Volume 26 No. 2 1996 ISSN 0146-6453

Annals of the ICRP

ICRP PUBLICATION 73

Radiological Protection and Safety in Medicine

Pergamon

RADIATION PROTECTION

ICRP PUBLICATION 73

Radiological Protection and Safety in Medicine

ADOPTED BY THE COMMISSION IN MARCH 1996

PUBLISHED FOR
The International Commission on Radiological Protection

PERGAMON

UK — Elsevier Science Ltd, The Boulevard, Langford Lane, Kidlington, Oxford OX5 1GB, UK

USA — Elsevier Science Inc., 660 White Plains Road, Tarrytown, New York 10591-5153, USA

JAPAN — Elsevier Science Japan, Tsunashima Building Annex, 3-20-12 Yushima, Bunkyo-ku, Tokyo 113, Japan

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First edition 1996
ISBN 0 08 042738 3
ISSN 0146-6453

Published quarterly (March, June, September, December)
June 1996 issue

Typeset by Cotswold Typesetting Ltd, Gloucester
Printed and bound in Great Britain by BPC Wheatons Ltd, Exeter

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PREFACE

In September 1993, the International Commission on Radiological Protection established a Task Group of Committee 3 to develop a report on radiological protection and safety in medicine. The aim was to clarify how the recommended system of radiological protection as described in *ICRP Publication 60* (ICRP, 1991a) should be applied in medicine. The Task Group was composed of:

C. Zuur (Chairman)
P. J Allisy-Roberts
P. Ortiz
Y. Sasaki

G. Drexler (Corresponding member)
F. Mettler (Commission)

J. Liniecki (Critical reviewer)

After reviewing the draft prepared by the Task Group, the Commission established a small Joint Task Group of the Commission and Committee 3 to produce a final text. This Group comprised F. Mettler (Chairman) and H. J. Dunster from the Commission, and C. Zuur and H. Ringertz, from Committee 3.

During the preparation of this report, the composition of Committee 3 was:

H. Jammet (Chairman)[✠]
G. A. M. Webb (Vice-chairman)
J. Lochard (Secretary)
P. J. Allisy-Roberts
G. Drexler
J. E. Gray
W. Jaschke
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Y. Sasaki
C. Zuur

[✠] Deceased.

1. INTRODUCTION

(1) Ionising radiation has been used in medicine almost since its discovery at the end of the 19th century. The International Commission on Radiological Protection (ICRP), was established in 1928, then called the International X-ray and Radium Protection Committee, following a decision by the Second International Congress of Radiology. Its recommendations were then concerned solely with medical practice. In 1950, it was restructured and renamed. Since then, its field of interest has widened, and it now deals with essentially all situations in which humans are exposed to ionising radiation. It continues to retain a special relationship with the International Society of Radiology, and has published several reports on the protection of patients (e.g. ICRP, 1982, 1985, 1987). It maintains a standing committee (Committee 3) devoted to radiological protection in medicine.

(2) The Commission's emphasis on radiological protection in medicine is not merely historical in origin. More people are exposed to ionising radiation from medical practice, and in many cases the individual doses are higher than from any other human activity. In countries with advanced health care systems, the annual number of diagnostic procedures approaches one for every member of the population. Furthermore, the doses to patients for the same type of examination differ widely from place to place, suggesting that there is considerable scope for dose reduction.

(3) Radiation exposures in medicine are predominantly to the individuals undergoing diagnosis, screening, or therapy. But staff and other individuals helping to support and comfort patients are also open to exposure. These individuals include parents holding children during diagnostic procedures, and others, normally family or close friends, who may come close to patients following the administration of radiopharmaceuticals or during brachytherapy. Exposure to members of the general public also occurs, but it is almost always very small. Radiological protection in medicine has to deal with all these exposures.

(4) In 1990, the Commission completely revised its basic recommendations. They were issued in 1991 as *ICRP Publication 60* (ICRP, 1991a). These recommendations are intended to apply to a very wide range of situations and activities. They contain background material on topics such as the biological effects of ionising radiation and explanations of the underlying judgements on which the recommendations were based.

(5) Subsequently, the Commission concluded that it would be helpful to those concerned with the practice and management of medicine to provide a shorter report, derived from Publication 60 but specifically aimed at this medical readership. This report is the result. The Commission intends to follow it with three more detailed reports on protection in radiodiagnosis, nuclear medicine, and radiotherapy.

(6) This report omits much of the background information and policy development found in *ICRP Publication 60* and expands some of the material so that it falls more directly into the context of medical practice. Readers who are concerned with the development of national policies and guidance or who provide specialist protection services are recommended to make use of *Publication 60*. For convenience of reference, and to indicate the scope of the complete recommendations, the Summary of Recommendations included in *Publication 60* is reprinted here as Annex A.

(7) This report is addressed principally to physicians and physicists directly engaged in medical radiology, including diagnosis in medicine and dentistry, nuclear medicine and radiotherapy, and to those responsible for the management of institutions operating in these

fields. It is also addressed to those in national and international regulatory and advisory bodies concerned with radiological protection in these topics. The Commission hopes that the report will also make a contribution to medical education and training.

1.1. The Biological Basis of the Commission's Policy

(8) The Commission's recommendations apply only to ionising radiation, hereafter abbreviated to radiation. Its policy stems directly from the available information on the biological effects of radiation. The following account is highly simplified, and is intended to do no more than explain the basis of the Commission's policies. A more complete account is given in *Publication 60*. Annex B of this report contains a bibliography of the principal reviews of the quantitative information, including material on the effects of exposure *in utero*.

(9) The biological effects of radiation can be grouped into two kinds: **deterministic** and **stochastic**.

(a) If the effect results only when many cells in an organ or tissue are killed, the effect will be clinically observable only if the radiation dose is above some threshold. The magnitude of this threshold will depend on the dose rate (i.e. dose per unit time), the organ, and the clinical effect. With increasing doses above the threshold, the probability of occurrence will rise steeply to unity (100%), i.e. every exposed person will show the effect, and the severity of the effect will increase with dose. The Commission calls these effects deterministic.

(b) There is good evidence from cellular and molecular biology that radiation damage to the DNA in a single cell can lead to a transformed cell that is still capable of reproduction. Despite the body's defences, which are normally very effective, there is a small probability that this type of damage, promoted by the influence of other agents not necessarily associated with radiation, can lead to a malignant condition. Because the probability is small, this will occur in only a few of those exposed. If the initial damage is to the germ cells in the gonads, hereditary effects may occur. These effects, both **somatic** and **hereditary**, are called stochastic.

(10) In the Commission's view, there is sufficient evidence to reach the conclusion that stochastic effects attributable to radiation can occur, albeit at very low probability, even at very low doses, i.e. there will be no threshold of dose below which there will be no risk. The probability of a stochastic effect attributable to the radiation increases with dose and is probably proportional to the dose at low doses. At higher doses and dose rates, the probability often increases with dose more markedly than simple proportion. At even higher doses, close to the thresholds of deterministic effects, the probability increases more slowly, and may begin to decrease, because of the competing effect of cell killing.

1.2. The Special Application of the Commission's Policy to Medicine

(11) Several features of medical practice require an approach to radiological protection that is slightly different from that in other practices. In the first place, the exposure of patients is deliberate. Except in radiotherapy, it is not the aim to deliver a dose of radiation, but rather to use the radiation to provide diagnostic information or to conduct interventional radiology. Nevertheless, the dose is given deliberately and cannot be reduced indefinitely without prejudicing the intended outcome. Secondly, the patient needs a special relationship with the medical and nursing staff. For this reason, the system of protecting the staff from the source,

e.g. shielding, should be designed to minimise any sense of isolation experienced by the patient. This is particularly relevant in nuclear medicine and brachytherapy, where the source is within the patient. Thirdly, in radiotherapy, the aim is to destroy the target tissue. Some deterministic damage to surrounding tissue and some risk of stochastic effects in remote non-target tissues are inevitable. Finally, hospitals and radiology facilities have to be reasonably accessible to the public, whose exposure is thus more difficult to control than it is in industrial premises.

(12) The Recommendations in *Publication 60* take account of these features, but they do not address most of them specifically. This report is intended to provide that extension.

2. THE QUANTIFICATION OF RADIATION DOSE AND RISKS

2.1. Dosimetric Quantities

(13) The basic physical quantity used in radiological protection is the **absorbed dose**, D_T, averaged over an organ or defined tissue, T, where D_T is the energy deposited in the organ divided by the mass of that organ. The unit of absorbed dose is called the gray (Gy).

(14) Some radiations are more effective than others in causing stochastic effects. To allow for this, a further quantity has been introduced. This is the **equivalent dose**, H_T, which is the average absorbed dose in an organ or tissue multiplied by a dimensionless radiation weighting factor, w_R. For almost all the radiations used in medicine, the radiation weighting factor is unity, so the absorbed dose and the equivalent dose are numerically equal. The exceptions are alpha particles, for which the radiation weighting factor is 20, and neutrons, for which the radiation weighting factor is between 5 and 20, depending on the energy of the neutrons incident on the body. To avoid confusion with the absorbed dose, the unit of equivalent dose is called the sievert (Sv).

(15) Radiation exposure of the different organs and tissues in the body results in different probabilities of harm and different severities. The Commission calls the combination of probability and severity of harm '**detriment**', meaning health detriment. Details are given later in this section. To reflect the combined detriment from stochastic effects due to the equivalent doses in all the organs and tissues of the body, the equivalent dose in each organ and tissue is multiplied by a **tissue weighting factor**, w_T, and the results are summed over the whole body to give the **effective dose**, E. It is given by the expression

$$E = \sum_T w_T . H_T .$$

The unit of effective dose is called the sievert (Sv).

The links between the quantities are illustrated in Fig. 1. More information about effective dose is given in Section 2.2.

(16) These dosimetric quantities relate to individuals. For some purposes, it is useful to take account of the number of individuals exposed. This has led to the use of the **collective effective dose**. This quantity is simply the product of the average effective dose in a defined group of individuals and the number of individuals in the group.

(17) Absorbed doses in organs and effective doses cannot be measured directly. Measurable quantities are therefore selected to represent them. These include simple quantities such as absorbed dose in a tissue equivalent material at the surface of a body or in a phantom.

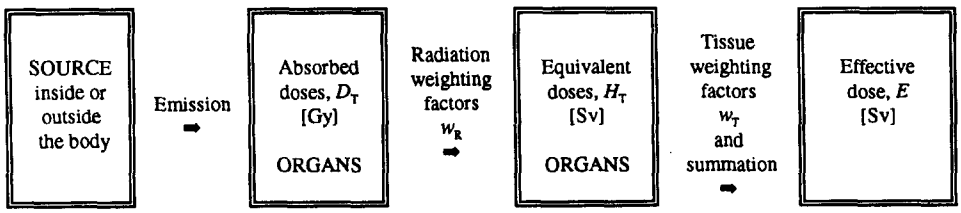

Fig. 1. The relationship between absorbed dose, D_T, equivalent dose, H_T, and effective dose, E.

2.2. Risk-based Quantities and Estimates of Risk from Postnatal Exposure

(18) For many purposes in radiological protection, it is necessary to make estimates of the consequences of an exposure to radiation. As far as possible, the Commission uses observed data from human exposures to draw general conclusions, but in most situations the doses and dose rates, and consequently the probability of medical consequences, are much smaller than those for which epidemiological information can be obtained. The epidemiology has therefore to be supplemented by biological research on the mechanisms of radiation effects so that the results from epidemiology can be extended with some confidence down to these smaller doses and dose rates. Furthermore, the length of the follow-up time in epidemiological studies is rarely long enough to study the exposed population to extinction, so a projection model is needed to estimate lifetime risks from the incomplete data. Finally, the exposed study populations are never the same as the populations for which the risk estimates are needed, so the results have to be transferred from population to population.

(19) For these reasons, the Commission calls its risk estimates 'nominal'. The estimates are expressed as the coefficient linking an effective dose to the attributable lifetime probability of fatal cancer or of serious hereditary effects in the progeny of an exposed individual. The values are for a generalised population of both sexes with a typical age distribution and typical baseline rates of mortality and cancer. This generalised population is defined in *Publication 60* and is based on the average of five diverse countries.

(20) The Commission uses the concept of detriment to mean the health detriment due to stochastic effects. This is obtained by weighting the fatality probability coefficient for each organ and tissue by a factor to take account of the expected length of life lost for different cancers and the additional, but less detrimental, non-fatal cases that will occur. An addition is made for hereditary disorders. Detriment can best be thought of as the probability of causing a level of total harm judged to be equivalent to one death that causes a loss of lifetime of 15 years. The tissue weighting factors are derived from this meaning of detriment. Detriment coefficients are provided for the equivalent dose in organs and tissues and for effective dose. Detailed information is given in Annex B of *Publication 60* and a summary is given here in Table 1. The observed human data relate to high doses, often above about 1 Gy and usually at high dose rates, but a reduction factor of 2 (referred to as the dose and dose rate effectiveness factor, DDREF) has been applied to derive the coefficients in Table 1 for the lower doses and dose rates normally experienced. The reduced coefficients are appropriate for all diagnostic doses and to most of the doses in tissues remote from the target tissues in radiotherapy.

(21) The values in Table 1 relate to the whole population. The values for different age groups would be different by amounts that would depend on the age at exposure and the organs and tissues exposed. For the exposure of young children, the coefficients would be higher, perhaps by a factor of 2 or 3. For many common types of diagnostic examination, the higher coefficients will be offset by the reduction in dose relative to that to an adult. For an age at exposure of about 60 years, the coefficients would be lower, perhaps by a factor of 3. At higher ages at exposure, the coefficients are even less (see Annex C of *Publication 60*).

(22) Despite the wide range of organ doses in radiology and the differences in age structure, the collective effective dose and the nominal detriment coefficients provide a reasonably good indicator of the detriment in a population exposed in diagnostic radiology and nuclear medicine (UNSCEAR, 1993). The quantities are less satisfactory for assessing the detriment in radiotherapeutic procedures, even if the target tissues are excluded from the

Table 1. Nominal fatality and detriment coefficients[a] for organ equivalent dose and effective dose

Organ or tissue	Nominal fatality coefficient (% per Sv)	Nominal detriment coefficient (% per Sv)
Bladder	0.30	0.29
Bone marrow	0.50	1.04
Bone surface	0.05	0.07
Breast (females only)	0.40	0.73
Colon	0.85	1.03
Liver	0.15	0.16
Lung	0.85	0.80
Oesophagus	0.30	0.24
Ovary (females only)	0.20	0.29
Skin	0.02	0.04
Stomach	1.10	1.00
Thyroid	0.08	0.15
Remainder[b]	0.50	0.59
Sub-total	5.00	5.92
Gonads	Probability of severe hereditary disorders 1.00	Hereditary detriment 1.33
Total (rounded)	5.00 (Fatal cancers, uniform whole-body exposure)	7.3 (Including hereditary detriment)

[a] These nominal coefficients are average values for the whole population of equal numbers of males and females of all ages (except for the breast and ovary, which are for females only). To obtain values for equal numbers of males and females, the values in the table need to be divided by 2. They apply to the moderately low doses and dose rates associated with diagnostic procedures. See also Paragraphs 21 and 22.

[b] For purposes of calculation, Remainder is composed of the adrenals, brain, extra-thoracic section of the respiratory tract, small intestine, kidney, muscle, pancreas, spleen, thymus and uterus.

calculation of effective dose, partly because some of the doses to organs or parts of organs outside the target volume may be near, or above, the thresholds for deterministic effects. The detriment coefficients will then underestimate the stochastic detriment, because at these doses the use of a DDREF is inappropriate. Since the coefficients take no account of deterministic effects, these must be considered separately. On the other hand, the population of therapy patients is very different from the general population, both in age and in life expectancy. This causes the detriment coefficients to overestimate the detriment to most of these patients.

(23) All the coefficients in Table 1 relate to the nominal risk. The Commission believes that this generalisation is adequate for protection purposes, but if national data are available, they can be used to derive alternative values.

(24) As with all estimates derived from epidemiology, the coefficients do not apply to individuals, unless it can be assumed that the individual is typical of the nominal population. Nevertheless, since there are no better data, they can be used to provide a semi-quantitative basis for judging the likely consequences of radiation exposures to individual patients.

(25) Because of the different age distributions, the detriment coefficients of workers and the general public differ slightly. The detriment coefficients for effective dose are summarised in Table 2.

(26) The tissue weighting factors have been derived from the detriment coefficients in Table 1. Because of the uncertainties in the original data, the contributions to the total have been rounded and the organs grouped into four classes, each with its own weighting factor. These are for bone, surface and skin, 0.01; bladder, breast, liver, oesophagus, thyroid and remainder, 0.05; bone marrow, colon, lung and stomach, 0.12; and gonads, 0.2.

Table 2. Nominal probability coefficients for stochastic effects (probability per unit effective dose)

	Detriment[a] (% per Sv)			
Exposed population	Fatal cancer[b]	Non-fatal cancer	Severe hereditary effects	Total
Adult workers	4.0	0.8	0.8	5.6
Whole population	5.0	1.0	1.3	7.3

[a] Rounded values.
[b] For the sum of fatal cancers, the detriment coefficient is equal to the probability coefficient.

2.3. Estimates of Risk from Prenatal Exposure

(27) Although special efforts are made to restrict exposures to the conceptus of a pregnant patient or worker, some exposures do occur. The implications of prenatal exposures are summarised below. References to more extensive information are given in Annex B.

(28) The effects on the conceptus of exposure to radiation depend on when the exposure occurs relative to conception. Exposure of the embryo in the first 3 weeks following conception is not likely to result in deterministic or stochastic effects after birth. During the period of major organogenesis (4–14 weeks after conception), animal data suggest that malformations may be caused in the organ under development at the time of exposure. These effects are deterministic in character with a threshold in man estimated from animal experiments to be in the range 0.1–0.5 Gy.

(29) Throughout the period from 3 weeks after conception until the end of pregnancy, it is likely that radiation exposure can cause stochastic effects, such as an increased probability of cancer. The available data are not consistent; however, the Commission assumes that the nominal fatality probability coefficient is about the same as for children.

(30) Values of intelligence quotient (IQ) lower than expected have been reported in some children exposed *in utero* at Hiroshima and Nagasaki. The data are consistent with a general downward shift in the distribution of IQ with increasing dose. The Commission assumes that this shift is proportional to dose. A coefficient of about 30 IQ points per sievert relates to the dose to the foetus in the period from 8 to 15 weeks after conception. On this basis, the change in the IQ of an individual that can be caused by a dose of about 100 mSv will be no more than three IQ points. Small shifts in IQ cannot be clinically identified. The effects on IQ are less marked following exposure in the period from 16 to 25 weeks after conception and have not been observed for other periods. All the observations on IQ relate to high doses and high dose rates.

3. THE FRAMEWORK OF RADIOLOGICAL PROTECTION

(31) In *Publication 60*, the Commission stated its view of the primary aim of radiological protection.

> The primary aim of radiological protection is to provide an appropriate standard of protection for man without unduly limiting the beneficial practices giving rise to radiation exposure.
> (*Publication 60*, paragraph 15)

(32) In most situations arising from the medical uses of radiation, the radiation sources are deliberately used and are under control. Such situations are called by the Commission '**practices**'. In some situations, the existence of the sources is not a matter of choice; they already exist. The presence of radon in workplaces is a universal example. Environmental contamination following serious accidents is another. The exposures they cause can be reduced, but rarely eliminated, by remedial measures. Such actions are called 'intervention', not to be confused with interventional radiology.

(33) The basic components of the Commission's system of protection for practices have been set out in Paragraph 112 of *Publication 60*. They can be summarised as follows.

(a) No practice involving exposures to radiation should be adopted unless it produces at least sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes. (Called 'justification of a practice'.)
(b) In relation to any particular source of radiation within a practice, all reasonable steps should be taken to adjust the protection so as to maximise the net benefit, economic and social factors being taken into account. (Called 'optimisation of protection'.)
(c) Finally, a limit should be applied to the dose (other than from medical exposures) received by any individual as the result of all the practices to which he is exposed. (Called 'application of individual dose limits'.)

(34) In simple terms, this framework is derived from three principles that apply to many human activities, and especially to medicine:

(a) the justification of a practice implies doing more good than harm,
(b) the optimisation of protection implies maximising the margin of good over harm, and
(c) the use of dose limits implies an adequate standard of protection even for the most highly exposed individuals.

More details are given in the following sections.

(35) In most situations, other than radiotherapy, it is not necessary to approach the thresholds for deterministic effects. The Commission's policy is therefore to limit exposures so as to keep doses below these thresholds. The possibility of stochastic effects cannot be totally eliminated, so the policy is to avoid unnecessary sources of exposure and to take all reasonable steps to reduce the doses from those sources of exposure that are necessary or cannot be avoided.

(36) In using these principles to develop a practical system of protection that fits smoothly into the conduct of the activity, the Commission uses a division into three types of exposure: **medical exposure**, which is principally the exposure of persons as part of their diagnosis or treatment; **occupational exposure**, which is the exposure incurred at work, and principally as a result of work; and **public exposure**, which comprises all other exposures. In some respects,

the system of protection is applied differently to these types of exposure, so it is important to clarify the distinctions.

(37) Medical exposure is essentially limited to

(a) the exposure of individuals for diagnostic and therapeutic purposes, including screening and medico-legal purposes (for convenience, all these individuals are called patients herein) and
(b) exposures (other than occupational) incurred knowingly and willingly by individuals such as family and close friends helping either in hospital or at home in the support and comfort of patients undergoing diagnosis or treatment.

Exposures incurred by volunteers as part of a programme of biomedical research that provides no direct benefit to the volunteers are also dealt with by the Commission on the same basis as medical exposure.

(38) Although occupational exposure to any hazardous agent is conventionally defined as all exposures occurring at work, the Commission limits its use of the term to those exposures "that can reasonably be regarded as being the responsibility of the operating management". This means that the exposure of all those working on the premises, due to the sources under the management's control, is occupational exposure, whoever employs the workers and whether or not they are involved in the radiation procedures of the institution. A system of designated areas is suggested in Section 8.1 to avoid unreasonable complexity in the control of occupational exposure.

(39) Public exposure encompasses all other exposures. It is implicit in *Publication 60* that public exposures that are not susceptible to human control, such as cosmic rays at ground level, are excluded from the scope of the Commission's recommendations.

(40) In the design of equipment and procedures and in the planning of their application, attention should also be paid to accidental and unintended exposures. Such exposures that are not certain to occur are called **potential exposures**. Their control requires consideration of the probability of occurrence of the exposure as well as the magnitude of the resulting dose. Considerations of dose alone are not enough. The use of potential exposure is important in the design of equipment, especially radiotherapy equipment. In other medical applications, the formal use of potential exposure is rarely necessary (but see also Section 9).

4. THE JUSTIFICATION OF A PRACTICE

(41) In principle, the decision to adopt or continue any human activity involves a review of the benefits and disadvantages of the possible options. This review usually provides a number of alternative procedures that will do more good than harm. The more elaborate process of judging which of these options is the 'best', e.g. choosing between the use of X-rays or ultrasound, is still necessary and is more complex. The harm, more strictly the detriment, to be considered is not confined to that associated with the radiation—it includes other detriments and the economic and social costs of the practice. Often, the radiation detriment will be only a small part of the total. For these reasons the Commission limits its use of the term 'justification' to the first of the above stages, i.e. it requires only that the net benefit be positive. To search for the best of all the available options is usually a task beyond the responsibility of radiological protection organisations.

(42) Most of the assessments needed for the justification of a practice are made on the basis of experience, professional judgement, and common sense, but quantitative decision-aiding techniques are available and, if the necessary data are accessible, should be considered.

(43) There are three levels of justification of a practice in medicine.

(a) At the first and most general level, the use of radiation in medicine is accepted as doing more good than harm. Its justification is now taken for granted.
(b) At the second level, a specified procedure with a specified objective is defined and justified, e.g. chest radiographs for patients showing relevant symptoms. The aim of this **generic justification** is to judge whether, in most cases, the radiological procedure will improve the diagnosis or treatment or will provide necessary information about the exposed individuals. More details are given in Section 4.1.
(c) At the third level, the application of the procedure to an individual patient should be justified, i.e. the particular application should be judged to do more good than harm. More details are given in Section 4.2.

4.1. The Generic Justification of a Defined Procedure

(44) The generic justification of the procedure is a matter for national professional bodies, sometimes in conjunction with national regulatory authorities. The total benefits from a medical procedure include not only the direct health benefits to the patient, but also the benefits to the patient's family and to society. Although, in medicine, the main exposures are to patients (medical exposure), the exposures to staff (occupational exposure) and to members of the public who are not connected with the procedures (public exposure) should be taken into account. The possibility of accidental or unintended exposures (potential exposure) should also be considered. The decisions should be reviewed from time to time as new information becomes available about the risks and effectiveness of the existing procedure and about new procedures.

(45) It should be noted that the generic justification of a medical procedure does not necessarily lead to the same choice of the best procedure in all situations. For example, chest fluoroscopy for the diagnosis of serious pulmonary conditions may do more good than harm, but chest radiography is likely to be the procedure of choice in a country with substantial resources, because the ratio of good to harm would be larger. However, fluoroscopy might be

the procedure chosen in countries with fewer resources, if it would still produce a net benefit and if no better alternatives were available.

(46) In a similar manner, the generic justification for routine radiological screening for some types of cancer will depend on the national incidence and on the availability of effective treatment for detected cases. National variations are to be expected.

(47) The justification of diagnostic investigations for which the benefit to the patient is not the primary objective needs special consideration. In the use of radiography for insurance purposes, the primary benefit usually accrues to the insurer, but there may be some economic benefit for the individual examined. Examinations ordered by physicians as a defence against medico-legal malpractice claims may have only marginal advantages for the individual patient.

4.2. The Justification of a Procedure for an Individual Patient

(48) Beyond checking that the required information is not already available, no additional justification is needed for the application of a generically justified simple diagnostic procedure to an individual patient with the symptoms or indications for which the procedure has already been justified generically. For complex diagnostic procedures and for therapy, generic justification may not be sufficient. Individual justification by the radiological practitioner and the referring physician is then important and should take account of all the available information. This includes the details of the proposed procedure and of any alternatives, the characteristics of the individual patient, the expected dose to the patient, and the availability of information on previous or expected examinations or treatment.

5. THE OPTIMISATION OF PROTECTION

5.1. General Principles

(49) The optimisation of protection is the most powerful of the components of the system of radiological protection. It should pervade all stages of the use of radiation in medicine, from the design of premises, equipment, and procedures through to day-to-day applications. Its use starts from the encouragement of a way of thought with which any relevant task is approached. The underlying idea can be expressed as: "Are there any reasonable steps that I can take to improve protection?" In this context, 'reasonable' is sometimes replaced by 'reasonably practicable'. Clearly, much depends on the interpretation of 'reasonable'. The aim is to make the improvements unless they are shown to be too costly, or to complicate unduly the procedures to which they apply, or to reduce unduly the benefits of the procedure. As with justification, experience, professional judgement, and common sense play major roles in the procedures of optimisation, all of which are consistent with the good practice of medicine.

(50) The optimisation of protection is usually applied at two levels: (1) the design and construction of equipment and installations, and (2) the day-to-day methods of working, called here the working procedures. In non-medical applications, the design stage is usually the more important, because it reduces the dependence on human factors in the working procedures. In medicine, emphasis should also be placed on the optimisation of protection in the working procedures, because these have a direct influence on the care of patients.

(51) The basic aim of the optimisation of protection is to adjust the protection measures relating to the application of a source of radiation within a practice in such a way that the net benefit is maximised. As in the justification of a practice, many features of the application of a source influence the net benefit of that application but are outside the scope of radiological protection. These features include the management structure, financial provisions, and most aspects of building design and location.

(52) The concepts involved can be set out in simple terms, but their practical application can range from simple common sense to complex quantitative processes. In selecting the provisions for protection in relation to a source, there is always a choice of options. Some choices are between discrete options that can be adopted or not. For example, in radiography, use can be made of either an aluminium or a carbon fibre film cassette. Other choices are more quantitative, for example, the choice of thickness of a shield or of the duration of a fluoroscopic examination.

(53) The choice of the protection option directly alters the level of exposure of the patient, the staff, and sometimes the public. But the choice also alters the scale of resources applied to protection. These resources may be reflected directly in financial costs, but they may also involve less easily quantified social costs such as other health risks to staff or manufacturers. Common sense indicates that the change from one option to the next should, at least, provide a reduction in exposures that compensates for the extra use of resources. The use of this criterion means that protection options that progressively decrease the exposures should be considered in turn until the move to the next option could be achieved only with a deployment of resources that is seriously out of line with the consequent reduction of exposures. The protection can then be said to be optimised and the exposures to be as low as reasonably achievable (or as low as reasonably practicable), economic and social factors having been taken into account.

(54) One further complication is particularly relevant to medical practice: the choice of the protection option certainly influences the levels of exposure and the use of resources. In addition, it may sometimes influence the quality of the product or service provided by the source in question. For example, reducing the dose to the patient may reduce the quantity or quality of the information provided by fluoroscopy or radiography. The reduction in exposure must then be sufficient to offset both this loss of information *and* the extra resources implied by the move to the next option.

(55) Thus the optimisation of protection involves weighing up the relative importance of the exposures, the use of resources, and the quality of the final product. Clearly these features are not readily commensurate. A great deal of optimisation of protection is therefore done by a judgemental process and is sometimes almost intuitive. There are, however, several formal quantitative techniques for dealing with this type of judgement. They range from simple cost–benefit analysis to multi-attribute analysis with non-linear utility (preference) functions. A structured approach to these techniques has been described by the Commission in *ICRP Publication 55*, Optimization and Decision-Making in Radiological Protection (ICRP, 1989). In medicine, these structured techniques are needed mainly in the design of major equipment. The optimisation of protection in working procedures is more commonly based on qualitative common sense judgements.

(56) It is important not to let a formal approach to optimisation detract from the basic principle of doing what is reasonable to improve protection. For example, the optimum choice of the protection option may make unreasonable demands on the available resources, including funds. It would then be appropriate to accept a sub-optimum solution, because the optimum solution would be virtually unattainable. The optimisation of protection means the same as keeping the doses "as low as reasonably achievable, economic and social factors being taken into account".

(57) In the protection of the patient, the quantities used in the optimisation of protection sometimes relate to a single individual. However, some protective actions, particularly at the design stage and in the specification of routine procedures, affect the doses to many individuals and it becomes necessary to consider collective costs and benefits. When the cost of the detriment is derived from the collective dose, it is important to define the situation for which an optimum level of protection is being sought. For example, it would be wrong to aim at a reduction in the collective dose from radiology as a whole, because in many countries the aim should be to increase the amount of radiology available. The total collective dose might then, quite properly, increase with increased medical care. When optimisation is concerned with collective dose, it is the collective dose per unit of practice, e.g. of a defined type and number of examinations, that is relevant.

(58) If a practice seems to be unjustified initially, the optimisation of protection may be sufficient to make the net benefit positive and thus to make the practice justified. If a practice seems to be justified, applying the optimisation of protection (and taking account of all the relevant factors) can only increase the net benefit and can never cause the practice to become unjustified.

5.2. The Use of Constraints in Optimisation

(59) The optimisation of protection often involves the balancing of collective detriment and collective benefits. Used in isolation, this balancing may not adequately protect individuals. In particular, the benefits of the practice and the detriments of the exposures may be received by different individuals, thus introducing a degree of inequity. Unless the

detriment to individuals is at a low level, this balancing of benefits and detriments raises ethical problems. In earlier recommendations (ICRP, 1977), the Commission used the dose limit to provide the necessary extra protection for individuals. The source-related dose constraint was introduced in *Publication 60* to provide more flexibility. The dose constraint has the function of restricting the choice of the options considered in the optimisation of protection to those options that do not cause individual doses to exceed the dose constraint. A dose constraint is specific to the source, the work, and the situation for which the protection is to be optimised. It should be used prospectively and not as a form of subsidiary dose limit to be applied retrospectively.

(60) The constraint has the secondary function of ensuring that the sum of doses to an individual from the different practices to which he may be exposed does not exceed the dose limit.

(61) In the protection of the patient, the detriments and the benefits are received by the same individual, the patient, and the dose to the patient is determined principally by the medical needs. Dose constraints for patients are therefore inappropriate, in contrast to their importance in occupational and public exposure. Nevertheless, some limitation of diagnostic medical exposures is needed and the use of a diagnostic reference level is recommended in Section 8.4. In other medical exposures, such as the exposure of families and friends, and in the exposure of volunteers in biomedical research programmes that provide no direct benefit to the volunteers, dose constraints are needed to limit inequity and because there is no further protection in the form of a dose limit.

(62) The selection of the value of a constraint is discussed in *Publication 60*. It is often possible to reach conclusions about the level of individual doses likely to result from well-managed activities. This information can then be used to establish a dose constraint for similar activities. The class of activity should be specified in fairly broad terms, such as interventional radiology. It will usually be appropriate for dose constraints to be fixed at the national or local level.

5.3. The Optimisation of Protection in Medical Exposure

(63) Because most procedures causing medical exposures are clearly justified and because the procedures are usually for the direct benefit of the exposed individual, somewhat less attention has been given to the optimisation of protection in medical exposure than in other applications of radiation sources. In addition to the procedures of justification, there is considerable scope for dose reductions in diagnostic radiology. Simple, low-cost measures are available for reducing doses without loss of diagnostic information, but the extent to which these measures are used varies widely.

(64) The optimisation of protection in medical exposures does not necessarily mean the reduction of doses to the patient. For example, diagnostic radiographic equipment often uses antiscatter grids to improve the contrast and resolution of the image, yet removing the grid would allow a reduction in dose by a factor of 2–4. For radiography of the abdomen of adults, where the scattered radiation is important, the net benefit would be reduced by removing the grid because the benefit of the dose reduction would be more than offset by the loss of quality of the image. The optimisation of protection would not call for the removal of the grid. In the radiography of small children, the amount of scattered radiation is less and the benefit of the dose reduction resulting from the removal of the grid is not fully offset by the small deterioration of the image. The optimisation of protection then calls for the reduction in dose allowed by the removal of the grid.

(65) It is difficult to make a quantitative balance between loss of diagnostic information and reduction of dose to the patient. It is sometimes easier to use a diagnostic performance criterion and to reduce doses to the point where the criterion is only just achieved. This cut-off approach is not the best method of optimising protection, because it ignores the degradation of diagnostic information until the point where this degradation is close to becoming unacceptable.

(66) In radiotherapy, it is necessary to differentiate between the dose to the target tissue and the dose to other parts of the body. If the dose to the target tissue is too small, the therapy will be ineffective. The exposures will not have been justified and the optimisation of protection does not arise. In therapy, the protection of tissues outside the target volume is an integral part of dose planning, which can be regarded as including the same aims as the optimisation of protection.

(67) The exposure (other than occupational) of individuals helping to support and comfort patients is also medical exposure. This definition includes the exposures of families and friends of patients discharged from hospital after diagnostic or therapeutic nuclear medicine procedures. The procedure of optimisation of protection for these groups is no different from that for public exposure, except that the exposures need not be restricted by dose limits. The optimisation procedure should, however, include dose constraints (see Section 8.3). The exposure of volunteers in biomedical research is also dealt with in Section 8.3.

5.4. The Optimisation of Protection in Occupational Exposure

(68) In many situations, it will be sufficient to optimise protection in the occupational exposure of medical and supporting staff in the same way as in any other type of employment. However, some restrictions on the protection options may have to be applied when the protection arrangements would restrict the care given to patients. For example, the exclusion of workers from high dose areas can still be achieved, but it may be necessary for the patient to remain in sight, which may limit the materials available for some of the shielding. To avoid oppressive isolation of patients, access to teletherapy equipment will often be through a gated maze rather than an interlocked door. These limitations should be kept in mind, but should not seriously prejudice the level of protection.

(69) Brachytherapy without a system for after-loading sources presents serious problems of dose limitation for nursing staff. The optimisation of protection will usually indicate a case for after-loading.

(70) The use of dose constraints will depend heavily on the organisation of staff. The constraints used in the optimisation of protection for those who work only, or predominantly, in X-ray diagnosis, can be low. Higher values may be appropriate for the protection of brachytherapy nurses. In selecting constraints, attention will have to be paid to employees who move between several types of work during a year.

6. INDIVIDUAL DOSE LIMITS

(71) Individual dose limits have been set by the Commission for occupational and public exposure so that a continued exposure just above the dose limits would result in additional risks from the relevant practices that could reasonably be described as 'unacceptable' in normal circumstances. It is implicit in the definition of a practice that its adoption and continued use are matters of choice.

(72) Provided that the doses to patients have been properly justified, it is not appropriate to apply dose limits to medical exposures, because such limits would often do more harm than good. They would sometimes prevent diagnostic information from being obtained and would prevent all radiotherapy. Furthermore, the benefits and detriments from medical exposures apply to the same individual, the patient; there is no inequity (see also Section 8.3).

(73) Dose limits do apply to occupational and public exposures from medical procedures, although, in most situations, the use of the optimisation of protection now makes them of limited relevance.

(74) The dose limits recommended by the Commission are given in Table 3. In short, the limit for effective dose in occupational exposure is 20 mSv in a year, with the flexibility to go to 50 mSv in a single year provided that the total effective dose in 5 consecutive years does not exceed 100 mSv, an average annual dose of 20 mSv. Additional limits apply to the lens of the eye (150 mSv in a year), the skin (500 mSv in a year), and the hands and feet (500 mSv in a year), because these tissues may not be adequately protected by the limit on effective dose. For public exposure, the dose limit is expressed as an annual limit of 1 mSv in a year, with 5-year averaging available in 'special circumstances'.

(75) No special restrictions need to be applied to the exposure of individuals merely because their doses have exceeded a dose limit. Such events should call for a thorough examination, usually by the regulatory authority, of the design and operational aspects of protection in the installation concerned, rather than for restrictions or penalties applied to an exposed individual. If the dose is unknown and is thought to be high, referral to a physician would be appropriate.

Table 3. Recommended dose limits[a]

Application	Dose limit	
	Occupational	Public
Effective dose	20 mSv per year, averaged over defined periods of 5 years[b]	1 mSv in a year[c]
Annual equivalent dose in		
lens of the eye	150 mSv	15 mSv
skin[d]	500 mSv	50 mSv
hands and feet	500 mSv	—

[a] The limits apply to the sum of the relevant doses from external exposure in the specified period and the 50-year committed dose (to age 70 years for children) from intakes in the same period.

[b] With the further provision that the effective dose should not exceed 50 mSv in any single year. Additional restrictions apply to the occupational exposure of pregnant women.

[c] In special circumstances, a higher value of effective dose could be allowed in a single year, provided that the average over 5 years does not exceed 1 mSv per year.

[d] The limitation on the effective dose provides sufficient protection for the skin against stochastic effects. An additional limit is needed for localised exposures in order to prevent deterministic effects

(76) The adoption of a rigid dose limit for the conceptus of a pregnant woman who is occupationally exposed would pose practical problems. The early part of a pregnancy is covered by the normal protection of workers, which is essentially the same for males and females. Once the pregnancy has been declared, and notified to the employer, additional protection of the conceptus should be considered. The Commission considers that its existing advice has sometimes been interpreted too rigidly. It now recommends that the working conditions of a pregnant worker, after the declaration of pregnancy, should be such as to make it unlikely that the additional equivalent dose to the conceptus will exceed about 1 mSv during the remainder of the pregnancy. In the interpretation of this recommendation, it is important not to create unnecessary discrimination against pregnant women.

(77) The Commission wishes to re-emphasise its view that "the use of its system of protection, particularly the use of source-related dose constraints, will usually provide an adequate guarantee of compliance (with this recommendation), without the need for specific restrictions on the employment of pregnant women".

7. RADIATION PROTECTION BY INTERVENTION

(78) Intervention is the term applied to the remedial actions taken to reduce doses, or their consequences, resulting from an accident or from the misuse of a radiation source. Intervention is indicated only when the remedial actions are expected to do more good than harm. The decision to intervene should be influenced by the reduction achievable of the doses or consequences. Action to reduce the probability of subsequent accidents is important, but it is not part of intervention.

(79) In medicine, such intervention is appropriate only for radioactive materials. Accidents and errors may occur with X-ray generators and accelerators, but the termination of the exposures is easy and does not constitute intervention. In fractionated radiotherapy, an error in an early fraction can be partly corrected by adjusting further fractions, but this is best thought of as part of dose planning rather than as intervention.

(80) Several examples of intervention in medicine are listed here.

(a) The dose from an excessive or erroneous administration of radioiodine may be reduced by the early administration of stable iodine as potassium iodide or iodate to reduce the uptake of radioiodine by the thyroid.

(b) The dose from a missing brachytherapy source can be reduced by measures to locate the source and warnings to those who may be exposed.

(c) The dose from a major spill of radioactive materials in nuclear medicine may be reduced by the early isolation of the contaminated area and by the controlled evacuation of staff and patients.

(d) The doses resulting from the improper disposal and subsequent damage or mishandling of a teletherapy source may be both serious and widespread. Major countermeasures in the public domain may have to include evacuation, destruction of property, and decontamination of substantial areas. A widespread monitoring programme will be indispensable. Guidance on the levels of averted dose that would justify such intervention is given in *ICRP Publication 63* (ICRP, 1991c).

(81) The decision to intervene in all these situations is based on the same approach as in any work with radioactive materials. Most of the actions, e.g. those following a major spill of radioactive materials, should be specified in the emergency plans and should be initiated immediately, without reference to formal intervention levels.

(82) In common with other workplaces, hospitals and similar medical premises in radon-prone areas may have high concentrations of radon, usually in the rooms on the lower floors. Guidance on possible remedial measures is given by the Commission in *ICRP Publication 65* (ICRP, 1993). Radon concentrations above which intervention should be considered should be established by national authorities.

8. PRACTICAL METHODS OF PROTECTION

(83) This section deals with the principal methods of protection applicable to occupational and public exposures in the use of radiation in medicine. It does not deal in detail with protection of the patient because this is usually specific to an individual branch of medicine, such as X-ray radiography or nuclear medicine. The Commission intends to deal with protection in these branches in more detail in later reports.

8.1. Occupational Exposure

(84) The control of occupational exposure in medicine can be simplified and made more effective by the designation of workplaces into two types: controlled areas and supervised areas. In a **controlled area**, normal working conditions, including the possible occurrence of minor mishaps, require workers to follow well-established procedures and practices aimed specifically at controlling radiation exposures. A **supervised area** is one in which the working conditions are kept under review, but special procedures are not normally needed. The definitions are best based on operational experience and judgement. In areas where there is no problem of contamination by unsealed radioactive materials, designated areas may sometimes be defined in terms of the dose rate at the boundary. The use of mobile sources calls for some flexibility in the definition of designated areas.

(85) Signs at the entrances to controlled areas should be used to indicate to employees, especially to maintenance staff, that special procedures apply in the area and that radiation sources are likely to be present. The conditions in supervised areas should be such that any employee should be able to enter with a minimum of formality.

(86) Outside these designated areas, the dose rates from sources and the risk of contamination by unsealed radioactive material should be low enough to ensure that, in normal conditions, the level of protection for those who work in the premises will be comparable with the level of protection required in public exposure. The exposures of these workers, though small, are still occupational exposures.

(87) One difficult decision in all occupational exposure is the selection of workers who should be individually monitored. Three major factors should influence the decision: (1) the expected level of dose or intake in relation to the relevant limits, (2) the likely variations in the doses and intakes, and (3) the complexity of the measurement and interpretation procedures comprising the monitoring programme. This third factor results in an approach to the monitoring for external exposure that is different from that for intakes of radioactive materials. Individual monitoring for external radiation is fairly simple and does not require a heavy commitment of resources. In medicine, it should be used for all those who work in controlled areas. It should be considered for those who work regularly in supervised areas unless it is clear that their doses will be consistently low. Monitoring for internal exposure is much more complex and should be used routinely only for workers who work regularly in areas that are designated as controlled areas specifically in relation to the control of contamination and in which there are grounds for expecting significant intakes. Guidance on individual monitoring for intakes is given in *ICRP Publication 54* (ICRP, 1988).

(88) In addition to its primary function of providing information for the control of exposures, a programme of individual monitoring may be helpful in confirming the

classification of workplaces and in detecting fluctuations in working conditions. It gives useful reassurance and may provide data of use in reviewing optimisation programmes.

(89) In several areas of medicine the control of occupational exposures is of particular importance. One of these is the nursing of brachytherapy patients when the sources have been implanted, rather than inserted by after-loading techniques. A second is palpation of patients during fluoroscopy. A third is interventional radiology, as in heart catheterisation. In all these procedures, careful shielding and limitation of time are needed. Individual monitoring with careful scrutiny of the results is also important. In brachytherapy, the frequent and careful accounting for sources is essential.

8.2. Public Exposure

(90) Public access to hospitals and to radiology rooms is not unrestricted, but it is more open than is common in industrial operations. There are no radiological protection grounds for imposing restrictions on the public access to non-designated areas. Because of the limited duration of public access, a similar policy can be adopted for supervised areas if this is of benefit to patients or visitors. Public access to controlled areas, especially to brachytherapy and nuclear medicine areas, should be limited to patients' visitors, who should be advised of any restrictions on their behaviour.

(91) Some public exposure may be caused by wastes from nuclear medicine departments. The implications of discharges to sewers and of airborne effluents from incinerators should be assessed. Restrictions should be placed on the activity permitted for disposal by these routes and on the disposal of solid wastes.

(92) The adventitious exposure of members of the public in waiting rooms and public transport is not high enough to require special restrictions on the movement of nuclear medicine patients, except for those being treated for cancer (see also Section 8.3).

8.3. Exposure of Volunteers

(93) The use of volunteers in biomedical research makes a substantial contribution to medicine and to human radiobiology. Some of the research studies are of direct value in the investigation of disease, others provide information on the metabolism of pharmaceuticals and of radioelements that may be absorbed from contamination of the workplace or the environment. Not all these studies take place in medical institutions, but the Commission treats the exposure of all volunteers as if it were medical exposure.

(94) The ethical and procedural aspects of the use of volunteers in biomedical research have been addressed by the Commission in *ICRP Publication 62* (ICRP, 1991b). The key aspects include the need to guarantee a free and informed choice by the volunteers, the adoption of dose constraints linked to the social worth of the studies, and the use of an ethics committee that can influence the design and conduct of the studies. It is important that the ethics committee should have easy access to radiation protection advice.

(95) Friends and relations helping in the support and comfort of patients are also volunteers, but there is a direct benefit both to the patients and to those who care for them. Their exposures are defined as medical exposure, but dose constraints should be established for use in defining the protection policy both for visitors to patients and for families at home when nuclear medicine patients are discharged from hospital. Such groups may include children. The Commission has not recommended values for such constraints, but a value in the region of a few millisieverts per episode is likely to be reasonable. This constraint is not to

be used rigidly. For example, higher doses may well be appropriate for the parents of very sick children.

8.4. Operational Guides and Reference Levels

(96) Many of the decisions in radiological protection can be standardised, so that it is not necessary to repeat the process of assessment and decision-making on each occasion. The simplest way of achieving this is to use the basic policies to create a series of values of measurable or assessable quantities that can be used as surrogates for the full assessment.

(97) Operational guides are statements of managerial policy addressed to employees and to the designers of equipment and premises. They are often expressed as annual doses, within which the management wishes to operate. They are neither limits nor targets, and they should be supplemented by an overriding requirement to do better, whenever that is reasonably achievable.

(98) Reference levels are values of measured quantities above which some specified action or decision should be taken. They include recording levels, above which a result should be recorded, lower values being ignored; investigation levels, above which the cause or the implications of the result should be examined; intervention levels, above which some remedial action should be considered; and, more generally, action levels, above which some specified action should be taken. The use of these levels can avoid unnecessary or unproductive work and can help in the effective deployment of resources. They can also be helpful in radiation protection by drawing attention to situations of potentially high risk.

(99) One particular form of reference level applies to diagnostic radiography and diagnostic nuclear medicine. In *Publication 60*, the Commission recommended that consideration should be given to the use of dose constraints, or investigation levels, selected by the appropriate professional organisation or regulatory authority, for application in some common diagnostic procedures. They should be applied with flexibility, to allow higher doses where indicated by sound clinical judgement. This recommendation now needs expressing in more detail.

(100) The Commission now recommends the use of **diagnostic reference levels** for patients. These levels, which are a form of investigation level, apply to an easily measured quantity, usually the absorbed dose in air, or in a tissue-equivalent material at the surface of a simple standard phantom or representative patient. In nuclear medicine, the quanity will usually be the administered activity. In both cases, the diagnostic reference level will be intended for use as a simple test for identifying situations where the levels of patient dose or administered activity are unusually high. If it is found that procedures are consistently causing the relevant diagnostic reference level to be exceeded, there should be a local review of the procedures and the equipment in order to determine whether the protection has been adequately optimised. If not, measures aimed at reduction of the doses should be taken.

(101) Diagnostic reference levels are supplements to professional judgement and do not provide a dividing line between good and bad medicine. It is inappropriate to use them for regulatory or commercial purposes.

(102) Diagnostic reference levels apply to medical exposure, not to occupational and public exposure. Thus, they have no link to dose limits or constraints. Ideally, they should be the result of a generic optimisation of protection. In practice, this is unrealistically difficult and it is simpler to choose the initial values as a percentile point on the observed distribution of doses to patients. The values should be selected by professional medical bodies and reviewed at intervals that represent a compromise between the necessary stability and the

long-term changes in the observed dose distributions. The selected values will be specific to a country or region.

(103) In principle, it might be possible to choose a lower reference level below which the doses would be too low to provide a sufficiently good image quality. However, such reference levels are very difficult to set, because factors other than dose also influence image quality. Nevertheless, if the observed doses or administered activities are consistently well below the diagnostic reference level, there should be a local review of the quality of the images obtained.

(104) Diagnostic reference levels should be related only to common types of diagnostic examination and to broadly defined types of equipment. The levels are not intended to be used in a precise manner and a multiplicity of levels will reduce their usefulness.

(105) Reference levels for therapeutic procedures are not appropriate. The doses to the target tissues are chosen for each individual patient as part of the dose-planning procedures and must be large enough to be effective.

(106) The multiplicity of circumstances in which reference levels are used, and their relationships with dose limits and dose constraints, sometimes lead to confusion. The summary in Table 4 may be helpful.

Table 4. The characteristics of limits, constraints and reference levels

Quantity	Characteristic
Restrictions	
Dose limit	Set by national authority, mandatory, applies to occupational and public exposure, not to medical exposure (doses to patients)
Dose constraint	Integral part of the optimisation of protection, to be used only prospectively, set by national authority or operating management, applies in occupational and public exposure and to volunteers in biomedical research and in non-occupational care of patients
Reference Levels	
Diagnostic reference level	Set by professional bodies, advisory, applies to dose to patients or intake of pharmaceutical, calls for local review if consistently exceeded
Recording level	Set by operating management or national authority, allows records to exclude trivial information, advisory but should be applied consistently, applies principally to occupational exposure with particular reference to monitoring of individuals and workplaces
Investigation level	Set by operating management, calls for local investigation (often very simple) if exceeded, applies mainly to occupational exposure
Intervention level	Set by national authority, applies in public exposure to the dose that can be averted by a specified countermeasure, often mandatory
Action level	Any level calling for specified action, used particularly in decisions to initiate intervention and then refers to a measurable quantity (e.g. dose rate or activity concentration) above which the relevant countermeasure is likely to achieve a reduction in dose greater than the intervention level

9. ACCIDENTS AND EMERGENCIES

(107) Not all exposures occur as forecast. There may be an accidental exposure owing to failure of equipment, human mistakes, external events such as fires, or a combination of all three. Prior to the event, there is a potential for exposure, but no certainty that it will occur. These exposures, which have an annual probability of occurrence of less than one, are called potential exposures to distinguish them from the exposures resulting from normal operations, which include the occurrence of the inevitable minor mishaps (see also Section 3). Although such events can be anticipated by a safety analysis (an analysis that provides estimates of the probabilities of failures and their consequences), their details and the time of occurrence cannot be predicted. Nevertheless, it is often possible to apply some degree of control to both the probability and the magnitude of potential exposures. At this stage, there should be two objectives, prevention and mitigation. Prevention is the reduction of the probability of the sequences of events that may cause or increase radiation exposures. Mitigation is the limitation and reduction of the exposures if any of these sequences do occur.

(108) The formal definition of potential exposure requires the statement of the probability of the event causing a dose, the specification of the type of harm associated with that dose, and the conditional probability of occurrence of that harm given that the dose has occurred. These components can be aggregated to give the overall probability that the harm will occur to the individual at risk. This aggregation is of limited utility because the probability can be assessed only by a safety assessment. The estimate of the magnitude of the probability can never be confirmed. Furthermore, the situation changes if the dose actually occurs. Unless the dose is small, the magnitude and thus the consequences of the dose will become the main issues. The fact that the event was improbable will no longer be of interest.

(109) These complications limit the quantitative use of potential exposure. In medicine, it will often be sufficient to take all reasonable steps to reduce the probability and magnitude of accidental and unintended doses, without the formal use of potential exposure.

9.1. Accident Prevention

(110) Accident prevention should be an integral part of the design of equipment and premises and of the working procedures. It should not be thought of as an extra feature to be provided as an afterthought.

(111) A key feature of accident prevention has long been the use of multiple safeguards against the consequences of failures. This approach, now often called 'defence in depth', by analogy with military strategy, is aimed at preventing a single failure from having serious consequences. Some defences are provided by the design of equipment, others by the working procedures.

(112) Although the main emphasis in accident prevention should be on the equipment and procedures in therapy, some attention should be paid to accidents with diagnostic equipment.

(113) Therapy equipment should be designed to reduce operator errors by automatically rejecting demands outside the design specification or by questioning the validity of the instruction. Enclosures should be designed to exclude staff during exposures, without unduly isolating the patient.

(114) Therapy equipment should be calibrated after installation and after any modification and should be routinely checked by a standard test procedure that will detect significant changes in performance.

(115) Working procedures should require key decisions, especially in radiotherapy, to be subject to independent confirmation. The patient's identity and the correct link to the prescribed treatment should be double-checked. In therapeutic nuclear medicine, dual checks should be made on the correctness of the pharmaceutical and its activity.

(116) Radioactive sources used for therapy can cause very serious exposures if they are mislaid or misused. Brachytherapy sources should be subject to frequent and thorough accounting checks and provision should be made for their eventual disposal. The possible presence of implanted sources or therapeutic activities of radiopharmaceuticals should be taken into account in the handling of deceased patients.

9.2. Emergency Plans and the Mitigation of Consequences

(117) Despite precautions, accidents are an inevitable feature of human activities. Emergency plans are essential. The radiological protection aspects should be an integral part of the general accident plans of the institution. The design of the plans should depend on the results of a critical examination of the faults that might lead to accidents and the possible form and severity of such accidents. Very few accidents are unprecedented, and a review of past events will go far in helping in the design of emergency procedures.

(118) Emergency plans should provide for the mitigation of the consequences of accidents. They should be clearly set out and regularly exercised. The aims of these plans should be made clear to those to whom they apply.

10. INSTITUTIONAL ARRANGEMENTS

(119) Radiological protection and, more generally, the achievement of a high standard of safety depend critically on the performance of people. The institutional arrangements can greatly influence that performance. These arrangements differ widely between countries and between different types of installation within countries. Only general guidance can be given here.

10.1. Responsibility and Authority

(120) The primary responsibility for achieving and maintaining a satisfactory control of radiation exposures rests directly on the management bodies of the operating institutions. In hospitals, and sometimes in private medical premises, there may be a dual management system with the medical staff carrying the responsibility for their patients and the administration carrying responsibility for the general running and financing of the institution. Since responsibility can be exercised only by those who have the authority to act, it is essential to establish clear-cut lines of responsibility for conducting the procedures giving rise to radiation exposures. In particular, it is important to clarify the separate responsibilities of the referring physicians who request radiological procedures, the radiologists who undertake the procedures, and the administrators who provide the resources.

(121) Governments have the responsibility for establishing, or recognising, agencies to provide a national framework of medical policy, including the policies for radiological protection. National authorities may also have to take direct responsibility for operations when, as following a serious accident causing environmental contamination, there is no relevant management body. Regulatory and advisory bodies are responsible for their requirements and advice, but this does not detract from the responsibilities of the operating managements.

(122) In all organisations, the responsibilities and the associated authority are delegated to an extent depending on the complexity of the duties involved. The working of this delegation should be examined regularly. There should be a clear line of retrospective accountability running right to the top of each organisation. The delegation of responsibilities does not detract from that accountability.

10.2. Management Requirements

(123) Requirements, operating instructions, regulatory instruments, and other administrative devices are important, but they are not, of themselves, enough to achieve an appropriate standard of radiological protection and safety. Everyone in an undertaking, from the individual workers and their representatives to the senior management, should regard protection and accident prevention as integral parts of their everyday functions. In recent years, these attitudes have become known as a safety culture.

(124) A safety culture is very important, but it is not self-sustaining. Without continuing regeneration by management action, it ceases to be effective. In medicine, a safety culture may be undermined by a tradition that the benefit to the patient justifies overriding the protection of the medical staff. In terms of radiological protection, this tradition is now rarely

valid. There are few situations in which the protection of the staff needs to be prejudiced by the needs of the patient.

(125) The safety culture should be reinforced by the issuing of clear operating instructions and by the creation of a formal management structure for dealing with radiological protection, including the optimisation of protection. These instructions should take account of any requirements applied to the design of the equipment and of the installation as a whole, and should cover subsidiary operations such as inspection and maintenance. If appropriate, the management structure should include a radiation safety committee to give advice on the radiological protection arrangements. The details of the management structure and of the operating instructions will depend on the form and scale of the operating organisation, but their importance should be recognised even in small or informal organisations.

(126) The management structure should include the provision of an occupational service for protection and health. In a large institution this service may be an integral part of the organisation. In small units, it can be provided by outside contractors. The service should provide specialist advice on protection matters and arrange any necessary monitoring provisions. The service should provide conventional occupational health surveillance aimed at judging the fitness of workers for their tasks. It is now very rare for the radiation component of the working environment to have any significant influence on that judgement. The level of health surveillance should therefore not be determined by the occupational radiation exposures, unless this is a national requirement.

(127) Provision should be made for the medical counselling of workers who become concerned about the radiation safety of their work. These may include women workers who are, or may be, pregnant and volunteers who are deliberately exposed in radiobiological research programmes. Provision should also be made for giving any necessary advice to families when patients are discharged after nuclear medicine procedures.

10.3. Education and Training

(128) One important need is to provide adequate resources for the education and training in radiological protection for future professional and technical staff in medical practice. The training programme should include initial training for all incoming staff and regular updating and retraining.

10.4. Compliance with the Intended Standard of Protection

(129) All the organisations concerned with radiological protection should have a duty to verify their compliance with their own objectives and procedures. They should establish a system for reviewing their organisational structures and their procedures, a function analogous to financial auditing. All these verification procedures should involve the radiation safety committee and should include consideration of potential exposures by a review of the safety provisions. Verification procedures should include quality assurance programmes and some form of inspection.

(130) Quality assurance programmes are essential for maintaining the intended standards in all the functions of the undertaking. Their scope should specifically include radiological protection and safety.

(131) Standardisation can also play a major role in maintaining an adequate level of protection. It is often better to use a familiar standardised procedure than to introduce

temporary modifications to give minor improvements. The introduction of frequent changes of procedure is likely to lead to errors.

(132) Any system of verification includes record-keeping. The requirements for recording occupational exposures will usually be determined by the regulatory authorities. Diagnostic exposures rarely need to be measured, but if they are, records should be kept of any comparisons with diagnostic reference levels. In radiotherapy, the data from dose planning, administered activity (in nuclear medicine), and, for therapy patients, the activity at the time of discharge should be included in the patients' records.

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ANNEX A. SUMMARY OF THE 1990 RECOMMENDATIONS

This Annex comprises the Summary of Recommendations in *ICRP Publication 60* and contains the principal recommendations and new concepts in *Publication 60*. It excludes the tables from that Summary, all of which have been included or summarised in the main text of this report.

Introduction

(S1) The Recommendations are intended to be of help to regulatory and advisory agencies and to management bodies and their professional staff. They deal only with ionising radiation and with the protection of man. The Commission emphasises that ionising radiation needs to be treated with care rather than fear and that its risks should be kept in perspective with other risks. Radiological protection cannot be conducted on the basis of scientific considerations alone. All those concerned have to make value judgements about the relative importance of different kinds of risk and about the balancing of risks and benefits.

Quantities used in Radiological Protection

(S2) The Commission uses macroscopic dosimetric quantities while recognising that microdosimetric quantities based on the statistical distribution of events in a small volume of material may eventually be more appropriate. The principal dosimetric quantities in radiological protection are the mean absorbed dose in a tissue or organ, D_T, the energy absorbed per unit mass; the equivalent dose in a tissue or organ, H_T, formed by weighting the absorbed dose by the radiation weighting factor, w_R; and the effective dose, E, formed by weighting the equivalent dose by the tissue weighting factor, w_T, and summing over the tissues. The time integral of the effective-dose rate following an intake of a radionuclide is called the committed effective dose, $E(<?)$, where $<?$ is the integration time (in years) following the intake. The unit of absorbed dose is the gray (Gy), and the unit of both equivalent and effective dose is the sievert (Sv). The values of the radiation and tissue weighting factors are given in Section 2 of the main text of this report (see paragraphs 14 and 26).

(S3) Another useful quantity is the collective effective dose, which is the product of the mean effective dose in a group and the number of individuals in that group. With some reservations, it can be thought of as representing the total consequences of the exposure of a population or group.

(S4) The Commission uses 'dose' as a generic term that can apply to any of the relevant dosimetric quantities. The Commission also uses the term **'exposure'** in a generic sense to mean the process of being exposed to radiation or radioactive material. The significance of an exposure in this sense is determined by the resulting doses.

Biological Aspects of Radiological Protection

(S5) Ionising radiation causes both deterministic and stochastic effects in irradiated tissue. Radiological protection aims at avoiding deterministic effects by setting dose limits below

their thresholds. Stochastic effects are believed to occur, albeit with low frequency, even at the lowest doses and therefore have been taken into account at all doses.

(S6) Deterministic effects result from the killing of cells, which, if the dose is large enough, causes sufficient cell loss to impair the function of the tissue. The probability of causing such harm will be zero at small doses, but above some level of dose (the threshold for clinical effect) the probability will increase steeply to unity (100%). Above the threshold, the severity of the harm will increase with dose. Thresholds for these effects are often at doses of a few Gy or dose rates of a fraction of a Gy per year.

(S7) An important observation in children exposed *in utero* during a critical 8–15 week period at Hiroshima and Nagasaki is a downward shift in the distribution of IQ with increasing dose, which can result, after higher doses, in an increase in the probability of severe mental retardation. The effect is presumed to be deterministic with a threshold related to the minimum shift in IQ that can be recognised.

(S8) Stochastic effects may result when an irradiated cell is modified rather than killed. Modified somatic cells may, after a prolonged delay, subsequently develop into a cancer. There are repair and defence mechanisms that make this a very improbable outcome. Nevertheless, the probability of a cancer resulting from radiation increases with increments of dose, probably with no threshold. The severity of the cancer is not affected by the dose. If the damage occurs in a cell whose function is to transmit genetic information to later generations, any resulting effects, which may be of many different kinds and severity, are expressed in the progeny of the exposed person. This type of stochastic effect is called 'hereditary'.

(S9) The Commission has estimated the probability of a fatal cancer by relying mainly on studies of the Japanese survivors of the atomic bombs and their assessment by bodies such as UNSCEAR and BEIR. These committees have estimated the lifetime cancer risk by considering the accumulated data to 1985, the new dosimetry (DS86) and projection to lifetime by a multiplicative or modified multiplicative model, for high dose, high dose rate exposure. The Commission has concluded, after reviewing the available experimental information on dose response relationships and the influence of dose and dose rate, that the most probable response is linear quadratic in form for low LET radiation. The linear coefficient at low doses or low dose rates is obtained from the high dose, high dose rate estimates of risk by dividing by a DDREF (dose and dose rate effectiveness factor) of 2. The nominal fatal cancer probabilities for a working population and for a general population, which differ somewhat because of the greater sensitivity of young people, are given in Table S-3 [omitted, see Table 2 of the main text]. The Commission has made its own estimates of how this fatal cancer risk is distributed among organs and the length of life lost for cancer in each of these organs, by further analysis of the data on the atomic bomb survivors.

(S10) The estimates of severe hereditary effects are also based on the assessments of UNSCEAR and BEIR of experimental data on genetic effects in animals. Evidence suggests that these estimates are not less than the corresponding effects in man. For low doses and low dose rates, the probability coefficient for severe hereditary effects in all generations (resulting about equally from dominant and X-linked mutations on the one hand, and multifactorial diseases weighted for severity on the other) are given for both a working population and a general population in Table S-3 [omitted, see Table 2 of the main text].

(S11) The Commission uses the term detriment to represent the combination of the probability of occurrence of a harmful health effect and a judgement of the severity of that effect. The many aspects of detriment make it undesirable to select a single quantity to represent the detriment and the Commission has therefore adopted a multi-dimensional concept. The principal components of detriment are the following stochastic quantities: the

probability of attributable fatal cancer, the weighted probability of attributable non-fatal cancer, the weighted probability of severe hereditary effects and the length of life lost if the harm occurs. The values of this aggregated detriment at low dose for both a working population and a general population are also given in Table S-3 [omitted, see Table 2 of the main text].

(S12) The Commission has also assessed the distribution of the detriment in organs and tissues by considering first the fatal cancer probability in each of them, multiplying by an appropriate factor for non-fatal cancer (which is determined by the severity (lethality factor) for that cancer), adding in the probability of severe hereditary effects and adjusting for the relative length of life lost. This distribution of aggregate detriment among organs is represented, after appropriate rounding, by the tissue weighting factors, w_T, given in Table S-2 [omitted, see paragraph 26 of the main text].

(S13) The effective dose is the sum of the weighted equivalent doses in all the tissues and organs of the body. It is given by the expression

$$E = \sum_T w_T . H_T$$

where H_T is the equivalent dose in tissue or organ, T, and w_T is the weighting factor for tissue T. The effective dose can also be expressed as the sum of the doubly weighted absorbed dose in all the tissues and organs of the body.

The Conceptual Framework of Radiological Protection

(S14) A system of radiological protection should aim to do more good than harm, should call for protection arrangements that maximise the net benefit, and should aim to limit the inequity that may arise from a conflict of interest between individuals and society as a whole.

(S15) Some human activities increase the overall exposure to radiation. The Commission calls these human activities "practices". Other human activities can decrease the overall exposure by influencing the existing causes of exposure. The Commission describes these activities as "intervention".

(S16) The Commission uses a division into three types of exposure: occupational exposure, which is the exposure incurred at work, and principally as a result of work; medical exposure, which is principally the exposure of persons as part of their diagnosis or treatment; and public exposure, which comprises all other exposures.

(S17) In practices and in intervention, it will often be virtually certain that exposures will occur and their magnitude will be predictable, albeit with some degree of error. Sometimes, however, there will be a potential for exposure, but no certainty that it will occur. The Commission calls such exposures "potential exposures".

The system of protection in practices

(S18) The system of radiological protection recommended by the Commission for proposed and continuing practices is based on the following general principles.

(a) No practice involving exposures to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes. (The justification of a practice.)
(b) In relation to any particular source within a practice, the magnitude of individual doses, the number of people exposed, and the likelihood of incurring exposures where

these are not certain to be received should all be kept as low as reasonably achievable, economic and social factors being taken into account. This procedure should be constrained by restrictions on the doses to individuals (dose constraints), or the risks to individuals in the case of potential exposures (risk constraints), so as to limit the inequity likely to result from the inherent economic and social judgements. (The optimisation of protection.)

(c) The exposure of individuals resulting from the combination of all the relevant practices should be subject to dose limits, or to some control of risk in the case of potential exposures. These are aimed at ensuring that no individual is exposed to radiation risks that are judged to be unacceptable from these practices in any normal circumstances. Not all sources are susceptible to control by action at the source and it is necessary to specify the sources to be included as relevant before selecting a dose limit. (Individual dose and risk limits.)

The system of protection in intervention

(S19) The system of radiological protection recommended by the Commission for intervention is based on the following general principles.

(a) The proposed intervention should do more good than harm, i.e. the reduction in detriment resulting from the reduction in dose should be sufficient to justify the harm and the costs, including social costs, of the intervention.

(b) The form, scale, and duration of the intervention should be optimised so that the net benefit of the reduction of dose, i.e. the benefit of the reduction in radiation detriment, less the detriment associated with the intervention, should be maximised.

Dose limits do not apply in the case of intervention. Principles (a) and (b) can lead to intervention levels which give guidance to the situations in which intervention is appropriate. There will be some level of projected dose above which, because of serious deterministic effects, intervention will almost always be justified.

(S20) Any system of protection should include an overall assessment of its effectiveness in practice. This should be based on the distribution of doses achieved and on an appraisal of the steps taken to limit the probability of potential exposures. It is important that the basic principles should be treated as a coherent system. No one part should be taken in isolation.

The Control of Occupational Exposure

Dose constraints

(S21) An important feature of optimisation is the choice of dose constraints, the source-related values of individual dose used to limit the range of options considered in the procedure of optimisation. For many types of occupation, it is possible to reach conclusions about the level of individual doses likely to be incurred in well-managed operations. This information can then be used to establish a dose constraint for that type of occupation. The class of occupation should be specified in fairly broad terms, such as work in X-ray diagnostic departments, the routine operation of nuclear plant, or the inspection and maintenance of nuclear plant. Limits prescribed by regulatory agencies and restrictions applied by managements to specific operations as part of the day-to-day control of exposures are not constraints in the sense used here. In general, they should be established on the basis

of the results of optimisation. It will usually be appropriate for dose constraints to be fixed at the national or local level.

Dose limits

(S22) The dose limits for application in occupational exposure are summarised in Table S-4 [omitted, see Table 3 of the main text].

(S23) Dose limits are needed as part of the control of occupational exposure, both to impose a limit on the choice of dose constraints and to provide a protection against errors of judgement in the application of optimisation.

(S24) In setting dose limits, the Commission's aim is to establish, for a defined set of practices, and for regular and continued exposure, a level of dose above which the consequences for the individual would be widely regarded as unacceptable. In the past, the Commission has used the attributable probability of death or severe hereditary disorders as the basis for judging the consequences of an exposure. This quantity is still a major factor, but is no longer regarded by the Commission as sufficient to describe the detriment.

(S25) The Commission recommends a limit on effective dose of 20 mSv per year, averaged over 5 years (100 mSv in 5 years), with the further provision that the effective dose should not exceed 50 mSv in any single year. The 5-year period would have to be defined by the regulatory agency, e.g. as discrete 5-year calendar periods. The Commission would not expect the period to be introduced and then applied retrospectively. It is implicit in these recommended dose limits that the dose constraint for optimisation should not exceed 20 mSv in a year.

(S26) Subject to medical advice in individual cases, there need be no special restrictions applied to the exposure of an individual following a control period in which the exposure of the individual has exceeded a dose limit. Such events should call for a thorough examination, usually by the regulatory agency, of the design and operational aspects of protection in the installation concerned, rather than for restrictions or penalties applied to the exposed individual. If the dose is unknown, or is thought to be high, referral to a physician should be considered.

(S27) The recommended limits should apply to all forms of occupational exposure, unless special provisions have been made by the regulatory agency. Because of the difficulties of responding rapidly to an increase in stringency in operations in plant and equipment already in existence, the Commission recognises that regulatory agencies may wish to make temporary use of higher dose limits. Such arrangements should be regarded as transient.

(S28) The dose limit forms only a part of the system of protection aimed at achieving levels of dose that are as low as reasonably achievable, economic and social factors being taken into account. It is not to be seen as a target. It represents, in the Commission's view, the point at which regular, extended, deliberate occupational exposure can reasonably be regarded as only just tolerable.

(S29) The restrictions on effective dose are sufficient to ensure the avoidance of deterministic effects in all body tissues and organs except the lens of the eye, which makes a negligible contribution to the effective dose, and the skin, which may well be subject to localised exposures. Separate dose limits are needed for these tissues. The annual limits are 150 mSv for the lens and 500 mSv for the skin, averaged over any 1 cm^2, regardless of the area exposed.

(S30) For internal exposure, annual limits on intake will be based on a committed effective dose of 20 mSv. The estimated intakes may be averaged over a period of 5 years to provide

some flexibility. The occupational limits for radon are under review. Meanwhile, the values given in *ICRP Publication 47* (ICRP, 1986) remain valid [now, see *ICRP Publication 65* (ICRP, 1993)].

The occupational exposure of women

(S31) The basis for the control of the occupational exposure of women who are not pregnant is the same as that for men and the Commission recommends no special occupational dose limit for women in general.

(S32) Once pregnancy has been declared, the conceptus should be protected by applying a supplementary equivalent dose limit to the surface of the woman's abdomen (lower trunk) of 2 mSv for the remainder of the pregnancy and by limiting intakes of radionuclides to about $\frac{1}{20}$th of the ALI. The Commission wishes to emphasise that the use of its system of protection, particularly the use of source-related dose constraints, will usually provide an adequate guarantee of compliance with this limit without the need for specific restrictions on the employment of pregnant women. The principal criterion will then be that the employment should be of a type that does not carry a significant probability of high accidental doses and intakes. High-dose and high-risk occupations from which pregnant women should be excluded should be defined by regulatory agencies.

The Control of Medical Exposure

(S33) In the justification of a practice leading to medical exposures, the practice should be defined in broad terms. However, each procedure, either diagnostic or therapeutic, is subject to a separate decision, so that there is an opportunity to apply a further, case-by-case justification for each procedure. This will not be necessary for simple diagnostic procedures based on common indications, but may be important for complex investigations and for therapy.

(S34) There is considerable scope for dose reductions in diagnostic radiology using the techniques of optimisation of protection. 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 judgement.

(S35) Constraints should also be considered in the optimisation of protection for medical exposures when the procedures are not intended to be of direct value to the exposed individual, as in scientific and clinical studies involving the exposure of volunteers.

(S36) Medical exposures are usually intended to provide a direct benefit to the exposed individual. If the practice is justified and the protection optimised, the dose in the patient will be as low as is compatible with the medical purposes. The Commission therefore recommends that dose limits should not be applied to medical exposures. Further, it is not appropriate to include the doses incurred by patients in the course of diagnostic examinations or therapy when considering compliance with dose limits applied to occupational or public exposures.

(S37) Diagnostic and therapeutic procedures causing exposures of the abdomen of women likely to be pregnant should be avoided unless there are strong clinical indications. Information on possible pregnancy should be obtained from the patient herself. If the most recent expected menstruation has been missed, and there is no other relevant information, the woman should be assumed to be pregnant.

The Control of Public Exposure

(S38) The control of public exposure in all normal situations is exercised by the application of controls at the source rather than in the environment. The controls are achieved almost entirely by the procedures of constrained optimisation and the use of prescriptive limits. It is often convenient to class together individuals who form a homogeneous group with respect to their exposures to a single source. When such a group is typical of those most highly exposed by that source, it is known as a critical group. The dose constraint should be applied to the mean dose in the critical group from the source for which the protection is being optimised.

Dose limits

(S39) The scope of dose limits for public exposure is confined to the doses incurred as the result of practices. Doses incurred in situations where the only available protective action takes the form of intervention are excluded from that scope. Separate attention has to be paid to potential exposures. Radon in dwellings and in the open air, radioactive materials, natural or artificial, already in the environment, and other natural sources are examples of situations that can be influenced only by intervention. Doses from these sources are therefore outside the scope of the dose limits for public exposure. The conduct of intervention involves occupational exposure and should be treated accordingly.

(S40) The Commission now recommends that the limit for public exposure should be expressed as an effective dose of 1 mSv in a year. However, in special circumstances, a higher value of effective dose could be allowed in a single year, provided that the average over 5 years does not exceed 1 mSv per year.

(S41) In selecting the limit on effective dose, the Commission has sought a value that would be only just short of unacceptable for continued exposure as the result of deliberate practices, the use of which is a matter of choice. This does not imply that higher doses from other sources, such as radon in dwellings, should be regarded as unacceptable. The existence of these sources may be undesirable but is not a matter of choice. The doses can be controlled only by intervention, which will also have undesirable features.

(S42) Limits are also needed for the lens of the eye and skin since these tissues will not necessarily be protected against deterministic effects by the limit on effective dose. The Commission recommends annual limits of 15 mSv for the lens and 50 mSv for the skin averaged over any 1 cm^2, regardless of the area exposed. The recommended limits are summarised in Table S-4 [omitted, see Table 3 of the main text].

Potential Exposures

(S43) The initial treatment of potential exposures should form part of the system of protection applied to practices, but it should be recognised that the exposures, if they occur, may lead to intervention. At this stage, there should be two objectives, prevention and mitigation. Prevention is the reduction of the probability of the sequences of events that may cause or increase radiation exposures. Mitigation is the limitation and reduction of the exposures if any of these sequences do occur. A great deal can be accomplished at the stages of design and operation to reduce the consequences of accident sequences so that intervention may not become necessary.

(S44) In order to maintain a strict coherence in the treatment of actual and potential exposures, it would be necessary to extend the concept of detriment to include the probability of occurrence of the situation giving rise to the detriment. Techniques for achieving this are

still being developed. A comprehensive approach to this problem calls for the application of multi-attribute analysis.

(S45) A simpler approach is possible for both individual and collective exposures if the doses will be small even if the event occurs. If the doses, should they occur, will not be in excess of dose limits, it is adequate to use the product of the expected dose and its probability of occurrence as if this were a dose that was certain to occur. The conventional procedures of justification and optimisation can then be applied.

The System of Protection in Intervention

(S46) Before a programme of intervention is initiated, it should be demonstrated that the proposed intervention will be justified, i.e. do more good than harm, and that the form, scale and duration of the intervention have been chosen so as to optimise the protection. The processes of justification and optimisation both apply to the protective action, so it is necessary to consider them together when reaching a decision. Justification is the process of deciding that the disadvantages of each component of intervention, i.e. of each protective action, are more than offset by the reductions in the dose likely to be achieved. Optimisation is the process of deciding on the method, scale and duration of the action so as to obtain the maximum net benefit. In simple terms, the difference between the disadvantages and the benefits, expressed in the same terms, e.g. costs, including social costs with an allowance for anxiety, should be positive for each protective action adopted and should be maximised by settling the details of that action.

Radon in Dwellings

(S47) Radon in dwellings needs special attention because both the individual and the collective doses from radon are higher than those from almost any other source. If improvements are needed in existing dwellings, they have to be achieved by intervention involving modifications to the dwellings or to the behaviour of the occupants.

(S48) The Commission recommended the use of action levels to help in deciding when to require or advise remedial action in existing dwellings. The choice of an action level is complex, depending not only on the level of exposure, but also on the likely scale of action, which has economic implications for the community and for individuals. For new dwellings, guides or codes for their construction in selected areas can be established so that it is highly probable that exposures in these dwellings will be below some chosen reference level. The Commission has initiated a further review of current experience with a view to issuing revised recommendations in due course. Meanwhile the guidance in *ICRP Publication 39* (ICRP, 1984) should still be used [now, see *Publication 65* (ICRP, 1993)].

Intervention after Accidents

(S49) The benefit of a particular protective action within a programme of intervention should be judged on the basis of the reduction in dose achieved or expected by that specific protective action, i.e. the dose averted. Thus each protective action has to be considered on its own merits. In addition, however, the doses that would be incurred via all the relevant pathways of exposure, some subject to protective actions and some not, should be assessed. If the total dose in some individuals is so high as to be unacceptable even in an emergency, the feasibility of additional protective actions influencing the major contributions to the total

dose should be urgently reviewed. Doses causing serious deterministic effects or a high probability of stochastic effects would call for such a review.

(S50) Occupational exposures of emergency teams during emergency and remedial action can be limited by operational controls. Some relaxation of the controls for normal situations can be permitted in serious accidents without lowering the long-term level of protection. This relaxation should not permit the exposures in the control of the accident and in the immediate and urgent remedial work to give effective doses of more than about 0.5 Sv except for life-saving actions, which can rarely be limited by dosimetric assessments. The equivalent dose to skin should not be allowed to exceed about 5 Sv. Once the immediate emergency is under control, remedial work should be treated as part of the occupational exposure incurred in a practice.

Practical Implementation of the Commission's Recommendations

(S51) Chapter 7 of the recommendations emphasises the importance of the operational level of radiological protection and shows how this should be developed from the requirements of regulatory agencies and the recommendations of the Commission. The Commission now recommends that the designation of controlled and supervised areas should be decided either at the design stage or locally by the operating management on the basis of operational experience and judgement. The classification of working conditions based upon expected dose is no longer recommended. The Chapter gives advice on the measurement of doses (monitoring and record keeping) and on medical surveillance. It also discusses emergency planning and the bases for exemption from regulatory requirements. It deals with both practices and intervention.

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ANNEX B. THE BIOLOGICAL EFFECTS OF IONISING RADIATION

An Annotated Bibliography of Authoritative Reviews

This bibliography indicates the location of reviews of information on the biological effects of ionising radiation when such information is relevant to radiological protection. The sources are the International Commission on Radiological Protection (ICRP) and the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR).

The notes on the items indicate the scale of the documents and the principal topics. The references are to the reference list at the end of this Annexe.

ICRP Publication 60, 1990 Recommendations of the ICRP (ICRP, 1991a)

Chapter 3 (14 pages) provides a general summary of the effects on man of the biological effects of radiation. It deals with deterministic and stochastic effects, both somatic and hereditary, and both pre- and postnatal exposures are covered. Quantitative risk estimates are provided.

Annex B (70 pages) provides more detailed material in support of Chapter 3.

Risks Associated with Ionising Radiations (ICRP, 1991b)

This publication contains five papers prepared by individual authors with the guidance of a Task Group of ICRP Committee 1 on Radiation Effects. The papers were approved by Committee 1. They provide further support for the material in *Publication 60*. The papers are:

Risk Estimates for Carcinogenic Effects of Radiation (30 pages), A. C. Upton.

The Relative Contribution of Different Organ Sites to the Total Cancer Mortality Associated with Low-dose Radiation Exposure (27 pages), C. E. Land and W. K. Sinclair.

Low-dose Radiation Epidemiological Studies: An Assessment of Methodological Problems (15 pages), B. Modan.

Genetic Effects of Ionising Radiation in Man (20 pages), K. Sankaranarayanan.

Ionising Radiation and the Developing Human Brain (24 pages), W. J. Schull.

Genetic and Somatic Effects of Ionizing Radiation (UNSCEAR, 1986)

This is one of the periodic reports to the UN General Assembly, the Annexes of which contain extensive scientific reviews of worldwide levels of radiation exposure and of biological effects. Much of this report has been superseded by the 1993 and 1994 Reports of UNSCEAR, see below, but Annexe C, Biological Effects of Prenatal Irradiation (104 pages), which is concerned with experimental animal data but also contains a summary of conclusions relating to man, is still relevant.

Sources and Effects and Risks of Ionizing Radiation (UNSCEAR, 1988)

Annex G, Early Effects in Man of High Doses of Radiation (103 pages), deals with both whole body and organ doses. It includes material on diagnostic indicators and biological

dosimetry. An appendix reports findings from the exposure and treatment of victims of the Chernobyl accident.

Sources and Effects of Ionizing Radiation (UNSCEAR, 1993)

Five of the annexes to this report are relevant.

*Annex E, Mechanisms of Radiation Oncogenesis (68 pages), provides a substantial descriptive review of the molecular biology of oncogenesis.

*Annex F, Influence of Dose and Dose Rate on Stochastic Effects of Radiation (111 pages), brings together molecular biology, cellular biology, microdosimetry, and epidemiology with the aim of allowing a better interpretation of the human high-dose epidemiology data.

Annex G, Hereditary Effects of Radiation (75 pages), starts with an account of the types of hereditary mechanisms in man and of the background incidence of hereditary disorders. It then progresses to risk estimates. In the absence of direct data on humans, these are derived from experimental studies on animals.

Annex H, Radiation Effects on the Developing Human Brain (63 pages), describes the development of the human brain *in utero* and provides an account of radiation-induced abnormalities with quantitative risk estimates.

Annex I, Late Deterministic Effects in Children (53 pages), after a general description of the mechanism of deterministic effects, deals with late effects in the principal organs and tissues of the body.

Sources and Effects of Ionizing Radiation (UNSCEAR, 1994)

This report, a continuation of the 1993 report, contains two annexes, both of which have some relevance to radiological protection in medicine.

*Annex A, Epidemiology Studies of Radiation Carcinogenesis (173 pages), after a valuable introduction on the role, methods, and limitations of epidemiology, brings together and analyses epidemiology studies on internal and external exposures to both high and low LET radiations. The data on solid tumours and leukaemia, taken together, indicate significant risks down to 0.2 Gy, with some indications of risks at somewhat lower doses. The data do not suggest a need to modify the risk estimates used in *Publication 60*.

Annex B, Adaptive Responses to Radiation in Cells and Organisms (87 pages), concludes that there is convincing evidence for adaptive responses to radiation exposure of cells, including those inducing repair mechanisms in DNA, but that it would be premature to conclude that any benefit to the whole organism would outweigh the detrimental effects of the exposure.

General Comment

The documents listed here show a broad consensus of views on radiation risk from a wide range of studies. Conflicting data have been carefully reviewed and rejected only where the studies show methodological weaknesses.

In addition to *Publication 60* and the associated risk publications, the Commission particularly commends, as general background, the papers marked with an asterisk.

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ICRP Publication –, *Dose-related Quantities for Radiological Protection Against External Radiation.* A joint report with ICRU (1966).

ICRP Publication –, *General Principles for Radiation Protection of Workers* (1996/97).

ICRP Publication –, *Protection from Potential Exposure: Application to Selected Radiation Sources* (1996/97).

ICRP Publication –, *Age-dependent Doses to Members of the Public from Intake of Radionuclides, Part 6, Embryo and Fetus* (1996/97).

ICRP Publication –, *Individual Monitoring for Intakes of Radionuclides by Workers: Design and Interpretation* (Update of Publication 54) (1996/97).

ICRP Publication –, *Principles for the Protection of the Public against Chronic Exposure Situations* (1996/97).

ICRP Publication –, *Genetic Susceptibility to Cancer* (1997).

ICRP Publication –, *Basic Anatomical and Physiological Parameters for use in Radiological Protection, Part 2, Anatomy, Physiology and Elemental Composition* (1997/98).

ICRP Publication –, *Risk Estimation for Multifactorial Diseases* (1997/98).

ICRP Publication –, *Age-dependent Doses to Members of the Public from Intake of Radionuclides, Part 7, Reliability of Dose Coefficients* (1997/98).

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ICRP Publication –, *Limits for Intakes of Radionuclides by Workers: Revision of Publication 30* (2000).

Technical reports

Use of the Respiratory Tract Model for Calculating Doses for Specified Inhaled Chemical Forms of Radionuclide (1997).