - administered activity
MUA - maximum usual activity
DRL - diagnostic reference level

Table 2
Listing of Reference Levels

Medical Imaging Task	(General, U.S.) CRCPD 1988	(General, U.K.) IPSM 1992	(BSS) IAEA 1996	(General) EC 1990,1996a, 1999a	(General, U.S.) AAPM 1999	(General) NRPB 1999
Radiographs [values are ESD in mGy, except as noted for CRCPD, AAPM and NRPB]						
[NOTE: CRCPD entries were converted from ESE in mR (x 0.00876) to ESAK in mGy]						
Dental Panoramic						65
Dental (periapical)			7			[DWP in mGy mm]
AP Dental	[ESAK in mGy]		5		[ESAK in mGy]	
Dental Cephalometric	0.3				0.25	
Dental Intraoral (bitewing)	function of kVp & speed				2.3 (70 kVp,E)	mandibular molar
(ex: 70 kVp and E speed)	2.1 to 3.1 (range)				3.5 (70 kVp,D)	4, **1.8** [PED, mGy]
PA or AP Skull		5	5	5		5, **1.5**
LAT Skull	1.3, 0.6	3	3	3		3, **1**
AP Cervical Spine	1.2, 0.8				1.25	
PA Chest	0.1, 0.04 no grid	0.3	0.4	0.3	0.25	0.3
	0.2, 0.1 grid					
LAT Chest		1.5	1.5	1.5		1.5
AP Thoracic Spine			7			
LAT Thoracic Spine			20			
AP Full Spine	2.3, 1.3					
AP Abdomen	4.3, 2.6	10	10		4.5	10, **6**
AP or PA Lumbar Spine	3.9, 3.1	10	10	10	5	10, **5**
LAT Lumbar Spine	[two film speeds:	30	30	30		30, **12**
LAT Lumbar Spine	200, then 400]	40	40	40		40, **24**
(lumbo-sacral joint)						
AP Pelvis		10	10	10		10, **4**
AP Hip Joint			10			[reference dose,
AP Urinary Tract				10		then **achievable dose**]
(plain film or before contrast)				10		
AP Urinary Tract (after contrast)						

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Table 2 (*continued*)

Medical Imaging Task	(Paediatric) NRPB 2000 0–yr	1–yr	5–yr	10–yr	15–yr	(Paediatric) EC 1996b, 1999a	(General)NRPD 1999
Paediatric Radiographs [values are ESD in uGy, except for MCU exam]							
AP & PA Chest		50	70	120		100 (5-yr old)	100 (5-yr old)
LAT Chest						200 (5-yr old)	200 (5-yr old)
AP Chest Newborns	50					80 (newborn)	80 (newborn)
PA or AP Skull		800	1100	1100	1100	1500 (5-yr old)	1500 (5-yr old)
LAT Skull		500	800	800	800	1000 (5-yr old)	1000 (5-yr old)
AP Pelvis (infants)						200 (infant)	200 (infant)
AP Pelvis (older children)		500	600	700	2000	900 (5-yr old)	900 (5-yr old)
AP or PA Abdomen (with vertical beam)		400	500	800	1200	1000 (5-yr old)	1000 (5-yr old)
MCU exam (**Note: DAP in mGy cm^2**)	600	900	1200	2400			
[Note: quality criteria, but not reference levels also given for the following pediatric radiographs in EC (1996b)]							
PA or AP Full Spine		Micturating Cystourethrography				AP or PA Urinary tract	
PA or AP Segmental Spine		AP or PA Urinary Tract				(after contrast)	
LAT Segmental Spine		(without or before contrast)					

Medical Imaging Task	(General, U.K.) IPSM 1992	(BSS) IAEA 1996	(CT) EC 1999b	(General) NRPB 1999	(General) EC 1999a		(General, U.S.) AAPM 1999
Fluoroscopy [values are in mGy per minute)							
Normal Mode		25					(mode not given)
High-level Mode		100					65
		[ESD rate]					[ESAK rate]
Examinations [values are DAP in Gy cm^2]							
Lumbar Spine	15			15	nv	10	
Barium Enema	60			60	60	60	
Barium Meal	25			5	25	25	
Intervenous Urography	40			40			
Abdomen	8			8			
Pelvis	5			5	nv	4	
Chest					nv	1	
Urography					40	20	
					[values cited: U.K.; then Nordic]		
					[nv, no value]		

(*continued on next page*)

Table 2 (*continued*)

Medical Imaging Task	(General, U.K.) IPSM 1992	(BSS) IAEA 1996	(CT) EC 1999b	(General) NRPB 1999	(General) EC 1999a	(General, U.S.) AAPM 1999
Computed Tomography [values are MSAD in mGy]						
CT Head		50				
CT Lumbar Spine		35				
CT Abdomen		25				
Computed Tomography [values are in mGy ($CTDI_w$, CTDI) or mGy cm (DLP), as noted]						
			[$CTDI_w$ (slice), then DLP (exam)]			[CTDI (exam)]
Routine Head			60, 1050	60, 1050		60 [head]
Routine Chest			30, 650	30, 650		40 (all body sites)
Routine Abdomen			35, 780	35, 800		
Routine Pelvis			35, 570	35, 600		
Face & Sinuses			35, 360			
Vertebral Trauma			70, 460			
HRCT of Lung			35, 280			
Liver and Spleen			35, 900			
Osseous Pelvis			25, 520			
[Note: quality criteria, but not reference levels also given for the following CT procedures in EC 1999b]						
Skull Base	Pharynx			Kidneys		
Petrous Bone	Larynx			Pancreas		
Orbits	Lumbar Spine, Discal Hernia			Adrenal Glands		
Sella and Hypophysis	Spinal Cord			Osseous Shoulder		
Salivary Glands (parotid and submandibular)	Chest, Mediastinal Vessels					

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Table 2 (*continued*)

Medical imaging task	(General, U.S.) CRCPD 1988	(General) EC 1990, 1996a, 1999a	(BSS) IAEA 1996	(General) NRPB 1999 [+ ARSAC 1998]	(Mammography) EC 1993, 1996c	(Mammography, U.S.) FDA 1997
Mammography [values are ESD, ESAK, AGD or MGD in mGy, as noted]						
[Note: CRCPD entries were converted from ESE in mR (nominal BF = 1.1) and AGD in mrad]						
LAT Breast		10 (1999a)				
MLO Breast		7 (1990), 10 (1996a; 1999a)		***3, 2, 1.5**		
CC Breast		7 (1990), 10 (1999a)		***3, 2, 1.5**	12, 11, **2.3**	**[3]**
Screen-film (no grid)	3.3, **0.6**		1			
Screen-film (grid)	6.7, **1.4**	10 (1996a)	3			
Xerox (positive)	8.6, **4.0**					
Xerox (negative)	6.5, **3.4**					
	[ESD, then AGD]	[ESD]	[AGD]	**[MGD] [*suspension level, reference dose,** then **achievable dose]**	[ESD, ESAK, **AGD**]	**[AGD] [dose limit]**

Medical Imaging Task	(General) EC 1999a	(BSS) IAEA 1996	(Nuclear Medicine) ARSAC 1998	(Nuclear Medicine) SSK 2000
Nuclear Medicine [values are A in MBq, for adults] ... Examples				
Bone Imaging [MDP/HDP]	400 600	600	600	750
Liver/Spleen Studies [colloid]	80 80	80	80	no value
Liver/Spleen Studies [IDA]	40 150	150	150	150
Lung Perfusion Imaging [MAA]	100 100	100	100	200
Renal Imaging [DMSA]	80 80	160	80	70
Dynamic Renal Scanning [DTPA]	80 300	350	300	150
Dynamic Renal Scanning [MAG3]	40 100	100	100	200
[all technetium-99m]	[Netherlands, U.K.; DRLs]	[guidance levels]	[DRLs (MUAs)]	[DRLs]

[Note: EC 1999a gives values for several other countries. EC 1999a and SSK 2000 give a set of values for children.]

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Table 2 (*continued*)

List of Symbols and Acronyms:
ESD - entrance surface dose (includes backscatter)
ESD rate - entrance surface dose rate (includes backscatter)
ESAK - entrance surface air kerma (free-in-air)
PED - patient entrance dose (free-in-air)
ESE - entrance skin exposure (free-in-air)
MSAD - multiple scan average dose
CTDI - computed tomography dose index (U.S.)
List of Symbols and Acronyms: (*continued*)
CTDIw - weighted computed tomography dose index (EC)
DLP - dose length product
DAP - dose area product
DWP - dose width product
AGD - average glandular dose
MGD - mean glandular dose
A - administered activity
MUA - maximum usual activity

AP - anterioposterior
PA - posterioanterior
LAT - lateral
CT - computed tomography
HRCT - high resolution computed tomography
MLO - mediolateral oblique
CC - craniocaudal
BF - backscatter factor

IDA - iminodiacetic acid
MAA - macroaggregated albumin
DMSA - dimercaptosuccinic acid
DTPA - diethylenetriaminepentacetic acid
MAG3 - mercaptoacetyltriglycine
DRL - diagnostic reference level
MDP - methylene diphosphonate
HDP - hydroxymethylene diphosphonate
MCU - micturating cystourethrography

4. UNDERLYING CONSIDERATIONS

(11) In order to interpret correctly the relationship between a change in the numerical value of a quantity used as a diagnostic reference level and the corresponding change in patient tissue doses that determine the relative patient risk, the following considerations are important:

(a) The numerical value of the diagnostic reference level should be tied to defined clinical and technical requirements for the medical imaging task. A selected numerical value for one situation may not be applicable to different clinical and technical requirements, even if the same area of the body is being imaged. The requirements can be general or specific.
(b) The relative tissue dose distribution in the body should not change appreciably among patients undergoing the selected medical imaging task. A proportional change in the measured quantity should correspond to a proportional and uniform percentage change in the individual tissue doses. If the relative tissue–dose distribution in the body is appreciably different from that used to establish the diagnostic reference level, due to a different field size, field location, beam quality, or other technical factor that alters the internal dose distribution, then interpretation of a change in the measured quantity with regard to the change in tissue doses (and therefore the patient risk) would be ambiguous.

In setting diagnostic reference levels, regional, national, and local authorised bodies and professional groups should be cognisant of these considerations.

5. ADDITIONAL ADVICE ON DIAGNOSTIC REFERENCE LEVEL FROM ICRP COMMITTEE 3

5.1. Objective of a diagnostic reference level

(12) The objective of a diagnostic reference level is to help avoid radiation dose to the patient that does not contribute to the clinical purpose of a medical imaging task. This is accomplished by comparison between the numerical value of the diagnostic reference level (derived from relevant regional, national, or local data) and the mean or other appropriate value observed in practice for a suitable reference group of patients or a suitable reference phantom.

(13) A reference group of patients is usually defined within a certain range of physical parameters (e.g. height, weight). If an unselected sample of patients were used as a reference group, it would be difficult to interpret whether the observed value for the sample is higher or lower than the diagnostic reference level. A diagnostic reference level is not applied to individual patients.

5.2. Uses for a diagnostic reference level

(14) A diagnostic reference level can be used:

(a) To improve a regional, national, or local distribution of observed results for a ***general medical imaging task***, by reducing the frequency of unjustified high or low values;
(b) To promote attainment of a narrower range of values that represent good practice for a ***more specific medical imaging task***; or
(c) To promote attainment of an optimum range of values for a ***specified medical imaging protocol***.

Uses (14 a, b, and c) are differentiated by the degree of specification for the clinical and technical conditions selected by the authorised body for a given medical imaging task.

(15) Appropriate local review and action is taken when the value observed in practice is consistently outside the selected upper or lower level. This process helps avoid unnecessary tissue doses being received by patients in general and, therefore, helps avoid unnecessary risk for the associated radiation health effects.

5.3. Definitions and examples

(16) Definitions of the terms ***general medical imaging task***, ***more specific medical imaging task***, and ***specified medical imaging protocol*** are given below, along with examples of quantities and their application to diagnostic reference levels for the uses referred to in paragraphs (14 a, b, and c). The examples do not constitute ICRP recommendations; however, they illustrate generally the additional ICRP Committee 3 advice.

(17) The term ***general medical imaging task*** refers to an imaging task for a general clinical purpose, with minimum specification of other factors, e.g. a posterioanterior (PA) chest radiograph with the clinical purpose and technique factors unspecified. Examples of quantities and their application to improve a regional, national, or local distribution of observed values for a ***general medical imaging task*** [paragraph (14 a)] are:

(a) Entrance surface air kerma (in air, no backscatter) or entrance surface dose (in a specified material, with backscatter) in mGy, for a given radiographic projection (e.g. PA chest);
(b) Dose area product (DAP) in mGy cm^2 for a given type of fluoroscopic examination that has a well-defined anatomical region of clinical study (e.g. barium enema); and
(c) Administered activity (A) in MBq for a given nuclear medicine imaging task using a given radiopharmaceutical (e.g. lung perfusion with Tc-99^m MAA).

(18) The term ***more specific medical imaging task*** refers to an imaging task for a clearly defined clinical purpose, but allows for differences among medical establishments in other technical and clinical details, e.g. a PA chest radiograph with the clinical purpose and the general technique (such as high kVp) specified, but the detailed technique factors unspecified. Examples of quantities and their application to promote attainment of a narrower range of values that represent good practice for a ***more specific medical imaging task*** [paragraph (14 b)] are:

(a) Entrance surface air kerma (in air, no backscatter) or entrance surface dose (in a specified material, with backscatter) in mGy, for a specific radiographic imaging task. The clinical purpose is defined, but the x-ray equipment, technique factors, and image quality criteria may vary among establishments;
(b) Dose length product (DLP) in mGy cm for a given type of computed tomography (CT) examination that has a well-defined anatomical region of clinical study (e.g. routine abdominal CT scan), with specified clinical objective, image quality criteria, and technical factors. The x-ray equipment (i.e., the CT system) may vary among establishments; and
(c) Dose area product (DAP) in mGy cm^2 for a specific fluoroscopic examination. The clinical purpose is clearly defined, but the type of equipment, technique factors, and patient characteristics may differ within or among establishments. The relative tissue dose distribution is expected to be minimally variable, such that a proportional change in DAP corresponds to a nearly proportional change in absorbed dose for each of the irradiated tissues.

(19) The term ***specified medical imaging protocol*** refers to a clinical protocol with a fully defined set of specifications that is followed, or serves as a nominal baseline, at a single establishment (or several allied establishments), e.g., a protocol for a PA chest radiograph that specifies the clinical purpose, the technical conduct of the procedure, the image quality criteria, any unique patient characteristics, and other appropriate factors. Examples of quantities and their application to promote

attainment of an optimum range of values for a ***specified medical imaging protocol*** [paragraph (14 c)] are:

(a) Milliampere second (mAs) for a specific CT protocol. The clinical purpose, type of equipment, technique factors, and patient characteristics are defined.
(b) Administered activity (A) in MBq for a specific imaging protocol for single photon emission computed tomography (SPECT). The clinical purpose, type of equipment, technique factors, and patient characteristics are defined.

5.4. Note on fluoroscopically guided interventional procedures

(20) For fluoroscopically guided interventional procedures, diagnostic reference levels, in principle, could be used to promote the management of patient doses with regard to avoiding unnecessary stochastic radiation risks. However, the observed distribution of patient doses is very wide, even for a specified protocol, because the duration and complexity of the fluoroscopic exposure for each conduct of a procedure is strongly dependent on the individual clinical circumstances. A potential approach is to take into consideration not only the usual clinical and technical factors, but also the relative 'complexity' of the procedure. More than one quantity (i.e., multiple diagnostic reference levels) may be needed to evaluate patient dose and stochastic risk adequately.

(21) Diagnostic reference levels are not applicable to the management of deterministic radiation risks (i.e., radiation-induced skin injuries) from fluoroscopically guided interventional procedures. In this case, the objective is to avoid deterministic effects in individual patients undergoing justified, but long and complex procedures. The need here is to monitor in real time whether the threshold doses for deterministic effects are being approached or exceeded for the actual procedure as conducted on a particular patient. The relevant risk quantity is absorbed dose in the skin at the site of maximum cumulative skin dose. A helpful approach is to select values for maximum cumulative absorbed dose in the skin at which various clinical actions regarding the patient's record or care (related to potential radiation-induced skin injuries) are taken (ICRP, 2000). Then, during actual procedures, appropriate quantities that can help indicate the maximum cumulative absorbed dose in the skin are monitored.

5.5. Local flexibility in setting diagnostic reference levels

(22) Diagnostic reference levels should be used by authorised bodies to help manage the radiation dose to patients so that the dose is commensurate with the clinical purpose.

(23) The concept of a diagnostic reference level permits flexibility in the choice of quantities, numerical values, and technical or clinical specifications, in order to allow authorised bodies to meet the objectives relevant to their circumstances. The guiding principles for setting a Diagnostic Reference Level (DRL) are:

(a) The regional, national, or local objective is clearly defined, including the degree of specification of clinical and technical conditions for the medical imaging task;
(b) The selected value of the DRL is based on relevant regional, national, or local data;
(c) The quantity used for the DRL can be obtained in a practical way;
(d) The quantity used for the DRL is a suitable measure of the relative change in patient tissue doses and, therefore, of the relative change in patient risk for the given medical imaging task; and
(e) The manner in which the DRL is to be applied in practice is clearly illustrated.

(24) ICRP Committee 3 encourages authorised bodies to set diagnostic reference levels that best meet their specific needs and that are consistent for the regional, national, or local area to which they apply.

References

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