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DRAFT RECOMMENDATIONS OF THE INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION

ABSTRACT

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EDITORIAL

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PREFACE

Since issuing its latest basic recommendations in 1991 as ICRP *Publication 60* (ICRP, 1991b), the Commission has reviewed these recommendations regularly and, from time to time, has issued supplementary reports in the *Annals of the ICRP*. The extent of these supplementary reports has indicated the need for the consolidation and rationalisation presented here. New scientific data have also been published since *Publication 60*, and while the biological and physical assumptions and concepts remain robust, some updating is required. The overall estimates of cancer risk attributable to radiation exposure have not changed greatly in the past 16 years. Conversely, the estimated risk of hereditable effects is currently lower than before. In any case, the new data provide a firmer basis on which to model risks and assess detriment. In addition, there have been societal developments in that more emphasis is now given on the protection of individuals and stakeholder involvement in the management of radiological risk. Finally, it has also become apparent that the radiological protection of non-human species should receive more emphasis than in the past.

Therefore, while recognising the need for stability in international and national regulations, the Commission has decided to issue these revised recommendations having three primary aims in mind:

- To take account of new biological and physical information and of trends in the setting of radiation safety standards;
- To improve and streamline the presentation of the recommendations; and
- To maintain as much stability in the recommendations as is consistent with the new scientific information.

In its revised System of Protection, the Commission now moves from the previous process-based approach of practices and interventions to an approach based on the radiation exposure situation. The Commission now emphasises the similarity of the protective actions taken regardless of exposure situation. By increasing the attention to the process of optimisation in all radiation exposure situations, the Commission is of the opinion that the level of protection for what has until now been categorised as interventions will be improved, compared to the recommendations in *Publication 60* (ICRP, 1991). Thus the system of protection can now be applied to all situations of radiation exposure.

These Recommendations were drafted by the Main Commission of ICRP, based on an earlier draft that was subjected to public and internal consultation in 2004. A draft version of the present Recommendations was subjected to consultation in 2006. By introducing more transparency and by involving the many organisations and individuals having an interest in radiological protection in the revision process, the Commission is expecting a better understanding and acceptance of its recommendations.

The membership of the Main Commission during the period of preparation of the present Recommendations was:

(2001-2005)

R.H. Clarke (Chairman)	A.J. González	Y. Sasaki
R.M. Alexakhin	L.-E. Holm (Vice-Chairman)	C. Streffer
J.D. Boice jr	F.A. Mettler jr	A. Sugier (2003-2005)
R. Cox	Z.Q. Pan	B.C. Winkler (✠ 2003)
G.J. Dicus	R.J. Pentreath (2003-2005)	

Scientific Secretary: J. Valentin

(2005-2009)

L.-E. Holm (Chairman)	J.-K. Lee	N. Shandala
J.D. Boice jr	Z.Q. Pan	C. Streffer
C. Cousins	R.J. Pentreath	A. Sugier
R. Cox (Vice-Chairman)	R.J. Preston	
A.J. González	Y. Sasaki	

Scientific Secretary: J. Valentin

The work of the Commission was greatly aided by significant contributions from P. Burns, H. Menzel, and J. Cooper. It also benefited from discussions at a series of international meetings organised by the OECD Nuclear Energy Agency on the revised recommendations.

The Commission wishes to express its appreciation to all international and national organisations, governmental as well as non-governmental, and all individuals that contributed in the development of these Recommendations.

EXECUTIVE SUMMARY

(to be completed)

(a) The major features of the revised Recommendations are:

- Updating the radiation and tissue weighting factors in the dosimetric quantity effective dose and updating the radiation detriment based on the latest available scientific information of the biology and physics of radiation exposure.
- Maintaining the Commission's three fundamental principles of radiological protection, namely justification, optimisation and the application of dose limits, and clarifying how they apply to radiation sources delivering exposure and to individuals receiving exposure.
- Abandoning the process based protection approach using practices and interventions, and moving to a situation based approach applying the same source-related principles to all controllable exposure situations, which the revised recommendations characterise as planned, emergency, and existing exposure situations
- Maintaining the Commission's individual dose limits for effective dose and equivalent dose from all regulated sources that represent the maximum dose that would be accepted in planned situations by regulatory authorities;
- Re-enforcing the principle of optimisation of protection, which should be applicable in the same way to all exposure situations, with restrictions on individual doses, namely dose constraints for planned exposure situations and reference levels for emergency and existing exposure situations.
- Including a policy approach and developing a framework for radiological protection of non-human species, noting that there is no detailed policy provided at this time.

(b) [This dummy will be replaced with further executive summary text, the paragraphs of which are lettered rather than numbered]

1. INTRODUCTION

(1) Chapter 1 deals with the history of the Commission and its recommendations. It sets out the aims and form of this report and indicates why the Commission concerns itself only with protection against ionising radiation.

1.1. The history of the Commission

(2) The International Commission on Radiological Protection, hereafter called the Commission, was established in 1928, with the name of the International X ray and Radium Protection Committee, following a decision by the Second International Congress of Radiology. In 1950 it was restructured and renamed as now. The Commission still remains a commission of the International Society of Radiology; it has greatly broadened its interests to take account of the increasing uses of ionising radiation and of practices that involve the generation of radiation and radioactive materials.

(3) The Commission is an independent charity, i.e. a non-profit-making organisation. The Commission works closely with its sister body, the International Commission on Radiation Units and Measurements (ICRU), and has official relationships with the World Health Organization (WHO) and the International Atomic Energy Agency (IAEA). It also has important relationships with the International Labour Organization (ILO) and other United Nations bodies, including the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the United Nations Environment Programme (UNEP). Other organisations with which it works include the Commission of the European Communities ('European Commission', EC), the Nuclear Energy Agency of the Organization for Economic Co-operation and Development (OECD NEA), the International Organization for Standardization (ISO), and the International Electrotechnical Commission (IEC). The Commission also maintains contact with the professional radiological community through its strong links with the International Radiation Protection Association (IRPA). The Commission also takes account of progress reported by national organisations.

1.2. The development of the Commission's recommendations

(4) The first general recommendations of the Commission were issued in 1928 and concerned the protection of the medical profession through the restriction of working hours with medical sources (IXRPC, 1928). This restriction is now estimated to correspond to an individual dose of about 1000 millisievert (mSv) per year. The early recommendations were concerned with avoiding threshold effects, initially in a qualitative manner. A system of measurement of doses was needed before protection could be quantified and dose limits could be defined. In 1934, recommendations were made implying the concept of a safe threshold about ten times the present annual occupational dose limit (IXRPC, 1934). The tolerance idea continued, and in 1951, the Commission proposed a limit that can now be estimated to be around 3 mSv per week for low LET radiation (ICRP, 1951). By 1954 the support for a threshold was greatly diminished because of the epidemiological evidence emerging of excess malignant disease amongst American radiologists and the first indication of excess leukaemia in the Japanese A-bomb survivors (ICRP, 1955).

(5) The development of both the military and industrial uses of nuclear energy led the Commission in the early 1950s to introduce recommendations for the protection of the public. In the Commission's 1956 Recommendations, (ICRP, 1957), restrictions of annual doses were set to 50 mSv for workers and 5 mSv for the public. In parallel, to take account of the recognition of stochastic effects and the impossibility of demonstrating the existence or non-existence of a threshold for these types of effects, the Commission recommended '*that every effort be made to reduce exposures to all types of ionising radiation to the lowest possible level*' (ICRP, 1954). This was successively formulated as the recommendation to maintain exposure 'as low as practicable' (1959), 'as low as readily achievable' (1966), and later on 'as low as reasonably achievable, economic and social considerations being taken into account' (1973).

(6) The Commission's first report in the current series, numbered *Publication 1* (1959), contained the recommendations approved in 1958. Subsequent general recommendations have appeared as *Publication 6* (1964), *Publication 9* (1966), *Publication 26* (1977), and finally *Publication 60* (1991b). These general recommendations have been supported by many other Publications providing advice on more specialised topics.

(7) In *Publication 26*, the Commission first quantified the risks of stochastic effects of radiation and proposed a System of Dose Limitation (ICRP, 1977) with its three principles of justification, optimisation of protection and individual dose limitation. The optimisation principle successively evolved from 'as low as practicable' (1959) to 'as low as readily achievable' (1966), and later on 'as low as reasonably achievable, economic and social considerations being taken into account' (1973). In 1990, the Commission largely revised the recommendations partly because of revisions upward of the estimates of risk from exposure to radiation, and partly to extend its philosophy to a System of Radiological Protection from the system of dose limitation (ICRP, 1991). The principles of justification, optimisation and individual dose limitation remained, and a distinction between 'practices' and 'interventions' was introduced to take into account different degree of controllability of the various types of exposure situations. Moreover, more emphasis was put on the optimisation of protection with constraints so as to limit the inequity that is likely to result from inherent economic and societal judgements.

(8) The annual dose limit of 50 mSv for workers[1] set in 1956, was retained until 1990, when it was further reduced to 20 mSv per year on average based on the revision of the risk for stochastic effects estimated from the Hiroshima–Nagasaki atomic bomb survivors (ICRP, 1991). Meanwhile, the annual dose limit of 5 mSv for members of the public was reduced to 1 mSv per year on average in 1978 (ICRP 1978) and this value was retained in *Publication 60*.

(9) Since *Publication 60*, there has been a series of publications that have provided additional guidance for the control of exposures from radiation sources (See list of references). When the 1990 Recommendations are included, these reports specify some 30 different numerical values for restrictions on individual dose for differing circumstances. Furthermore, these numerical values are justified

[1] Some terms and units used in older reports have been converted to current terminology for consistency.

in many different ways (ICRP, 2006). In addition the Commission began to develop policy guidance for protection of non-human species in *Publication 91* (ICRP, 2003).

(10) It is against this background that the Commission has now decided to adopt a revised set of Recommendations while at the same time maintaining stability with the previous recommendations.

(11) The Commission's extensive review of the vast body of literature on the health effects of ionising radiation has not indicated that any fundamental changes are needed to the system of radiological protection. There is, therefore, more continuity than change in these revised recommendations; some recommendations are to remain because they work and are clear; others differ because understanding has evolved; some items have been added because there has been a void; and some concepts are better explained because more guidance is needed.

(12) The revised recommendations consolidate and add to previous recommendations issued in various ICRP publications. The existing numerical recommendations in the policy guidance given since 1991 remain valid unless otherwise stated. Thus, the revised recommendations should not be interpreted as suggesting any substantial changes to radiological protection regulations that are appropriately based on its previous Recommendations in *Publication 60* and subsequent policy guidance. These recommendations reiterate the importance of optimisation in radiological protection and extend the successful experience in the implementation of this requirement for practices (now included in planned exposure situations) to other situations, i.e. emergency and existing exposure situations.

(13) The Commission will follow up these recommendations with reports applying the process of optimisation in different situations. Such applications may also be the scope of work of the international agencies that undertake some of this process as part of their revision of their Basic Safety Standards (i.e., the revision of IAEA 1996a).

(14) These consolidated Recommendations are supported by a series of supporting documents, which elaborate on important aspects of the Commission's policy and underpin the recommendations:

- Low-dose extrapolation of radiation-related cancer risk (*Publication 99*, ICRP, 2006).

- Biological and epidemiological information on health risks attributable to ionising radiation: A summary of judgements for the purposes of radiological protection of humans (Annex A to these Recommendations).

- Quantities used in radiological protection (Annex B to these Recommendations).

- Optimisation of radiological protection (in *Publication 101*, ICRP, 2006).

- Assessing dose to the representative person (in *Publication 101*, ICRP, 2006).

- A framework for assessing the impact of ionising radiation on non-human species (*Publication 91*, ICRP, 2003)

- In addition the Commission is providing guidance on justification and optimisation and the scope of radiological protection and on radiological protection in medical practice[2],

(15) The principal objective of the Commission has been, and remains, the achievement of the radiological protection of human beings. It has nevertheless previously had regard to the potential impact on other species, although it has not made any general statements about the protection of the environment as a whole. Indeed, in its *Publication 60* (ICRP, 1990) it stated that, at that time, the Commission concerned itself with mankind's environment only with regard to the transfer of radionuclides through the environment, because this directly affects the radiological protection of human beings. The Commission did, however, also express the view that the standards of environmental control needed to protect humans to the degree currently thought desirable would ensure that other species are not put at risk.

(16) The Commission continues to believe that this is likely to be the case in general terms under *planned exposure situations* (see Section 5.2 for the definition of planned exposure situations), and that the human habitat will therefore have been afforded a fairly high degree of protection. There are, however, other environments to consider, where humans are absent or where the Commission's recommendations for protection of humans have not been used, and other exposure situations will arise where environmental consequences may need to be taken into account. The Commission is also aware of the needs of some national authorities to demonstrate, directly and explicitly, that the environment is being protected even under planned exposure situations. It therefore now believes that the development of a clearer framework is required in order to assess the relationships between exposure and dose, and between dose and effect, and the consequences of such effects for non-human species, on a common scientific basis. This is discussed further in Chapter 8.

(17) The advice of the Commission is aimed principally at authorities, bodies, and individuals that have responsibility for radiological protection. The Commission's recommendations have helped in the past to provide a consistent basis for national and regional regulatory standards, and the Commission has been concerned to maintain stability in its recommendations. The Commission provides guidance on the fundamental principles on which appropriate radiological protection can be based. It does not aim to provide regulatory texts. Nevertheless, it believes that such texts should be developed from, and be broadly consistent with, its guidance.

(18) There is a close connection between the Commission's recommendations and the International Basic Safety Standards, right from the early 1960s. The International Basic Safety Standards have always followed the establishment of new recommendations from the Commission; for example, the 1977 and the 1990 ICRP recommendations were the basis for the revised International Basic Safety Standards published in 1982 and 1996, respectively.

(19) These recommendations, as in previous reports, are confined to protection against ionising radiation. The Commission recognises the importance of adequate

[2] In preparation – this footnote will be removed in the printed version

control over sources of non-ionising radiation. The International Commission on Non-ionizing Radiation Protection, ICNIRP, provides recommendations concerning such sources (ICNIRP, 2004).

1.2.1. The evolution of dose quantities and their units

(20) The first dose unit, roentgen(r), was established for quantity of x-rays in 1928 by the ICRU but the quantity itself was not named. The first official use of the term 'dose' together with the amended definition of the unit r was in the 1937 recommendations of the ICRU (ICRU, 1938). The ICRU suggested the concept of absorbed dose and officially defined the name and its unit 'rad' in 1953 for extension of dose concept to certain materials other than air (ICRU 1954).

(21) The first dose quantity incorporating relative biological effectiveness (RBE) of different types of radiation used by the ICRU was the 'RBE dose in rems', which was a RBE-weighted sum of absorbed dose in rads prescribed in the 1956 recommendations of the ICRU. This dose quantity was replaced by the dose equivalent, a result of joint efforts between the ICRU and the Commission, which was defined by the product of absorbed dose, quality factor of the radiation, dose distribution factor and other necessary modifying factors (ICRU 1962). The 'rem' was retained as the unit of dose equivalent. Furthermore, the ICRU defined another dose quantity kerma and changed the name of exposure dose to simple 'exposure' in its 1962 recommendations.

(22) In its 1976 recommendations, the Commission introduced a new dose equivalent quantity for limitation of stochastic effects by defining weighted sum of dose equivalents of various tissues and organs of the human body, where the weighting factor was named as 'tissue weighting factor'(ICRP, 1977). The Commission named this new quantity 'effective dose equivalent' at the 1978 Stockholm meeting (ICRP 1978). At the same time, the SI names of unit of dose quantity were adopted to replace rad by gray (Gy) and rem by sievert (Sv).

(23) In 1990, the Commission re-defined the body-related dose quantities departing from the ICRU definitions. For protection purposes, the absorbed dose averaged over a tissue or organ was defined as the basic quantity. In addition, considering that biological effects are not solely governed by the linear energy transfer, the Commission decided to use the radiation weighting factors, which were selected based on the RBE in inducing stochastic effects at low doses, instead of the quality factors used in calculation of the dose equivalent. To distinguish from the dose equivalent, the Commission named the new quantity 'equivalent dose'. Accordingly, the effective dose equivalent was renamed as 'effective dose'. There were some modifications in the tissue weighting factors to account the new information on health effects of radiation.

(24) More details of the dosimetric quantities and their units currently in use appear in Chapter 4.

1.3. Structure of the Recommendations

(25) Chapter 2 deals with the aims and the scope of the recommendations. Chapter 3 deals with biological aspects of radiation and Chapter 4 discusses the quantities and units used in radiological protection. Chapter 5 describes the

conceptual framework of the system of radiological protection and Chapter 6 deals with the implementation of the Commission's recommendations for the three different types of exposure situations. Chapter 7 describes the medical exposure of patients and Chapter 8 discusses protection of the environment.

2. THE AIMS AND SCOPE OF THE RECOMMENDATIONS

2.1. The aims of the Recommendations

(26) The primary aim of the Commission's Recommendations is to contribute to an appropriate level of protection for people and the environment against the detrimental effects of radiation exposure without unduly limiting the desirable human endeavours and actions that may be associated with such exposure.

(27) This aim cannot be achieved solely on the basis of scientific knowledge on radiation exposure and its health effects. It requires a model for protecting humans and the environment against radiation. The recommendations are based on scientific knowledge and on expert judgement. Scientific data, such as those concerning health risks attributable to radiation exposure are a necessary prerequisite, but societal and economic aspects of protection have also to be considered. All of those concerned with radiological protection have to make value judgements about the relative importance of different kinds of risk and about the balancing of risks and benefits. In this, radiological protection is not different from other fields concerned with the control of hazards. The Commission believes that the basis for, and distinction between, scientific estimations and value judgements should be made clear whenever possible, so as to increase the transparency, and thus the understanding, of how decisions have been reached.

(28) Radiological protection deals with two types of harmful effects. High doses will cause deterministic effects (also called *tissue reactions*, see Chapter 3), often of acute nature, which only appear if the dose exceeds a threshold value. Both high and low doses may cause stochastic effects (cancer or hereditary effects), which may be observed as a statistically detectable increase in the incidences of these effects occurring long after exposure.

(29) The health objectives of the Commission's system of human radiological protection are relatively straightforward: to manage and control exposures to ionising radiation so that tissue reactions (deterministic effects) are prevented, and the risks of cancer and heritable effects (stochastic effects) are minimised.

(30) In contrast, there is no simple or single universal definition of 'environmental protection' and the concept differs from country to country, and from one circumstance to another. Other ways of considering radiation effects are therefore likely to prove to be more useful for non-human species, such as those that cause early mortality, or morbidity, or reduced reproductive success. The Commission's aim is therefore that of preventing or reducing the frequency of such radiation effects to a level where they would have a negligible impact on the maintenance of biological diversity, the conservation of species, or the health and status of natural habitats, communities and ecosystems. In achieving this aim, however, the Commission recognises that exposure to radiation is but one factor to consider, and is often likely to be but a minor one. It will therefore seek to ensure that its approach, primarily by giving guidance and advice, is both commensurate with the level of risk, and compatible with other approaches being made to protect the environment from all other human impacts, particularly those arising from similar human activities.

2.2. The structure of the system of protection

(31) Because of the variety of radiation exposure situations and of the need to achieve a consistency across a wide range of applications, the Commission has established a formal system of radiological protection aimed at encouraging a structured approach to protection. The system has to deal with a large number of sources of exposure, some already being in place, and others that may be introduced deliberately as a matter of choice by society or as a result from emergencies. These sources are linked by a network of events and situations to individuals and groups of individuals comprising the present and future populations of the world. The system of protection has been developed to allow this complex network to be treated by a logical structure.

(32) The system of protection of humans is based on the use of a) reference anatomical and physiological models of the human being for the assessment of radiation doses, b) studies at the molecular and cellular level, c) experimental animal studies and d) epidemiological studies. The use of models has resulted in the derivation of practical, tabulated information on the committed 'dose per unit intake' of different radionuclides or 'dose per unit air kerma or fluence' that can be applied to workers, patients and the public. The use of epidemiological and experimental studies has resulted in the estimation of risks associated with the external and internal radiation exposure. For biological effects, the data come from human experience supported by experimental biology. For cancer and hereditary effects, the Commission's starting points are the results of epidemiological studies and of studies on animal genetics. These are supplemented by information from experimental studies on the mechanisms of carcinogenesis and heredity, in order to provide risk estimates at the low doses of interest in radiological protection.

(33) In view of the uncertainties surrounding the values of tissue weighting factors and the estimate of detriment, the Commission considers it appropriate for radiological protection purposes to use age and sex averaged tissue weighting factors and numerical risk estimates. Moreover this obviates the requirement for sex- and age-specific radiological protection criteria which could prove unnecessarily discriminatory. However, for the purposes of retrospective evaluation of radiation-related risks, such as in epidemiologic studies, it is appropriate to use sex- and age-specific data and calculate sex- and age-specific risks. The Commission also wishes to emphasise that effective dose is intended for use as a protection quantity on the basis of reference values and therefore is not recommended for epidemiological evaluations, nor should it be used for detailed specific retrospective investigations of human exposure and risk. This is especially important in cases of individual doses exceeding dose limits. Rather, absorbed dose should be used with the most appropriate biokinetic biological effectiveness and risk factor data. The details of the Commission's methods for calculating detriment are discussed in Annexes A and B.

(34) The Commission's risk estimates are called 'nominal' because they relate to the exposure of a nominal population of females and males with a typical age distribution and are computed by averaging over age groups and both sexes. The dosimetric quantity recommended for radiological protection, effective dose, is also computed by age- and sex-averaging. There are many uncertainties inherent in the definition of nominal factors to assess effective dose. As with all estimates derived from epidemiology, the nominal risk coefficients do not apply to specific individuals. If one accepts these assumptions, then the estimates of fatality and

detriment coefficients are adequate both for planning purposes and for general prediction of the consequences of exposures of a nominal population. For the estimation of the likely consequences of an exposure of an individual or a known population, it is preferable to use absorbed dose, specific data relating to the relative biological effectiveness of the radiations concerned, and estimates of the probability coefficients relating specifically to the exposed individual or population.

(35) The system for assessment is robust and is, in several aspects, in conformity with what is used in other fields of environmental protection, e.g. the identification of health hazards, characterisation of the relevant biological processes, and risk characterisation involving reference values.

(36) Situations in which the (equivalent) dose thresholds for deterministic effects in relevant organs could be exceeded should be subjected to protective actions under almost any circumstances, as already recommended by the Commission (ICRP, 1999b). It is prudent to take uncertainties in the current estimates of thresholds for deterministic effects into account, particularly in prolonged exposures situations. Consequently, annual doses rising towards 100 mSv will almost always justify the introduction of protective actions.

(37) At radiation doses below 100 mSv in a year, the increase in the incidence of stochastic effects is assumed by the Commission to occur with a small probability and in proportion to the increase in radiation dose over the background dose. Use of this so-called linear, non-threshold (LNT) model is considered by the Commission to be the best practical approach to managing risk from radiation exposure. The Commission recommends therefore that the LNT model, combined with a dose and dose rate effectiveness factor (DDREF) for extrapolation from higher doses, remains a prudent basis for radiological protection at low doses and low dose rates (ICRP 2006b).

(38) Even within a single class of exposure, an individual may be exposed by several sources, so an assessment of the total exposure has to be attempted. This assessment is called *'individual-related'*. It is also necessary to consider the exposure of all the individuals exposed by a source or group of sources. This procedure is called a *'source-related'* assessment. The Commission emphasises the primary importance of source-related assessments, since action can be taken for a source to assure the protection of individuals from that source.

(39) The probabilistic nature of stochastic effects and the properties of the LNT model make it impossible to derive a clear distinction between 'safe' and 'dangerous', and this creates some difficulties in explaining the control of radiation risks. The major policy implication of the LNT model is that some finite risk, however small, must be assumed and accepted at any level of protection. This leads to the Commission's system of protection with its three fundamental principles of protection (for the distinction between source-related and individual-related approaches, see Section 5.5):

Source-related principles (apply in all situations):

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

This means that by introducing a new radiation source or by reducing existing exposure, one should achieve an individual or societal benefit that is higher than the detriment it causes.

- **The principle of optimisation of protection:** the likelihood of incurring exposures, the number of people exposed, and the magnitude of their individual doses should all be kept as low as reasonably achievable, taking into account economic and societal factors.

  This means that the level of protection should be the best under the prevailing circumstances, maximising the margin of benefit over harm. In order to avoid severely inequitable outcomes of this optimisation procedure, there should be restrictions on the doses or risks to individuals from a particular source (dose or risk reference levels and constraints).

Individual-related principle (applies in planned situations):

- **The principle of application of dose limits:** The total dose to any individual from all planned exposure situations other than medical exposure of patients should not exceed the appropriate limits specified by the Commission.

These principles are discussed in more detail in Chapter 5.

(40) In protecting individuals from the harmful effects of ionising radiation, it is the control (in the sense of restriction) of radiation doses that is important, no matter what the source. Exposures from some situations are excluded from legislation because they are not amenable to control.

(41) The principal components of the system of radiological protection can be summarised as follows:

- A characterisation of the possible situations where radiation exposure may occur (planned, emergency, and existing situations);

- A classification of the types of exposure (those that are certain to occur and potential exposures, as well as occupational exposure, medical exposure of patients and public exposure);

- An identification of the exposed individuals (workers, patients, and members of the public);

- A categorisation of the types of assessments, namely source-related and individual-related;

- A precise formulation of the principles of protection: justification, optimisation of protection, and individual dose limitation as they apply to source-related and individual-related protection (see above);

- A description of the levels of individual doses that require protective action (dose limits, dose constraints and reference levels);

- A delineation of the conditions for the safety of radiation sources, including their security and the requirements for emergency prevention and preparedness; and

- The implementation of the recommendations by users, authorities, employers, the workforce, and the public at large.

(42) In these Recommendations, the Commission uses the same conceptual approach in the source-related protection, and emphasises the optimisation of protection regardless of the type of source, exposure situation or exposed individual. Source-related restrictions on doses or risks are applied during the optimisation of protection. In principle, protective options that imply doses above the level of such restrictions should be rejected. The Commission has previously used the term 'constraint' for these restrictions for practices. For reasons of consistency, the Commission will continue to use this term in the context of planned exposure situations as such situations encompass the normal operation of practices. The Commission recognises, however, that the word 'constraint' is interpreted in many languages as a rigorous limit. Such a meaning was never the Commission's intention as their application must depend upon local circumstances.

(43) Levels for protective action may be selected on the basis of generic considerations including the Commission's general recommendations (see Table 8) or best practice. In any specific set of circumstances, particularly in an emergency or an existing exposure situation, it could be the case that no viable protective option can immediately satisfy the level of protective action selected from generic considerations. Thus interpreting a constraint rigorously as a form of limit could seriously and adversely distort the outcome of an optimisation process. For this reason, the Commission proposes to use the term 'reference level' for the restriction on dose or risk applied during optimisation in emergency or existing exposure situations. The Commission wishes to emphasise, however, that the difference in name between planned exposure situations and the other two exposure situations does not imply any fundamental difference in the application of the system of protection. Further guidance on the application of the optimisation principle in emergency situations and existing exposure situations is provided in Chapter 6.

2.3. The scope of the Recommendations

(44) The Commission's system of radiological protection applies to all radiation sources and controllable radiation exposures from any source, regardless of its size and origin. The term *radiation* is used to mean ionising radiation. The Commission has been using the term *radiation exposure* (or *exposure* in short) in a generic sense to mean the process of being exposed to radiation or radionuclides, the significance of exposure being determined by the resulting radiation dose (ICRP, 1991). The term '*source'* is used to indicate the cause of an exposure, and not necessarily a physical source of radiation (see Section 5.1). In general for the purposes of applying the recommendations a source is an entity for which radiological protection can be optimised as an integral whole (see Section 6.2).

(45) The Commission has aimed to make its recommendations applicable as widely and as consistently as possible. In particular, the Commission's recommendations cover exposures to both natural and man-made sources. The recommendations can apply in their entirety only to situations in which either the source of exposure or the pathways leading to the doses received by individuals can

be controlled by some reasonable means. Sources in such situations are called *controllable sources.*

(46) There can be many sources and some individuals may be exposed to radiation from more than one of them. Provided that doses are below the threshold for tissue reactions, the presumed proportional relationship between the additional dose attributable to the situation and the corresponding increase in the probability of stochastic effects makes it possible to deal independently with each component of the total exposure and to select those components that are important for radiological protection. Furthermore, it is possible to subdivide these components into groups that are relevant to various purposes.

(47) The Commission has previously distinguished between practices that add doses and interventions that reduce doses (ICRP, 1991b). The principles of protection have been formulated somewhat differently in the two cases. Many have seen the distinction between them as artificial. Therefore, the Commission now uses a situation based approach to characterise the possible situations where radiation exposure may occur as *planned, emergency*, and *existing exposure situations*); and applies one set of fundamental principles of protection for all of these situations (See Section 5.4).

(48) The term '*practice*' has, however, become widely used in radiological protection. The Commission will continue to use this term to denote an enterprise that causes an increase in exposure to radiation or in the risk of exposure to radiation. An enterprise can be a business, trade, industry or any other productive activity; it can also be a government undertaking, a charity or some other act of enterprising. It is implicit in the concept of a practice that the radiation sources that it introduces or maintains can be controlled directly by action on the source.

(49) For the medical profession, the term 'practice' typically refers to the medical care that a practitioner provides to patients. In order to improve the understanding of the concept 'practice' by the medical community, one option would be to use the term 'radiological practice in medicine' for medical situations in order to differentiate it from the usual meaning of 'practice' in medicine.

(50) The term '*intervention'* has also become widely used in radiological protection and has been incorporated into national and international standards to describe situations where actions are taken to reduce exposures. The Commission believes that it is more appropriate to limit the use of this term to describe protective *actions* that reduce exposure, while the terms 'emergency' or 'existing exposure' will be used to describe radiological *situations* where such protective actions to reduce exposures are required.

2.4. Exclusion and exemption

(51) The fact that the Commission's recommendations are concerned with any level and type of radiation exposure does not mean that all exposures, all sources, and all human enterprises making use of radiation, can or need to be regulated.

(52) There are two distinct concepts that define the extent of radiological protection control, namely (i) the exclusion of certain exposure situations from radiological protection legislation on the basis that they are unamenable to control

with regulatory instruments, and (ii) the exemption from radiological protection regulatory requirements of situations that are unwarranted to be controlled when the effort to control is judged to be excessive compared to the associated risk. A legislative system for radiological protection should first establish what should be within the legal system and what should be outside it and therefore excluded from the law and its regulations. Secondly, the system should also establish what could be exempted from some regulatory requirements because regulatory action is unwarranted. For this purpose, the legislative framework should permit the regulator to exempt situations from specified regulatory requirements, particularly from those of an administrative nature such as notification or exposure assessment. While exclusion is firmly related to defining the scope of the control system, it may not be sufficient as it is just one mechanism. Exemption, on the other hand, relates to the power of regulators to determine that a source or practice need not be subject to some or all aspects of regulatory control.

(53) Exposures that may be excluded from radiological protection legislation include uncontrollable exposures and exposures that are essentially not amenable to control regardless of their magnitude. Uncontrollable exposures are those that cannot be restricted by regulatory action under any conceivable circumstance, such as exposure to the radionuclide ^{40}K incorporated into the human body. Exposures that are not amenable to control are those for which control is obviously impractical, such as exposure to cosmic rays at ground level. The decision as to what exposures are not amenable to control requires a judgment by the legislator, which may be influenced by cultural perceptions. For instance, national attitudes to the regulation of exposures to natural occurring radioactive materials are extremely variable.

(54) Further guidance on exclusion and exemption is provided in the document *The Scope of Radiological Protection Regulations* (ICRP, 2006x).

3. BIOLOGICAL ASPECTS OF RADIOLOGICAL PROTECTION

(55) Most adverse health effects of radiation exposure may be grouped in two general categories:

- tissue reactions (also called deterministic effects) due in large part to the killing/ malfunction of cells following high doses; and
- cancer and heritable effects (also called stochastic effects) involving either cancer development in exposed individuals due to mutation of somatic cells or heritable disease in their offspring due to mutation of reproductive (germ) cells.

Consideration is also given to effects on the embryo and fetus, and to diseases other than cancer.

(56) In *Publication 60* (ICRP, 1991b) the Commission classified the radiation effects that result in tissue reactions as deterministic effects and used the term stochastic effects for radiation-induced cancer and heritable disease. Effects caused by injury in populations of cells were called non-stochastic in *Publication 41* (ICRP, 1984), and this was replaced by the term deterministic, meaning 'causally determined by preceding events' in *Publication 60* (ICRP 1991). The generic terms, deterministic and stochastic effects, are not always familiar to those outside the field of radiological protection. For this and other reasons (see Annex A) Chapter 3 and Annex A use the directly descriptive terms tissue reactions and cancer/heritable effects respectively. However, the Commission recognises that the generic terms, deterministic and stochastic effects, have a firmly embedded use in its system of protection and will use the generic and directly descriptive terms synonymously, according to context. In this respect the Commission notes that some radiation-associated health consequences, particularly some non-cancer effects (see Section 3.2.6), are not yet sufficiently well understood to assign to either of the generic categories. Since 1990, the Commission has reviewed many aspects of the biological effects of radiation. The views developed by the Commission are summarised in this Chapter with emphasis on effective doses of up to around 100 mSv (or absorbed doses of around 100 mGy) delivered as a single dose or accumulated annually. A more detailed summary of the post 1990 developments in radiation biology and epidemiology is provided in Annex A and *Publication 99* (ICRP, 2006a) together with explanations of the judgements that underpin the recommendations made in this Chapter.

3.1 The induction of tissue reactions (deterministic effects)

(57) The induction of tissue reactions is generally characterised by a dose-threshold. The reason for the presence of this dose-threshold is that radiation damage (serious malfunction or death) of a critical population of cells in a given tissue needs to be sustained before injury is expressed in a clinically relevant form. Above the dose-threshold the severity of the injury, including impairment of the capacity for tissue recovery, increases with dose.

(58) Early (days to weeks) tissue reactions to radiation in cases where the threshold dose has been exceeded may be of the inflammatory type resulting from the release of cellular factors or they may be reactions resulting from cell loss (*Publication 59*; ICRP 1991a). Late tissue reactions (months to years) can be of the generic type if they arise as a direct result of damage to that tissue. By contrast other

late reactions may be of the consequential type if they arise as a result of the early cellular damage noted above (Dörr and Hendry, 2001). Examples of these radiation-induced tissue reactions are given in Annex A.

(59) Reviews of biological and clinical data have led to further development of the Commission's judgements on the cellular and tissue mechanisms that underlie tissue reactions and the dose thresholds that apply to major organs and tissues. However, in the absorbed dose range up to around 100 mGy (low LET or high LET) no tissues are judged to express clinically relevant functional impairment. This judgement applies to both single acute doses and to situations where these low doses are experienced in a protracted form as repeated annual exposures.

(60) Annex A provides updated information on dose thresholds (corresponding to doses that result in about 1% incidence) for various organs and tissues. On the basis of current data the Commission judges that the occupational and public dose limits, including the limits on equivalent dose for the skin, hands/feet and eye, given in *Publication 60* (ICRP, 1991b) remain applicable for preventing the occurrence of deterministic effects (tissue reactions); see Section 5.9 and Table 6. However new data on the radiosensitivity of the eye are expected and the Commission will consider these data when they become available. In addition, in Annex A, reference is made to the clinical criteria that apply to dose limits on equivalent doses to the skin.

3.2 The induction of late-expressing health effects of radiation (stochastic effects)

(61) The Commission includes cancer, non-cancer, and heritable diseases in the late-expressing health effect category. In the case of cancer, epidemiological and experimental studies provide compelling evidence of radiation risk albeit with uncertainties at low doses. In the case of heritable diseases, even though there is no direct evidence of radiation risks to humans, experimental observations argue strongly that such risks for future generations should be included in the system of protection.

3.2.1 Risk of cancer

(62) The accumulation of cellular and animal data relevant to radiation tumorigenesis has, since 1990, greatly strengthened the view that DNA damage response processes in single target cells are of critical importance to the development of cancer after radiation exposure. These data together with advances in knowledge of the cancer process in general, give increased confidence that detailed information on DNA damage response/repair and the induction of gene/chromosomal mutations can contribute significantly to judgements on the radiation-associated increase in the incidence of cancer at low doses. This knowledge also influences judgements on relative biological effectiveness (RBE), radiation weighting factors, and dose and dose-rate effects. Of particular importance are the advances in understanding radiation effects on DNA like the induction of complex forms of DNA double strand breaks, the problems experienced by cells in correctly repairing these complex forms of DNA damage, and the consequent appearance of gene/chromosomal mutations. Advances in microdosimetric knowledge concerning aspects of radiation-induced DNA damage have also contributed significantly to this understanding (see Annexes A and B).

(63) Although there are recognised exceptions, for the purposes of radiological protection the Commission judges that the weight of evidence on fundamental cellular processes coupled with dose-response data supports the view that in the low dose range, below around 100 mSv, it is scientifically reasonable to assume that the incidence of cancer or hereditary effects will rise in direct proportion to an increase in the equivalent dose in the relevant organs and tissues.

(64) Therefore, the practical system of radiological protection recommended by the Commission will continue to be based upon the assumption that at doses below around 100 mSv a given increment in dose will produce a directly proportionate increment in the probability of incurring cancer or hereditary effects attributable to radiation. This dose-response model is generally known as 'linear non-threshold' or LNT. This view accords with that given by UNSCEAR (2000), NCRP (2001), and by NAS/NRC (2006). By contrast, a recent report from the French Academies (2005) argues in support of a practical threshold for radiation cancer risk. However from an analysis conducted by ICRP (*Publication 99*, ICRP 2006), the Commission considers that the adoption of the LNT model combined with a judged value of a dose and dose rate effectiveness factor (DDREF) provides a prudent basis for the practical purposes of radiological protection, i.e., the management of risks from low dose radiation exposure.

(65) However, the Commission emphasises that whilst the LNT model remains a scientifically plausible element in its practical system of radiological protection, biological/epidemiological information that would unambiguously verify the hypothesis that underpins the model is unlikely to be forthcoming (see also UNSCEAR, 2000; NCRP, 2001). Because of this uncertainty on effects at low doses the Commission judges that it is not appropriate, for the formal purposes of public health, to calculate the hypothetical number of cases of cancer or heritable disease that might be associated with very small radiation doses received by large numbers of people over very long periods of time (see also Section 5.8).

(66) In arriving at its practical judgement on the LNT model, the Commission has considered potential challenges associated with information on cellular adaptive responses, the relative abundance of spontaneously arising and low dose-induced DNA damage and the existence of the post-irradiation cellular phenomena of induced genomic instability and bystander signalling (ICRP, 2006). The Commission recognises that these biological factors together with possible tumour-promoting effects of protracted irradiation may influence radiation cancer risk but that current uncertainties on their mechanisms and tumorigenic consequences of the above processes are too great for the development of practical judgements. The Commission also notes that since the estimation of nominal cancer risk coefficients is based upon direct human epidemiological data, any contribution from these biological mechanisms would be included in that estimate. Uncertainty with regard to the role of these processes in cancer risk will remain until their relevance to cancer development in vivo is demonstrated and there is knowledge of the dose dependence of the cellular mechanisms involved.

(67) Since 1990 further epidemiological information has accumulated on the risk of organ-specific cancer following exposure to radiation. Much of this new information has come from the continuing follow-up of survivors of the atomic bomb explosions in Japan in 1945 – the Life Span Study (LSS). For cancer mortality the follow-up is 47 years (October 1950 – December 1997); for cancer incidence the

follow-up period is 41 years (January 1958 – December 1998). These latter data, which were not available in 1990, can provide more reliable estimates of risk principally because cancer incidence allows for more accurate diagnosis. The Commission has therefore placed emphasis on incidence data for its present recommendations. In addition, epidemiological data from the LSS provide further information on the temporal and age-dependent pattern of radiation cancer risk, particularly the assessment of risk amongst those exposed at early ages. Overall, current cancer risk estimates from the LSS are not greatly changed since 1990 but the improved quality of the cancer incidence data provide a more firm foundation for the risk modelling described in Annex A.

(68) The LSS is not, however, the sole source of information on radiation cancer risk and the Commission has considered data from medical, occupational and environmental studies (UNSCEAR 2000, NAS/NRC 2006). For cancers at some sites there is reasonable compatibility between the data from the LSS and those from other sources. However it is recognised by the Commission that for a number of organs/tissues there are indications of differences in radiation risk estimates among the various data sets, with the LSS estimates being generally higher. Most studies on environmental radiation exposures currently lack sufficient data on dosimetry and tumour ascertainment to contribute directly to risk estimation by the Commission but are expected to be a potentially valuable data source in the future.

(69) A dose and dose-rate effectiveness factor (DDREF) has been used by the Commission to project cancer risk determined at high doses and high dose rates to the risks that would apply at low doses and low dose rates. In general, cancer risk at these low doses and low dose rates is judged, from a combination of epidemiological, animal, and cellular data, to be reduced by the value of the factor ascribed to DDREF. In its 1990 Recommendations the Commission made the broad judgement that a DDREF of 2 should be applied for the general purposes of radiological protection.

(70) In principle, epidemiological data on protracted exposure, such as those from environmental and occupational circumstances, should be directly informative on judgements of DDREF. However the statistical precision afforded by these studies and other uncertainties associated with the inability to adequately control for confounding factors (see Annex A), do not allow for a precise estimate of DDREF at this time. Accordingly the Commission has decided to continue to use broad judgements in its choice of DDREF based upon dose-response features of experimental data, the LSS, and the results of probabilistic uncertainty analysis conducted by others (NCRP 1997, EPA 1999, NCI/CDC 2003, Annex A).

(71) The BEIR VII Committee (NAS/NRC 2006) recently undertook probabilistic analyses. The approach taken was a Bayesian analysis of combined dose-response data. The data sets considered were a) solid cancer in the LSS; b) cancer and life shortening in animals; and c) chromosome aberrations in human somatic cells. The modal value of DDREF from these analyses was 1.5 with a range of 1.1 to 2.3 and the BEIR VII Committee chose the value of 1.5. However a DDREF of 2 was compatible with these data and the Committee recognised the subjective and probabilistic uncertainties inherent in this specific choice. Further, the BEIR VII Committee noted that for the induction of gene and chromosomal mutations values of DDREF generally fall in the range of 2-4, and for the induction of cancer in animals and life shortening in animals values of DDREF generally fall in the range of 2-3. The Commission emphasises that a DDREF is considered for

solid cancers and not leukaemia for which a linear-quadratic response is seen, i.e. a lower risk per unit dose at low doses than at high doses.

(72) In considering all the data noted above, and recognising the broad range of experimental animal data showing reduction in carcinogenic effectiveness and life-shortening following protracted exposures, the Commission finds no compelling reason to change its 1990 recommendations of a DDREF of 2. However, the Commission emphasises that this continues to be a broad whole number judgement for the practical purposes of radiological protection which embodies elements of both subjective and probabilistic uncertainty. This risk reduction factor of 2 is used by the Commission to derive the nominal risk coefficients for cancer overall given in Table 1 but the Commission recognises that, in reality, different dose and dose rate effects may well apply to different organs/tissues.

3.2.2 Risk of hereditary effects

(73) Although there continues to be no direct evidence that exposure of parents to radiation leads to excess heritable disease in offspring, the Commission judges that there is compelling evidence that radiation causes mutation in reproductive (germ) cells in experimental animals. Accordingly, the risk of hereditary effects continues to be included in the Commission's system of radiological protection. The Commission also notes reports (reviewed in UNSCEAR, 2001) which argue, on the basis of A-bomb survivor and mouse genetic data, that the risk of heritable diseases tended to be overestimated in the past.

(74) There are some post-1990 human and animal data on the quantitative aspects of radiation-induced germ cell mutation that impact on the Commission's judgement on the risk of induction of genetic disease expressing in future generations. There have also been substantial advances in the fundamental understanding of human genetic diseases and the process of germ line mutagenesis including that occurring after radiation. The Commission has re-appraised the methodology used in *Publication 60* for the estimation of hereditary risks including risks of multifactorial diseases (*Publication 83*; ICRP, 1999b). The Commission has now adopted a new framework for the estimation of hereditary risks that employs data from human and mouse studies (UNSCEAR, 2001; NAS/NRC, 2006). Also, for the first time, a scientifically justified method for the estimation of risk of multifactorial disease has been included. Mouse studies continue to be used to estimate genetic risks because of the lack of clear evidence in humans that germline mutations caused by radiation result in demonstrable genetic effects in offspring.

(75) The new approach to hereditary risks continues to be based on the concept of the doubling dose (DD) for disease-associated mutations used in *Publication 60*. However, the methodology differs in that recoverability of mutations in live births is allowed for in the estimation of DD. An additional difference is that direct data on spontaneous human mutation rates are used in conjunction with radiation-induced mutation rates derived from mouse studies. This new methodology (see Annex A, Box 2) is based on the UNSCEAR 2001 report and has also been used recently by NAS/NRC (2006). The present ICRP estimate of the second generation risk of about 0.2% per Gy is essentially the same as that cited by UNSCEAR 2001 (see Annex A and UNSCEAR 2001, Table 46). However, given the major changes in methodology, the close similarity of the present 2nd generation risk to that of *Publication 60* is wholly coincidental. In *Publication 60* genetic risks were expressed at a theoretical equilibrium between mutation and selection. In the light of

further knowledge the Commission judges that many of the underlying assumptions in such calculations are no longer sustainable. The same view has been expressed by UNSCEAR (2001) and NAS/NRC (2006). Accordingly the Commission now expresses genetic risks up to the second generation and judges that this procedure will not lead to a significant underestimation of genetic risk. This issue is discussed in detail in Annex A where it is argued on the basis of UNSCEAR calculations (UNSCEAR 2001) that there are no substantial differences between genetic risks expressed at 2 and 10 generations.

(76) The new estimate for genetic risks up to the second generation is around 0.2% per Sv. This value relates to continuous low dose-rate exposures over these two generations, i.e., doses to the parental and child generations and effects observed in children and grandchildren. As a result, these revised estimates of genetic risk have reduced the judged value of the tissue weighting factor for the gonads considerably (see Chapter 4). However, the Commission emphasises that this reduction in the gonadal tissue weighting factor provides no justification for allowing controllable gonadal exposures to increase in magnitude.

3.2.3 Detriment-adjusted nominal risk coefficients for cancer and hereditary effects

(77) New information on the risks of radiation-induced cancer and hereditary effects has been used in risk modelling and disease detriment calculations in order to estimate sex-averaged nominal risk coefficients.

(78) It remains the policy of the Commission that its recommended nominal risk coefficients should be applied to whole populations and not to sub-groups therein. The Commission believes that this policy provides for a general system of protection that is simple and sufficiently robust. In retaining this policy the Commission does however recognise that there are significant differences in risk between males and females (particularly for the breast) and in respect of age at exposure. Annex A provides data and calculations relating to these differences.

(79) The calculation of sex-averaged nominal risk coefficients for cancer involves the estimation of nominal risks for different organs and tissues, adjustment of these risks for lethality and quality of life and, finally, the derivation of a set of site-specific values of relative detriment, which includes heritable effects from gonadal exposures. These relative detriments provide the basis of the Commission's system of tissue weighting which is explained in Annex A (Box 1) and summarised in Chapter 4.

(80) On the basis of these calculations the Commission proposes nominal risk coefficients for detriment-adjusted cancer risk as $5.5\ 10^{-2}$ Sv^{-1} for the whole population and $4.1\ 10^{-2}$ Sv^{-1} for adult workers. For hereditary effects, the detriment-adjusted nominal risk in the whole population is estimated as $0.2\ 10^{-2}$ Sv^{-1} and in adult workers as $0.1\ 10^{-2}$ Sv^{-1}. These estimates are shown in Table 1, where they are compared with the estimate of detriment used in the 1990 Recommendations in *Publication 60* (ICRP, 1991b).

(81) The most significant change from *Publication 60* is the 6-8 fold reduction in the nominal risk coefficient for hereditary effects. This reduction comes about mainly because the Commission has chosen to express such risks up to the second

generation rather than at a theoretical equilibrium. This change is discussed and justified in Annex A.

Table 1. Detriment-adjusted nominal risk coefficients for cancer and hereditary effects (10^{-2} Sv^{-1})

Exposed population	Cancer		Heritable effects		Total	
	Present[1]	*Publ. 60*	Present[1]	*Publ. 60*	Present[1]	*Publ. 60*
Whole	5.5	6.0	0.2	1.3	6.0	7.3
Adult	4.1	4.8	0.1	0.8	4.0	5.6

[1]Values from Annex A.

(82) Note that although all coefficients are presented as fractional values, this presentation is used for the purposes of traceability to Annex A only and does not imply a level of precision (see paragraphs 78 and 79).

(83) The present detriment-adjusted nominal risk coefficient for cancer shown in Table 1 has been computed in a different manner from that of *Publication 60*. The present estimate is based upon lethality and life impairment weighted data on cancer incidence, whereas in *Publication 60* detriment was based upon fatal cancer risk weighted for non-fatal cancer, relative life lost for fatal cancers and life impairment for non-fatal cancer.

(84) In spite of changes in the cancer risk data and their treatment, the present nominal risk coefficients are wholly compatible with those presented by the Commission in *Publication 60* (ICRP 1990). Given the uncertainties discussed in Annex A, the Commission considers that the small reduction in the estimate of nominal risk since 1990 is of no practical significance.

(85) It is therefore the recommendation of the Commission that the approximated overall risk coefficient of 5% per Sv on which current international radiation safety standards are based continues to be appropriate and should be retained for the purposes of radiological protection.

3.2.4 Radiation effects in the embryo and fetus

(86) The risks of tissue reactions and malformation in the irradiated embryo and fetus have been reviewed in *Publication 90* (ICRP, 2003a). In the main, this review reinforced the judgements on in-utero risks given in *Publication 60* although on some issues new data allow for clarification of views. On the basis of *Publication 90*, the Commission has reached the following conclusions on the in-utero risks of tissue injury and malformation at doses below about 100 mGy of low LET radiation.

(87) The new data confirm embryonic susceptibility to the lethal effects of irradiation in the pre-implantation period of embryonic developments. At doses under 100 mGy, such lethal effects will be very infrequent.

(88) In respect of the induction of malformations, the new data strengthen the view that there are gestation age-dependent patterns of in-utero radiosensitivity with

maximum sensitivity being expressed during the period of major organogenesis. On the basis of animal data it is judged that there is a true dose-threshold of around 100 mGy for the induction of malformations; therefore, for practical purposes, the Commission judges that risks of malformation after in-utero exposure to doses well below 100 mGy are not expected.

(89) The *Publication 90* (ICRP, 2003a) review of A-bomb survivor data on the induction of severe mental retardation after irradiation in the most sensitive pre-natal period (8-15 weeks post-conception) now supports a true dose-threshold of at least 300 mGy for this effect and therefore the absence of risk at low doses. The associated data on IQ losses estimated at around 25 points per Gy are more difficult to interpret and the possibility of a non-threshold dose response cannot be excluded. However, even in the absence of a true dose-threshold, any effects on IQ following in utero doses under 100 mGy would be of no practical significance. This judgement accords with that developed in *Publication 60* (ICRP, 1991b).

(90) *Publication 90* also reviewed data concerning cancer risk following in-utero irradiation. The largest studies of in-utero medical irradiation provided evidence of increased childhood cancer of all types. The Commission recognises that there are particular uncertainties on the risk of radiation-induced solid cancers following in-utero exposure. Nonetheless, the Commission considers that it is prudent to assume that life-time cancer risk following in-utero exposure will be similar to that following irradiation in early childhood i.e. at most, a few times that of the population as a whole.

3.2.5 Genetic susceptibility to cancer

(91) The issue of individual genetic differences in susceptibility to radiation-induced cancer was noted in *Publication 60* and reviewed in *Publication 79* (ICRP, 1999a). Since 1990, there has been a remarkable expansion in knowledge of the various single gene human genetic disorders, where excess spontaneous cancer is expressed in a high proportion of gene carriers – the so-called high penetrance genes which can be strongly expressed as excess cancer. Studies with cultured human cells and genetically altered laboratory rodents have also contributed much to knowledge and, with more limited epidemiological and clinical data, suggest that most of the rare single gene, cancer prone disorders will show greater-than-normal sensitivity to the tumorigenic effects of radiation.

(92) There is also a growing recognition, with some limited supporting data, that variant genes of lower penetrance through gene-gene and gene-environment interactions can result in a highly variable expression of cancer following radiation exposure.

(93) On the basis of the data and judgements developed in *Publication 79* and further information reviewed in the UNSCEAR (2000; 2001) and NAS/NRC (2006) reports, the Commission believes that strongly expressing, high penetrance, cancer genes are too rare to cause significant distortion of population-based estimates of low dose radiation cancer risk. However, there are likely to be implications for individual cancer risks, particularly for second cancers in gene carriers receiving high-dose radiotherapy for a first neoplasm; although the features of low-dose radiation risk are not entirely clear.

(94) Although the Commission recognises that variant cancer genes of low penetrance may, in principle, be sufficiently common to impact upon population-based estimates of radiation cancer risk, the information available is insufficient to provide a meaningful quantitative judgement on this issue.

3.3 The induction of diseases other than cancer

(95) Since 1990 evidence has accumulated that the frequency of non-cancer diseases is increased in some irradiated populations. The strongest statistical evidence for the induction of these non-cancer effects at effective doses of the order of 1 Sv derives from the most recent mortality analysis of the Japanese atomic bomb survivors followed after 1968 (Preston et al., 2003). That study has strengthened the statistical evidence for an association with dose – particularly for heart disease, stroke, digestive disorders and respiratory disease. However, the Commission notes current uncertainties on the shape of the dose-response at low doses and that the LSS data are consistent both with there being no dose threshold for risks of disease mortality and with there being a dose threshold of around 0.5 Sv. Additional evidence of the non-cancer effects of radiation, albeit at high doses, comes from studies of cancer patients receiving radiotherapy but these data do not clarify the issue of a possible dose threshold (Annex A). It is also unclear what forms of cellular and tissue mechanisms might underlie such a diverse set of non-cancer disorders.

(96) Whilst recognising the potential importance of the observations on non-cancer diseases, the Commission judges that the data available do not allow for their inclusion in the estimation of detriment following radiation doses less than around 100 mSv.

4. QUANTITIES USED IN RADIOLOGICAL PROTECTION

4.1. Introduction

(97) Radiological protection is concerned with controlling exposures to ionising radiation, so that the risk of radiation-induced cancer and hereditary disease (stochastic effects) is limited to acceptable levels and tissue reactions (deterministic effects) are prevented. For assessing doses from radiation exposures, special *dosimetric quantities* have been developed. The fundamental *protection quantities* adopted by the Commission are based on measures of the energy deposited in organs and tissues of the human body. For relating the radiation dose to radiation risk (detriment), it is also necessary to take into account variations in the biological effectiveness of radiations of different quality as well as the varying sensitivity of organs and tissues to ionising radiation.

(98) In *Publication 26* (ICRP, 1977) the protection quantities *dose equivalent*, for organs and tissues of the human body, and *effective dose equivalent* were introduced. The definition and method of calculation of these quantities were modified in *Publication 60* (ICRP, 1991b) to give the quantities *equivalent dose* and *effective dose*. The development of the quantities effective dose equivalent and effective dose has made a significant contribution to radiological protection as it has enabled doses to be summed from whole and partial body exposure from external radiation of various types and from intakes of radionuclides.

(99) Equivalent dose and effective dose cannot be measured directly in body tissues. The protection system therefore includes *operational quantities* that can be measured and from which the equivalent dose and the effective dose can be assessed.

(100) The general acceptance of effective dose and the demonstration of its utility in radiological protection are important reasons for maintaining it as the central quantity for dose assessments in radiological protection. There are, however, a number of aspects of the dosimetry system given in *Publication 60* that need to be addressed and clarified as summarised below and given in more detail in Annex B. Care is also needed in describing the situations in which effective dose should be and should not be used. In some situations tissue absorbed dose or equivalent dose are more appropriate quantities.

4.2. Considerations of health effects

(101) Radiological protection in the low dose range is primarily concerned with protection against radiation-induced cancer and hereditary disease. These effects are taken to be probabilistic in nature and to increase in frequency in proportion to the radiation dose, with no threshold (see Chapter 3 or Annex A). For the definition and calculation of effective dose the recommended radiation weighting factors, w_R, allow for the differences in the effect of various radiations in causing stochastic effects while tissue weighting factors, w_T, allow for the variations in radiation sensitivity of different organs and tissues to the induction of stochastic effects (see

Section 4.3.4 and Annex B). The radiation weighting factors for radiations characterised by a high linear energy transfer, so called high-LET radiations (see Section 4.3.3), are derived for stochastic effects at low doses.

(102) At high doses and especially in emergency situations, radiation exposures may cause tissue reactions (deterministic effects). Such clinically observable damage occurs above threshold doses. The extent of damage depends upon the absorbed dose and dose rate as well as radiation quality (see Annexes A and B) and the sensitivity of the tissue. In general, values of relative biological effectiveness (RBE) for tissue reactions caused by high-LET radiations are found to be lower than those obtained for stochastic effects at low doses and the relative sensitivity of tissues also differs. The quantities equivalent dose and effective dose should not be used in the quantification of higher radiation doses and in making decisions on the need for any treatment related to tissue reactions. For such purposes, doses should be evaluated in terms of absorbed dose (in gray, Gy) and where high-LET radiations (e.g. neutrons or alpha particles) are involved, an absorbed dose weighted with an appropriate RBE, should be used (see Annex B).

4.3. Dose quantities

(103) The procedure for the assessment of effective dose adopted by the Commission is to use *absorbed dose* as the fundamental physical quantity, to average it over specified organs and tissues, to apply suitably chosen weighting factors to take account of differences in biological effectiveness of different radiations to give the quantity equivalent dose, and to consider differences in sensitivities of organs and tissues to stochastic health effects. Values of the equivalent dose to organs and tissues weighted for the radiosensitivity of these organs and tissues are then summed to give the effective dose. This quantity is based on the exposure to radiation from external radiation fields and from incorporated radionuclides as well as on the primary physical interactions in human tissues and on judgements about the biological reactions resulting in stochastic health effects (Annex B).

4.3.1. Absorbed dose

(104) In radiation biology, clinical radiology, and radiological protection the absorbed dose, D, is the basic physical dose quantity and is used for all types of ionising radiation and any irradiation geometry. It is defined as the quotient of mean energy, $\mathrm{d}\bar{\varepsilon}$, imparted by ionising radiation in a volume element and the mass, dm, of the matter in that volume, that is

$$D = \frac{\mathrm{d}\bar{\varepsilon}}{\mathrm{d}m} \tag{4.1}$$

(105) The SI unit of absorbed dose is J kg^{-1} and its special name is gray (Gy). Absorbed dose is derived from the mean value of the stochastic quantity of energy imparted, ε, and does not reflect the random fluctuations of the interaction events in tissue. While it is defined at any point in matter, its value is obtained as an average over a mass element dm and hence over many atoms or molecules of matter. Absorbed dose is a measurable quantity and primary standards exist to determine its

value. The definition of absorbed dose has the scientific rigour required for a basic physical quantity (Annex B).

4.3.2. Averaging of dose

(106) When using the quantity absorbed dose in practical protection applications, doses are averaged over tissue volumes. It is assumed that for low doses, the mean value of absorbed dose averaged over a specific organ or tissue can be correlated with radiation detriment for stochastic effects in that tissue with an accuracy sufficient for the purposes of radiological protection. The averaging of absorbed doses in tissues or organs and the summing of weighted mean doses in different organs and tissues of the human body comprise the basis for the definition of the protection quantities which are used for limiting stochastic effects at low doses. This approach is based upon the assumption of a linear, non-threshold, dose-response relationship (LNT) and allows the addition of doses for external and internal exposure.

(107) The averaging of absorbed dose is carried out over the mass of a specified organ (e.g. liver) or tissue (e.g. muscle) or the sensitive region of a tissue (e.g. endosteal surfaces of the skeleton). The extent to which the mean dose value is representative of the absorbed dose in all regions of the organs, tissues or tissue regions depends for external irradiation on the homogeneity of the exposure and on the range of the radiation incident on the body. The homogeneity of the dose distribution in the low dose range depends also upon microdosimetric properties. For radiations with low penetration or limited range (e.g., low-energy photons or charged particles) as well as for widely distributed tissues and organs (e.g. red bone marrow, lymphatic nodes or skin) the absorbed dose distribution within the specified organ or tissue will be even more heterogeneous. In cases of extreme partial body exposure, tissue damage may occur even if the mean organ or tissue dose or the effective dose is below the dose limit. A special limit on local skin dose, for example, takes account of this situation in the case of exposure by low-penetrating radiation.

(108) For radiations emitted by radionuclides retained within body organs or tissues, so-called internal emitters, the absorbed dose distribution in organs depends on the penetration and range of the radiations. Thus, the absorbed dose distribution for radionuclides emitting alpha particles, soft beta particles, low-energy photons or Auger electrons may be highly heterogeneous (see Annex B). This heterogeneity applies in particular to radionuclides in the respiratory and alimentary systems, and the skeleton. Specific dosimetric models have been developed to take account of such heterogeneity in the distribution and retention of activity and of sensitive regions in these particular cases.

4.3.3. Equivalent dose and radiation weighting factors

(109) The protection quantities are used to specify exposure limits for keeping the occurrence of stochastic health effects below unacceptable levels and for avoiding tissue reactions in workers and members of the public. The definition of the protection quantities is based on the average absorbed dose, $D_{T,R}$ in the volume of a specified organ or tissue T (see Table 3), due to radiation of type R (see Table 2). The radiation R is given by the type and energy of radiation either incident on the

body or emitted by radionuclides residing within it. The protection quantity *equivalent dose* in an organ or tissue, H_T, is then defined by

$$H_T = \sum_R w_R D_{T,R} \qquad (4.2)$$

where w_R is the radiation weighting factor for radiation R. The sum is performed over all types of radiations involved. The unit of equivalent dose is J kg^{-1} and has the special name sievert (Sv).

(110) In the early 1960s, radiation weighting in the definition of radiological protection quantities was related to the radiation quality factor as a function of LET and denoted as L in the $Q(L)$ function of *Publication 26* (ICRP, 1977). In *Publication 60* (ICRP, 1991b) the method of radiation weighting was changed for calculating the protection quantities equivalent dose and effective dose. The Commission selected a general set of radiation weighting factors (w_R) that were considered to be appropriate for application in radiological protection. The values of w_R were defined largely on the basis of the relative biological effectiveness (RBE) of the different radiations.

(111) A revised set of w_R values has been adopted in these recommendations based upon a re-evaluation of the available data (see Annexes A and B). The values of w_R for neutrons and protons given in these recommendations differ from those given in *Publication 60* (see below and Annex B). A w_R value for charged pions has been included. The value of w_R for photons is the same for x rays and gamma rays of all energies. The numerical values of w_R are specified in terms of type and in the case of neutrons in terms of energy of radiation either incident on the human body or emitted by radionuclides residing in the body (Table 3). The values of w_R are selected by judgement from a broad range of experimental RBE data which are relevant to stochastic effects. The RBE values increase to a maximum (RBE_M) with decreasing radiation dose (ICRP, 2003c). The values of RBE_M have been used for w_R selection and are assigned fixed values for radiological protection purposes.

Table 2**.** Recommended radiation weighting factors.

Radiation type	**Radiation weighting factor, w_R**
Photons	1
Electrons and muons	1
Protons and charged pions	2
Alpha particles, fission fragments, heavy ions	20
Neutrons	A continuous function of neutron energy (see Fig. 1 and Equation 4.3)

All values relate to the radiation incident on the body or, for internal radiation sources, emitted from the incorporated radionuclide(s).

(112) ***Reference radiation.*** Values of RBE obtained experimentally depend on the reference radiation chosen. Generally low-LET photon radiation is taken as the reference although no specific energy has been agreed upon for this purpose. For the selection of radiation weighting factors in *Publication 60*, a broad range of experimental RBE data using either high energy x rays above about 200 kV or ^{60}Co

or ^{137}Cs gamma radiation was considered (see Annex B). This approach is also used in these recommendations.

(113) ***Photons, electrons, and muons.*** Photons, electrons, and muons are radiations with LET values of less than 10 keV/μm. These radiations have always been given a radiation weighting of 1. There are good arguments (see Annex B) to continue to use a w_R of 1 for all low-LET radiations (Annex B, Table 3). This does not, however, imply that there are no differences in radiation quality of photons of different energies. The proposed simplification is sufficient only for the intended application of equivalent dose and effective dose, e.g. for dose limitation, assessment and controlling of doses in the low dose range. In cases where individual retrospective risk assessments have to be made, more detailed information on the radiation field and appropriate RBE values may need to be considered if relevant data are available. Heterogeneity of the radiation dose within cells, as can occur with tritium or Auger emitters incorporated into DNA, may also require specific analysis (see Annex B).

(114) ***Neutrons.*** The radiation weighting factor for neutrons reflects the relative biological effectiveness of neutrons following external exposure. The biological effectiveness of neutrons incident on the human body is strongly dependent on neutron energy (see Annex B).

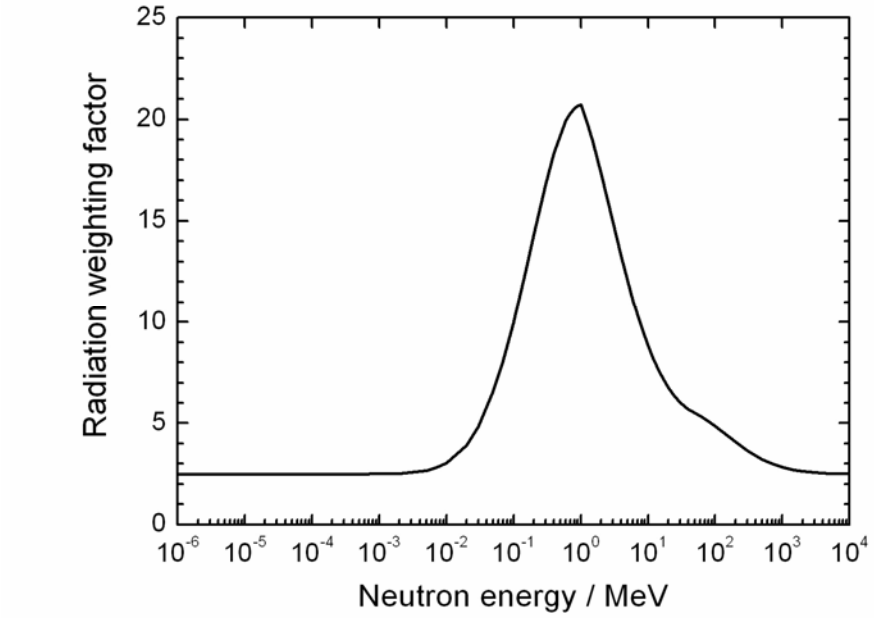

Fig. 1**.** Radiation weighting factor, w_R, for neutrons versus neutron energy.

(115) In *Publication 60* (ICRP, 1991b), the radiation weighting factor for neutrons was defined by a step function. It is now recommended that the radiation weighting factor for neutrons be defined by a continuous function (Fig. 1). It should be noted, however, that the use of a continuous function is based on the practical consideration that most neutron exposures involve a range of energies. The recommendation of the function does not imply a higher precision of the basic data. A detailed discussion on the selection of the w_R-function for neutrons is given in Annex B. The most significant changes compared to the data in *Publication 60* are the decrease of w_R in the low-energy range, which takes account of the large contribution of secondary photons to the absorbed dose in the human body, and the decrease of w_R at neutron energies above 100 MeV. The following continuous

function in neutron energy E_n (MeV) is recommended for the calculation of radiation weighting factors for neutrons:

$$w_R = \begin{cases} 2.5 + 18.2\, e^{-[\ln(E_n)]^2/6} & , \quad E_n < 1 \text{ MeV} \\ 5.0 + 17.0\, e^{-[\ln(2E_n)]^2/6} & , \quad 1 \text{ MeV} \le E_n \le 50 \text{ MeV} \\ 2.5 + 3.25 e^{-[\ln(0.04E_n)]^2/6} & , \quad E_n > 50 \text{ MeV} \end{cases} \qquad (4.3)$$

This function, i.e., equation (4.3) and Fig. 1, has been derived empirically and is consistent with existing biological and physical knowledge (Annex B).

(116) ***Protons and pions.*** When considering exposure to protons, only external radiation sources are of importance in practical radiological protection. In the proton component of cosmic radiation fields or fields near high-energy particle accelerators, very high-energy protons dominate and protons with energies of few MeV are of minor significance even when their increased biological effectiveness at low energies is taken into account. For radiological protection, it is judged to be sufficiently accurate to adopt a single w_R value for protons of all energies that is mainly based on radiobiological data for high-energy protons above 10 MeV. The range of 10 MeV protons in tissue is 1.2 mm and decreases with lower energies. These protons will be absorbed in skin. (Annex B). A single radiation weighting factor of 2 is recommended for external proton radiation for general use (ICRP 2003c). It replaces the value of 5 recommended in *Publication 60* (ICRP 1991b).

(117) Pions are negatively or positively charged or neutral particles encountered in radiation fields resulting from interactions of the primary cosmic rays with nuclei at high altitudes in the atmosphere. These particles contribute to the exposure in aircraft. They are also found as part of the complex radiation fields behind shielding of high-energy particle accelerators and thus contribute to the occupational exposure of accelerator staff. Considering that the energy distribution of pions in radiation fields is very broad, the use of a single weighting factor of 2 is recommended for all charged pions.

(118) ***Alpha particles.*** Humans may be exposed to alpha particles from internal emitters, e.g. from inhaled radon progeny or ingested alpha-emitting radionuclides such as isotopes of plutonium, polonium, radium, thorium and uranium. There are a number of epidemiological studies, as well as animal data, that provide information on the risk from incorporated alpha emitters. However, the distribution of radionuclides in organs and tissues is complex and the estimation of dose is dependent on the models used. Hence the calculated doses are associated with substantial uncertainties and result in a broad range of RBE values from epidemiological as well as experimental studies (*Publication 92*, ICRP 2003c, and Annex B).

(119) Despite substantial uncertainties in estimates of dose and risk from intakes of alpha emitting radionuclides, the available human and animal data indicate that the RBE depends on the biological end-point under consideration. The limited human data that allow estimation of alpha particle RBE values suggest values of around 10 – 20 for lung and liver cancer and lower values for bone cancer and leukaemia. Judgements on the available data and the selection of a w_R value for alpha particles have been reviewed in *Publication 92* (ICRP, 2003c). As recent data do not provide compelling evidence for a change of the radiation weighting factor

for alpha particles, the w_R value of 20 adopted in *Publication 60* (ICRP, 1991b) is retained.

(120) ***Fission fragments and heavy ions.*** Doses from fission fragments are of importance in radiological protection, mainly in internal dosimetry, and the situation regarding radiation weighting factors is similar to that for α-particles. The short ranges of heavy ions and fission fragments in organs and tissues and the resulting ionisation density have a strong influence on their biological effectiveness. A radiation weighting factor of 20 (see Table 2), which equals that for α-particles, is recommended (see Annex B).

(121) Heavy ions are encountered in external radiation fields in air flight at high altitudes and in space exploration. There are very limited RBE data for heavy ions and most of these are based on *in vitro* experiments. For heavy charged particles incident on and stopped in the human body the radiation quality of the particle changes markedly along its track. The selection of a single w_R value of 20 for all types and energies of heavy charged particles is a conservative estimate and is recommended as sufficient for general application in radiological protection. For applications in space, where these particles contribute significantly to the total dose in the human body, a more realistic approach may have to be used.

4.3.4. Effective dose and tissue weighting factors

(122) The effective dose, E, introduced in *Publication 60* (ICRP, 1991b) is defined as:

$$\begin{aligned} E &= \sum_T w_T \sum_R w_R D_{T,R} \\ &= \sum_T w_T H_T \end{aligned} \qquad (4.4)$$

where w_T is the tissue weighting factor for tissue, T and $\Sigma w_T = 1$. The sum is performed over all organs and tissues of the human body considered to be sensitive to the induction of stochastic effects. These w_T values are chosen to represent the contributions of individual organs and tissues to overall radiation detriment from stochastic effects. The unit of effective dose is J kg^{-1} with the special name sievert (Sv). The unit is the same for equivalent dose and effective dose as well as for some operational dose quantities (see Section 4.3.7). Care must be taken to ensure that the quantity being used is clearly stated.

(123) The organs and tissues for which w_T values are specified are given in Table 3 (also see Annex A). They represent mean values for humans averaged over both sexes and all ages and thus do not relate to the characteristics of particular individuals.

(124) On the basis of epidemiological studies on cancer induction in exposed populations and risk assessments for hereditary effects a set of w_T values were chosen for the new recommendations (Table 3) based on the respective values of relative radiation detriment (see Table 5, Annex A). In addition, the following judgements were applied:

- The detriments for heritable effects and cancer following gonadal irradiation (i.e., to ovaries or testes) were combined to give a w_T of 0.08.

- The thyroid weighting factor was set to 0.04 due to the higher risk of thyroid cancer in childhood, i.e., young children are considered to be a particularly radiosensitive sub-group.

- Cancer risks in salivary glands and brain, whilst not precisely quantified, are judged to be greater than that of the other tissues and organs comprising the remainder fraction, and for this reason each is ascribed a w_T of 0.01 (see Annex A)

- For the purposes of radiological protection, the w_T values are assumed to be valid for both sexes and all age groups.

(125) The w_T for the remainder tissues (0.12) applies to the weighted mean dose of the 13 organs and tissues for each sex listed in the footnote to Table 3. The so-called splitting rule in the treatment of the remainder in *Publication 60* (ICRP 1991b) is no longer used and hence the effective dose is additive. The sum of the w_T values is 1 by definition (see explanations below and Annex B for further details).

Table 3**.** Recommended tissue weighting factors.

Tissue	w_T	$\sum w_T$
Bone-marrow (red), Colon, Lung, Stomach, Breast, Remainder Tissues*	0.12	0.72
Gonads	0.08	0.08
Bladder, Oesophagus, Liver, Thyroid	0.04	0.16
Bone surface, Brain, Salivary glands, Skin	0.01	0.04

*Remainder Tissues: Adrenals, Extrathoracic (ET) region, Gall bladder, Heart, Kidneys, Lymphatic nodes, Muscle, Oral mucosa, Pancreas, Prostate (♂), Small intestine, Spleen, Thymus, Uterus/cervix (♀).

4.3.5. Sex averaging

(126) In radiological protection it is useful to determine a single value of effective dose for both sexes (see paragraph 33). Therefore, the tissue weighting factors of Table 3 are sex-averaged values and are valid for the male and female breast, testes and ovaries (carcinogenic and hereditary effects) taken together in the value for the gonads, and other organs and tissues with assigned explicit w_T values. The effective dose is computed from the equivalent dose assessed for organ or tissue T of the male, H_T^M, and female, H_T^F, including the remainder tissues, as in the following equation (see Annex B)

$$E = \sum_T w_T \left[\frac{H_T^M + H_T^F}{2} \right] . \qquad (4.5)$$

(127) Analogous to the approach for other organs and tissues the equivalent dose to the remainder is defined separately for males and females and these values are included in Equation (4.5). The equivalent dose to the remainder tissues is computed as the arithmetic mean of the equivalent doses to the tissues listed in the footnotes to

Table 3. The equivalent dose to the tissues of remainder of the male, H_{rem}^{M}, and female, H_{rem}^{F}, are computed as

$$H_{\mathrm{rem}}^{\mathrm{M}} = \frac{1}{13}\sum_{\mathrm{T}}^{13} H_{\mathrm{T}}^{\mathrm{M}} \quad \text{and} \quad H_{\mathrm{rem}}^{\mathrm{F}} = \frac{1}{13}\sum_{\mathrm{T}}^{13} H_{\mathrm{T}}^{\mathrm{F}} \quad . \qquad (4.6)$$

The summation in Equation (4.5) extends over the equivalent dose to remainder tissues in the male and female (Annex B).

(128) The effective dose for protection purposes is based on the mean doses in organs or tissues of the human body. It is defined and estimated in a reference person. The quantity provides a value which takes account of the given exposure situation but not of the characteristics of a specific individual. In particular, the weighting factors are mean values representing an average over many individuals of both sexes. The reference person can be either a worker or a member of the public represented by defined individual exposure conditions, habits and age group(s).

4.3.6. Reference Phantoms

(129) The equivalent dose and effective dose are not measurable quantities. Their values are generally determined using coefficients relating them to measurable quantities. For the calculation of conversion coefficients for external exposure, computational phantoms are used for dose assessment in various radiation fields. For the calculation of dose coefficients from intakes of radionuclides, biokinetic models for radionuclides, reference physiological data, and computational phantoms are used (see Annex B).

(130) Previous calculations of dose coefficients have used various sex-invariant mathematical models such as the MIRD phantom (Snyder et al., 1969) or the Cristy age-specific phantoms (Cristy, 1980; ICRP, 1994b; 1996). The Commission has now defined the anatomical and physiological characteristics of reference persons reported in *Publication 89* (ICRP, 2002), which supplements and supersedes those given in *Publication 23* (ICRP, 1975). The Commission now uses reference computational phantoms of the adult male and female body that are based on medical tomographic images. The phantoms are made up of 3-dimensional **vo**lume pixels (voxels). The voxels that make up defined organs have been adjusted to approximate the organ masses assigned to the reference adult male and female in *Publication 89* (ICRP, 2002). These models are used, for example, to compute the mean absorbed dose, D_{T}, in an organ or tissue T, from reference radiation fields external to the body and the relationship of the effective dose to the operational quantities specific to the radiation field. They will be used in future calculations of dose coefficients for external radiation fields and for the intake of radionuclides (see Annex B).

4.3.7. Operational quantities

(131) As the body-related protection quantities, equivalent dose and effective dose, are not measurable in practice, operational quantities are used for the assessment of effective dose or mean equivalent doses in tissues or organs. These quantities aim to provide a conservative estimate for the value of the protection

quantities related to an exposure, or potential exposure of persons under most irradiation conditions. They are often used in practical regulations or guidance. Different types of operational quantities are used for internal and external exposures as summarised below. More details are given in Annex B.

(132) For the monitoring of external exposures, operational quantities for area and individual monitoring have been defined by ICRU (see Annex B). For area monitoring, the operational quantities are the ambient dose equivalent, $H^*(10)$ and the directional dose equivalent, $H'(0.07,\Omega)$, For individual monitoring, the operational quantity is the personal dose equivalent, $H_p(d)$, which is the dose equivalent in ICRU (soft) tissue at an appropriate depth, d, below a specified point on the human body. The specified point is normally taken to be where the individual dosemeter is worn. For the assessment of effective dose, $H_p(10)$ with a depth $d = 10$ mm is chosen and for the assessment of the dose to the skin and to the extremities the personal dose equivalent, $H_p(0.07)$, with a depth $d = 0.07$ mm. For the rare case of monitoring the dose to the lens of the eye, a depth $d = 3$ mm has been proposed. In practice, however, $H_p(3)$ has rarely been used and personal dosemeters are usually not available that allow this to be measured (see Annex B). Operational dose equivalent quantities are measurable quantities and instruments for radiation monitoring are calibrated in terms of these quantities. In routine monitoring the values of these dose quantities are taken as a sufficiently precise assessment of effective dose and skin dose, respectively, in particular, if their values are below the protection limits.

(133) The system of dose assessment for intakes of radionuclides relies on the calculation of the intake of a radionuclide which can be considered as an operational quantity for the dose assessment from internal exposure. The intake can be estimated either from direct measurements (e.g. external monitoring of the whole body or of specific organs and tissues) or indirect measurements (e.g. urine, faeces or environmental samples) and the application of biokinetic models. The effective dose is then calculated from the intake using dose coefficients recommended by the Commission for a large number of radionuclides. Dose coefficients are given for members of the public of various ages and for adults who are occupationally exposed.

4.4. Assessment of radiation exposure

4.4.1. External radiation exposure

(134) The assessment of doses from exposure to radiation from external sources is usually performed either by individual monitoring using personal dosemeters worn on the body or e. g. in cases of prospective assessments, by measuring or estimating $H^*(10)$ and applying appropriate conversion coefficients. The operational quantities for individual monitoring are $H_p(10)$ and $H_p(0.07)$. If the personal dosemeter is worn on a position of the body representative for its exposure, the value of $H_p(10)$ provides at low doses and under the assumption of a uniform whole body exposure an effective dose value sufficiently precise for radiological protection practices.

4.4.2. Internal radiation exposure

(135) Radionuclides incorporated in the human body irradiate the tissues over time periods determined by their physical half-life and their biological retention within the body. Thus they may give rise to doses to body tissues for many months or years after the intake. The need to regulate exposures to radionuclides and the accumulation of radiation dose over extended periods of time has led to the definition of committed dose quantities. The committed dose from an incorporated radionuclide is the total dose expected to be delivered within a specified time period. The *committed equivalent dose,* $H_T(\tau)$, in a tissue or organ T is defined by:

$$H_T(\tau) = \int_{t_0}^{t_0+\tau} \dot{H}_T(t)\,\mathrm{d}t \qquad (4.7)$$

where τ is the integration time following the intake at time t_0. The quantity *committed effective dose* $E(\tau)$ is then given by:

$$E(\tau) = \sum_T w_T H_T(\tau) \qquad (4.8)$$

(136) For compliance with dose limits, the Commission continues to recommend that the committed dose is assigned to the year in which the intake occurred. For workers, the committed dose is normally evaluated over the 50-y period following the intake. The commitment period of 50 y is a rounded value considered by the Commission to be the life expectancy of a young person entering the workforce. The committed effective dose from intakes of radionuclides is also used in prospective dose estimates for members of the public. In these cases a commitment period of 50 years is considered for adults. For infants and children the dose is evaluated to the age of 70 years.

(137) For assessing doses from occupational intakes of radionuclides the effective dose is based on the worker's intake and the reference dose coefficient. The calculations of dose coefficients for specified radionuclides (Sv Bq^{-1}) use defined biokinetic and dosimetric models. Models are used to describe the entry of various chemical forms of radionuclides into the body and their distribution and retention after entering the blood. The computational male and female phantoms are also used to compute, for a series of sources, the fraction of the energy emitted from a source region S that is absorbed in target region T. These approximations are considered to be adequate for the main tasks in radiological protection.

(138) Sex-averaged committed effective dose coefficients $e(\tau)$[1] for the intake of specified radionuclides are calculated according to the equation:

$$e(\tau) = \sum_T w_T \left[\frac{h_T^M(\tau) + h_T^F(\tau)}{2} \right] \qquad (4.9)$$

[1] The lower case symbols *e* and *h* are used by convention to denote coefficients of the effective dose *E* and the equivalent dose *H*

where w_T is the tissue weighting factor for tissue T, and $h_T^M(\tau)$ and $h_T^F(\tau)$ are the committed equivalent dose coefficients for tissue T of the male and female, respectively for the commitment period τ. The summation in Equation (4.9) also extends over the committed equivalent dose coefficients for the remainder tissues in both the male and female.

4.4.3. Occupational exposure

(139) In monitoring occupational exposures to external radiation, individual dosemeters measure the personal dose equivalent $H_P(10)$. This measured value is taken as an assessment of the effective dose under the assumption of a uniform whole body exposure. For internal exposure, committed effective doses are generally determined from an assessment of the intakes of radionuclides from bioassay measurements or other quantities (e.g. activity retained in the body or in daily excreta). The radiation dose is determined from the intake using recommended dose coefficients (see Annex B).

(140) The doses obtained from the assessment of occupational exposures from external radiation and from intakes of radionuclides are combined for the assignment of the value of total effective dose, E for demonstrating compliance with dose limits and constraints using the following formula:

$$E \cong H_p(10) + E(50) \qquad (4.10)$$

where $H_p(10)$ is the personal dose equivalent from external exposure and $E(50)$, the committed effective dose from internal exposure, which is assessed by:

$$E(50) = \sum_j e_{j,inh}(50) \cdot I_{j,inh} + \sum_j e_{j,ing}(50) \cdot I_{j,ing} \qquad (4.11)$$

where $e_{j,inh}(50)$ is the committed effective dose coefficient for activity intakes by inhalation of a radionuclide j, $I_{j,inh}$ is the activity intake of a radionuclide j by inhalation, $e_{j,ing}(50)$ is the committed effective dose coefficient for activity intakes of a radionuclide j by ingestion, and $I_{j,ing}$ is the activity intake of a radionuclide j by ingestion. In the calculation of the effective dose from specific radionuclides, allowance may need to be made for the characteristics of the material taken into the body. The dose coefficients used in eqn. (4.11) are those specified by ICRP with no departure from the anatomical, physiological, and biokinetic characteristics of the reference person. Account may be taken of the physical and chemical characteristics of the intake, including the activity medium aerodynamic diameter (*AMAD)* of the inhaled aerosol and the chemical form of the particulate matter to which the specified radionuclide is attached. The effective dose assigned in the worker's dose record, is that value the reference person would experience due to the radiation fields and activity intakes encountered by the worker. The commitment period of 50 years represents the period of possible dose accumulation over a life-time (this is only relevant for radionuclides with long physical half-lives and long retention in body tissues).

(141) The radiation dose from radon isotopes and their decay products may also need to be taken into account in the overall dose assessment (ICRP 1994c).

(142) The incorporation of radionuclides through uncontrolled events involving wounds has implications beyond compliance with work practices and thus these events are not included in eqn. (4.11). The significance of these events must be evaluated and recorded, appropriate medical treatment provided, and further restriction of the worker's exposure considered if warranted.

(143) External exposures to airborne noble gas radionuclides in the workplace may need to be assessed beyond that indicated by $H_p(10)$. In such cases it is necessary to include in eqn. (4.11) a term representing the product of the time-integrated airborne concentration of the noble gas and an effective dose coefficient for so-called submersion exposure. Such dose coefficients are specified by ICRP for both prospective and retrospective applications. In the rare case of a significant contribution to external exposure of weakly-penetrating radiation, the term $0.01H_p(0.07)$ should be added in eqn. (4.10) for the assessment of effective dose.

(144) In certain situations, such as exposure of aircrew or where individual monitoring is not performed, an assessment of effective dose may be performed by area monitoring applying the quantity ambient dose equivalent, $H^*(10)$, and calculating effective dose using appropriate conversion coefficients. The Commission reaffirms its recommendation in *Publication 60* (ICRP, 1991b) that exposures to aircrew by cosmic radiation during aviation should be regarded as occupational exposure.

4.4.4. Public exposure

(145) The annual effective dose to members of the public is the sum of the effective dose obtained within one year from external exposure and the committed effective dose from radionuclides incorporated within this year. The dose is not obtained by direct measurement of individual exposures as for occupational exposure but is mainly determined by environmental measurements, habit data and modelling. It can be estimated by effluent monitoring for existing facilities or simulation and prediction of effluents from the technical installation or source during the design period. Information on concentrations of radionuclides in the environment are used in conjunction with radioecological modelling (pathway analysis of environmental transport, e.g. from the release of radionuclides and transport through soil – plants – animals to humans) to assess doses from external radiation exposure and intakes of radionuclides (see Annex B).

4.4.5. Medical exposure of patients

(146) The use of effective dose for assessing the exposure of patients has severe limitations that must be considered when quantifying medical exposure. Effective dose can be of value for comparing doses from different diagnostic procedures and for comparing the use of similar technologies and procedures in different hospitals and countries as well as the use of different technologies for the same medical examination. For planning the exposure of patients and risk-benefit assessments, however, the equivalent dose or the absorbed dose to irradiated tissues is the more relevant quantity.

(147) Medical exposures of patients to external radiation are commonly concerned with limited parts of the body only, and it is important that medical staff are fully aware of the doses to normal tissue in the irradiated fields. Considering the low tissue weighting factors for skin and relatively low values for a number of other

tissues, very localised partial body exposures can result in appreciable equivalent doses to local tissues. Similar considerations apply to doses from intakes of radionuclides. Care has to be taken in such situations so that undesirable tissue reactions occur are avoided as best possible under the circumstances.

(148) The assessment and interpretation of effective dose from medical exposure of patients is very problematic when organs and tissues receive only partial exposure or a very heterogeneous exposure which is the case especially with x-ray diagnostics.

4.4.6. Application of the effective dose

(149) The main and primary uses of effective dose in radiological protection for both occupational workers and the general public to exposures from controlled sources are as follows:

- prospective dose assessment for planning and optimisation of protection;
- retrospective dose assessment for demonstrating compliance with dose limits. Effective dose provides an instrument for demonstrating compliance with dose limits or dose constraints in radiological protection.

(150) In this sense effective dose is used for regulatory purposes worldwide. In practical radiological protection applications, effective dose is used for controlling possible stochastic effects in workers and the public. The calculation of effective dose or corresponding conversion coefficients for external exposure, as well as dose coefficients for internal exposure, are based on absorbed dose, weighting factors (w_R and w_T) and reference values for the human body and its organs and tissues. Effective dose is not based on data from individual persons (see Annex B). In its general application, effective dose does not provide an individual-specific dose but rather that for a reference person under a given exposure situation.

(151) There may be some circumstances in which parameter values may be changed from the reference values in the calculation of effective dose. It is, therefore, important to distinguish between those reference parameter values that might be changed in the calculation of effective dose under particular circumstances of exposure and those values that cannot be changed under the definition of effective dose (e.g. the weighting factors). Thus, in the assessment of effective dose in occupational situations of exposure, changes may be made that, for example, relate to the characteristics of an external radiation field (e.g., direction of exposure) or to the physical and chemical characteristics of inhaled or ingested radionuclides. In such cases it is necessary to clearly state the deviation from the reference parameters.

(152) For retrospective assessments of doses in specified individuals that may substantially exceed dose limits, effective dose can provide an approximate first measure of the overall detriment. If radiation dose and risk need to be assessed in a more accurate way, further specific estimates of organ or tissue doses are necessary, especially if organ-specific risks for the specified individuals are needed.

(153) Effective dose is a quantity developed for radiological protection that is not suitable for use in epidemiological studies of radiation risks. Epidemiological

analyses should be based whenever available on estimates of absorbed doses to tissues and organs, taking full account, to the extent possible, of the circumstances of exposure and the characteristics of the exposed population. Similarly, organ or tissue doses, not effective doses, are required for calculations of probability of causation of cancer in exposed individuals.

(154) In cases of high doses the use of effective dose is inappropriate for the assessment of tissue reactions. In such situations it is necessary to estimate absorbed dose and to take into account the appropriate RBE as the basis for any assessment of radiation effects (see Annex B).

4.4.7. Collective dose

(155) For the purpose of optimisation of radiological protection, the Commission has introduced the collective dose quantities (ICRP, 1977; 1991). These quantities take account of the group of persons exposed to radiation and the period of exposure. They are obtained as the sum of all individual doses over a specified time period from a source. The specified quantities have been defined as the collective equivalent dose, S_T, which relates to a tissue or an organ T, and the collective effective dose, S (ICRP, 1991). The special name used for the collective dose quantity is the 'man sievert'. Since the intention of the collective dose is to serve as an instrument in the optimisation of radiological protection only the collective effective dose is retained in the present system.

(156) The collective effective dose, S, is based on the assumption of a linear dose effect relationship for stochastic effects without a threshold (the LNT concept). Under these conditions it is possible to regard effective doses as additive.

(157) Collective effective dose is an instrument for optimisation, for comparing radiological technologies and protection procedures. Collective effective dose is not intended as a tool for epidemiologic risk assessment and it is therefore inappropriate to use it in risk projections for such studies. Specifically, the computation of cancer deaths based on collective doses involving trivial exposures to large populations is not reasonable and should be avoided. Such computations based on collective effective dose were never intended and are an incorrect use of this radiological protection quantity.

(158) To avoid aggregation of, e.g., very low individual doses over extended time periods and wide geographical regions, limiting conditions need to be set. The dose range and the time period should be stated. The collective effective dose due to individual effective dose values between E_1 and E_2 is defined as:

$$S(E_1, E_2, \Delta T) = \int_{E_1}^{E_2} E \, \frac{\mathrm{d}N}{\mathrm{d}E} \, \mathrm{d}E \qquad (4.12)$$

where $\mathrm{d}N/\mathrm{d}E$ denotes the number of individuals who are exposed to an effective dose between E and $E + \mathrm{d}E$ and ΔT specifies the time period within which the effective doses are summed (see Annex B).

4.5 Uncertainties and judgements

(159) In the evaluation of radiation doses, models are necessary to simulate the geometry of the external exposure, the biokinetics of the intake and retention of radionuclides in the human body, and the human anatomy. These models and their parameter values have been developed in many cases from experimental investigations and human studies in order to derive 'best estimates' or 'central estimates' of model parameter values. Similar considerations apply to the choice of tissue and radiation weighting factors. It is recognised that there are appreciable uncertainties in the values of some of the parameters and in the formulation or structures of the models themselves. Judgement is needed on the best choice of the necessary parameters for dose assessments (see Annex B).

(160) Uncertainty refers to the level of confidence that can be placed in a given parameter value or prediction of a model. It is an important factor in all extrapolation procedures. In this connection the variability of individual parameters and the accuracy of measurements are also of great importance. The accuracy of measurements and judgements will become less with decreasing doses and increasing complexity of the system. Variability refers to quantitative differences between individual members of the population in question. All these aspects are taken into account in model development in the judgements (see Annex B).

(161) The lack of certainty or precision in radiation dose models varies for the various parameters and the circumstances in defined situations. Therefore it is not possible to give values for the uncertainties across the range of ICRP models, despite the fact that their assessment is an important part of model development. Uncertainties may need to be assessed, however, for special cases, and approaches to their use have been described in a number of publications e.g., (Goossens et al., 1997; CERRIE 2004, ICRP 1994, 2006, Bolch et al., 2003, Farfan et al., 2005). In general it can be said that uncertainties for assessments of radiation doses from internal exposures including the biokinetics of radionuclides are larger than those from external exposures. The degree of uncertainty differs between various radionuclides.

(162) The Commission is aware of the lack of certainty or precision in radiation dose models and efforts are undertaken to critically evaluate and to reduce them wherever possible. In regulatory processes, the dosimetric models and parameter values that the Commission recommends are fixed by convention and are therefore not subject to uncertainty. Equally the Commission considers that the biokinetic and dosimetric models which are needed for the purpose of dose assessment are defined as reference data and, therefore, are not uncertain. These models and values are re-evaluated periodically and may be changed by ICRP on the basis of such evaluations when new scientific data and information are available.

(163) Regulatory compliance is determined using point estimates of effective dose that apply to reference persons, regarding these point estimates as subject to no uncertainties. In retrospective assessments of doses that may approach or exceed limits, it may be considered appropriate to make specific individual estimates of dose and risk and also to consider uncertainties in these estimates.

(164) Despite changes in dosimetric modelling, as well as differences in the computation of effective dose, previous assessments of equivalent dose or effective

dose should be considered adequate. The Commission does not recommend re-computation of existing values with the new models and parameters.

5. THE SYSTEM OF RADIOLOGICAL PROTECTION OF HUMANS

(165) In dealing with radiological situations, it is convenient to think of the processes causing human exposures as a network of events and situations. Each part of the network starts from a source. Radiation or radioactive material then passes through environmental pathways leading to the exposure of individuals. Finally, the exposure of individuals to radiation or radioactive materials leads to doses to these individuals. Protection can be achieved by taking action at the source, or at points in the exposure pathways, and occasionally by modifying the location or characteristics of the exposed individuals. For convenience, the environmental pathway is usually taken to include the link between the source of exposure and the doses received by the individuals. The available points of action have a substantial effect on the system of protection.

(166) Everybody is exposed to ionising radiation from natural and man-made sources. In its totality, this network is unmanageable. Fortunately, the assumed proportional relationship between an increment of dose and an increment of risk of stochastic effects makes it possible to deal separately with parts of the network and to select those parts that are of relevance in a given situation. To make these selections, however, it is necessary to define for each part of the network the objectives, the organisations (and individuals) responsible for protection, the lines of responsibility, and the feasibility of obtaining the necessary information. This remains a complex procedure, and the Commission suggests two simplifications in managing radiological situations.

(167) The first simplification was used in the 1990 Recommendations and recognises that individuals are exposed to several categories of exposure, which can be dealt with separately (ICRP, 1991). For example, most workers who are exposed to radiation sources as part of their work are also exposed to environmental sources as members of the public, and to medical exposure as patients. The Commission's policy continues to be that the control of exposures due to work need not be influenced by the exposures from these other sources. This policy is still reflected in the new recommendations by the separation of the exposure into three categories: occupational exposure, medical exposure of patients, and public exposure (see Section 5.3). The Commission continues to recommend that no attempt be made to add the exposures to the same individual from the different categories of exposure.

(168) The second simplification is that in dealing with the network of prolonged exposure pathways, a distinction is drawn between source-related considerations and individual-related considerations. Although within each category of exposure individuals can be exposed to several sources, for the purpose of protection procedures to be applied to the sourcem each source, or group of sources, can be treated on its own (ICRP, 1991b). It is then necessary to consider the exposure of all the individuals who could be exposed by this source or group of sources. This procedure is called a 'source-related assessment' (see Section 5.5).

(169) For the practical control of exposures, in *Publication 60* the network of events and situations causing these exposures was divided in two broad classes of situations: practices and interventions. Practices were defined as human activities increasing exposure either by introducing whole new blocks of sources, pathways, and individuals, or by modifying the network of pathways from existing sources to

man and thus increasing the exposure of individuals or the number of individuals exposed. Interventions were defined as human activities that decrease the overall exposure by influencing the existing form of the network. These activities may remove existing sources, modify pathways or reduce the number of exposed individuals. In the revised system of protection the Commission now moves from such a process based approach to an approach based on the characteristics of three types of radiation exposure situation, i.e., planned, emergency, and existing exposure situations.

5.1. The definition of a source

(170) The Commission uses the term 'source' to indicate any physical entity or procedure that results in a potentially quantifiable radiation dose to a person or group of persons. It can be a physical source (e.g., radioactive material or an x-ray machine), a facility (e.g., a hospital or nuclear power plant), or a class of operations or physical sources having similar characteristics (e.g., maintenance work in an installation, nuclear medicine procedures, background or environmental radiation). If radioactive substances are released from an installation to the environment, the installation as a whole may be regarded as a source; if they are already dispersed in the environment, the portion of them to which people are exposed may be considered a source. Most situations will give rise to a predominant source of exposure for any single individual, or representative person, making it possible to treat sources singly when considering actions. Provided that the user and the regulator both apply the spirit of the Commission's broad policies, the definition of a source is straightforward.

(171) In general, the definition of a source will be linked to the selection of relevant constraints or reference levels, as appropriate, for optimisation. Difficulties will arise if the policy is distorted, e.g. by artificially subdividing a source in order to avoid the need for protective action, or by excessively aggregating sources to exaggerate the need for action.

5.2. Types of exposure situations

(172) The Commission intends its recommendations to be applied to all sources and to individuals exposed to radiation in the following three types of exposure situations which address all conceivable circumstances:

- *Planned exposure situations* are situations involving the planned introduction and operation of sources. This would also include their decommissioning, disposal of associated radioactive waste, and rehabilitation of the previously occupied land in the case of installations. Planned exposure situations include both normal exposures and potential exposures insofar as the latter comply with pertinent risk constraints.

- *Emergency exposure situations* are unexpected situations that occur during the operation of a planned situation, or from a malicious act, requiring urgent action.

- *Existing exposure situations* are exposure situations that already exist when a decision on control has to be taken, including natural background radiation and

residues from past practices that have been operated outside the Commission's recommendations, or long-term exposure situations.

It follows that what the Commission has called 'practices' could be the origin of planned, emergency, and existing exposure situations. In principle, planned exposure situations also include medical exposures of patients, but because of the characteristics of such exposures, they are discussed separately. The principles of protection for planned situations also apply to planned work in connection with existing and emergency exposure situations.

5.3. Categories of exposure

(173) The Commission distinguishes between three categories of exposures; occupational exposures, public exposures, and medical exposures of patients.

5.3.1. Occupational exposure

(174) Occupational exposure is defined by the Commission as all radiation exposure of workers incurred as a result of their work. Excluded exposures and exposures from exempt practices or exempt sources generally do not need to be accounted for in the calculation of occupational exposure. The Commission has noted the conventional definition of occupational exposure to any hazardous agent as including all exposures at work, regardless of their source. However, because of the ubiquity of radiation, the direct application of this definition to radiation would mean that all workers should be subject to a regime of radiological protection. The Commission therefore limits its use of 'occupational exposures' to radiation exposures incurred at work as a result of situations that can reasonably be regarded as being the responsibility of the operating management.

(175) The employer has the main responsibility for the protection of workers. However, the licensee (if not identical to the employer) also has a responsibility for the occupational exposure. If workers are engaged in work that involves, or could involve, a source that is not under the control of their employer, the licensee responsible for the source and the employer should cooperate by the exchange of information and otherwise as necessary to facilitate proper radiological protection at the workplace.

5.3.2. Public exposure

(176) Public exposure encompasses all exposures other than occupational and medical exposures of patients (see Section 5.3.3). It is incurred as a result of a range of radiation sources. The component of public exposure due to natural sources is by far the largest, but this provides no justification for reducing the attention paid to smaller, but more readily controllable, exposures to man-made sources.

5.3.3. Medical exposure of patients including their comforters and carers

(177) Radiation exposures of patients can occur in diagnostic, screening, interventional, and therapeutic procedures. There are several features of radiological practices in medicine that require an approach that differs from the radiological protection in other planned exposure situations. The exposure is intentional and for the direct benefit of the patient. Particularly in radiotherapy, the biological effects of

high-dose radiation, e.g., cell killing, are used for the benefit of the patient to treat cancer and other diseases. The application of these recommendations to the medical uses of radiation therefore requires separate guidance.

5.4. The identification of the exposed individuals

(178) It is necessary to deal separately with at least three categories of exposed individuals, namely workers, the public, and patients. They essentially correspond to individuals whose exposures fall into the three categories of exposure defined in Section 5.3. A given individual can be exposed as a worker, and/or as a member of the public, and/or as a patient.

5.4.1. Workers

(179) A worker is defined by the Commission as any person who is employed, whether full time, part time or temporarily, by an employer and who has recognised rights and duties in relation to occupational radiological protection. A self-employed person is regarded as having the duties of both an employer and a worker.

(180) One important function of an employer is that of maintaining control over the sources of exposure and over the protection of workers who are occupationally exposed. In order to achieve this, the Commission recommends the classification of areas of work rather than the classification of workers. Requiring that the areas of workplaces containing sources be formally designated helps their control. The Commission uses two such designations: *controlled areas* and *supervised areas*. A controlled area is one in which normal working conditions, including the possible occurrence of minor mishaps, require the 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.

(181) Workers in 'controlled areas' of workplaces should be well informed and specially trained, and form a readily identifiable group. Such workers are most often monitored for radiation exposures incurred in the workplace, and occasionally may receive special medical surveillance.

The exposure of pregnant workers

(182) In the 1990 Recommendations, the Commission concluded that for the purpose of controlling occupational exposure, there was no reason to distinguish between the two sexes. The Commission does not deviate from this policy with these new recommendations. However, if a female worker has declared that she is pregnant, additional controls have to be considered to protect the embryo/fetus. It is the Commission's policy that the methods of protection at work for women who are or may be pregnant should provide a level of protection for the embryo/fetus similar to that provided for members of the public. The Commission considers that this policy will be adequately applied if the mother is exposed, prior to her declaration of pregnancy, under the system of protection recommended by the Commission. Once pregnancy has been declared, and the employer notified, additional protection of the embryo/fetus should be considered. The working conditions of a pregnant worker, after declaration of pregnancy, should be such as to make it unlikely that the additional equivalent dose to the fetus would exceed about 1 mSv during the remainder of the pregnancy. Additional guidance on protection of the fetus is provided in Section 7.4.

(183) The restriction of the dose to the fetus does not mean that it is necessary for pregnant women to avoid work with radiation or radioactive materials completely, or that they must be prevented from entering or working in designated radiation areas (see paragraph 180). It does, however, imply that the employer should carefully review the exposure conditions of pregnant women. In particular, their employment should be of such a type that the probability of accidental doses and radionuclide intakes is extremely low. Specific recommendations on the control of exposures to pregnant workers are given in *Publication 84* and *88* (ICRP, 2001a,b). The Commission has also published information in *Publication 95* (ICRP, 2004b) that enables doses to offspring following intakes to breast-feeding mothers to be calculated. The Commission recommends that in order to protect the embryo/fetus or infant, females who may be pregnant or are nursing should not be involved in emergency actions involving high radiation doses. (ICRP, 2005).

(184) In *Publication 88* (ICRP, 2001b), the Commission gave dose coefficients for the embryo, fetus, and newborn child from intakes of radionuclides by the mother before or during pregnancy. In general, doses to the embryo, fetus, and newborn child are similar to or less than those to the reference adult person; however, there are exceptions where the dose can exceed that of the reference adult by a factor of around 10. In *Publication 95* (ICRP, 2004b) the Commission provided information on radiation doses to the breast-feeding infant due to intakes of radionuclides in maternal milk. For most of the radionuclides considered, doses to the infant from radionuclides ingested in breast milk are estimated to be small in comparison with doses to the reference adult. It is rare that the dose to the newborn child can exceed that of the reference adult by a factor of more than about three.

5.4.2. Members of the public

(185) A member of the public is defined by the Commission as any individual who receives an exposure that is neither occupational nor medical (see also Section 5.4.3). Furthermore, the embryo/fetus should be afforded a level of protection similar to that of a member of the public. A large range of different natural and man-made sources is contributing to the exposure of members of the public.

(186) In general, especially for public exposure, each source will result in a distribution of doses over many individuals. For the purposes of protection of the public, the Commission has used the 'critical group' concept to characterise an individual receiving a dose that is representative of the more highly exposed individuals in the population (ICRP 1977, 1985). Dose restrictions have been applied to the mean dose in the appropriate critical group. Over the last decades, there have been developments in the techniques used to assess doses to members of the public, notably the increasing use of probabilistic techniques. There has also been a considerable body of experience gained in the application of the critical group concept. The adjective 'critical' has the connotation of a crisis, which was never intended by the Commission. Second, the word 'group' may be confusing in the context that the assessed dose is the dose to an individual, whether hypothetical or an actual member of the public. The Commission now recommends the use of 'the representative person' for the purpose of radiological protection of the public instead of the earlier critical group concept. The Commission provides guidance on characterising the 'representative person' and assessing doses to the representative person in *Publication 101* (ICRP, 2006b).

(187) The representative person may be hypothetical. Nevertheless, it is important that the habits (e.g. consumption of foodstuffs, breathing rate, location, usage of local resources) used to characterise the representative person are typical habits of a small number of individuals representative of those most highly exposed and not the extreme habits of a single member of the population. Consideration may be given to some extreme or unusual habits, but they should not dictate the characteristics of the representative persons considered.

5.4.3. Patients, including their comforters and carers

(188) The Commission defines the patient as an individual who receives an exposure associated with a diagnostic, screening, interventional, or therapeutic procedure. The Commission's dose limits and dose constraints are not recommended for individual patients because they may reduce the effectiveness of the patient's diagnosis or treatment, thereby doing more harm than good. The emphasis is therefore on the justification of the medical procedures and on the optimisation of protection ant the use of diagnostic reference levels (see Chapter 7).

(189) The exposure of patients who may be pregnant is dealt with in Section 7.4.

5.5. Levels of radiological protection

(190) Even within a single type of exposure (occupational / public / medical), an individual may be exposed by several sources, so an assessment of the total exposure has to be attempted. It is not always possible to carry out such an assessment comprehensively. Generally, only a small number of the relevant sources can be identified and quantified. This should, however, include all exposures to individuals from(ny variant) regulated sources causing substantial exposures to the individual. This approach is called *'individual-related'*.

(191) In the 1990 Recommendations, it was suggested that each regulated source or group of sources could usually be treated on its own. It is then necessary to consider the exposure of all the individuals exposed by this source or group of sources. This procedure is called a *'source-related'* approach. The Commission now emphasises the primary importance of the source-related approach, since action can be taken for a source to assure the protection of a group of individuals from that source. An appropriate level of protection from sources is achieved by optimisation using dose constraints in planned exposure situations and using reference levels in emergency or existing exposure situations (see Section 5.9)

(192) Planned exposure situations, however, involve the exposure of individuals with a magnitude that can be foreseen in advance, albeit with some uncertainty. This element of deliberate exposure distinguishes these exposure situations from existing and emergency situations. Sole reliance on source-related restrictions may not afford sufficient protection as individuals could be exposed to a number of different sources in planned exposure situations. Therefore, a restriction on the sum of the doses from sources in planned exposure situations is required. The Commission refers to these individual-related restrictions as dose limits.

(193) It is rarely possible to assess the total exposure of an individual from all such sources. It is therefore necessary to make approximations to the dose to be compared with the quantitative limit, especially in the case of public exposure. For

occupational exposures, the approximations are more likely to be accurate because the operating management has access to the necessary information to identify and control the dose from all the relevant sources. Figure 2 illustrates the differences in concept between individual dose limits and constraints or reference levels for protection from a source in all situations and the use, in planned situations only, of individual-related dose limits.

Dose Limits	Constraints and Reference Levels
	
From all regulated sources in planned situations	**From a single source in all exposure situations**

Fig. 2. Dose limits compared with dose constraints and reference levels to protect members of the public or workers.

(194) For planned exposure situations, the source-related restriction to the dose that individuals may incur is the *dose constraint*. For potential exposures, the corresponding concept is the *risk constraint.* For emergency and existing exposure situations, the source-related restriction is the reference level (see Chapter 6). The concepts of a dose constraint and reference level are used in conjunction with optimisation of protection to assure that all exposures are kept as low as reasonably achievable, social and economic factors being taken into account. Constraints and reference levels can thus be described as key tools in the optimisation process that will assure appropriate levels of protection under the prevailing circumstances.

(195) In the case of radiation exposures due to intakes, the term ‘dose’ in the Commission’s quantitative recommendations implies the committed dose, i.e., including the appropriate time integral of the dose rate (cf. Section 4.4). The dose is thus defined as the sum of the time integral, over a year, of the effective dose rate due to external irradiation caused by a exposure situation, and the committed effective dose due to internal contamination from any intakes, during the year, of the radionuclides involved in the situation.When the Commission refers to dose accumulated in a given period of time, it is implicit that any committed doses from intakes occurring in that same period are included.

5.6. The principles of radiological protection

(196) In the 1990 Recommendations, the Commission gave principles of protection for practices separately from intervention situations. The Commission continues to regard these principles as fundamental for the system of protection, and has now formulated a set of principles that apply to planned, emergency, and existing controllable situations. In the new recommendations, the Commission also

clarifies how the fundamental principles apply to radiation sources and to the individual, as well as how the source-related principles apply to all controllable situations.

Two principles are source related and apply in all situations:

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

  This means that by introducing a new radiation source or by reducing existing exposure, one should achieve an individual or societal benefit that is higher than the detriment it causes.

- **The principle of optimisation of protection:** the likelihood of incurring exposures, the number of people exposed and the magnitude of their individual doses should all be kept as low as reasonably achievable, taking into account economic and societal factors**.**

  This means that the level of protection should be the best under the prevailing circumstances, maximising the margin of benefit over harm. In order to avoid severely inequitable outcomes of this optimisation procedure, there should be restrictions on the doses or risks to individuals from a particular source (dose or risk reference levels and constraints).

One principle is individual related and applies in planned situations:

- **The principle of application of dose limits:** The total dose to any individual from all planned exposure situations other than medical exposure of patients should not exceed the appropriate limits specified by the Commission.

(197) Dose limits are determined by the national regulatory authority on the basis of international recommendations and apply to workers and to members of the public in planned exposure situations. Dose limits do not apply to medical exposure of patients, or to public exposures in emergency situations, or to existing exposure situations.

5.7. Justification

(198) Justification is a necessary prerequisite for any decision regarding radiological protection actions.

(199) The Commission recommends that, when activities involving an increased or decreased level of radiation exposure, or a risk of potential exposure, are being considered, the expected change in radiation detriment should be explicitly included in the decision-making process. The negative consequences to be considered are not confined to that associated with the radiation – it includes other risks and the costs of the activity. Often, the radiation detriment will be a small part of the total. The justification should also include the analysis if other techniques that do not require exposure to ionising radiation are more appropriate. Justification thus goes far beyond the scope of radiological protection. It is for these reasons that the Commission limits its use of the term justification to require that the net benefit be positive. To search for the best of all the available alternatives is usually a task beyond the responsibility of radiological protection authorities.

(200) There are two different approaches to applying the principle of justification in situations involving occupational and public exposure, which depend upon whether or not the source can be directly controlled. The first approach is used in the introduction of planned situations where radiological protection is planned in advance and the necessary actions can be taken on the source. Application of the justification principle to these situations requires that no planned situation should be introduced unless it produces sufficient net benefit to the exposed individuals or to society to offset the radiation detriment it causes. In this context, a planned situation is a generic type of practice, the essential features of which are common to specific practices of the same type. Judgements on whether it would be justifiable to introduce or continue particular types of practice involving exposure to ionising radiation are important. Alternatives to existing practices may develop overtime, which would probably require these to be periodically re-examined to ensure that they are still justified.

(201) The second approach is used where exposures can be controlled mainly by action to modify the pathways of exposure and not by acting directly on the source. The main examples are existing and emergency exposure situations. In these circumstances, the principle of justification is applied in making the decision as to whether to take action to avert further exposure. Any decision taken to reduce doses, which always have some disadvantages, should be justified in the sense that they should do more good than harm.

(202) In both approaches, the responsibility for judging the justification usually falls on governments or national authorities to ensure an overall benefit in the broadest sense to society and thus not to each individual. However, input to the justification decision may include many aspects that could be informed by users or other actors outside of government. As such, justification will generally be carried out through appropriate social processes, depending upon, among other things, the size of the source concerned. There are many aspects of justification, and different organisation may be involved and responsible. For example, the operator may justify the building of a power plant based on economic considerations, while the government may be concerned more with safety considerations. In this context, radiological protection considerations will serve as one input to the broader decision process.

(203) Medical exposure of patients calls for a different and more detailed approach to the process of justification. The medical use of radiation should be justified, as is any other planned situation, although that justification lies more often with the profession than with government or the competent regulatory authority. The principal aim of medical exposures is to do more good than harm to the patient, due account being taken of the radiation detriment from the exposure of the radiological staff and of other individuals. The responsibility for the justification of the use of a particular procedure falls on the relevant medical practitioners, who need to have special training in radiological protection. Justification of medical procedures therefore remains part of the Commission's Recommendations (see Section 7.1).

5.7.1. Unjustified procedures

(204) The Commission considers that certain procedures could be deemed to be unjustified without further analysis, unless there are exceptional circumstances supporting the use of those procedures. These include:

- Increasing, by deliberate addition of radioactive substances or by activation, the activity of commodities or consumer products, such as food, beverages, cosmetics, toys, and personal jewellery or adornments.
- Radiological examination for occupational, legal, or health insurance purposes undertaken without reference to clinical indications, unless the examination is expected to provide useful information on the health of the individual examined, or the specific type of examination is justified by those requesting it in consultation with relevant professional bodies. This means that a clinical evaluation of the image acquired must be carried out, otherwise the exposure is not justified.
- Mass screening of population groups involving radiation exposure, unless the expected advantages for the individuals examined or for the population as a whole are sufficient to compensate for the economic and societal costs, including the radiation detriment, account being taken of the potential of the screening procedure for detecting disease, the likelihood of effective treatment of cases detected, and, for certain diseases, the advantages to the community of control of the disease.

5.8. Optimisation of protection

(205) The process of optimisation of protection is intended for application to those protective actions that have been deemed to be justified. The principle of optimisation of protection with a restriction on individual dose is central to the system of protection applying to all three exposure situations: planned situations, emergency situations, and existing exposure situations. This principle has been applied very successfully in planned situations (specifically practices) where protective actions can be initiated at the design stage. The Commission's intention is to extend this experience to the other two types of exposure situations, the emergency and existing exposure situations. The dose constraints and reference levels are important tools to aid optimisation of protection in all three exposure situations.

(206) The principle of optimisation is defined by the Commission as the source related process to keep the likelihood of incurring exposures where these are not certain to be received, the number of people exposed, and the magnitude of individual doses as low as reasonably achievable below the appropriate risk and dose constraints or reference levels, taking into account economic and societal factors.

(207) The Commission has earlier provided guidance on how to apply the optimisation principle mainly for planned situations (ICRP, 1983, 1988, and 1991b), and these recommendations remain valid. The decision aiding techniques are still essential to find the optimised radiological protection solution in an objective manner; theses techniques include methods for quantitative optimisation such as cost-benefit analyses**.** However, the way the principle of optimisation should be implemented is now viewed as a broader process encompassing the protection of

individuals, safety culture and the involvement of concerned parties (ICRP, 1998, 1999). The Commission is aware that this approach reflects the way in which many users are currently applying the principle of optimisation in planned exposure situations.

(208) The optimisation must be implemented through an on-going, iterative process that involves the:

- evaluation of the exposure situation to identify the need for action (the framing of the process);
- selection of an appropriate value for the constraint or reference level;
- identification of the possible protection options to keep the exposure as low as reasonably achievable;
- selection of the best option under the prevailing circumstances taking account of the constraint or reference level;
- implementation of the selected option through an effective optimisation programme;
- regular reviews of the exposure situation to evaluate if the prevailing circumstances call for the implementation of corrective protection actions; and
- consideration of the avoidance of emergencies and other potential exposures for planned situations.

(209) Experience has shown how optimisation of protection has improved radiological protection outcomes for some planned situations. Constraints provide a desired bound for the optimisation process. Some sources and technologies are able to satisfy constraints that are set at a low level, while others are only able to meet constraints set at a higher level: this is normal, and should be reflected in the freedom of national authorities to authorise dose constraints that are appropriate for particular circumstances.

(210) In all situations, the process of optimisation with the use of constraints or reference levels is applied in planning protective actions and in establishing the appropriate level of protection under the prevailing circumstances. The doses to be compared with the dose constraint or reference levels are usually prospective doses, i.e., doses that may be received in the future, as it is only those doses that can be influenced by decisions on protective actions. They are not intended as a form of retrospective dose limit, even if they are considered in the feedback process. The optimisation processes should be interactive and iterative involving users and national authorities.

(211) The optimisation of protection is a forward-looking iterative process aimed at preventing or reducing future exposures. It is continuous, taking into account both technical and socio-economic developments and requires both qualitative and quantitative judgements. The process should be systematic and carefully structured to ensure that all relevant aspects are taken into account. Optimisation is a frame of mind, always questioning whether the best has been done in the prevailing circumstances, and if all that is reasonable has been done to reduce doses. It also requires the commitment at all levels in all concerned organisations as well as adequate procedures and resources.

(212) The best option is always specific to the exposure situation and represents the best level of protection that can be achieved under the prevailing circumstances. Therefore it is not relevant to determine, *a priori*, a dose level below which the optimisation process should stop. Depending on the exposure situation, the best option could be close to or well below the appropriate source-related constraint or reference level. This means that the optimisation process may result in doses lower than any level that could be proposed as an 'entry level' into the system of radiological protection.

(213) Optimisation of protection is not minimisation of dose. Optimised protection is the result of an evaluation, which carefully balances the detriment from the exposure (economic, human, societal, political, etc.) and the resources available for the protection of individuals. Thus the best option is not necessarily the one with the lowest dose.

(214) In addition to the reduction of the magnitude of individual exposures, a reduction of the number of exposed individuals should also be considered. The comparison of protection options for the purpose of optimisation must entail a careful consideration of the characteristics of the individual exposure distribution within an exposed population. A particular issue is the one related to the comparison of the distribution of the exposures over long time periods and future populations.

(215) When the exposures occur over large populations, large geographical areas, or long time periods, the total collective effective dose is not a useful tool for making decisions because it may aggregate information excessively and could be misleading for selecting protection actions. To overcome the limitations associated with collective effective dose, each relevant exposure situation must be carefully analysed to identify the individual characteristics and exposure parameters that best describe the exposure distribution among the concerned population for the particular circumstance. Such an analysis– by asking when, where and by whom exposures are received – results in the identification of various population groups with homogeneous characteristics for which collective effective doses can be calculated within the optimisation process.

(216) In *Publications 77* and *81* (ICRP, 1998a; 2000a), the Commission recognised that both the individual doses and the size of the exposed population become increasingly uncertain as time increases. The Commission is of the opinion that in the decision-making process, less weight could be given to very low doses and to doses received in the distant future. The Commission does not intend to give detailed guidance on such weighting, but rather stresses the importance of demonstrating in a transparent manner how any weighting has been carried out.

(217) All aspects of optimisation cannot be codified; optimisation is more an obligation of means than of results. It is not the role of the regulatory authority to focus on specific outcomes for a particular situation, but rather on processes, procedures, and judgements. An open dialogue must be established between the authority and the operating management, and the success of the optimisation process will depend strongly on the quality of this dialogue.

5.9. Dose constraints and reference levels

(218) The concepts of *dose constraint* and *reference level* apply to any exposure situation (i.e., planned, emergency, or existing) and are used in conjunction with the optimisation of protection to restrict individual doses (even if this precludes some protection options entailing lower collective doses). A level of individual dose always needs to be defined, above which one plans not to go (or, for existing exposure situations, not to stay), and below which one strives to reduce all actual doses. All exposures, above or below this level of individual dose, are subject to optimisation of protection.

(219) For the sake of continuity with its earlier Recommendations (ICRP, 1991), the Commission retains the term 'dose constraint' for this level of dose in planned exposure situations (with the exception of medical exposure of patients). For emergency and existing exposure situations, the Commission proposes the term 'reference level' to describe this level of dose. The difference in terminology between planned and other exposure situations (emergency and existing) has been retained by the Commission to express the fact that the restriction on individual doses can be complied with from the beginning of the optimisation process in planned situations, while with the other situations the optimisation process may apply to levels of individual doses above the reference level. Diagnostic reference levels are already being used in the medical diagnosis (i.e., planned situations) to indicate whether, in routine conditions, the levels of patient dose or administered activity from a specified imaging procedure are unusually high or low for that procedure. If so, a local review should be initiated to determine whether protection has been adequately optimised or whether corrective action is required.

(220) The important message from the Commission is that a similar approach is used in optimisation, regardless of the type of source or the exposure situation. By increasing the attention to the process of optimisation in all radiation exposure situations, the Commission is of the opinion that the level of protection for what has until now been categorised as interventions will be improved, compared to the recommendations in *Publication 60* (ICRP, 1991).

(221) Thus, the chosen value for a constraint or a reference level will depend upon the prevailing circumstances of the exposure under consideration. It must also be realised that neither of them represent a demarcation between 'safe' and 'dangerous' or reflect a step change in the associated health risk for individuals.

(222) In Table 4 the different types of dose restrictions used in the Commission's system of protection (limits, constraints, reference levels) are shown in relation to type of exposure situation and category of exposure.

Table 4. The types of dose restrictions used in the Commission's system of protection in relation to type of exposure situation and category of exposure.

Type of situation	Occupational Exposure	Public Exposure	Medical Exposure
Planned exposure	Dose limit Dose constraint	Dose limit Dose constraint	Diagnostic reference level
Emergency exposure	Reference level[a]	Reference level	N.A.[b]
Existing exposure	Reference level	Reference level	N.A.[b]

[a] Long-term recovery operations should be treated as part of planned occupational exposure
[b] Not applicable

5.9.1. Dose constraints

(223) A dose constraint is a prospective and source related restriction on the individual dose from a source in planned exposure situations (except in medical exposure of patients), which serves as an upper bound on the dose in the optimisation of protection for that source. Dose constraints for planned situations represent a basic level of protection and will always be lower than the pertinent dose limit. During planning it must be ensured that the source concerned does not imply doses exceeding the constraint; optimisation of protection will establish a level of dose below the constraint.

(224) A dose constraint can be defined as a level of dose above which it is unlikely that protection is optimised for a given source of exposure, and for which, therefore, action must almost always be taken. The action necessary if a dose constraint is exceeded would normally begin by determining whether protection has been optimised, and if it has not, should include taking steps to reduce doses to acceptable levels. For potential exposures this source-related restriction is called a risk constraint (see Section 6.1.3). Compliance with the dose constraint is not sufficient, and optimisation of protection will be necessary to establish an acceptable level of dose below the constraint.

(225) The concept of dose constraints was introduced in *Publication 60* as a means to assure that the optimisation process did not create inequity, i.e. the possibility that some individuals in an optimised protection scheme may be subject to much more exposure than the average:

> *'Most of the methods used in the optimisation of protection tend to emphasise the benefits and detriments to society and the whole exposed population. The benefits and detriments are unlikely to be distributed through society in the same way. Optimisation of protection may thus introduce a substantial inequity between one individual and another. This inequity can be limited by incorporating source-related restrictions on individual dose into the process of optimization. The Commission calls these source-related dose constraints, previously called upper bounds. They form an integral part of the optimization of protection. For potential exposures, the corresponding concept is the risk constraint'* (ICRP, 1991).

This statement continues to be the Commission's view.

(226) For occupational exposures, the dose constraint is a value of individual dose used to limit the range of options considered in the process of optimisation. For public exposure, the dose constraint is an upper bound on the annual doses that members of the public could receive from the planned operation of any controlled source.

5.9.2. Reference levels

(227) In emergency or existing controllable exposure situations, the reference levels represent the level of dose or risk, above which it is judged to be inappropriate to plan to allow exposures to occur, and below which optimisation of protection should be implemented. The chosen value for a reference level will depend upon the prevailing circumstances of the exposure under consideration.

(228) Once protective actions have been implemented through optimisation subject to reference levels, doses can be measured or assessed to workers and members of the public. The reference level is then used as a benchmark against which protection options can be judged retrospectively. The distribution of doses that has resulted from the implementation of a planned protective strategy may or may not include exposures above the reference level. Efforts should be aimed at reducing any exposures that are above the reference level to a level that is below, if possible. While resource allocation should focus on those exposures above the reference level, it should not be forgotten that optimised protection should be applied to all exposed individuals, whether their exposure is above or below the reference level.

(229) Protection is optimised with reference to a specific situation. Should exposure conditions evolve with time, as in the case of an emergency situation for example, the applicable reference level should be revisited to see whether the selected values continue to address protection needs.

5.9.3. Factors influencing the choice of source-related dose constraints and reference levels

(230) In providing guidance on values for dose constraints and reference levels, the Commission has assumed a linear relationship between radiation dose and risk of cancer in exposed organs or tissues or hereditary effects. The Commission considers that, for the purposes of radiological protection, the assumption of linearity applies up to acute or annual doses of about 100 mSv. At higher doses, there is an increased likelihood of tissue injuries and a significant risk of stochastic effects. For these reasons, the Commission considers that the maximum value for a reference level is 100 mSv incurred either acutely or in a year, although reference levels this high would only be established under extreme (unavoidable) circumstances. There is no net individual or societal benefit that can compensate for higher levels of exposures, except in exceptional situations such as the saving of life or the prevention of a serious disaster.

(231) Many of the numerical criteria recommended by the Commission in *Publication 60* and subsequent publications can be, with the exception of the limits, regarded as constraints or reference levels. The values fall into three defined bands (see Table 5) with the attributes described in the following paragraphs. The

Commission considers that it is useful to present these values in this manner as it enables selection of an appropriate value for a constraint or a reference level for a specific situation that has not been addressed explicitly by the Commission. The values are expressed in terms of projected incremental doses (mSv in a year).

(232) The first band, less than 1 mSv, applies to situations where individuals receive exposures – usually planned – that are of no direct benefit to them but there is a benefit to society. The exposure of members of the public from the planned operation of practices is a prime example of this type of situation. Constraints and reference levels in this band would be selected for situations where there is general information and environmental surveillance or monitoring or assessment and where individuals may receive information but no training. The corresponding doses would represent a marginal increase above the natural background and are at least two orders of magnitude lower than the maximum value for a reference level, thus providing a rigorous level of protection.

(233) The second band, from 1 mSv to 20 mSv, applies in circumstances where individuals receive direct benefits from an exposure situation but not necessarily from the exposure, or the source of the exposure, itself. Constraints and reference levels in this band will often be set in circumstances where there is individual surveillance or dose monitoring or assessment, and where individuals benefit from training or information. Examples are the constraints set for occupational exposure in planned situations. Exposure situations involving abnormally high levels of natural background radiation may also be in this band.

(234) The third band, from 20 mSv to 100 mSv, applies in unusual, and often, extreme situations where actions taken to reduce exposures would be disruptive or where the source cannot be controlled. Reference levels and, occasionally, constraints could also be set in this range in circumstances where benefits from the exposure situation are commensurately high. Action taken to reduce exposures in a radiological emergency is the main example of this type of situation. The Commission's upper value for a reference level of 100 mSv is set so as to restrict or avoid the probability of significant health effects and, as such, should be considered to apply to the total dose to an individual from all sources. In most such instances one source will be dominant and the upper value could be applied to that source.

(235) The Commission's banding of constraints and reference levels applies across all three exposure situations and refers to the projected dose over a time period that is appropriate for the situation under consideration. In the case of the continuing exposures in both planned and existing exposure situations, the values refer to the additional dose conventionally expressed as dose per year. For emergency situations, the values refer to acute exposures, which would not be expected to be repeated.

(236) In emergency and existing exposure situations, it could be argued that the source-related restriction would not provide sufficient protection where there are multiple sources. Generally, however, there is a dominant source and the selection of the appropriate reference level ensures the required level of protection. The Commission still considers that the source-related principle of optimisation below the constraint or reference level is the most effective tool for protection, whatever the situation.

(237) A necessary stage in applying the principle of optimisation of protection is the selection of an appropriate value for the dose constraint or the reference level. The relevant national authorities will often play a major role in this process. The first step is to characterise the relevant exposure situation in terms of the nature of the exposure, the benefits from the exposure situation to individuals and society, and the practicability of reducing or preventing the exposures. Comparison of these attributes with the characteristics described in Table 5 should enable the selection of the appropriate band for the constraint or the reference level. The specific value for the constraint may then be established by a process of generic optimisation that takes account of national or regional attributes and preferences together, where appropriate, with a consideration of international guidance and good practice elsewhere. The Commission provides additional guidance below on the selection of constraints and reference levels for occupational, medical and public exposure in the three exposure situations.

Table 5. Framework for source-related dose constraints and reference levels with examples of constraints for workers and the public from single dominant sources for all situations that can be controlled (effective dose in a year).

Bands of Projected Effective Dose[1] (mSv)	**Characteristics of the Situation**	**Radiological Protection Requirements**	**Examples**
20 to 100	Individuals exposed by sources that are either not controllable or where actions to reduce doses would be disproportionately disruptive. Exposures are usually controlled by action on the exposure pathways. Individuals may or may not receive benefit from the exposure situations.	Consideration should be given to reducing doses. Increasing efforts should be made to reduce doses as they approach 100 mSv. Individuals should receive information on radiation risk and on the actions to reduce doses. Assessment of individual doses should be undertaken.	Reference level for evacuation in a radiological emergency.
1 to 20	Individuals will usually receive direct benefit from the exposure situation but not necessarily from the exposure itself. Exposures may be controlled at source or, alternatively, by action in the exposure pathways.	Where possible, general information should be made available to enable individuals to reduce their doses. For planned situations, individual monitoring and training should take place.	Constraints set for occupational exposure in planned situations. Reference level for radon in dwellings.
0.01 to 1	Individuals are exposed to a source that gives them no direct benefit but benefits society in general. Exposures are usually controlled by action taken directly on the source for which radiological protection requirements can be planned in advance.	General information on the level of exposure should be made available. Periodic checks should be made on the exposure pathways as to the level of exposure.	Constraints set for public exposure in planned situations.

[1] Acute or annual dose.

5.10. Dose limits

(238) Dose limits apply only in planned situations but not to medical exposures of patients. The Commission has concluded that the existing dose limits that it recommended in *Publication 60* continue to provide an appropriate level of protection (ICRP, 1991b). The nominal detriment coefficients for both a workforce and the general public are consistent with, although numerically somewhat lower than, those given in 1990. These slight differences are of no practical significance (see Annex A). Within a category of exposure, occupational or public, dose limits apply to the sum of exposures from sources related to practices that are already justified.

(239) For occupational exposure in planned situations, the Commission continues to recommend that the limit should be expressed as an effective dose of 20 mSv per year, averaged over defined 5 year periods (100 mSv in 5 years), with the further provision that the effective dose should not exceed 50 mSv in any single year.

(240) For public exposure in planned situations, the Commission continues to recommend that the limit 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.

(241) The limit on effective dose applies to the sum of external exposures and internal exposures due to intakes of radionuclides. In *Publication 60* (ICRP, 1991), the Commission stated that intakes may be averaged over a period of 5 years to provide some flexibility, and the Commission maintains this view.

(242) Dose limits do not apply in situations where an informed, exposed individual is engaged in volunteered life-saving actions or is attempting to prevent a catastrophic situation. For informed volunteers undertaking urgent rescue operations, the normal dose restriction may be relaxed. However, responders undertaking recovery and restoration operations in emergency exposure situations should be considered occupationally exposed workers and should be protected according to normal occupational radiological protection standards, and their exposures should not exceed the occupational dose limits recommended by the Commission. Since the Commission recommends specific protection measures for female workers who may be pregnant or are nursing an infant (see Section 5.4.1) , and taking account of the unavoidable uncertainties surrounding early response measures in the event of an emergency exposure situations, female workers in those conditions should not be employed as first responders undertaking life-saving or other urgent actions.

(243) The recommended limits are summarised in Table 6. In addition to the limits on effective dose, limits were set in *Publication 60* for the lens of the eye and localised areas of skin because these tissues will not necessarily be protected against tissue reactions by the limit on effective dose. The relevant values were set out in terms of the equivalent dose. These dose limits remain unchanged and are reproduced in the present Table 6. However, new data on the radiosensitivity of the eye with regard to visual impairment are expected. The Commission will consider these data and their possible significance for the equivalent dose limit for the lens of the eye when they become available.

(244) The dose limits for tissues are given in equivalent dose. The reason for this is that the Commission assumes that the relevant RBE values for the deterministic effects are always lower than w_R values for stochastic effects. It is, thus, safely inferred that the dose limits provide at least as much protection against high-LET radiation as against low-LET radiation. The Commission, therefore, believes that it is sufficiently conservative to use w_R with regard to deterministic effects. In special situations where high-LET radiation is the critical factor and where it predominantly exposes a single tissue (such as the skin), it will be more appropriate to express the exposure in terms of the absorbed dose and to take into account the appropriate RBE (see Annex B). To avoid confusion, it is necessary to clearly mention whenever an RBE-weighted absorbed dose in Gy is used.

(245) The Commission's multi-attribute approach to the selection of dose limits necessarily includes societal judgements applied to the many attributes of risk. These judgements would not necessarily be the same in all contexts and, in particular, might be different in different societies. It is for this reason that the Commission intends its guidance to be sufficiently flexible to allow for national or regional variations. In the Commission's view, however, any such variations in the protection of the most highly exposed individuals are best introduced by the use of source-related dose constraints selected by the national authorities and applied in the process of optimisation of protection.

Table 6. Recommended dose limits in planned exposure situations[1]

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

[1] Limits on effective dose are for the sum of the relevant effective doses from external exposure in the specified time period and the committed effective dose from intakes of radionuclides in the same period. For adults, the committed effective dose is computed for a 50-year period after intake, whereas for children it is computed for the period up to age 70 years.
[2] The limitation on effective dose provides sufficient protection for the skin against stochastic effects.
[3] Averaged over 1 cm^2 area of skin regardless of the area exposed (see also ICRP 1991a).
[4] 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.
[5] 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

6. IMPLEMENTATION OF THE COMMISSION'S RECOMMENDATIONS

(246) The previous chapter describes the Commission's system of protection to be applied in all situations requiring a decision on the control of radiation exposures. This chapter addresses the implementation of the system in the three types of exposure situations: planned exposure situations, emergency exposure situations, and existing exposure situations. Particular attention is focused on areas where implementation of the recommendations may not be immediately straightforward. In a number of these areas, there is further guidance from the Commission as indicated in the text. A section comparing the radiological protection criteria in these recommendations with those in the previous recommendations, *Publication 60* (ICRP, 1991b) and derivative publications, is included. The last section of this chapter addresses common aspects of the implementation of the Commission's recommendations, notably the responsibilities of the users and regulators.

6.1. Planned exposure situations

(247) Planned exposure situations are where radiological protection can be planned in advance, before exposures occur, and where the magnitude and extent of the exposures can be reasonably predicted. The term encompasses sources and situations that have been appropriately managed within the Commission's previous recommendations for practices. In introducing a planned exposure situation all aspects relevant to radiological protection should be considered. These aspects will include, as appropriate, design, construction, operation, decommissioning, waste management and rehabilitation of previously occupied land. Planned exposure situations also cover the medical exposure of patients, including their comforters and carers. The principles of protection for planned situations also apply to planned work in connection with existing and emergency exposure situations. Recommendations for planned situations are substantially unchanged from those provided in *Publication 60* (ICRP, 1991) and subsequent publications for the normal operation of practices and protection in medicine. Because of its specific characteristics, medical exposure is discussed separately in Chapter 7.

(248) All categories of exposure can occur in planned exposure situations, i.e. occupational exposure, public exposure and medical exposure of patients. Planned situations are therefore of interest for the protection of workers (Section 6.1.1), members of the public (Section 6.1.2) and of patients, including their comforters and carers (Chapter 7). The design and development of planned situations should have proper regard for potential exposures that may result from deviations from normal operating conditions. Due attention is paid to the assessment of potential exposures and to the growing issue of the safety and security of radiation sources (Section 6.1.3).

6.1.1. Occupational exposure

(249) The Commission continues to recommend that occupational exposure in planned exposure situations be controlled by the procedures of optimisation below a source-related constraint (see Section 5.7) and the use of prescriptive dose limits (see Section 5.9). A constraint should be defined at the design stage of a planned exposure situation for its operation. For many types of work in planned exposure situations, 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 work. This work should be specified in fairly broad terms, such as work in industrial radiography, the routine operation of nuclear power plants, or work in medical establishments. It will usually be appropriate for such dose constraints to be set at the operational level. When using a dose constraint, a designer should specify the sources to which the constraint is linked so as to avoid confusion with other sources to which the workforce might be concurrently exposed. The source-related dose constraint for occupational exposure in planned situations should be set for each source (or group of sources) to ensure that the dose limit is not exceeded (see Section 5.9). Experience gained in managing workers exposed to radiation will inform the choice of a value for a constraint for occupational exposure. For this reason, large established organisations, having a comprehensive radiological protection infrastructure, will often set their own constraints for occupational exposure. Smaller organisations with less relevant experience may require further guidance on this topic from the appropriate expert bodies or authorities.

(250) Protection of transient or itinerant workers requires particular attention because of the shared responsibility of several employers and sometimes several regulatory authorities. Such workers include contractors for maintenance operations in nuclear power plants and industrial radiographers, who are not on the staff of the operator. In order to provide for their protection, adequate consideration needs to be given to the previous exposures of these workers so as to ensure that dose limits are also respected, and specific follow-up of their exposure must be implemented. Thus there should be an adequate degree of co-operation between the employer of the itinerant worker and the operators of the plants for whom contracts are being undertaken. Regulatory authorities should ensure that regulations are adequate is this respect.

(251) The Commission has previously recommended general principles for the radiological protection of workers (*Publication 75*, ICRP 1997a). These principles remain valid.

6.1.2. Public exposure

(252) In planned exposure situations, the Commission continues to recommend that public exposure be controlled by the procedures of optimisation below the source-related constraint and by the use of dose limits. In general, especially for public exposure, each source will cause a distribution of doses over many individuals, so the concept of a *representative person* should be used to represent the more highly exposed individuals (ICRP, 2006). Constraints for members of the public in planned situations should be smaller than public dose limits, and would typically be set by the national regulatory authorities.

(253) For the control of public exposure from waste disposal, the Commission has previously recommended that a value for the dose constraint for members of the public of no more than about 0.3 mSv in a year would be appropriate (ICRP, 1998a). These recommendations were further elaborated for the planned disposal of long-lived radioactive waste in *Publication 81* (ICRP, 1998c). The Commission has also issued guidance that in circumstances where there are planned discharges of long-lived radionuclides to the environment, planning assessments should consider whether build up in the environment would result in the constraint being exceeded. Where such verification considerations are not possible or are too uncertain, it would

be prudent to apply a dose constraint of the order of 0.1 mSv in a year to the prolonged component of the dose (ICRP; 1999b). These recommendations remain valid.

6.1.3. Potential exposures

(254) In planned exposure situations, a certain level of exposure is reasonably expected to occur. However, higher exposures may arise following deviations from planned operating procedures, accidents including the loss of control of radiation sources and malevolent events. These exposures are referred to by the Commission as *potential exposures*. Deviations from planned operating procedures and accidents can often be foreseen and their probability of occurrence estimated, but they cannot be predicted in detail. Loss of control of radiation sources and malevolent events are less predictable and call for a specific approach.

(255) There is usually an interaction between potential exposures and the exposures arising from planned operations in normal operation; for example, actions taken to reduce the exposure from during normal operations may increase the probability of potential exposures. Thus, the storage of waste rather than its dispersal could reduce the exposures from discharges but would increase potential exposures.

(256) Potential exposures should be considered at the planning stage of the introduction of a planned exposure situation. It should be recognised that the potential for exposures may lead to actions both to reduce the probability of the events occurring, and limit and reduce the exposure (mitigation) if any event were to occur (ICRP, 1991; 1997). Due consideration should be afforded to potential exposures during application of the principles of justification and optimisation.

(257) Potential exposure broadly covers three types of events:

- Events where the potential exposures would primarily affect individuals who are also subject to planned exposures. The number of individuals is usually small, and the detriment involved is the health risk to the directly exposed persons. The processes by which such exposures occur are relatively simple, e.g., the potential unsafe entry into an irradiation room. The Commission has given specific guidance for the protection from potential exposures in *Publication 76* (ICRP; 1997). This guidance remains valid.
- Events where the potential exposures could affect larger number of people and not only involve health risks but also other detriments, such as contaminated land and the need to control food consumption. The mechanisms involved are complicated and an example is the potential for a major accident in a nuclear reactor or the malicious use of radioactive material. The Commission has provided a conceptual framework for the protection from such type of events in *Publication 64* (ICRP; 1993). This framework remains valid. In *Publication 96* (2005a), the Commission provides some additional advice concerning radiological protection after events involving malicious intent.
- Events in which the potential exposures could occur far in the future, and the doses be delivered over long time periods, e.g., in the case of solid waste disposal in deep repositories. Considerable uncertainties surround exposures taking place far in the far future. Thus dose estimates should not be regarded as measures of health detriment beyond times of around several hundreds of

years into the future. Rather, they represent indicators of the protection afforded by the disposal system. The Commission has given specific guidance for the disposal of long-lived solid radioactive waste in *Publication 81* (ICRP, 1998c). This guidance remains valid.

Assessment of potential exposures

(258) The evaluation of potential exposures, for the purpose of planning or judging protection measures, is usually based on: a) the construction of scenarios which are intended typically to represent the sequence of events leading to the exposures; b) the assessment of probabilities of each of these sequences; c) the assessment of the resulting dose; d) the evaluation of detriment associated with that dose; e) comparison of the results with some criterion of acceptability; and f) optimisation of protection which may require several reiterations of the previous steps.

(259) The principles of scenario construction and analysis are well known and are often used in engineering. Their application was discussed in *Publication 76* (ICRP, 1997). Decisions on the acceptability of potential exposures should take account of both the probability of occurrence of the exposure and its magnitude. In some circumstances, decisions can be made by separate consideration of these two factors. In other circumstances, it is useful to consider the individual probability of radiation-related death, rather than the effective dose (ICRP, 1997). For this purpose, the probability is defined as the product of the probability of incurring the dose in a year and the lifetime probability of radiation-related death from the dose conditional on the dose being incurred. The resulting probability can then be compared with a risk constraint. Both of these approaches are discussed in the Commission's recommendations for the disposal of long-lived solid radioactive waste in *Publication 81* (ICRP, 1998c).

(260) Risk constraints, like dose constraints, are source-related and in principle should equate to a similar health risk to that implied by the corresponding dose constraints for the same source. However, there can be large uncertainties in estimations of the probability of an unsafe situation and the resulting dose. Thus, it will often be sufficient, at least for regulatory purposes, to use a generic value for a risk constraint based on generalisations about normal occupational exposures, rather than a more specific study of the particular operation. Where the Commission's system of dose limitation has been applied and protection is optimised, annual occupational effective doses to an average individual may be as high as about 5 mSv in certain selected types of operation (UNSCEAR, 2000). For potential exposures of workers, the Commission therefore continues to recommend a generic risk constraint of $2\ 10^{-4}$ per year which is similar to the probability of fatal cancer associated with an average occupational annual dose of 5 mSv (ICRP, 1997). For potential exposures of the public, the Commission continues to recommend a risk constraint of $1\ 10^{-5}$ per year, corresponding to the probability of fatal cancer associated with the generic dose constraint of 0.3 mSv applied e.g. in the case of disposal of long-lived radioactive waste (ICRP, 1998c).

(261) The use of probability assessment is limited by the extent that unlikely events can be forecast. In circumstances where accidents can occur as a result of a wide spectrum of initiating events, caution should be exercised over any estimate of overall probabilities because of the serious uncertainty of predicting the existence of all the unlikely initiating events. In many circumstances, more information can be

obtained for decision making purposes by considering the probability of occurrence and the resultant doses, separately.

Safety and security of radiation sources and malevolent events

(262) Potential exposures associated with planned exposure situations may result from the loss of control of radiation sources. This situation has received a growing attention over recent years and deserves a special consideration from the Commission. The recommendations of the Commission presume that, as a precondition for adequate radiological protection, radiation sources are subject to proper security measures (ICRP, 1991b). The control of radiation exposure in all planned situations is exercised by the application of controls at the source rather than in the environment. The Commission's view is reflected in the International Basic Safety Standards (BSS), which require that the control of sources shall not be relinquished under any circumstances (IAEA, 1996a). The BSS also requires that sources be kept secure so as to prevent theft or damage. In addition, the Code of Conduct on the Safety and Security of Radioactive Sources establishes basic principles applicable to the security of radioactive sources (IAEA, 2004). The Commission supports the initiative of IAEA in this area.

(263) Security of radioactive sources is a necessary, but not sufficient, condition to ensure source safety. Radioactive sources can be secure, i.e. under proper control, and still not safe. Thus the Commission has historically included aspects of security in its system of protection (ICRP, 1991b). In the context of safety, security provisions are generally limited to general controls necessary to prevent loss, access, unauthorised possession or transfer and use of the material, devices or installations. Essential to safety are measures to ensure that control of radioactive material and access to radiation devices and installations are not relinquished.

(264) When the Commission's 1990 recommendations were developed measures specifically to protect against terrorism or other malicious acts were not afforded prominence. However, it has become evident that radiation safety must also include the potential for such scenarios. Past experience with unintentional breaches in source security or because a discarded, or orphan, source was found indicates what might occur if radioactive materials are used intentionally to cause harm, e.g., by deliberate dispersion of radioactive material in a public area. Such events have the potential of exposing people to radiation and causing significant environmental contamination, which would require specific radiological protection measures (ICRP, 2005a).

6.2. Emergency exposure situations

(265) Even if all reasonable steps have been taken during the design stage to reduce the probability and consequences of potential exposures, such exposures may become actual and need to be considered in relation to emergency preparedness and response. Emergency exposure situations are unexpected situations that may require urgent protective actions to be implemented. Exposure of members of the public or of workers, as well as environmental contamination can occur in these situations. Exposures can be complex in the sense that they may result from several independent pathways, perhaps acting simultaneously. Response actions can be planned because potential emergency situations can be assessed in advance, to a greater or lesser accuracy depending upon the type of facility or situation being considered. However, because actual emergency situations are inherently

unpredictable, the exact nature of necessary protection measures cannot be known in advance but must flexibly evolve to meet actual circumstances. The complexity and variability of these situations give them a unique character that merits their specific treatment by the Commission in its recommendations.

(266) The Commission has set out general principles for planning intervention in the case of a radiation emergency in *Publications 60* and *63* (1991b; 1993b). Additional relevant advice is given in *Publications 86, 96, 97,* and *98* (ICRP 2000d; 2005a, 2005b, 2005c). While the general principles and additional advice remain valid, the Commission is now extending its guidance on the application of protective measures on the basis of recent developments in emergency preparedness and of experience since publication of its previous advice.

(267) Now, the Commission emphasises the importance of justifying and optimising protection strategies for application in emergency exposure situations, the optimisation process being restricted by reference levels (see Section 5.9). The possibility of multiple, independent, simultaneous, and time-varying exposure pathways makes it important to focus on the overall exposures that may occur from all pathways when developing and implementing protective measures. As such, an overall protection strategy is necessary, generally including the implementation of different protective measures. These measures may well vary with time, as the emergency situation evolves, and with place, as the emergency situation may affect distinct geographic areas differently. The overall exposure, which is projected to occur as a result of the emergency exposure situation, should no protective actions be employed, is called the *projected dose*. The dose that would result should a protection strategy be implemented is called the *residual dose*. In addition, each protective measure will avert a certain amount of exposure. This is referred to as *averted dose*, and is a useful concept for the optimisation of the individual protective measures that will make up the overall protection strategy.

(268) In emergency exposure situations particular attention should be given to the prevention of severe deterministic health effects as doses could reach high levels in short period of time. Moreover, in case of major events an assessment based on health effects would be insufficient and due considerations must be given to social, economic and other consequences. Another important objective is to prepare, to the extent practicable, for the resumption of social and economic activity considered as 'normal'.

(269) In emergency situations, reference levels should be applied in the process of optimisation. Reference levels for emergency situations are typically in the 20 mSv to 100 mSv band of projected dose as presented in Section 5.8.2. Projected and residual doses are compared with reference levels in initially assessing the need for invoking any pre-planned protection strategies, and in assessing the need for additional specific measures, that might be necessary to address actual circumstances.

(270) A protection strategy that does not reduce residual doses to below the reference level should be rejected at the planning stage. Once an emergency situation has occurred the reference level acts as a benchmark for assessing the effectiveness of protection strategies. Although particular attention should be given to exposures above the reference level, all exposures above or below the reference level, are subject to optimisation. Optimisation of protection in emergency exposure

situations should consider benefits and detriments beyond those associated with doses, for example the social detriment of permanent relocation, or the social benefit of reassurance measures. The use of reference levels in emergency exposure situations is illustrated in Figure 3.

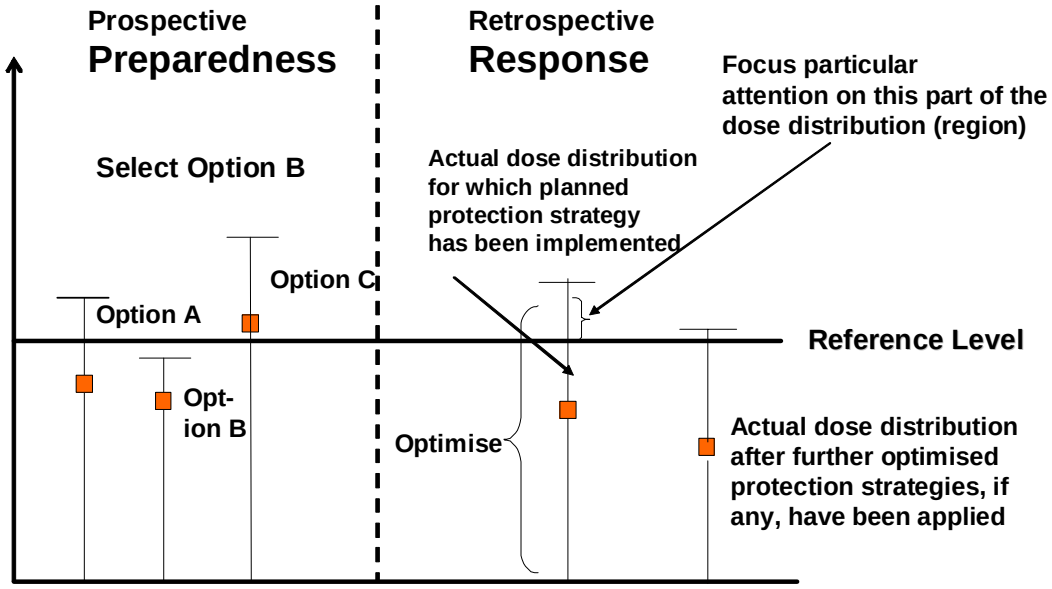

Figure 3. The application of reference levels in emergency preparedness and emergency response situations.

(271) Emergency plans should be developed (in more or less detail, as appropriate) for all possible scenarios. The development of an emergency plan (national, local or facility specific) is a multi-step iterative process that includes assessment, planning, resource allocation, training, exercises, audit, and revision. The radiation emergency response plans should be integrated into all-hazards emergency management programmes.

(272) When preparing a protection strategy for a particular emergency exposure situation, a number of different populations, each needing specific protective measures, may be identified. For example, the distance from the origin of an emergency situation (e.g., a facility, an emergency site) may be important in terms of identifying the magnitude of exposures to be considered, and thus the types and urgency of protective measures. With this diversity of exposed populations in mind, the planning of protective measures should be based on exposures to the representative persons, as described in *Publication 101* (ICRP, 2006), from the various populations that have been identified. After an emergency situation has occurred, planned protection measures should evolve to best address the actual conditions of all exposed populations being considered.

(273) In the event that an emergency exposure situation occurs, the first issue is to recognise its onset. The initial response should be to follow the emergency plan in a consistent but flexible way. The protection strategy initially implemented will be that described in the emergency plan for the relevant event scenario. Once the measures in the emergency plan have been initiated, emergency response can be characterised by an iterative cycle of review, planning, and execution. Three phases of an emergency exposure situation are considered: the early phase (which may be

divided into a warning and release phase), the intermediate phase (which starts with the cessation of the release when decisions are taken on the lifting of early phase countermeasures and initial longer term protective actions are implemented), and the late phase (the long term rehabilitation phase).

(274) Emergency response is inevitably a process that develops in time from a situation of little information to one of potentially overwhelming information, with the expectations for protection and involvement by those affected similarly increasing rapidly with time. At any stage, decision makers will necessarily have incomplete understanding of the situation regarding the future impact, the effectiveness of protective measures, the concerns of those directly and indirectly affected, amongst other factors. An effective response must therefore be developed flexibly with regular review of its impact. The reference level provides an important input to this review, providing a benchmark against which what is known about the situation and the protection afforded by implemented measures can be compared.

(275) Dialogue with stakeholders is an essential component of emergency preparedness and response. The stakeholders involved and the nature of their involvement will vary with circumstances and with time. However, with the possible exception of the urgent implementation of protective measures, stakeholder input and involvement will be necessary in the case of an emergency exposure situation, and for all exposed populations.

(276) The Commission is currently developing more detailed guidance on the protection of individuals during nuclear or radiological emergencies.

6.3. Existing exposure situations

(277) Existing exposure situations are those that already exist when a decision on control has to be taken. There are many types of existing exposure situations that may cause exposures high enough to warrant radiological protective actions, or at least their consideration. Among those of natural origin, radon in dwellings or the workplace, and naturally occurring radioactive material (NORM) are well-known examples. It may be also necessary to take radiological protection decisions concerning existing man-made exposure situations such as residues in the environment resulting from radiological emissions from operations that were not conducted within the Commission's system of protection, or contaminated territories resulting from an accident or a radiological event. There are also existing exposure situations for which it will be obvious that action to reduce exposures is not warranted. An example is exposure to cosmic rays at ground level, which is impractical to control. The decision as to what components of existing exposure are not amenable to control requires a judgment by the regulatory authority that will depend on the controllability of the source or exposure and also on the prevailing economic, societal and cultural circumstances. Principles for exclusion and exemption of radiation sources are presented and discussed in Section 2.3.

(278) Existing exposure situations can be complex in that they may involve several exposure pathways and they generally give rise to wide distributions of annual individual doses ranging from the very low to, possibly, several tens of millisieverts. Such situations often involve dwellings, for example in the case of

radon, and in many cases the behaviour of the exposed individuals determines the level of exposure. For example the distribution of individual exposures in a long-term contaminated territory directly reflects the diversity of the individual dietary habits of the affected inhabitants. The multiplicity of exposure pathways and the importance of individual behaviour may result in exposure situations that are difficult to control.

(279) The Commission's principles of justification and optimisation apply to all existing exposure situations. Furthermore, for equity considerations, every effort should be made to try to keep individual exposures below relevant reference levels expressed in term of individual dose. Because de facto exposures cannot be managed in an a priori fashion, the individual limit for planned exposure situations do not apply to existing exposure situations.

(280) A key parameter for the control of existing situation is time. The process will generally be iterative with the objective of reducing the doses to the individuals in a progressive manner. Such processes may take years or even decades according the situation. Authorities may decide to develop implementation plans including the characterisation of the exposure situation, the definition of priorities for reducing exposures and of protection strategies, as well as the requirements for information, monitoring, assessment, education and training and provision for regular progress reviews to assess the effectiveness of the implemented strategies.

(281) Application of the justification principle to existing situations requires a thorough evaluation of the exposure situation and of the means for potential control, keeping in mind that any action to reduce existing exposure will always have some disadvantages. Key considerations to justify reducing existing exposures are the level of exposure, the number of affected individuals, whether residences or daily life are affected, and the level of controllability of the exposure taking into account potential disruption of the living conditions by the available protection actions. The responsibility for judging the justification for reducing doses associated with an existing exposure situation usually falls on governments or national authorities.

(282) In applying the optimisation principle, the possibility of multiple, independent, simultaneous, and time-varying exposure pathways makes it important to focus on the overall exposures that may occur from all pathways when developing and implementing protection actions. Generally it is necessary to develop a protection strategy which includes the implementation of different protection actions.

(283) The Commission recommends that reference levels, set in terms of individual dose, should be used in conjunction with the implementation of the optimisation process in all existing exposure situations. The objective is to implement optimised protection strategies, or a progressive range of such strategies, which will reduce individual doses to below the reference level. However, exposures below the reference level should not be ignored; the process of optimisation of protection should be applied to establish whether a reduction in these doses should be undertaken. An endpoint for the optimisation process must not be fixed a priori and the optimised level of protection will depend on the situation. It is the responsibility of national authorities to decide on the legal status of the reference level, which is implemented to control a given situation. Retrospectively, when protection actions have been implemented, reference levels may also be used as benchmarks for assessing the effectiveness of the protection strategies. The use of

reference levels in existing situation is illustrated in Figure 4, which shows the evolution of the distribution of individual doses with time as a result of the optimisation process.

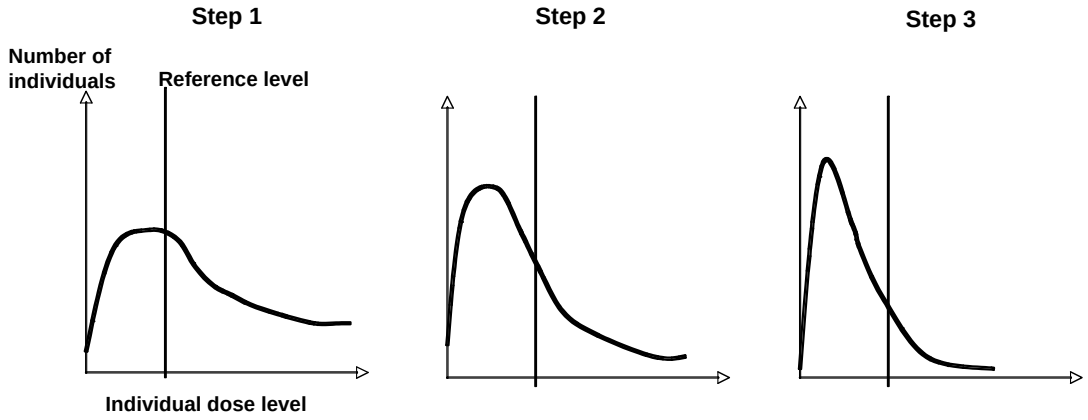

Fig. 4.. The use of a reference levels in existing situation and the evolution of the distribution of individual doses with time as a result of the optimisation process.

(284) Reference levels for existing situations should be set typically in the 1 to 20 mSv band of projected dose as presented in Section 5.8.2. They correspond to situations where individuals and/or the society will receive a benefit from the situation that outweighs the radiological detriment. It will often be important to make available to the concerned individuals general information on the exposure situation and the means to reduce doses. In situations where individual behaviours are key drivers of the exposures, individual monitoring or assessment as well as education and training may be important requirements. Living in contaminated territories after a nuclear accident or a radiological event is a typical situation of that sort.

(285) The main factors to be considered for setting the reference levels for existing situations are the feasibility of controlling the situation, and the past experience with the management of similar situations. In most existing situations, there is a desire from the exposed individual as well as from the authorities to reduce exposures to levels that are close or similar to situations considered as ‘normal’. The Commission therefore recommends that, whenever practicable, values for the reference levels should be set at the lower end of the 1 to 20 mSv band. This is particularly relevant in situations of exposures from material resulting from human activities, e.g. NORM residues and contamination from accidents. In such cases, reference levels may ideally be set at values similar to those used in planned exposure situations. The Commission recognises, however, that there will be circumstances in which the setting of reference levels at such values would not be feasible and there will be other circumstances where resumption to a situation considered as ‘normal’ can be achieved only following a program of progressive protective actions lasting years. It is generally the role and responsibility of the national authorities to establish the reference levels in consultation with the relevant stakeholders.

(286) Stakeholder involvement is an essential component of developing and implementing protection strategies for existing exposure situations. Past experience with the control of this type of exposure has demonstrated that stakeholder involvement enhances the quality of the decisions relating to protection. The role of stakeholders in the development of the justification and the optimisation processes

and the nature of their involvement in the actual control of exposures will largely depend on the circumstances. More detailed recommendations on stakeholder involvement in the optimisation of radiological protection are given in *Publication 101* (ICRP, 2006).

(287) The Commission is currently developing more detailed recommendations on the protection of individuals living in contaminated territories after a nuclear accident or a radiological event.

6.3.1. Indoor radon in dwellings and workplaces

(288) Exposure to radon in dwellings and workplaces is an existing exposure situation of general concern and one where the Commission has previously made specific recommendations (ICRP, 1994a). Since then, several epidemiological studies have confirmed the risk of radon-222 exposure even at relatively moderate concentrations (UNSCEAR, 2006). European and North American and Chinese residential case-control studies also demonstrate a significant association between the risk of lung cancer and exposure to residential radon-222 (Darby et al 2005, 2006; Krewski et al. 2005, 2006; Lubin et al. 2004). These studies have generally provided support for the Commission's recommendations on protection against radon.

(289) There is now a remarkable coherence between the risk estimates developed from epidemiological studies of miners and residential case-control radon studies. While the miner studies provide a strong basis for evaluating risks from radon exposure and for investigating the effects of modifiers to the dose response relation, the results of the recent pooled residential studies now provide a direct method of estimating risks to people at home without the need for (downward) extrapolation from miner studies (UNSCEAR, 2006). Notwithstanding the wide range of results from residential case-control studies and the important effects of confounding by smoking and other factors, overall the pooled European and North America case-control studies clearly demonstrate an association between risk of lung cancer and residential radon-222 exposure.

(290) The Commission's view on radon risk assessment has, up till now, been that it should be based on epidemiological studies of miners. Given the wealth of data now available on domestic exposure to radon, the Commission recommends that the estimation of risk from domestic radon exposure should be based on the results of pooled residential case control radon-222 studies. However, there is still great value in the miner epidemiology studies for investigating dose response relationships and confounding effects of smoking and exposure to other agents. The currently available epidemiological evidence indicates that risks other than lung cancer from exposure to radon-222 (and decay products) are likely to be small.

(291) The underlying theme of the Commission's recommendations on radon is the controllability of exposure. The ability to control exposure distinguishes the circumstances under which exposure to radon in workplaces, including underground mines, may need to be subject to the Commission's system of protection and where the need for action to limit radon exposure in dwellings should be considered. There are several reasons to treat radon-222 in this separate manner. The exposure route differs from that of other natural sources, and there are dosimetric and epidemiological issues peculiar to radon-222. For many individuals radon-222 is an important source of exposure which, in principle, can be controlled. The

Commission issued the current recommendations for protection against radon-222 at home and at work in *Publication 65* (ICRP, 1994a). The policy has found wide acceptance and the present recommendations broadly continue the same policy, with an adaptation to the new approach based on exposure situations with the central role given to the optimisation principle and the use of reference levels.

(292) In *Publication 65* (ICRP, 1994a), the policy was based upon first setting a level equivalent to an effective dose of 10 mSv per year from radon-222 where action would certainly be warranted to reduce the exposure. National authorities were expected to apply the optimisation of protection in a generic way to find a lower level at which to act, in the range from 3 to 10 mSv. The effective dose was converted into a value of radon-222 concentration, which was different between homes and workplaces largely because of the relative number of hours spent at each. For dwellings this range was a radon concentration of between 200 - 600 Bq m^{-3}, while the corresponding range for workplaces was 500 - 1500 Bq m^{-3}. The result of the optimisation was to set action levels above which action was required to reduce the dose.

(293) Now, the Commission recommends applying the source-related principles of radiological protection for controlling radon exposure. This means that national authorities need to set national reference levels to aid the optimisation of protection. Even though the nominal risk per Sv has changed slightly, the Commission, for the sake of continuity and practicality, retains the upper value of 10 mSv for the individual dose reference level and the corresponding activity concentrations as given in *Publication 65*. This means that the upper values for the reference level expressed in activity concentrations remain at 1500 Bq m^{-3} for workplaces and 600 Bq m^{-3} for homes (Table 7).

Table 7. Reference levels for radon-222[†]

Situation	Reference level
Domestic dwellings	600 Bq m^{-3}
Workplaces	1500 Bq m^{-3}

[†]Head or initial radionuclide of the decay chain activity level.

(294) It is the responsibility of the appropriate national authorities, as with other sources, to establish their own national reference levels, taking into account the prevailing economic and societal circumstances and then to apply the process of optimisation of protection in their country. All reasonable efforts should be made to reduce radon-222 exposures in homes and at working places below the reference levels that are set at the national level and to a level where protection can be considered optimised. The actions taken should be intended to produce substantial reduction in radon exposures. It is not sufficient to adopt marginal improvements aimed only at reducing the radon concentrations to a value just below the national reference level.

(295) The implementation of the optimisation process will result in concentration activities at home and at work below, and often well below, the national reference

levels. In general no further action will be required, apart from perhaps monitoring activity concentration sporadically to ensure that levels remain low. National authorities should, however, periodically review the values of the national reference levels for radon exposure to ensure that they remain appropriate.

(296) Responsibility for taking action against radon in houses and other premises will often fall on the individual owners, who cannot be expected to carry out a detailed optimisation exercise for each property. Therefore, in addition to reference levels, national authorities may also wish to specify levels at which protection against radon-222 can be considered optimised, i.e., where no further action is needed.

(297) In the interest of international harmonisation of occupational safety standards, a single action level value of 1000 Bq m^{-3} was established in the BSS (IAEA, 1996). For the same reasons, the Commission considers that this internationally established value might be used globally to define the entry point for occupational protection requirements for exposure situations to radon. In fact, this international level serves *inter alia* for a much needed globally harmonised monitoring and record-keeping system. This is relevant for determining when the occupational radiological protection requirements apply - i.e., what is actually included within the system of regulatory control.

(298) It is now recognised that in some occupational exposure situations, particularly mines, radon-222 exposure can be merged with other exposures to ionising radiation, making it difficult to apply a criterion specified in terms of radon concentration. In such exposure situations, the Commission recommends that the reference level for radon-222 exposure in the workplace should be set in terms of dose at a value that ensures compliance with the Commission's occupational dose limits. In general, for occupational radon exposure, a level should be set at which the system of protection is applied and the resulting doses should be recorded in the worker's dose record.

(299) The Commission reaffirms that radon exposures at work at levels below the reference level selected by national authorities should not be regarded as part of occupational exposure whereas exposures from radon levels above the reference level should be considered as part of occupational exposure (ICRP, 1997a).

6.4. Protection of the embryo/fetus in emergency and existing exposure situation

(300) For planned exposure situations, the Commission continues to recommend that the embryo/fetus should be afforded a level of protection similar to that of any member of the public (cf. Section 5.4.1). For existing and emergency exposure situations, where doses are not planned in advance, protection measures aimed at reducing extant doses may or may not be required. Since natural background radiation causes annual effective doses of at least around 1 mSv, existing or emergency exposure situations will inevitable lead to total doses exceeding this value, and it is not feasible to limit the annual dose to the embryo/fetus to 1 mSv. The issue here is to what extent special provisions will be required for pregnant women in these situations.

(301) In *Publication 82* (ICRP, 1999b), the Commission concluded provisionally that prenatal exposure would not be a specific protection case in prolonged exposure

situations with prolonged annual effective doses well below about 100 mSv. This was because organ malformations would not be expected at such dose levels, a practical threshold for mental retardation could be assumed (in particular taking account of the short period of sensitivity during gestation), and the lifetime risk of stochastic effects induced during pregnancy would be small compared with the risk induced by the prolonged exposure after birth. In *Publication 84* (ICRP, 2000c), the Commission provided practical recommendations concerning in-utero exposures and re-iterated its position that there is no need to make any general distinction between the two sexes in the control of occupational exposures, but when a female worker is known to be pregnant, additional measures should be considered in order to protect the embryo/fetus. Dose coefficients for the embryo/fetus due to intakes of radionuclides by the mother were provided in *Publication 88* (ICRP, 2001a). The Commission's interim conclusion in *Publication 90* (ICRP, 2003a) was that newly available information on in-utero risk at low doses (up to a few tens of mSv) supported the advice developed in *Publications 60*, *82*, *84*, and *88*.

(302) The Commission continues to judge that protection of the embryo/fetus should not be a specific protection case in prolonged existing and emergency exposure situations involving annual effective doses well below 100 mSv. Optimisation of protection for the general population should be sufficient to afford an adequate level of protection to the embryo/fetus of pregnant women in the population. However, as indicated in Section 5.10, the Commission recommends that female workers who are or may be pregnant or are nursing an infant should not be employed as first responders undertaking life-saving or other urgent actions in emergency exposure situations.

6.5. Comparison of radiological protection criteria

(303) The current recommended values for protection criteria are compared in Table 8 with those provided by the previous recommendations in *Publication 60* (ICRP, 199b) and the derivative publications. The comparison shows that the current recommendations are essentially the same as the previous recommendations for planned exposure situations. In the case of existing and emergency situations, the current recommendations generally encompass the previous values but are wider in their scope of application.

Table 8. Comparison of protection criteria between the 1990 and the 2007 Recommendations

Categories of exposure (Publications)	1990 recommendations and subsequent publications	2007 recommendations
Planned exposure situations		
	Individual dose limits [a]	
Public exposure (60)	1 mSv/year	1 mSv/year
Occupational exposure (60,68,75) including recovery operations (96)	20 mSv/year average over defined periods of 5 years	20 mSv/year average over defined periods of 5 years
- lens of the eyes	150 mSv/year [b]	150 mSv/year [b]
- skin	500 mSv/year [b]	500 mSv/year [b]
- hands and feet	500 mSv/year [b]	500 mSv/year [b]
- intake of radionuclides	20 mSv/year [c]	20 mSv/year [c]
- pregnant women, remainder of pregnancy	2 mSv to the surface of abdomen, 1 mSv to the fetus	1 mSv to the fetus
	Dose constraints [a]	
Public exposure (60)		
- radioactive waste disposal (77)	≤0.3 mSv/year	≤0.3 mSv/year
- long-lived radioactive waste disposal (81)	0.3 mSv/year	0.3 mSv/year
- prolonged exposure (82)	0.3 mSv/year and <1 mSv/year	0,3 mSv/year and 1 mSv/year
- prolonged component from long-lived nuclides (82)	0.1 mSv/year	0.1 mSv/year
- individual volunteers for biomedical research (62)		
If benefit of society is:		
- minor	< 0.1 mSv	< 0.1 mSv
- intermediate	~ 1mSv	~ 1mSv
- moderate	1-10 mSv	1-10 mSv
- substantial	> 10 mSv	> 10 mSv
Occupational exposure (60)	Below 20 mSv/year	Below 20 mSv/year
Emergency exposure situations		
	Intervention levels [d]	**Reference levels [a]**
Radiological emergency (63)		
- foodstuffs	10 mSv/year	
- sheltering	5-50 mSv	To be selected between
- evacuation	50-500 mSv/day	20 to 100 mSv/year according
- distribution of stable iodine	50-500 mSv (thyroid) [b]	to the situation
- relocation	1000 mSv	(See Sections 5.9 and 6.2)

Radiological attack (96) ***Occupational exposure:*** - rescue operations ***Public exposure:*** - sheltering - temporary evacuation - distribution of stable iodine - relocation	No dose restrictions ~ 10 mSv in 2 days ~ 50 mSv in 1 week ~ 100 mSv (thyroid) [b] ~ 1000 mSv [d] or ~ 100 mSv the first year	To be selected between 20 to 100 mSv /year according the situation (See Sections 5.9 and 6.2)
Existing exposure situations		
	Actions levels [a]	**Reference levels [a]**
Radon (65) - at home - at work	3–10 mSv/year (200–600 Bq m^{-3} in homes) 3-10 mSv/year (500 –1500 Bq m^{-3} for workers)	10 mSv/year (600 Bq m^{-3} in homes) 10 mSv/year (1500 Bq m^{-3} for workers)
	Generic reference levels [e]	**Reference levels [a]**
NORM, natural background radiation, radioactive residues in human habitat (82) Interventions for prolonged exposure: - unlikely to be justifiable - may be justifiable - almost always justifiable	 < ~ 10 mSv/year > ~ 10 mSv/year towards 100 mSv/year	To be selected between 1 and 20 mSv/year according the situation (See Sections 5.9 and 6.3)

[a] Effective dose unless otherwise specified
[b] Equivalent dose
[c] Committed effective dose
[d] Averted dose

6.6. General considerations

(304) This section addresses the general implementation of the Commission's recommendations, dealing with factors which are common to the three types of exposure situations. It focuses on organisational features that may help in the implementation of the Commission's recommendations. Since the organisational structures will differ from country to country, the chapter is illustrative rather than exhaustive. The International Atomic Energy Agency and the Nuclear Energy Agency of OECD issue further advice on the infrastructure required for radiological protection in various circumstances to their member states (see, e.g., IAEA, 1996a; 2000, 2002 and NEA, 2005). Generic advice on organisation for health and safety at work is provided by the International Labour Organization, the World Health Organization and the Pan-American Health Organization.

6.6.1. The infrastructure for radiological protection and safety

(305) An infrastructure is required to ensure that an appropriate standard of protection is maintained. This infrastructure includes at least a legal framework, a regulatory authority, the operating management of any undertaking involving

ionising radiation (including the design, operation, and decommissioning of equipment and installations as well as adventitious enhancement of natural radiation including aviation and space flight), and the employees at such undertakings. It may include additional bodies and persons responsible for protection and safety.

(306) The legal framework must provide for the regulation as required of undertakings involving ionising radiation and for the clear assignment of responsibilities for protection and safety. A regulatory authority must be responsible for the regulatory control, whenever required, of undertakings involving radiation and for the enforcement of the regulations. This regulatory authority must be clearly separate from organisations that conduct or promote activities causing radiation exposure.

(307) The nature of radiological hazards necessitates a number of special features in the legal framework and the provision of expertise within the regulatory authority. The important issues are that radiological questions are addressed properly, that the appropriate expertise is available, and that decisions concerning radiation cannot be unduly influenced by non-radiological considerations.

(308) The operating management of an undertaking involving radiation has, in most cases, the primary practical responsibility for radiological protection. However, in some cases, there may not be a relevant operating management available. For instance, the radiation may not have been caused by any human undertaking, or an undertaking may have been abandoned and the proprietors could have disappeared. In such cases, the national regulatory authority, or some other designated body, will have to accept some of the responsibilities usually carried by the operating management.

(309) The primary responsibility for achieving and maintaining a satisfactory control of radiation exposures rests on the management bodies of the institutions conducting the operations giving rise to the exposures. When equipment or plant is designed and supplied by other institutions, they, in turn, have a responsibility to see that the items supplied will be satisfactory, if used as intended. Governments have the responsibility to set up national authorities, which then have the responsibility for providing a regulatory, and often also an advisory, framework to emphasise the responsibilities of the management bodies while, at the same time, setting and enforcing overall standards of protection. They may also have to take direct responsibility when, as with exposures to many natural sources, there is no relevant management body.

(310) 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 accountability running right to the top of each organisation. The delegation of responsibilities does not detract from that accountability. There is also an interaction between the various kinds of organisation. Advisory and national authorities should be held accountable for the advice they give and any requirements they impose.

(311) Requirements, operating instructions, regulatory approvals and licences, and other administrative devices are not, of themselves, enough to achieve an appropriate standard of radiological protection. Everyone in an undertaking, from the individual workers and their representatives to the senior management, should regard protection and emergency prevention as integral parts of their every-day

functions. Success and failure in these areas are at least as important as they are in the primary function of the undertaking.

(312) The imposition of requirements expressed in general terms and the acceptance of advice do not reduce the responsibility, or the accountability, of the operating organisations. This is also true in principle of prescriptive requirements, where the regulatory authority prescribes in detail how protection standards are to be maintained. However, prescriptive requirements concerning the conduct of operations result in some de facto transfer of responsibility and accountability from the user to the regulator. In the long run, they also reduce the user's incentive for self-improvement. Therefore, it is usually better to adopt a regulatory regime that places a more explicit responsibility on the user, and forces the user to convince the regulator that adequate protection methods and standards are used and maintained.

(313) Therefore, the use of prescriptive requirements should always be carefully justified. In any event, they should never be regarded as an alternative to the process of optimising protection. It is not satisfactory to set design or operational limits or targets as an arbitrary fraction of the dose limit, regardless of the particular nature of the plant and the operations.

6.6.2. External expertise and advice; delegation of authority

(314) The prime responsibility for radiological protection and radiation safety in an undertaking involving ionising radiation rests with the operating organisation. In order to assume this responsibility, the organisation needs expertise in radiological protection. It is not always necessary or reasonable to demand that this expertise is available within the operating organisation. As an alternative, it may be acceptable and recommendable for the operating organisation to use consultants and advisory organisations, particularly if the operating organisation is small and the complexity of the radiological protection issues is limited.

(315) Such an arrangement will not in any way relieve the operating organisation of its responsibility. The role of a consultant or an advisory organisation will be to provide information and advice as necessary. It still remains the responsibility of the operating management to take decisions and actions on the basis of such advice, and individual employees still need to adhere to a 'safety culture', constantly asking themselves whether they have done all that they reasonably can to achieve a safe operation.

(316) Similarly, the use of consultants or advisory bodies will not in any way diminish or change the responsibility of the regulatory authority. Furthermore, it will be particularly important when the regulator uses consultants that these are free from any conflicts of interest and are able to provide impartial advice. The need for transparency in decision-making should also be kept in mind.

6.6.3. Mutual trust and emergency reporting

(317) The interaction between a regulatory authority and an operating organisation should be frank and open whilst still maintaining a degree of formality. Mutual understanding and respect are crucial in order to achieve satisfactory radiological protection.

(318) An important task for a regulatory authority is to provide operating organisations with information aimed at the prevention of emergencies. An accident and incident reporting routine with feedback to users is an indispensable part of such a system. In order for such a system to work and achieve its goals, mutual trust is required. Licensing constitutes the formal confirmation of a regulatory authority's trust in a user. However, operating organisations also need to be able to trust the regulatory authority. A primary requirement is that all users are treated in a fair and equal manner. For an incident reporting system to work properly, users must also trust authorities to regard safety improvements as more important than punishments. Realising this, some regulatory authorities use an approach where legal actions are reduced or removed altogether in response to honest reporting of a problem and immediate action to rectify the situation, but any attempt at hiding a problem is an offence in itself and will lead to legal actions.

6.6.4. Management requirements

(319) The first, and in many ways the most important, of the practical steps in implementing the Commission's recommendations is the establishment of a safety-based attitude in everyone concerned with all the operations from design to decommissioning. This can only be achieved by a substantial commitment to training and recognition that safety is a personal responsibility and is of major concern to the top management.

(320) The explicit commitment of an organisation to safety should be made manifest by written policy statements from the highest level of management, by the establishment of formal management structures for dealing with radiological protection, by issuing clear operating instructions, and by clear and demonstrable support for those persons with direct responsibility for radiological protection in the workplace and the environment (*Publication 75,* ICRP 1997). To translate this commitment into effective action, senior management should identify appropriate design and operational criteria, determine organisational arrangements, assign clear responsibilities to put these policies into effect, and establish a culture within which all those in the organisation recognise the importance of restricting both normal and potential exposures to ionising radiation. The aims of the management requirements should be to set out the practical basis for protecting all concerned. The detailed techniques cover such aspects as the choice of radiation source or radioactive material, the use of shielding and distance to reduce radiation fields, the restriction of the time spent in the proximity of sources, and the use of containment, usually in several stages, to limit the spread of radioactive materials into workplaces and the public environment.

(321) There should be plans for dealing with accidents. These plans should be subject to periodic review and result in written management requirements. Planning for the event of emergencies should be an integral part of normal operating procedures. Any changes in responsibility, e.g. from the usual line of command to an emergency controller, should be planned in advance.

(322) The organisational approach should include involvement and participation of all workers. It is sustained by effective communications and the promotion of competence that enables all employees to make a responsible and informed contribution to the health and safety effort. The visible and active leadership of senior managers is necessary to develop and maintain a culture supportive of health and safety management. The aim is not simply to avoid accidents, but to motivate

and empower people to work safely. It is important that management ensures that mechanisms are in place by which workers may provide feedback on radiological protection issues, and workers should be fully involved in developing methods to ensure that doses are as low as reasonably achievable.

(323) Another common responsibility of the operating management is to provide access to occupational services dealing with protection and health. The protection service should provide specialist advice and arrange any necessary monitoring provisions commensurate with the complexity of the operation and its potential hazards. The head of the protection service should have direct access to the senior operating management. The principal role of the occupational health service is the same as it is in any occupation.

6.6.5. Compliance with the intended standard of protection

(324) The measurement or assessment of radiation doses is fundamental to the practice of radiological protection. Neither the equivalent dose in an organ nor the effective dose can be measured directly. Values of these quantities must be inferred with the aid of models, usually involving environmental, metabolic, and dosimetric components. Ideally, these models and the values chosen for their parameters should be realistic, so that the results they give can be described as ‘best estimates’. Where practicable, estimates and discussion should be made of the uncertainties inherent in these results.

(325) All the organisations concerned with radiological protection should have a duty to verify their compliance with their own objectives and procedures. The operating management should establish a system for reviewing its organisational structure and its procedures, a function analogous to financial auditing. National authorities should conduct similar internal audits and should have the added duty of, and authority for, assessing both the level of protection achieved by operating managements and the degree of compliance with the regulatory provisions. All these verification procedures should include consideration of potential exposures by a verification of the safety provisions. Verification procedures should include a review of quality assurance programmes and some form of inspection. However, inspection is a form of sampling - it cannot cover all eventualities. It is best seen as a mechanism for persuading those inspected to put, and keep, their own houses in order.

7. MEDICAL EXPOSURE OF PATIENTS

(326) Medical exposures are predominantly to individuals undergoing diagnostic, fluoroscopically guided interventional, or radiation therapy procedures. But 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 from released patients also occurs, but it is almost always very small. In addition, volunteers in biomedical research often undergo medical procedures that are similar to procedures performed on patients. Medical exposure refers to all these types of exposures and the present Chapter, in particular, covers the following:

- The exposure of individuals for diagnostic, fluoroscopically guided interventional, and therapeutic purposes;
- 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 program of biomedical research that provides no direct benefit to the volunteers.

(327) The Commission has used the term 'practice' since *Publication 26* (ICRP, 1977) to refer to human activities. However, for the medical profession, the term 'practice' typically refers to the medical care that a practitioner provides to patients. For example, for a radiation oncologist, the term refers to initial consultation with the patient, accurate diagnosis and staging of the cancer, treatment planning, administering treatment and subsequent follow-up. Introduction of a practice in medicine typically derives from the peer-reviewed literature, where physicians learn about new uses of established procedures or new techniques. Elimination of a practice in medicine typically occurs when the practice results in an unexpectedly high morbidity or mortality (i.e., discontinued by the practitioners as a result of experience). Other practices are eliminated as they are replaced by newer and better technology or medical treatments. It is necessary to improve the understanding of the concept 'practice' as defined by the Commission and present radiological protection in medicine in a way that is readily understood by the medical community. To more clearly communicate the concept, the term '*radiological practice in medicine*' is used for medical situations in order to differentiate it from the usual meaning of 'practice' in medicine.

(328) Radiation exposures of patients can occur in diagnostic, fluoroscopically guided interventional, or therapeutic procedures. There are several features of *radiological practice in medicine* that require an approach that differs from the radiological protection in other planned exposure situations. The exposure is intentional and for the direct benefit of the patient. In radiotherapy, the biological effects of high-dose radiation (e.g., cell killing) are used for the benefit of the patient to treat cancer and other diseases. The application of the Commission's recommendations to the medical uses of radiation therefore requires separate guidance, and medical exposure of patients is therefore dealt with in the present Chapter.

(329) The objective is the management of doses to patients to be commensurate with the medical purposes. In diagnostic and fluoroscopically guided interventional procedures, this means avoiding unnecessary exposures and unproductive doses, while in radiotherapy it requires delivery of the required dose to the volume to be treated, avoiding unnecessary exposure of healthy tissues.

(330) The Commission's recommendations for radiological protection and safety in medicine are given in *Publication 73* (ICRP, 1996a), which remains valid. These recommendations note important differences between the implementation of the system of protection in medicine and implementation in the other two categories of exposure (occupational and public). These differences include:

- The principle of justification applies at three levels in medicine as described in Section 7.1.1.
- In applying the principle of optimisation of protection of the patient, the detriments and 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 management of patient exposure is needed and the use of diagnostic reference levels is recommended in *Publication 73* (ICRP, 1996a) with further guidance in *Supporting Guidance 2* (ICRP, 2001b).
- The limitation of the dose to the individual patient is not recommended because it may, by reducing the effectiveness of the patient's diagnosis or treatment, do more harm than good. The emphasis is then on the justification of the medical procedures and on the optimisation of protection.

(331) The basic framework for protection established in *Publication 73* (ICRP, 1996a) has been further elaborated upon in a series of publications described below. The recommendations, guidance, and advice in these publications remain valid, forming part of an increasing library of information on medical exposure by the Commission [see also *Radiological protection in medicine* (ICRP, 2007)].

(332) The exposure of patients is deliberate. Except in radiotherapy, it is not the aim to deliver radiation dose as a therapy, but rather to use the radiation to provide diagnostic information or to conduct a fluoroscopically guided interventional procedure. Nevertheless, the dose is given deliberately and cannot be reduced indefinitely without prejudicing the intended outcome. Medical uses of radiation are also voluntary in nature, combined with the expectation of direct individual health benefit to the patient. The decision is made with varying degrees of informed consent that includes not only the expected benefit but also the potential risks (including radiation). The degree of informed consent varies based on the exposure level and the possible emergent medical circumstances.

(333) The physicians and other health professionals involved in the procedures that irradiate patients (e.g., radiographers and technicians) should always be trained in the principles of radiological protection, including the basic principles of physics and biology. The final responsibility for the radiation exposure lies with the physician, who therefore should be aware of the risks and benefits of the procedures involved.

(334) Medical exposures of patients to external radiation are commonly concerned with limited parts of the body only, and it is important that medical staff are fully aware of the doses to normal tissue in the irradiated fields. With low tissue weighting factors for skin and relatively low values for a number of other tissues, very localised partial body exposures can result in appreciable equivalent doses to local tissues even though the corresponding effective dose may be small. Similar considerations apply to doses from intakes of radionuclides if there is markedly preferential uptake of the radioactive material to a particular tissue or organ. Care has to be taken in such situations so that no undesirable tissue reactions occur.

7.1. Justification for medical exposure of patients

(335) Medical exposure of patients calls for a different and more detailed approach to the process of justification. The medical use of radiation should be justified, as is any other planned exposure situation, although that justification lies more often with the profession than with government. The principal aim of medical exposures is to do more good than harm to the patient, subsidiary account being taken of the radiation detriment from the exposure of the radiological staff and of other individuals. The responsibility for the justification of the use of a particular procedure falls on the relevant medical practitioners. Justification of medical procedures therefore remains a principal part of the Commission's Recommendations.

(336) The principle of justification applies at three levels in the use of radiation in medicine:

- At the first level, the use of radiation in medicine is accepted as doing more good than harm to the patient.
- At the second level, a specified procedure with a specified objective is defined and justified (e.g., chest radiographs for patients showing relevant symptoms, or a group of individuals at risk to a condition that can be detected and treated). The aim of the second level of justification is to judge whether the radiological procedure will usually improve the diagnosis or treatment or will provide necessary information about the exposed individuals.
- 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 to the individual patient). Hence all individual medical exposures should be justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved.

The second and third levels of justification are discussed below.

7.1.1. The justification of a defined radiological procedure (level 2)

(337) The justification of the radiological procedure is a matter for national and international professional bodies, in conjunction with national health and radiological protection authorities and the corresponding international organisations. 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 the main exposures in medicine are to patients, the exposures to staff and to members of the

public who are not connected with the procedures should be considered. This falls into the category of occupational exposure. The possibility of emergency or unintended exposures should also be considered. The decisions should be reviewed from time to time, as more information becomes available about the risks and effectiveness of the existing procedure and about new procedures.

7.1.2. The justification of a procedure for an individual patient (level 3)

(338) Beyond checking that the required information is not already available, no additional justification is needed for the application of a simple diagnostic procedure to an individual patient with the symptoms or indications for which the procedure has already been justified in general. For complex diagnostic and fluoroscopically guided interventional procedures (e.g., some cardiac and neuroradiological procedures), the second level of justification may not be sufficient. Individual justification by the practitioner and the referring physician (the third level) is then important and should take account of all the available information. This includes the details of the proposed procedure and of alternative procedures, the characteristics of the individual patient, the expected dose to the patient, and the availability of information on previous or expected examinations or treatment. It will often be possible to speed up the procedure by defining referral criteria and patient categories in advance.

7.2. Optimisation of protection for patient doses in medical exposures

(339) The Commission now uses the same conceptual approach in source-related protection, irrespective of the type of source. In the case of exposure from diagnostic and fluoroscopically guided medical procedures, the *diagnostic reference level* has as its objective the optimisation of protection, but it is not implemented by constraints on individual patient doses. It is a mechanism to manage patient dose to be commensurate with the medical purpose (see Section 7.2.1).

(340) The important message from the Commission is that the goal of optimisation of protection is applicable, regardless of the type of source or the terminology used.

7.2.1. Diagnostic reference levels

(341) Diagnostic reference levels apply to radiation exposure of patients resulting from procedures performed for medical diagnostic purposes. They do not apply to radiation therapy, and also do not apply to occupational or public exposure. Diagnostic reference levels have no direct linkage to the numerical values of the Commission's dose limits or dose 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 or to a reference patient. The values should be selected by professional medical bodies (in conjunction with national health and radiological protection authorities) 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.

(342) Diagnostic reference levels are used in medical diagnosis to indicate whether, in routine conditions, the levels of patient dose or administered activity from a specified imaging procedure are unusually high or low for that procedure. If so, a local review should be initiated to determine whether protection has been adequately optimised or whether corrective action is required (ICRP, 1996a). The diagnostic reference level should be expressed as a readily measurable patient dose - related quantity for the specified procedure. Additional guidance is given in *Radiological Protection in Medicine* (ICRP, 2007) and in *Supporting Guidance 2* (ICRP, 2001b).

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

(344) Extensive information on the management of patient dose in fluoroscopically guided interventional procedures, computed tomography and digital radiology is provided in *Publications 85*, *87*, and *93*, respectively (ICRP 2000e; 2000f; 2003d).

7.2.2. Radiotherapy

(345) In radiotherapy, optimisation involves not only delivering the prescribed dose to the tumour, but also planning the protection of tissues outside the target volume. For radiotherapy considerations, including planning the protection of tissues outside the target volume, *Publication 44* (ICRP, 1985) should be consulted.

7.3. Effective dose in medical exposure

(346) The age distributions for workers and the general population (for which the effective dose is derived) can be quite different from that of the overall age distribution for the population undergoing medical procedures using ionising radiation, and will also differ from one type of medical procedure to another, depending on the age- and sex-prevalence of the individuals for the medical condition being evaluated. For these reasons, risk assessment for medical uses of ionising radiation is best evaluated using appropriate risk values for the individual tissues at risk and for the age and sex distribution of the individuals undergoing the medical procedures. Effective dose can be of value for comparing the relative doses from different diagnostic procedures and for comparing the use of similar technologies and procedures in different hospitals and countries as well as the use of different technologies for the same medical examination, provided the reference patient or patient populations are similar with regard to age and sex.

(347) The assessment and interpretation of effective dose from medical exposure of patients is very problematic when organs and tissues receive only partial exposure or a very heterogeneous exposure, which is the case especially with diagnostic and fluoroscopically guided interventional procedures.

7.4. Exposure of patients who are or may be pregnant

(348) Before any procedure using ionising radiation, it is important to determine whether a female patient is, or could be, pregnant. The feasibility and carrying through of medical exposures during pregnancy require specific consideration due to the radiation sensitivity of the developing embryo/fetus. The manner in which an examination is performed depends on the radiation dose to the embryo/fetus.

(349) Prenatal doses from most correctly performed diagnostic procedures present no measurably increased risk of prenatal or postnatal death, developmental damage including malformation, or impairment of mental development over the background incidence of these entities. Life-time cancer risk following in-utero exposure is assumed to be similar to that following irradiation in early childhood. Higher doses such as those involved in therapeutic procedures have the potential to result in developmental harm.

(350) The pregnant patient has a right to know the magnitude and type of potential radiation effects that might result from in-utero exposure. Almost always, if a diagnostic radiology examination is medically indicated, the risk to the mother of not doing the procedure is greater than the risk of potential harm to the embryo/fetus. However, some procedures and some radiopharmaceuticals that are used in nuclear medicine (e.g., radioiodides) can pose increased risks to the fetus. The Commission has given detailed guidance in *Publication 84* (1CRP, 2000c).

(351) It is essential to ascertain whether a female patient is pregnant prior to radiotherapy. In pregnant patients, cancers that are remote from the pelvis usually can be treated with radiotherapy. This however requires particular attention in treatment planning. The expected radiation dose to the fetus, including the scattering component, must be estimated. Cancers in the pelvis can rarely be adequately treated during pregnancy without severe or lethal consequences for the fetus.

(352) Termination of pregnancy is an individual decision affected by many factors. Absorbed doses below 100 mGy to the developing organism should not be considered a reason for terminating a pregnancy. At embryonic/fetal doses above this level, informed decisions should be made based upon individual circumstances, including the magnitude of the estimated embryonic/fetal dose and the consequent risks of serious harm to the developing organism and risks of cancer in later life.

(353) Radiation risks after prenatal radiation exposure are discussed in detail in *Publication 90* (ICRP, 2003). The exposure of patients who are or may be pregnant is dealt with in detail in *Publication 84* (ICRP, 2000c) and in the ICRP Committee 3 Report *Radiological Protection in Medicine* (ICRP, 2007), which also discuss the considerations to be taken into account regarding termination of pregnancy after radiation exposure. Radiation exposure of pregnant females in biomedical research is discussed in Section 7.7.

7.5. Medical exposure: Accident prevention in external beam therapy and brachytherapy

(354) Accident prevention in external beam therapy and brachytherapy should be an integral part of the design of equipment and premises and of the working procedures. A key focus of accident prevention has long been the use of multiple

safeguards against the consequences of failures. This approach, now often called 'defence in depth', 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. The Commission has given extensive advice on reducing the probability of potential exposure and preventing accidents in *Publications 76, 86, 97* and *98* (ICRP, 1997, 2000d, 2005b, 2005c).

7.6. Medical exposure: Release of patients after therapy and the protection of their carers and comforters

(355) Unsealed radionuclides are used in the diagnosis and treatment of various diseases in the form of radiopharmaceuticals that are given to the patient by injection, ingestion or inhalation. These may localise in body tissues until they decay or they may be eliminated through various pathways (e.g., urine).

(356) Precautions for the public are rarely required after diagnostic nuclear medicine procedures but some therapeutic nuclear medicine procedures, particularly those involving iodine-131, can result in significant exposure to other people, especially those involved in the care and support of patients. Hence, members of the public caring for such patients in hospital or at home require individual consideration.

(357) *Publication 94* (ICRP 2004a) provides recommendations for the release of patients after therapy with unsealed radionuclides. These recommendations include that young children and infants, as well as visitors not engaged in direct care or comforting, should be treated as members of the public for radiological protection purposes (i.e., be subject to the public dose limits of 1 mSv/year). For individuals directly involved in comforting and caring, other than young children and infants, a dose constraint of 5 mSv per episode (i.e., for the duration of a given release after therapy) is likely to be reasonable. This constraint is not to be used rigidly. For example, higher doses may well be appropriate for parents of very sick children.

(358) The Commission's recommendations regarding dose limits and dose constraints related to the release of patients following unsealed radionuclide therapy have been interpreted in different ways in various countries. Although these recommendations advise that a dose constraint of 5 mSv per episode would be reasonable for carers and comforters, who should not be subject to the public dose limit, this dose constraint has often been inappropriately interpreted as a rigid annual dose limit.

(359) The risk of cancer induction for adult carers and comforters from exposure to patients treated with radioiodine is low. However, the thyroid gland of persons under the age of 15 is more radiosensitive, so that particular care should be taken to avoid the contamination of infants, children, and pregnant women (i.e., the embryo or fetus).

(360) The recommendations do not explicitly state that urine should be stored or that patients should be hospitalised after therapy with high activities of radiopharmaceuticals. The decision to hospitalise or release a patient after therapy should be made on an individual basis considering several factors including residual activity in the patient, patient's wishes, family consideration (particularly the presence of children), environmental factors, and national or local regulations.

(361) The unintentional exposure of members of the public in waiting rooms and on public transport is not high enough to require special restrictions on nuclear medicine patients, except for those being treated with radioiodine (*Publications 73* and *94*; ICRP, 1996a; 2004a).

(362) In principle, similar reasoning applies when patients are treated with permanently implanted sealed sources. However, the available data show that, in the vast majority of cases, the dose to comforters and carers remains well below the recommended limit of 1 mSv/year. Only the (rare) case where the patient's partner is pregnant at the time of implantation may need specific precautions (*Publication 98,* ICRP, 2005).

(363) When performed in the first few months after implantation of a sealed source, cremation of bodies (frequent in some countries) raises several issues related to: (1) the activity that remains in the patient's ashes; and (2) the airborne dose, potentially inhaled by crematorium staff or members of the public. Available data shows that cremation can be allowed if 12 months have elapsed since implantation with ^{125}I (3 months for ^{103}Pd). If the patient dies before this delay has elapsed, specific measures must be undertaken (ICRP, 2005).

7.7. Volunteers for biomedical research

(364) The participation 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 radionuclides 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 in biomedical research as if it were medical exposure.

(365) The ethical and procedural aspects of the use of volunteers in biomedical research have been addressed by the Commission in *Publication 62* (ICRP, 1991c). The key aspects include the need to guarantee a free and informed choice by the volunteers, the adoption of dose constraints linked to the societal 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 radiological protection advice.

(366) In many countries, radiation exposure of pregnant females as subjects in biomedical research is not specifically prohibited. However, their involvement in such research is very rare and should be discouraged unless pregnancy is an integral part of the research. In these cases, strict controls should be placed on the use of radiation for the protection of the embryo/fetus.

8. PROTECTION OF THE ENVIRONMENT

(367) Interest in the protection of the environment has greatly increased in recent years, in relation to all aspects of human activity. Such interest has been accompanied by the development and application of various means of assessing and managing the many forms of human impact upon it. The Commission is thus aware of the growing need for policy advice and guidance on such matters in relation to radiological protection, even though such needs have not arisen from any new or specific concerns about the effects of radiation on the environment. The Commission also recognises that there is a current lack of consistency at international level with respect to addressing such issues in relation to radioactivity, and therefore believes that a more proactive approach is now necessary.

8.1. The objectives of radiological protection of the environment

(368) The Commission acknowledges that, in contrast to human radiological protection, the objectives of environmental protection are both complex and difficult to articulate. The Commission does however subscribe to the global needs and efforts required to maintain biological diversity, to ensure the conservation of species, and to protect the health and status of natural habitats and communities. It also recognises that these objectives may be met in different ways, that ionising radiation may be only a minor consideration - depending on the environmental exposure situation - and that a sense of proportion is necessary in trying to achieve them.

(369) The Commission has previously concerned itself with mankind's environment only with regard to the transfer of radionuclides through it, primarily in relation to planned exposure situations, because this directly affects the radiological protection of human beings. In such situations, it has been considered that the standards of environmental control needed to protect the general public would ensure that other species are not put at risk, and the Commission continues to believe that this is likely to be the case.

(370) However, the Commission considers that it is now necessary to provide advice with regard to all exposure situations, including those that may arise as a result of accidents and emergencies, and those that exist but were not planned. It also believes that it is necessary to consider a wider range of environmental situations, irrespective of any human connection with them. The Commission is also aware of the needs of some national authorities to demonstrate, directly and explicitly, that the environment is being protected, even under planned situations.

(371) The Commission therefore believes that the development of a clearer framework is required in order to assess the relationships between exposure and dose, and between dose and effect, and the consequences of such effects, for non-human species, on a common scientific basis. This issue was first discussed in *Publication 91* (ICRP, 2003b), and it was concluded that it was necessary to draw upon the lessons learned from the development of the systematic framework for the protection of human beings. This framework is based on an enormous range of knowledge that the Commission attempts to convert into pragmatic advice that will

be of value in managing different exposure situations, bearing in mind the wide range of errors, uncertainties, and knowledge gaps of the various data bases.

(372) The advantage of such a comprehensive and systematic approach is that, as the needs for change to any component of the system arise (as in the acquisition of new scientific data, or changes in societal attitudes, or simply from experience gained in its practical application) it is then possible to consider what the consequences of such a change may have elsewhere within the system, and upon the system as a whole. Such an approach would not work unless it was based on a numerical framework that contained some key points of reference.

8.2. Reference Animals and Plants

(373) In the case of human radiological protection, the Commission's approach to such issues has been greatly assisted by the creation of an entity called Reference Man (now called Reference Person). It has therefore concluded that a similar approach would be of value as a basis for developing further recommendations for the protection of other species. The Commission is therefore developing a small set of Reference Animals and Plants (Pentreath, 2005), plus their relevant data bases, for a few types of organisms that are typical of the major environments. Such entities will form the basis of a more structured approach to understanding the relationships between exposures and dose, dose and effects, and the potential consequences of such effects.

(374) The Reference Animals and Plants can be considered as hypothetical entities with certain assumed basic biological characteristics of a particular type of animal or plant, as described to the generality of the taxonomic level of Family, with defined anatomical, physiological, and life-history properties. They are not, therefore, necessarily the *direct* objects of protection themselves but, by serving as points of reference, they should provide a basis upon which some management decisions could be made. Simple dosimetric models, plus relevant data sets, are currently being developed for different stages of the life cycle of each type. Available data on radiation effects for each type are also being reviewed.

(375) Some form of practical means is obviously required in order to make judgements, based on our current level of knowledge of the effects of radiation on different types of animals and plants, in order to meet the Commission's objectives. With the exception of mammals, however, there is a general paucity of information upon which dose response curves can be established that would enable sensible conclusions to be drawn, particularly with respect to the relatively low dose rates likely to obtain in most exposure situations. Indeed, in general, the data bases on radiation effects for the majority of animals and plants are not dissimilar from those relating to 'chemical toxicity' studies, where the levels required to produce a given effect are many orders of magnitude greater than those expected in the majority of environmental situations.

(376) With radiation there is another source of reference, and that is the natural background radiation to which such animals and plants are continuously and 'typically' exposed. Thus additional radiation doses to animals and plants can be compared with those dose rates known or expected to have certain biological effects

in those types of animals and plants, and with the dose rates normally experienced by them in their natural environments.

(377) The Commission does not therefore propose to set any form of ‘dose limits’ with respect to environmental protection. By setting out data for some Reference Animals and Plants, in a transparently derived way, and upon which further managerial action may be considered, the Commission intends to offer more practical advice than in the past. The Commission will use this framework to gather and interpret data in order to provide more comprehensive advice in the future, particularly with regard to those aspects or features of different environments that are likely to be of concern under different radiation exposure situations.

GLOSSARY OF KEY TERMS AND CONCEPTS

Absorbed Dose, D: the fundamental dose quantity given by

$$D = \frac{\mathrm{d}\bar{\varepsilon}}{\mathrm{d}m}$$

where $\mathrm{d}\bar{\varepsilon}$ is the mean energy imparted by ionising radiation to the matter in a volume element and dm is the mass of the matter in this volume element. The SI unit for absorbed dose is joule per kilogram (J kg^{-1}) and its special name is gray (Gy).

Activity, A: The expectation value of the number of nuclear transformations occurring in a given quantity of material per unit time. The special unit of activity is the becquerel (Bq).

Adaptive Response: A post-irradiation cellular response which, typically, serves to increase the resistance of the cell to a subsequent radiation exposure.

Averted dose: The dose prevented or avoided by the application of a countermeasure or set of countermeasures, i.e. the difference between the projected dose if the countermeasure(s) had not been applied and the actual projected dose.

Becquerel (Bq): The special name for the SI unit of activity, 1 Bq = 1 s^{-1} (≈ 2.7 x 10^{-11} Ci).

Bioassay: Any procedure used to determine the nature, activity, location or retention of radionuclides in the body by in vivo measurement or by in vitro analysis of material excreted or otherwise removed from the body.

Bystander effect: A response in unirradiated cells that is triggered by signals received from irradiated neighbouring cells.

Categories of exposure; The Commission distinguishes between three categories of radiation exposure; occupational, public and medical exposures of patients.

Collective Dose: See collective effective dose.

Collective Effective Dose, S: The sum of individual effective doses of persons with effective dose values between E_1 and E_2 from a specified source and for a specified time period Δ T is

$$S(E_1, E_2, \Delta T) = \int_{E_1}^{E_2} E \, \frac{\mathrm{d}N}{\mathrm{d}E} \, \mathrm{d}E$$

where $\frac{\mathrm{d}N}{\mathrm{d}E}$ denotes the number of individuals who experience an effective dose between E and E + dE and Δ T specifies the time period within which the effective doses are summed. The unit of the collective effective dose is man sievert (man Sv).

Committed Effective Dose, E(τ): The sum of the products of the committed organ or tissue equivalent doses and the appropriate organ or tissue weighting factors (w_T), where τ is the integration time in years following the intake. The commitment period is taken to be 50 years for adults, and to 70 years for children.

Committed Equivalent Dose, $H_T(\tau)$: The time integral of the equivalent dose rate in a particular tissue or organ that will be received by an individual following intake of radioactive material into the body by a reference person, where τ is the integration time in years

Constraint: The most fundamental level of protection for the most highly exposed individuals from a source within a type of exposure to be used prospectively in the optimisation process in order.

Controlled area: A defined area in which specific protection measures and safety provisions are or could be required for controlling normal exposures or preventing the spread of contamination during normal working conditions, and preventing or limiting the extent of potential exposures. A controlled area is often within a supervised area, but need not be.

Detriment: A measure of the total harm to health experienced by an exposed group and its descendants as a result of the group's exposure to a radiation source. Detriment is a

multi-dimensional concepts; its principal components are the stochastic quantities probability of attributable fatal cancer, weighted probability of attributable non-fatal cancer, weighted probability of severe hereditary effects, and length of life lost if the harm occurs.

Deterministic effect: A health effect of radiation for which generally a threshold level of dose exists above which the severity of the effect is greater for a higher dose. Such an effect is described as a 'severe deterministic effect' if it is fatal or life threatening or results in a permanent injury that reduces quality of life. Deterministic effects are also called 'tissue reactions'.

Diagnostic reference level: used in medical diagnosis to indicate whether, in routine conditions, the patient dose or administered activity from a specified procedure are unusually high or low for that procedure.

Dose and dose-rate effectiveness factor (DDREF: A judged factor that generalises the usually lower biological effectiveness (per unit of dose) of radiation exposures at low doses and low dose rates as compared with exposures at high doses and high dose rates.

Dose coefficient: Used as a synonym for dose per unit intake, but sometimes also used to describe other coefficients linking quantities or concentrations of activity to doses or dose rates, such as the external dose rate a specified distance above a surface with a deposit of a specified activity per unit area of a specified radionuclide.

Dose constraint: A prospective and source related restriction on the individual dose from a source, which serves as an upper bound on the dose in optimisation of protection for that source. For occupational exposures, the dose constraint is a value of individual dose used to limit the range of options considered in the process of optimisation. For public exposure, the dose constraint is an upper bound on the annual doses that members of the public should receive from the planned operation of any controlled source.

Dose Equivalent, *H*: The product of D and Q at a point in tissue, where D is the absorbed dose and Q is the quality factor for the specific radiation at this point, thus

$H = D\,Q$.

The unit of dose equivalent is joule per kilogram (J kg^{-1}) or sievert (Sv).

Dose conversion convention: The assumed relationship between potential alpha energy exposure and effective dose. Used to estimate doses from measured or estimated exposure to radon (units: mSv per J·h/m^3).

Dose limit: The value of the effective dose or the equivalent dose to individuals from planned exposure situations that shall not be exceeded.

Doubling dose (DD): The dose of radiation (Gy) that is required to produce as many heritable mutations as those arising spontaneously in a generation.

Effective Dose, E: The sum of the equivalent doses in all specified tissues and organs of the body, given by the expression:

$$\text{or} \qquad E = \sum_{\mathrm{T}} w_{\mathrm{T}} \sum_{\mathrm{R}} w_{\mathrm{R}} D_{\mathrm{T,R}}$$

where H_{T} or $w_{\mathrm{R}} D_{\mathrm{T,R}}$ is the equivalent dose in a tissue or organ, T, and w_{T} is the tissue weighting factor.

Emergency: A non-routine situation or event that necessitates prompt action primarily to mitigate a hazard or adverse consequences for human health and safety, quality of life, property or the environment. This includes situations for which prompt action is warranted to mitigate the effects of a perceived hazard.

Emergency exposure situations: Unexpected situations that occur during the operation of a practice, requiring urgent action. Emergency situations may arise from practices.

Equivalent Dose, H_{T}: The radiation-weighted dose, H_{T}, in a tissue or organ T is given by:

$$H_{\mathrm{T}} = \sum_{\mathrm{R}} w_{\mathrm{R}} D_{\mathrm{T,R}}$$

where $D_{\mathrm{T,R}}$ is the mean absorbed dose from radiation R in a tissue or organ T and w_{R} is the radiation weighting factor. Since w_{R} is dimensionless, the unit for the equivalent dose is the same as for absorbed dose, J kg^{-1}, and its special name is sievert (Sv).

Exclusion: The deliberate exclusion of a particular category of exposure from the scope of an instrument of regulatory control on the grounds that it is not considered amenable to control through the regulatory instrument in question.

Exemption: The determination by a regulatory body that a source or practice need not be subject to some or all aspects of regulatory control on the basis that the exposure (including potential exposure) due to the source or practice is too small to warrant the application of those aspects or that this is the optimum option for protection irrespective of the actual level of the doses or risks.

Existing exposure situations: Situations that already exist when a decision on control has to be taken, including natural background radiation and residues from past practices that were operated outside the Commission's recommendations.

Exposed individuals: The Commission distinguishes between three categories of exposed individuals; workers (informed individuals), the public (general individuals), and patients, including their comforters and carers.

Gray (Gy): The special name for the SI unit of absorbed dose: 1 Gy = 1 J kg^{-1}.

Incidence: The rate of occurrence of a disease within a specified period of time, often expressed as a number of cases with a disease per 100,000 individuals per year (or per 10,000 person-years).

Induced genomic instability: The induction of an altered cellular state characterised by a persistent increase over many generations in the spontaneous rate of mutation or other genome-related changes.

Intake, *I*: Activity that enters the body through the respiratory tract or gastrointestinal tract from the environment.

Justification:

Legal person: Any organisation, corporation, partnership, firm, association, trust, estate, public or private institution, group, political or administrative entity or other persons designated in accordance with national legislation, who or which has responsibility and authority for any action having implications for protection and safety.

Life Span Study (LSS): The long-term cohort study of health effects in the Japanese atomic bomb survivors in Hiroshima and Nagasaki.

Linear energy transfer (LET): A measure of the ability of material to absorb ionising radiation; the radiation energy lost per unit length of path through a material.

Linear-non-threshold model (LNT): A hypothesis which is based on the concept that, in the low dose range, above background, radiation doses greater than zero will increase the risk of excess cancer and/or heritable disease in a simple proportionate manner

Linear quadratic dose response: A statistical model that expresses the risk of an effect (e.g. disease, death or abnormality) as the sum of two components, one proportional to dose (linear term) and the other one proportional to the square of dose (quadratic term).

Multifactorial diseases: Diseases that are attributable to multiple genetic and environmental factors.

Nominal risk coefficient: Sex and age at exposure averaged lifetime risk estimates for a representative population.

Non-cancer diseases: Diseases other than cancer eg. cardiovascular disease, and cataracts.

Operating management: The person or group of persons that directs, controls, and assesses an organisation at the highest level. Many different terms are used, including, e.g., chief executive officer (CEO), director general (DG), managing director (MD), and executive group.

Operational Quantities: Are used in monitoring and are practical applications for investigating the situations involving external exposure and intakes of radionuclides. They are defined for measurements and assessment of doses in the body.

Optimisation of protection (and safety): The process of determining what level of protection and safety makes exposures, and the probability and magnitude of potential exposures, as low as reasonably achievable, economic and societal factors being taken into account.

Personal dose equivalent, $H_p(d)$: The dose equivalent in ICRU tissue at an appropriate depth, d, below a specified point on the human body. The unit of personal dose equivalent is joule per kilogram (J kg^{-1}) and its special name is sievert (Sv). The specified point is usually given by the position where the individual dosemeter is worn.

Planned exposure situations: Everyday situations involving the planned operation of sources including decommissioning, disposal of radioactive waste and rehabilitation of the previously occupied land. Practices in operation are planned exposure situations.

Pooled analysis: An analysis of epidemiologic data from several studies based on original data from those studies that are analysed in parallel.

Potential exposure: Exposure that is not expected to be delivered with certainty but that may result from an accident at a source or owing to an event or sequence of events of a probabilistic nature, including equipment failures and operating errors.

Principles of protection: A set of principles that apply equally to all controllable exposure situations; the principle of justification, the principle of optimisation of protection, and the principle of application of limits on of maximum doses in planned situations.

Protection Quantities: Dose quantities that ICRP has developed for radiological protection that allow quantification of the extent of exposure to ionising radiation from both whole and partial body external irradiation and from intakes of radionuclides.

Radiation detriment: Radiation detriment is a concept used to quantify the harmful health effects of radiation exposure in different parts of the body. It is defined by ICRP as a function of several factors, including incidence of radiation-related cancer or hereditary defects, lethality of these conditions, quality of life, and years of life lost due to these conditions.

Radiation Weighting Factor (w_R): A dimensionless factor by which the organ or tissue absorbed dose is multiplied to reflect the higher biological effectiveness of high LET radiations compared with low LET radiations. It is used to derive the equivalent dose from the absorbed dose averaged over a tissue or organ.

Radiation worker: Any person who is employed, whether full time, part time or temporarily, by an employer and who has recognised rights and duties in relation to occupational radiological protection.

Reference animals and plants: A hypothetical entity, with the assumed basic biological characteristics of a particular type of animal or plant, as described to the generality of the taxonomic level of Family, with defined characteristics defined by the Commission for the purpose of radiological protection.

Reference person: An idealised human with characteristics defined by the Commission for the purpose of radiological protection, and with the anatomical and physiological characteristics defined in the report of the ICRP Task Group on Reference Man (*Publication 89*; ICRP, 2002).

Reference Value: The value of a parameter recommended by ICRP for use in a biokinetic model in the absence of more specific information, ie. the exact value used to calculate the dose coefficients presented in the report. Reference values may be specified to a greater degree of precision than that which would be chosen to reflect the certainty with which the value is known, in order to avoid the accumulation of rounding errors in a calculation.

Relative Biological Effectiveness (RBE): The ratio of a dose of a low-LET reference radiation to a dose of the radiation considered that gives an identical biological effect. RBE values vary with the dose, dose rate and biological endpoint considered. In radiological protection the RBE at very low doses (RBE_M) is especially of interest.

Relative life lost: The ratio of the proportion of observed years of life lost among people dying of a disease in an exposed population and the corresponding proportion in a similar population without the exposure.

Relative survival: The ratio of proportion of cancer patients who survive for a specified number of years (eg 5 years) following diagnosis to the corresponding proportion in a comparable set of cancer-free individuals.

Residual dose: In a chronic exposure situation, the dose expected to be incurred in the future after intervention has been terminated (or a decision has been taken not to intervene).

Sievert (Sv): The special name for the SI unit of radiation-weighted dose, former term equivalent dose, of effective dose and of operational dose quantities. The unit is joule per kilogram ($J\ kg^{-1}$).

Source: An entity for which radiological protection can be optimised as an integral whole, such as the x-ray equipment in a hospital, or the releases of radioactive materials from an

installation. Sources of radiation, such as radiation generators and sealed radioactive materials, and, more generally, the cause of exposure to radiation or to radionuclides.

.**Stochastic effects:** Effects resulting from damage in a single cell, such as cancer and hereditary effects. The frequency of the event, but not its severity, increases with an increase in the dose. For protection purposes it is assumed that there is no threshold dose.

Supervised area: A defined area not designated a controlled area but for which occupational exposure conditions are kept under review, even though no specific protection measures or safety provisions are normally needed.

Target Region: Region within the body in which radiation is absorbed. The region may be an organ, a tissue, the contents of the gastrointestinal tract or urinary bladder, or the surfaces of tissues as in the skeleton and the respiratory tract.

Threshold dose for tissue reactions: Dose estimated to result in only 1% incidence of tissue reactions.

Tissue reactions: Injury in populations of cells, in some cases modifiable by post-irradiation procedures including biological response modifiers. Characterised by a threshold dose, and an increase in the severity of the reaction as the dose is increased further. Also termed deterministic effects.

Tissue weighting factors: Tissue weighting factors allow the quantification of the relative sensitivity of different organs or tissues in the body for developing cancer, or to a lesser extent hereditary effects.

Track Structure: Spatial patterns of energy deposition in matter from the passage of a radiation track.

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ANNEX A

This is the ICRP Committee 1 Foundation Document on: 'Biological and Epidemiological Information on Health Risks Attributable to Ionising Radiation: A Summary of Judgements for the Purposes of Radiological Protection of Humans'. This document has already been subjected to public consultation and is not part of the present consultation on the draft Recommendations. However, the text of this Annex, which has been amended to take account of the comments received during consultation, is available at www.icrp.org/Health_risks.pdf .

ANNEX B

This is the ICRP Committee 2 Foundation Document on: 'Basis for Dosimetric Quantities Used in Radiological Protection'. Like Annex A, this has already been subjected to public consultation and is not part of the present consultation, but an appropriately amended version of the Annex is available at www.icrp.org/Dosimetry.pdf.

ADDITIONAL BUILDING BLOCKS

An ICRP Committee 3 document on medical radiation is subjected to public consultation in the spring of 2007 and can be viewed at http://www.icrp.org/remissvar/remissvar.asp**.** *Two ICRP Committee 4 documents, on the representative exposed person and on optimisation, are available as ICRP Publication 101. A Main Commission draft document on the scope of radiological protection was subjected to public consultation in 2006 and can be viewed via www.icrp.org/draft_scope.asp - this document is expected to be completed and published in 2007. .*